All India Institute of Medical Sciences
Bilaspur, Himachal Pradesh

Standard Operating Procedures

Institutional Ethics Committee for Biomedical and Health Research involving Human Participants

Effective from: 18th October 2021
Valid up to: 17th October 2026

2021

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Standard operating procedures for the institutional ethics committee for biomedical and health research involving human participants

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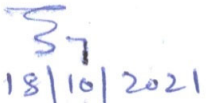
Name and designation	**Signature with date**
Prof. Vir Singh Negi, Professor, Executive Director, AIIMS, Bilaspur	

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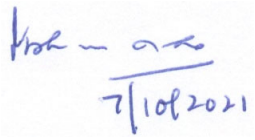
Prof. VM Katoch, Professor, Chairperson. Institutional Ethics Committee (Biomedical and Health Research), AIIMS, Bilaspur	

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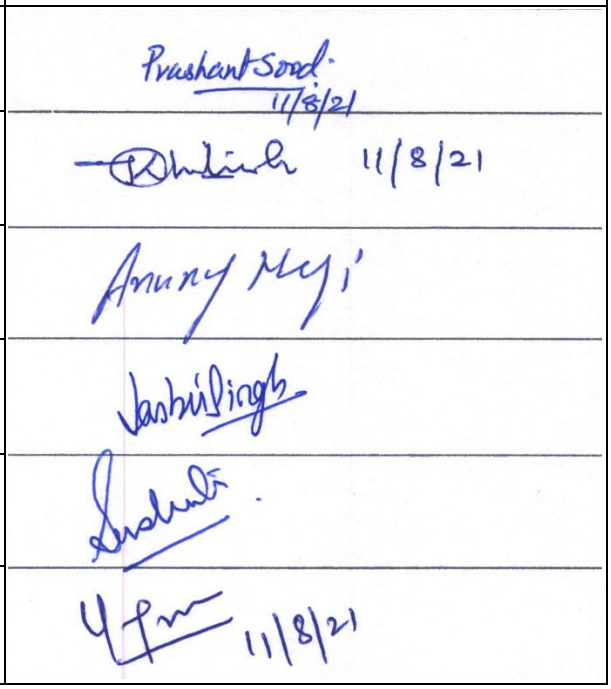
Dr. Prashant Sood, Additional Professor, Coordinator, IEC-SOP committee	
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The IEC-SOP committee also thanks and acknowledges Dr. Harpreet Kaur Sidhu, Associate Professor, Department of Obstetrics and Gynaecology, AIIMS, Bilaspur, and Dr. Meenakshi Meenu, Assistant Professor, Department of Pharmacology, AIIMS, Bilaspur, for their kind expertise and guidance in drafting these standard operating procedures.

Original cover design by: Dr. Prashant Sood, Coordinator, IEC-SOP committee

1 The preparation, reviewing, distribution and amendment of standard operating procedures for the Institutional Ethics Committee for biomedical and health research

1.1 Purpose

The purpose of this standard operating procedure (SOP) is to delineate the process of writing, reviewing, distribution and amendment of various SOPs required for the seamless functioning of the Institutional Ethics Committee (IEC) for biomedical and health research, at AIIMS, Bilaspur. This SOP lays down guidelines for formulating, drafting, revising and amending SOPs that conform to the current Indian and international regulations and guidelines.

1.2 Scope

This SOP covers the various procedures required for writing, reviewing, distributing and amending the SOPs required for carrying out the various activities of the IEC for biomedical and health research at AIIMS, Bilaspur.

1.3 Responsibility

It is the responsibility of the Chairperson of the IEC to appoint a SOP team for formulating new SOPs and revising existing ones. The SOP team will carry out its work by following the standard procedures, format and coding laid down by the National Guidelines for Ethics Committees reviewing Biomedical and Health Research involving Human Participants, ICMR Bioethics Unit. The Director of AIIMS, Bilaspur will be responsible for implement these SOPs. The responsibilities of various IEC stakeholders including the members, Member Secretary, Chairperson and the Secretariat are delineated below.

1.3.1 Responsibilities of the IEC Chairperson

- Appoint the SOP team comprising of the Member Secretary and two or more additional IEC members
- Approve the SOPs with signature and date of approval

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

1.3.2 Responsibilities of the SOP team

- Assess the request for SOP preparation and/or revision in consultation with the IEC Secretariat, Member Secretary and the Chairperson.
- Propose new / modified SOPs as requested
- Systematically delineate the procedures and details involved in the new / modified SOPs
- Plan, organise and implement a SOP notation system in accordance with the ICMR guidelines e.g. AIIMS-BLS/IEC-H/SOPxx/Vx/ANXxx
- Draft the new SOPs in consultation with the IEC members and with the help of the administrative staff
- Review the draft SOPs
- Submit the drafts for approval of the Chairperson

1.3.3 Responsibilities of the IEC Secretariat

- Assist the IEC Chairperson in constituting the SOP team
- Coordinate the activities of writing, reviewing, distributing and amending the SOPs
- Ensure that all IEC members and involved administrative staff have access to the SOPs
- Ensure that all IEC members and involved administrative staff work according to the current SOP versions
- Maintain and up-to-date distribution list for each SOP distributed to the IEC members
- Maintain a record of names and details of investigators to whom the SOPs have been distributed
- Maintain a file and list of all current SOPs
- Maintain a file of all past SOPs

1.3.4 Responsibilities of IEC members and involved administrative staff

- Sign and date the approved SOPs when they receive it and maintain a file of all the SOPs that are received by them
- Return all outdated SOPs to the IEC Secretariat

1.4 Detailed instructions

1.4.1 Identify the need for new or amended SOP

Any IEC member, faculty member, or investigator of AIIMS, Bilaspur can make a request to the IEC Secretariat for a new SOP or revisions and amendments of a current SOP to rectify any shortcomings, inconsistencies or discrepancies in the current SOPs. The request should be put forth to the IEC Chairperson either in writing through an email or letter using the stipulated

request form (AIIMS-BLS/IEC-H/SOP01/V1/ANX01). The Chairperson will forward the request to the Member Secretary and the request will be intimated to all the IEC members followed by a discussion at the next IEC full board meeting. If the IEC members agree to the request, the Chairperson will appoint the SOP team for completing the SOP formulation and/or revision. However, if the majority of IEC members do not agree with the request, then no further action will be taken and the IEC member, faculty or investigator who had made the request will be intimated by the Chairperson of the decision.

1.4.2 List of relevant procedures to be carried out by the SOP team

- Write all the procedures of IEC that are to be standardized in the form of an SOP
- Organize, divide and name each process

1.4.3 Write and review a new SOP

- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairperson. All SOPs are to be drafted according to the template provided in annexure AIIMS-BLS/IEC-H/SOP01/V1/ANX02.

- Each SOP should be given a number and a unique, self-explanatory, easily understandable title that falls within the SOP themes identified by the ICMR Bioethics Unit. The unique code allotted to the SOP will follow the format AIIMS-BLS/IEC-H/SOPxx/Vy, AIIMS-BLS stands for AIIMS, Bilaspur, IEC-H stands for the IEC for biomedical and health research at AIIMS, Bilaspur, SOP stands for standard operating procedure, “xx” represents a two-digit number, V stands for version, and “y” the version number e.g. AIIMS-BLS/IEC-H/SOP05/V1 implies version 1 of SOP 05 of IEC for biomedical and health research at AIIMS, Bilaspur. As depicted in the SOP template (AIIMS-BLS/IEC-H/SOP01/V1/ANX02), each SOP will bear a header carrying the Institute logo, the SOP number, the effective date (dd/mm/yyyy) on which it was approved and brought into effect by the Chairperson, and a short title of the SOP. Page numbers will be inserted in the footer of the SOP in the format Pages 1 of pp, where pp refers to the total number of pages in the SOP.

- The annexures included in a SOP will be encoded using the format AIIMS-BLS/IEC-H/SOPxx/Vy/ANXzz, where ANX stands for annexure and zz represents a two-digit number. The annexure number and title will be written on the top of each annexure.

1.4.4 Write and review a revised SOP

- If a SOP supersedes a previous version, the previous SOP version will be indicated in the document history form (AIIMS-BLS/IEC-H/SOP01/V1/ANX03) along with description of the main changes.

1.4.5 Review and preparation of final SOPs

- The new SOPs drafted by one or more members of the SOP team will be reviewed by the remaining members of the SOP team. Any suggestions received from the review will be incorporated as deemed appropriate by the SOP team. Copies of the revised drafts will be sent to the Chairperson and Member Secretary for circulation among IEC members.

- The draft SOPs will be reviewed and discussed by the IEC members at a full board meeting. The suggestions that are agreed upon by the IEC members will be discussed and incorporated in the draft SOPs.

- The SOP team would stand automatically dissolved once IEC takes a final decision on the new SOPs.

1.4.6 Approval of new/ revised SOPs

- The final version will be presented to the Chairperson for review and approval.

- The SOP manual will carry in its first few pages a record of dated signatures. These signatures will include those of the SOP team members, the IEC members who reviewed the SOPs, the IEC Member Secretary, the Chairperson (will also approve the SOPs), the Dean (Research), and the Director, AIIMS, Bilaspur (will also accept the SOPs).

1.4.7 Implement, distribute and file SOPs

- The approved SOP will be implemented from the effective date, which will be the date of approval by the Chairperson.

- The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.

- The approved SOP will be distributed to the IEC members and a log will be maintained.

- One hard copy of the complete original set of current version of the SOPs will be filed in the SOP master file, by IEC Secretariat. Photocopies made from the current original set will be stamped and signed by the Member Secretary or an authorized person for distribution. A distribution log should also be maintained as per the annexures AIIMS-

BLS/IEC-H/SOP01/V1/ANX04 and AIIMS-BLS/IEC-H/SOP01/V1/ANX05, for IEC members and other requests, respectively.

- Following the distribution of revised SOPs, all IEC members will be requested to return the previous version of the revised SOPs. One copy of the previous version will be filed in the file entitled "Superseded IEC SOPs" by IEC Secretariat, with each SOP clearly marked "Superseded". The evolution across all previous SOPs should be logged as per the format given in annexure AIIMS-BLS/IEC-H/SOP01/V1/ANX03.

- The full set of current SOPs will also be made available to all investigators through the Institute website.

- The IEC members and the Secretariat will review the SOPs at least once every 3 years.

1.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP01/ANX01 - Request form for the formulation or revision of a SOP
Annexure 2: AIIMS-BLS/IEC-H/SOP01/ANX02 - Standard template for drafting IEC SOPs
Annexure 3: AIIMS-BLS/IEC-H/SOP01/ANX03 - SOP document history
Annexure 4: AIIMS-BLS/IEC-H/SOP01/ANX04 - Distribution log of printed IEC SOPs circulated to IEC members
Annexure 5: AIIMS-BLS/IEC-H/SOP01/ANX05 - Distribution log of printed SOP copies provided on request
Annexure 6: AIIMS-BLS/IEC-H/SOP01/ANX06 – Document history

01

Annexure 1: AIIMS-BLS/IEC-H/SOP01/ANX01
Request form for the formulation or revision of a SOP

This form should be used to submit a request for a new or revised SOP based on problems or deficiencies observed in current IEC SOPs. An IEC member, faculty member, or research investigator of AIIMS, Bilaspur can submit such a request to the IEC.

A. New SOP

1. Proposed new SOP (SOP that does not exist in AIIMS, Bilaspur IEC SOPs:

2. Please provided details and justification for the proposed SOP:

B. SOP revision

1. Proposed revision of a current SOP:

2. Please provide details and justification for the proposed revision:

   - SOP number:
   - SOP Title:
   - Deficiency identified by:
   - Date identified on:

(To be filled in by the IEC Secretariat)

1. IEC meeting held on:
2. IEC decision:
   - New SOP to be formulated (Yes / No):
   - Revised SOP to be formulated (Yes / No):

3. If yes, designated members of the SOP team:

4. If new / revised SOP not being drafted, then reasons for the same:

5. Date of SOP revision / formulation:
6. Date of SOP approval:
7. Date when SOP made effective:

01

Annexure 2: AIIMS-BLS/IEC-H/SOP01/ANX02
Standard template for drafting IEC SOPs

Institute logo	SOP number (AIIMS-BLS/IEC-H/SOPxx/Vy) Effective date: (dd/mm/yyyy) Short SOP title
1. Purpose 2. Scope 3. Responsibility 4. Detailed instructions 5. Annexures (if any) 6. Workflow	
	Pages 1 of (total pages)

Prepared by	Reviewed by	Approved by	Accepted by
Members IEC-SOP team	Dean Member Secretary IEC members	IEC Chairperson	Director, AIIMS, Bilaspur
Signature with date	Signature with date	Signature with date	Signature with date

Annexure 3: AIIMS-BLS/IEC-H/SOP01/ANX03
SOP document history

SN	SOP title	SOP number and version	Effective date (dd/mm/yyyy)
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Annexure 4: AIIMS-BLS/IEC-H/SOP01/ANX04
Distribution log of printed IEC SOPs circulated to IEC members

SN	Recipient	Designation	SOP number	No. of copies	Signature	Date
1.		Chairperson				
2.		Dean				
3.		Member Secretary				
4.		Member				
5.		Member				
6.		Member				
7.		Member				
8.		Member				
9.		Member				
10.		Member				
11.		Member				
12.		Member				
13.		Member				
14.		Member				
15.		Member				

Annexure 5: AIIMS-BLS/IEC-H/SOP01/ANX01
Distribution log of printed SOP copies provided on request

SN	Recipient	Designation	SOP number	Number of copies	Date
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					

01

Annexure 6: AIIMS-BLS/IEC-H/SOP01/ANX06
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Chitresh Kumar; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

1.6 Workflow

	Activity	**Responsibility**
1.	Request for a new or revised SOP	IEC member, Institute faculty member, Institute research investigator
2.	Deliberation on request, formation of SOP team	Chairperson
3.	Drafting of new / revised SOP	SOP team
4.	Review of new / revised SOP	Member Secretary, IEC members
5.	Approval of new / revised SOP	Chairperson
6.	Acceptance of new / revised SOP	Institute Director
7.	Distribution, implementation and training for new / revised SOP	Member Secretary, IEC Secretariat

2 Constituting the Institutional Ethics Committee for biomedical and health research at AIIMS, Bilaspur

02

2.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the various procedures and terms of reference for the constitution, selection, roles, and responsibilities of the Institutional Ethics Committee (IEC) for biomedical and health research, at AIIMS Bilaspur. The SOP also delineates the procedures required for maintaining the confidentiality of all documents and activities of the IEC.

2.2 Scope

This SOP is relevant for the selection and constitution of the IEC for biomedical and health research at AIIMS, Bilaspur. It describes the various procedures to be followed, confidentialities to be maintained, and the role and responsibilities of the IEC for biomedical and health research at AIIMS, Bilaspur.

2.3 Responsibility

The selection of the Chairperson, Member Secretary and IEC members of the IEC for biomedical and health research at AIIMS, Bilaspur, will be done by the Director, AIIMS, Bilaspur. Once the IEC has been constituted, it is the responsibility of the IEC members and the IEC Secretariat to read, understand, implement and respect the IEC SOP laid down by the Institute.

2.4 Detailed instructions

2.4.1 Constitution of the Institutional Ethics Committee for biomedical and health research

The IEC will be established by Head of the Institution (Director). The Chairperson and IEC Member Secretary can suggest the name of potential members but the final decision will remain

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

with the Director. The IEC will be multidisciplinary and multi-sectoral in composition. It will be composed of a minimum of 7 to a maximum of 15 members, with 50% of the members being non-affiliate (or as per the latest CDSCO requirements). The Director will select and nominate the Chairperson and Member Secretary. The IEC will be constituted by the Director in consultation with the Chairperson. The Director will invite the members to join the IEC by sending official request letters. The nominated members will confirm their acceptance to the Director by providing the information required for the membership. The Director will ensure that the IEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of communities they serve. The Director will designate and instruct the Chairperson of the IEC or the Chairperson's representative to conduct the regular proceedings of the IEC for the Institute. The Director will also review the functioning of the IEC at regular intervals.

The committee should include at least one member whose primary area of expertise is non-scientific, a clinician and at least one member who is independent of the institution and the research site.

The IEC members should:

- Comprise medical, non-medical, scientific and non-scientific individuals including lay individuals to represent different points of view
- Have different backgrounds to promote complete and adequate review of research
- Possess appropriate qualifications as prescribed by applicable and current regulations and guidelines
- Be able to provide the expertise, time and commitment required to perform the functions of IEC
- Represent both gender, various relevant age-groups and social background to safeguard the interests and welfare of all sections of the society

The IEC may invite members from specific patient groups or other special interest groups for IEC meetings as and when required, based on the area of research being discussed e.g. HIV, genetic disorders, stem cell research etc., for considering their views. Such individuals will have to sign a confidentiality agreement and declare in writing any conflicts of interest prior to attending the meeting. They will attend the meeting as a "Guest/Observer" and will not have the right to vote.

2.4.2 Composition of IEC for biomedical and health research

- The IEC should have a minimum of seven members from the medical, non-medical, scientific and non-scientific disciplines. The members can include:

1. Chairperson (not affiliated to the Institute)
2. Vice-Chairperson (affiliated to the Institution, optional)

3. Member Secretary (institutional)
4. Joint Member Secretary (institutional, optional)
5. Four to five clinicians (more if necessary)
6. One or two experts from basic medical science (including a clinical pharmacologist, especially if overseeing drug, device, vaccines and biologics; and more if necessary)
7. One woman member
8. One medico-legal/ legal expert, or retired judge
9. One social scientist or representative of non-governmental voluntary agency, or a philosopher, ethicist, or a theologian
10. One lay person/ educated community person

- At least 50 % of the IEC members should be affiliated from outside AIIMS, Bilaspur.

- All members of the IEC should be well versed with the national and international ethics rules, good clinical practice guidelines, and other regulations governing the rights, safety and well-being of research participants.

- All IEC members are required to undergo above training and complete other development programs that are specified by the Central Licensing Authority from time to time.

- Any IEC member who has not received and successfully completed such training and developmental programs, will be disqualified from his/her IEC post and shall cease to be a member of the IEC.

2.4.2.1 IEC composition for evaluating clinical trials

- At least five members should be present for evaluating clinical trial, bioavailability and bioequivalence study proposals. These five members should include:

    - Medical scientist (preferably clinical pharmacologist)
    - Clinician
    - Legal expert
    - Social scientist or a representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person
    - Lay person

2.4.2.2 Intimating change in IEC composition

A registered IEC is required to intimate in writing any change in the membership or constitution of the committee to the licensing authority within 30 working days.

2.4.3 Criteria for selection of IEC members

A. Chairperson

- Must be from outside the institution
- Should be a person with high standing in society with minimum 2 years' experience of serving in an ethics committee
- The Chairperson can serve dual roles based on his/her qualifications e.g. the Chairperson could be a clinician, legal expert, basic medical scientist, and/or social scientist, in addition to managing the role of the Chairperson.

B. **Vice Chairperson** (optional)

- Must be from within the institution
- Should have minimum 2 years' experience of serving in an ethics committee

C. **Member Secretary** (and **Joint Member Secretary** [optional])

- Should be a staff member of the institution
- Should be a medical professional with a state medical council recognized postgraduate degree
- Should have domain specialty experience, clinical research and ethics knowledge, personal interest, capacity, and good communication skills
- The Member Secretary can serve dual roles based on his/her qualifications e.g. the Member Secretary could be a clinician, legal expert, basic medical scientist, and/or social scientist, in addition to managing the role of the Member Secretary.

D. Members

- IEC Members will be selected in their personal capacities based on their qualification, experience in their fields, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC. They should not have any known record of professional misconduct. Medical scientists and clinicians should have recognized postgraduate qualifications. Conflicts of interest should be avoided while making appointments, but where unavoidable, there should be transparency with regard to such interests.

2.4.4 Agreement regarding maintenance of confidentiality

It is the responsibility of all IEC members, whether reviewing research projects or attending IEC meetings, to read, understand, accept and sign the IEC confidentiality agreement. The IEC Secretariat staff will also sign the confidentiality agreement and all these documents will be filed by the IEC. The Secretariat will obtain the signature of the IEC Chairperson on the confidentiality agreement. The Secretariat will further email the electronic copy of the confidentiality agreement to the IEC members and receive duly completed, signed and dated

forms from them countersigned by the Chairperson. The Secretariat will acknowledge the receipt of the agreements and will store the original copies in the Secretariat office in the "Confidentiality Agreements" file. Photocopies of individual agreements will be stored in the individual member files.

2.4.5 Tenure of membership

- The tenure of IEC will be for a continuous period of 3 years from the date of appointment.
- Existing members can be reappointed after the completion of their term. There is no limit on the number of times a membership can be extended. Extension of a membership will be decided by the Director in consultation with the Dean of the Institute.
- Appointment procedures should be followed to ensure continuity of IEC functions, development and strengthening of expertise within the IEC, and to bring in new ideas, methods and approaches.
- One-fourth of the IEC members will change at every reconstitution of the IEC after a term is completed.

2.4.6 Appointment of new members

- New members of the IEC will also be appointed by the Head of the Institute.
- New members will be appointed under the following circumstances:
    - When a regular members complete their tenure
    - If a regular member resigns before the tenure is completed
    - If a regular member ceases to be a member for any reason (e.g. resignation, retirement, disqualification or death)
    - To fulfil the membership requirements as stated in this SOP

- New members will be identified by the Chairperson as per the membership requirements and after a discussion with the IEC. The names of potential new members may be suggested by the Chairperson and IEC members to the Head of the Institute. The final decision regarding the appointments will rest with the Head of the Institute.

2.4.7 Conditions to be fulfilled by a member after appointment

Members to be appointed to the IEC need to fulfil the following conditions:

- They need to submit a recent signed curriculum vitae
- They should furnish any ethics or GCP training certificates they might have. If unavailable at the time of induction as an IEC member, they must submit these within 12 months of the appointment.
- Should be willing to publicize their full name, profession and affiliation

- Should agree to sign the confidentiality agreement and maintain confidentiality on meetings, deliberations, research proposals, information on research participants and all related matters of the IEC.
- Should agree to read, understand, accept and follow the conflict of interest policy and sign the conflict of interest agreement.

2.4.8 Resignation, leave and disqualification of members

2.4.8.1 Resignation and leave

- An IEC member may resign from the membership by submitting a letter of resignation to the Chairperson. The member may or may not assign any reason for the resignation. The resignation will become effective from the day it is accepted by the Chairperson.

- The Director will appoint a new IEC member meeting a similar profile as the member who has resigned.

- If an IEC member proceeds for a leave longer than six months, the Director may replace the member with another member in consultation with the Dean of the Institute.

2.4.8.2 Disqualification for unsuitable conduct by an IEC member or not attending IEC meetings

A. Disqualification for unsuitable conduct by an IEC member

- A member may be disqualified from continuing in the IEC, if the IEC decides by a three-fourth majority specifically called for the purpose that the member's conduct has been inappropriate for being a part of the IEC.

- The process will be initiated if the IEC Chairperson or Member Secretary receives an allegation of misconduct in writing from an IEC member or a member of the public.

- The Chairperson will confirm that a *prima facie* case exists before initiating action. If the Chairperson deems that the matter is of grave concern and can damage the integrity of the IEC, the Chairperson may suspend the IEC member till a final decision is taken. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of the IEC.

- The Chairperson may either call an IEC meeting specifically to address the issue or the matter may be taken up for discussion during one of the regular IEC meetings. The meeting convened will follow the general rules of quorum. The allegations will be

discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.

- The member would stand disqualified, if members present in the IEC meeting approve the disqualification by voting a 2/3rd or greater majority. The Chairperson will convey the disqualification to the concerned member through a written communication.

B. Disqualification for not attending IEC meetings

A member may be disqualified from IEC membership if the member fails to attend more than three consecutive regular IEC meetings without prior intimation. The disqualification process will be conducted as follows:

- The Member Secretary will inform the Chairperson in writing, if a member has not attended more than three consecutive regular IEC meetings without prior intimation to the IEC.

- The Chairperson will initiate the process of review of membership of such a member by including the matter in the agenda of the next regular IEC meeting.

- A written communication will be sent to the concerned IEC member that the issue of disqualification will be discussed at the meeting, inviting the member to be present at the meeting to and put up his/ her case. Alternately, the concerned IEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing through a letter addressed to the Chairperson.

- The matter will be discussed and reviewed at the IEC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.

- The Chairperson or Member Secretary will inform the IEC members about the membership termination through either a confidential written communication or at the next IEC meeting.

2.4.9 Training of IEC members in research ethics

- Individuals selected as new members of the IEC will be required to attend at least one IEC meeting as an “Observer” before being inducted into the IEC.

- The Member Secretary or another designate IEC member will provided introductory training in research ethics, GCP and IEC SOPs to the new members.

- A newly inducted member should submit a certificate of training completion within 12 months of his/her appointment.

- All members including the Chairperson and Member Secretary will be encouraged to undergo continued training by participating in workshops, conferences and re-training programs related to ethics. They may participate in these activities either as a delegate, faculty or facilitator.

- The IEC will also conduct workshops on ethics in clinical research, GCP, and IEC SOPs from time to time, to impart training to its members and the Institute's faculty.

- The IEC may nominate or sponsor the expenses (as applicable) incurred by an IEC member or prospective members for attending conferences, continuing education workshops and training pertaining to ethics.

2.4.10 Hierarchy

- One Chairperson, one Member Secretary and one Joint Member Secretary (optional appointment) will be appointed from the IEC members.
- The Chairperson will head the committee.
- The Member Secretary and the Joint Member Secretary (optional appointment) will be the guardian of all IEC documents.
- All other IEC members will be regular committee members with equal ranking.

2.4.11 Functions of the Chairperson

The Chairperson will be responsible for the following IEC activities:

- Conducting meetings, leading all discussions and deliberations related to the review of research proposals.

- Presiding over all elections and administrative matters relevant to the IEC's functioning.

- Represent the IEC at various meetings and fora.

- Review, sign and approve various IEC documents and communications.

- Delegate his/her responsibilities to the Vice Chairperson (optional appointment) in accordance with the IEC rules and SOPs.

- In case both the Chairperson and the Vice Chairperson are unable to attend a scheduled IEC meeting, then an Acting Chairperson can either be nominated by the Chairperson from among the IEC members or the IEC members can elect one for the meeting. The Acting Chairperson will have all the powers of the Chairperson.

2.4.12 Functions of the Vice Chairperson (optional appointment)

- The Vice Chairperson will handle the various responsibilities of the Chairperson in the latter's absence.

2.4.13 Functions of the Member Secretary

- Receive research proposals that are submitted to the IEC
- Organize an efficient tracking system for all research projects under review with the IEC
- Prepare, distribute and maintain project files
- Schedule and organize IEC meetings
- Prepare and maintain IEC meeting agenda and minutes
- Maintain and archive all IEC documentation
- Review, approve and sign all relevant IEC documents and communications that fall under the Member Secretary's purview
- Communicate with IEC members, investigators and research applicants
- Notify the principal investigators various IEC decisions that are taken regarding submitted research proposals
- Arrange for the training of IEC members and administrative staff
- Plan and organize the drafting, review, revisions and distribution of various IEC SOPs and guidelines
- Provide necessary administrative support to the Chairperson in various IEC activities and processes
- Keep all IEC members abreast with contemporary issues, latest developments and current literature pertaining to ethics and IEC functioning
- Receive ethics committee review processing fee and issue official receipts for the fee
- Delegate various IEC responsibilities to appropriate authorized IEC members and staff
- Ensure that all IEC members and staff adhere to the rules laid down in the IEC SOPs
- Prepare and organize for regular IEC audits and inspections
- Prepare and furnish annual reports, annual financial statements and other relevant IEC documents to auditors and inspectors

2.4.14 Functions of Joint Member Secretary (optional appointment)

- The Joint Member Secretary when appointed will perform all the functions of the Member Secretary in the latter's absence.

2.4.15 Functions of the IEC members

- Attend IEC meetings and participate in various discussions and deliberations to facilitate appropriate decisions and actions on various IEC matters.
- Review and discuss research proposals submitted to the IEC for evaluation
- Monitor, review and recommend appropriate action on serious adverse event reports
- Monitor ongoing research studies and review their progress reports
- Perform on-site visits as and when required
- Evaluate final research project reports and the study outcomes
- Maintain confidentiality of all deliberations, meetings and documents of the IEC
- At every IEC meeting declare any conflicts of interest in writing to the Chairperson
- Participate in regular continuing education activities in biomedical ethics and research
- Intimate the IEC Secretariat details and documents of any training obtained in bioethics and biomedical research
- Furnish an updated curriculum vitae to the IEC Secretariat when requested
- Carry out tasks and responsibilities delegated by the Chairperson, Member Secretary and/or Joint Member Secretary
- Assist the Chairperson, Member Secretary and Joint Member Secretary in carrying out various IEC functions and tasks as per the guidelines laid down in the IEC SOPs
- Keep abreast in relevant laws and regulations related to bioethics

2.4.16 The IEC Secretariat

The IEC Secretariat will be composed of a scientific officer, IEC administrative officer, and supporting administrative staff. The Secretariat will support the Member Secretary and the Joint Member Secretary (when appointed) in all their functions. All staff members of the IEC Secretariat will also be required to sign the confidentiality agreement and these will be filed with the IEC.

2.4.17 Types of research projects to be reviewed by the IEC

The IEC is required to review the various scientific and ethical aspects of the research proposals that are submitted to the committee. This includes research proposals involving human participants which may be observational studies or interventional studies involving drug trials, procedure trials, dose modifications, alternate forms of dosage and drug delivery, duration of treatment modifications, and other health interventions. These studies may be sponsored by the Government of India, non-governmental organisations, international funding agencies,

pharmaceutical companies, or other private or government sponsors. The studies can include collaborations with national and international universities, organisations and institutions; dissertation projects for postgraduate MD, MS, DM, MCh, PhD, MSc, nursing, MPH and other courses offered by the Institute; research projects for undergraduate students carried out under the supervision of Institute faculty e.g. ICMR studentships, GJSTRAUS, etc.; and investigator initiated research studies that are self-funded, funded by the Institute or other Institutional funding bodies, or government funding agencies.

2.4.18 Quorum requirements

- IEC full board meetings will be held as scheduled provided there is quorum.

- For IEC meetings, the quorum will comprise of minimum five IEC members for regulatory clinical trials with at least one basic medical scientist (preferably a pharmacologist); one clinician; one legal expert; one social scientist, representative of non-governmental voluntary agency, philosopher, ethicist or theologian; and one lay person from the community; besides the Member Secretary and the Chairperson, as mandated by the New Drugs and Clinical Trials Rules, 2019.

- Without satisfying the above conditions, any decision taken by the IEC will remain null and void.

- In the absence of the Chairperson, the Vice Chairperson, or another member delegated by the Chairperson will chair the IEC meeting.

- In the absence of the Member Secretary, the Joint Member Secretary will perform the functions of the Member Secretary at an IEC meeting.

2.4.19 Decision making process

- All decisions in the IEC should be arrived at by consensus. In case a consensus in not reached on any matter, then voting should be carried out.

- The opinions of members that are not present at a meeting may be transmitted via email, telephone or fax. These opinions may be considered by the attending members during the meeting discussion. However, these opinions will not be counted as votes or quorum.

- Any IEC member with a conflict of interest pertaining to a matter or research proposal being discussed in the IEC meeting, will abstain from deliberations, decision making and voting on the matter / proposal, except for providing information when requested by the IEC. Such abstentions should be recorded in the meeting minutes.

- In case of tie in any matter that has been voted upon, the Chairperson can cast a vote to resolve the matter.

2.4.20 IEC subcommittees

IEC subcommittees may be constituted as and when required for expedited review of new or revised research proposals where major changes are not required, or for serious adverse events reporting. The proceedings and decisions of all subcommittees will be reported by the Member Secretary to the IEC in the next full board meeting.

2.4.20.1 Expedited review committee

The expedited review committee will comprise of the Member Secretary and two IEC members designated by the Chairperson. At least one member should be from outside the Institute. The subcommittee should report to the main IEC. The approvals granted by the expedited review committee should be ratified in the next full board IEC meeting.

2.4.20.2 Three-member subcommittee

The three-member subcommittee will consist of the Member Secretary (convener) and two outside IEC members designated by the Chairperson. This committee will take decisions regarding the proposals and clarifications submitted with proposals where major changes are not required. The subcommittee will report to the IEC.

2.4.20.3 SAE subcommittee

The SAE subcommittee will comprise of the Member Secretary, one senior faculty member of the Institute, who will also serve as the Chairperson of the SAE subcommittee, and 3-4 other members affiliated to AIIMS, Bilaspur. The SAE subcommittee will review SAE reports and assess issues pertaining to casualty, compensation and regulatory compliance. The decisions of the SAE subcommittee must be approved by the IEC at the next full board meeting.

2.4.21 Honorarium to IEC members

- The external IEC members will be provided a reasonable honorarium and reimbursement for their travelling expenses for attending IEC meetings.

2.4.22 IEC annual report

The Member Secretary will prepare an annual report to compile the yearly activities of the IEC, for submission to the Head of the Institute. The report should contain the following:

- Number and dates of full board IEC meetings
- Number and dates of expedited review and SAE committee meetings
- Number and type of proposals reviewed in a year (pharmaceutical sponsored, government sponsored, dissertations, investigator initiated etc.)
- Status of each research study whether completed, ongoing, completed or terminated.
- Number of research project approvals for full board review and expedited review with decisions in each category
- Brief details of workshops, training programs and other activities undertaken by the IEC, and those attended by the IEC members.
- Miscellaneous activities, if any.

2.4.23 Registration of ethics committee for clinical trials

- The Institutional Ethics Committee will make an application for grant of registration to the Central Licencing Authority (Central Drugs Standard Control Organization, CDSCO) using Form CT-01 (AIIMS-BLS/IEC-H/SOP02/V1/ANX04).

- The IEC will furnish the information and documents specified in Table 1 of the Third Schedule along with the above application form.

- The Central Licensing Authority will scrutinize the application and submitted documents, and may either approve the application, seek further clarification or reject the application with reasons and intimate the verdict in 45 working days from the date of receipt of application.

- If the IEC is aggrieved by the decision of rejection by the CDSCO, the IEC may file an appeal before the Central Government in the Ministry of Health and Family Welfare within 60 working days from the date of receipt of the order of rejection.

- The registration granted to the IEC will remain valid for a period of five years from the date of issue, unless suspended or cancelled by the licensing authority.

- When the validity of the IEC registration is about to expire, the IEC may make an application for renewal of the registration in Form CT-01 (AIIMS-BLS/IEC-H/SOP02/V1/ANX04) along with the necessary documents, 90 days prior to the date of registration expiry. If the application for renewal of registration is received by the licensing authority 90 days prior to the expiry, the registration will continue to remain in force until an order is passed by the licensing authority on the renewal application. This is subject to the condition that there are no changes in the documents submitted since the time of grant of registration, and the IEC renders a certificate to the effect indicating that there have been no changes.

- The registration renewal application will be scrutinized by the licensing authority along with inspection reports, if any, to issue the final verdict.

2.4.24 Registration of ethics committee for biomedical and health research

- An institutional ethics committee constituted for managing biomedical and health research will be required to register with the authority designated by the Central Government in the Ministry of Health and Family Welfare, Department of Health Research. The application for registration will be made in the Form CT-01 (AIIMS-BLS/IEC-H/SOP02/V1/ANX04), t the said authority; and at the Naitik portal of the Department of Health Research website (https://naitik.gov.in/DHR/UserRegistrationForm).

- The registration application should be accompanied with the information and documents as specified in Table 1 of the Third Schedule.

- On receipt of the application the licensing authority will grant a provisional registration to the IEC which will remain valid for a period of two years.

- After the grant of provisional registration, the licensing authority will scrutinise the documents and information provided by the applicant IEC, and if satisfied that the requirements of the NDCT 2019 rules have been complied with, grant final registration to the ethics committee. If the authority is not satisfied, it may reject the application with reasons recorded in writing and the final registration decision will supersede the provisional registration granted earlier.

- An applicant IEC that is aggrieved by the decision of the licensing authority may file an appeal within 60 working days from the date of receipt of the rejection. The appeal will have to be filed before the Central Government in the Ministry of Health and Family Welfare. The Central Government, may, after such enquiry as is considered necessary in the facts and circumstances of the case, and after giving an opportunity of being heard to the appellant, dispose of the appeal within a period of 60 working days.

- For renewal of registration the IEC will submit an application as per Form CT-01 (AIIMS-BLS/IEC-H/SOP02/V1/ANX04) along with necessary documents at least 90 days prior to the date of expiry of the final registration granted to the IEC. If the application for renewal of registration is received by the licensing authority 90 days prior to the date of expiry, the IEC registration will continue to be in force until an order is passed by the authority. This will be subject to the fact that there are no changes in the furnished documents from the documents submitted at the time of the final registration, and if the IEC renders a certificate to the effect indicating that there are no changes.

- The licensing authority will take a decision on the application for renewal of registration within 45 working days from the date of application.

- The registration granted will remain valid for a period of five years from the date of its issue, unless suspended or cancelled by the licensing authority.

2.4.25 Suspension or cancellation of IEC registration

- If the licensing authority is of the opinion that the ethics committee has failed to comply with any of the provisions of the Drugs and Cosmetics Act, or the national and international ethics rules, it may issue a show cause notice to the IEC specifying therein such non-compliance and the period within which the IEC should to the authority.

- The IEC may be given an opportunity by the licensing authority to be heard in person. The show cause notice sent by the licensing authority will bear the details and period within which the IEC is to respond and represent.

- After receiving the response of the IEC the Central Licencing Authority may take one of the following actions:

    - Withdraw the show cause notice
    - Issue warning to the IEC describing the deficiency or defect observed during inspection or otherwise, which may adversely affect the rights or well-being of the trial subjects or the validity of the clinical trial, bioavailability study or bioequivalence study being conducted
    - Reject the results of the clinical trial, bioavailability study or bioequivalence study
    - Suspend for such period as considered appropriate or cancel the registration of the ethics committee
    - Debar IEC member(s) from overseeing any clinical trials in the future for such period as may be considered appropriate by the Central Licensing Authority

- Where the IEC or any member of the IEC is aggrieved by an order of the Central Licensing Authority, such committee or member may within a period of 60 working days (for an IEC managing clinical trials) or 45 working days (for an IEC managing biomedical and health research) from the date of receipt of the order, file an appeal to the Central Government.

- Where an appeal has been filed, the Central Government may after necessary enquiry, and after giving an opportunity of being heard, pass such order in relation thereto as it thinks appropriate in the facts and circumstances of the case within a period of 60 working days from the date of filing of the appeal.

2.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP02/V1/ANX01 – Working rules for the administrative staff of the IEC for biomedical and health research
Annexure 2: AIIMS-BLS/IEC-H/SOP02/V1/ANX02 – Organisational chart of the IEC for biomedical and health research
Annexure 3: AIIMS-BLS/IEC-H/SOP02/V1/ANX03 – Confidentiality agreement form for IEC members and staff
Annexure 4: AIIMS-BLS/IEC-H/SOP02/V1/ANX04 – Form CT-01 for registration/renewal of ethics committee for clinical trials, bioavailability and bioequivalence studies, or biomedical health research
Annexure 5: AIIMS-BLS/IEC-H/SOP02/V1/ANX05 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP02/V1/ANX01
Working rules for the administrative staff of the IEC for biomedical and health research

An administrative assistant will be appointed in the IEC Secretariat who will assist the IEC Chairperson and Member Secretary in executing the various functions of the IEC. Additional staff may be appointed for assigning various duties as and when required. The eligibility criteria for the new staff appointments will be laid down depending on the required job profile. The justification for the new appointments, job profiles, required qualifications and office timings may be recommended by the IEC members during a regular IEC meeting and documentation in the meeting minutes. The Secretariat administrative staff will report to the Vice Chairperson (if from AIIMS, Bilaspur) and/or the Member Secretary. All administrative staff will be appointed by the Institute Director.

Duties of administrative assistant

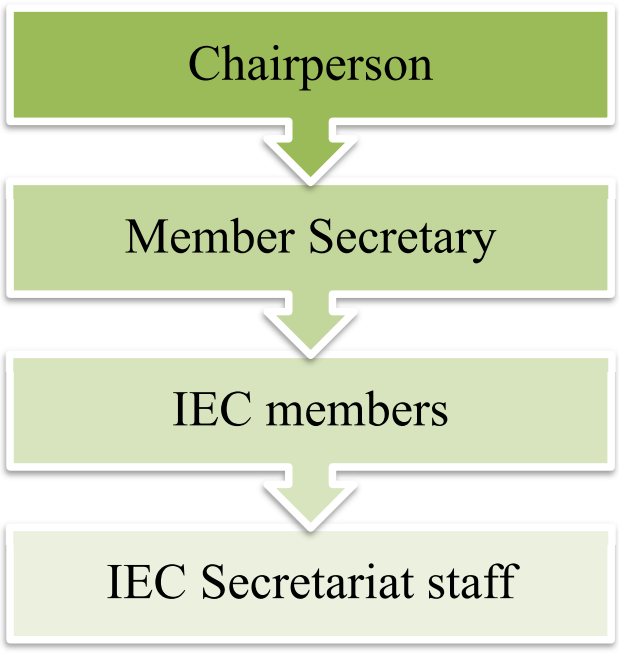
- Correspondence with IEC members and external experts
- Correspondence with research investigators
- Preparing the agenda and minutes of IEC meetings
- Answering queries of research investigators
- Filing and maintaining research project related documents
- Archiving and maintaining the research project files, SOPs, IEC correspondence and other IEC documents
- Maintaining an electronic database of IEC records

Duties of IEC attendants and helpers

Assisting the Secretariat in arranging IEC meetings
Receiving research project related documents and dispatching IEC letters and communications to investigators
Dispatching research project document sets to IEC members and external experts
Filing research project related documents
Archiving and maintaining research project files
Assisting the Secretariat during IEC meetings

Annexure 2: AIIMS-BLS/IEC-H/SOP02/V1/ANX0
Organisational chart of the IEC for biomedical and health research

Once the Institute Director constitutes the IEC, it will function in the following hierarchical order



Annexure 3: AIIMS-BLS/IEC-H/SOP02/V1/ANX03
Confidentiality agreement form for IEC members and staff

In recognition of the fact, that I …… (member's name, position in IEC, and affiliation) herein referred to as the "undersigned", have been appointed as a member of the AIIMS, Bilaspur, IEC for biomedical and health research, and have been asked to assess research proposals involving human research participants to ensure that the studies are conducted in a humane and ethical manner, adhering to the highest standards of care as per national, international and institutional guidelines. The appointment of the undersigned as a member of the IEC is based on individual merit and not as a representative of a home province, territory or community, or as a delegate of any organization, or for private interest. The fundamental duty of the undersigned is to independently review both the scientific and ethical aspects of the research proposals involving human participants submitted to the IEC, and offer objective and best possible recommendations for the study, based on the merits of the proposal. The IEC must meet the highest ethical standards in order to garner the trust and confidence of the local and national communities in the protection of the rights and well-being of research participants. The undersigned as a member of the IEC is expected to meet the same high ethical standards while carrying out its mandate.

This agreement encompasses any information that is deemed confidential, proprietary or privileged by the IEC, and is provided to the undersigned as part of the duties of an IEC member. All confidential information and any copies and notes thereof, shall remain the sole property of the IEC for biomedical and health research, at AIIMS, Bilaspur. The undersigned agrees to hold all confidential information in trust or confidence and agrees that it shall be used only for assigned purposes, and shall not be used for any other purpose or disclosed to any other party. Any written confidential information provided for review shall not be copied or retained.

The undersigned agrees not to disclose or utilize, directly or indirectly, any confidential or proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the undersigned confirms that his/her performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties. Confidential information includes any information submitted by the research investigators for ethics review, whether written or oral, including, but not limited to technical, scientific, financial, strategic, marketing or product information. It also includes, but is not limited to, information concerning the IEC digital processes, programs, code, financial information, pending projects and proposals, standard operating procedures, legal and regulatory affairs.

Confidential and proprietary information includes the above information even when it is not marked as such. "Confidential information" does not include information that: (a) was already in the undersigned's possession, as evidenced by written records; (b) becomes publicly available through no fault of the undersigned; or (c) is lawfully and in good faith made available to the undersigned by a third party. Where I am required by law, regulation, or court order to

disclose confidential and proprietary information, I will provide the IEC with a notice of such requests immediately, but in no event later than two working days after receipt of such a request. I agree to cooperate with the IEC if the committee wishes to seek a protective order.

I agree to take reasonable measures to protect all confidential information; subject to applicable legislation, including the Access to Information Act, not to disclose the confidential information to any person; not to use the confidential information for any purpose outside the committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all confidential information, (including any minutes or notes I have made as part of my committee duties), to the Chairperson upon termination of my functions as a committee member. I also understand that as a member I will be given copies of the study proposals/necessary documents for evaluation. These will be duly returned by me to the IEC for biomedical and health research, AIIMS, Bilaspur as and when requested. I will assure that the documents/proposals sent to me in electronic format will be stored in a secure, password protected electronic storage.

I …….. (name of IEC member) have read and accept the above mentioned conditions as delineated in this agreement.

Signature: Date:

Chairperson’s signature: Date:

(The original signed and dated agreement will be kept on file in the custody of the IEC. A copy of the agreement will be given to the undersigned.)

I acknowledge that I have received a copy of this agreement signed by the IEC Chairperson and me.

Signature: Date:

Annexure 4: AIIMS-BLS/IEC-H/SOP02/V1/ANX04
Form CT-01 for registration/renewal of ethics committee for clinical trials, bioavailability and bioequivalence studies, or biomedical health research

Eighth Schedule
Form CT-01
Application for registration/renewal of ethics committee relating to clinical trial, bioavailability and bioequivalence study or biomedical health research

I/We, ……
……..
(name, designation and full postal address of the applicant) of ……..
……..
(name and full address with contact details of the ethics committee) hereby apply for the grant of registration of ethics committee.

The details of the application are as under:

1. Name of the applicant:
2. Nature and constitution of the applicant: (proprietorship, company, society, trust, independent, institutional, other to be specified)
3. (i) Applicant address including telephone number, mobile number, fax number, and email id: (ii) Address for correspondence: Corporate or registered office or clinical trial site or bioavailability and bioequivalence study centre or biomedical health research
4. Details of accreditation, if any (self-attested copy of certificate to be attached):
5. I have enclosed the documents as specified in Table 1 of the Third Schedule of the New Drugs and Clinical Trials Rules, 2019.
6. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trial Rules, 2019.

Signature
(Name and designation)

Place:
Date:

Annexure 5: AIIMS-BLS/IEC-H/SOP02/V1/ANX05
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Chitresh Kumar; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

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3 Managing conflicts of interest among ethics committee members of the Institutional Ethics Committee for biomedical and health research

3.1 Purpose

The purpose of this standard operating procedure (SOP) is to identify and manage conflicts of interest among the members of the institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur.

3.2 Scope

This SOP covers the various procedures and policies pertaining to the identification, declaration and management of conflicts of interest that may arise in the IEC, and are applicable to all members of the IEC for biomedical and health research, at AIIMS, Bilaspur.

3.3 Responsibility

All IEC members are responsible for understanding the definition of conflict of interest and for identifying and self-declaration of their conflicts of interest in the manner stipulated in this SOP. The Chairperson will need to ensure that conflicts of interest are identified, declared and managed during the initial and continuing review of research studies.

3.4 Definitions and mandate

3.4.1 Conflicts of interest

A set of condition under which the professional judgement concerning a primary interest like a patient's welfare or the validity of a research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic, or political), or financial gain is termed as conflict of interest.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

3.4.2 Personal conflict of interest

- A personal conflict of interest is said to exist when there is immediate family relationship (spouse, parent, parent of spouse, child, sibling, sibling of spouse, dependent who resides with an IEC member, consultant, a person who receives 50% or more support from an IEC member, regardless of age), or other close personal relationship (step relationships included) with the principal investigator or co-investigators of a research proposal.

- A personal conflict of interest also exists when an IEC member or his/her immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff or financer.

- A research study submitted by a departmental colleague or senior may also be regarded as a potential personal conflict of interest.

3.4.3 Professional conflict of interest

An IEC member or his/her immediate family member serves as the trustee, director, manager or scientific advisor of the funding agency sponsoring the research.
A financial conflict of interest exists for an IEC member and/or his/her immediate family.
An IEC member, his/her spouse, or dependent receives monetary benefits including but not limited to, salary, payments for services (e.g. consulting fee, honorarium), equity interests (e.g. stocks, stock options, ownerships interests), and intellectual property rights (e.g. patents, copyrights, products or services being evaluated).

3.4.4 Mandate

The mandate for conflicts of interest is available under GSR 72(E) Registration of Ethics Committee, Ministry of Health and Family Welfare, Department of Health Notification, dated 8th February 2013.

- 2h: “There should be no conflict of interest. Members shall voluntarily withdraw from an ethics committee meeting while making a decision on an application which evokes conflicts of interest which may be indicated in writing to the chairperson prior to the review and should be recorded in the meeting minutes. All IEC members shall sign a declaration for conflicts of interest.”

Indian GCP, CDSCO states that:

- 2.4.2.6: “A member must voluntarily withdraw from the IEC while making a decision on an application which evokes a conflict of interest which should be indicate din writing to the Chairperson prior to the review and should be recorded in the meeting

minutes. If one of the IEC members has his/her own proposal for review, then the member should not participate when the project is discussed."

3.5 Detailed instructions

3.5.1 Voluntary disclosure of conflicts of interest

An IEC member should determine whether he/she has a conflict of interest before reviewing a research proposal, and declare all certain or potential conflicts of interest prior to engaging in any review process. IEC members should not participate in discussing or decision making on research proposals reviewed at any level (exemption, expedited review, or full board review) when they have conflicts of interest, except to provide information that is requested by the IEC.

- If an IEC member has a conflict of interest while reviewing outside a meeting (e.g. expedited review, amendments), he/she should notify the IEC Secretariat and return the research documents.

- If an IEC member has a conflict of interest for a study for which he/she has been assigned as a reviewer, he/she will inform the IEC secretariat so that the review is reassigned to another member.

- If an IEC member has a conflict of interest for review of a research study at an IEC meeting, he/she should inform the Chairperson and leave the meeting while the study is being discussed. He/she may stay in the meeting room only to answer questions about the research. This is also applicable to IEC meetings in which discussions on serious adverse events, deviations and violations, amendments, and continuing review reports are being discussed.

- Recusal: an IEC member who declares conflict of interest and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a *recusal*, not an abstention or an absence.

- If an IEC member finds that he/she has a conflict of interest during the conduct of a research project approved by the IEC, he/she shall report the conflict to the IEC at the next IEC meeting.

- At the beginning of each meeting, the IEC Chairperson shall ask the members to disclose any conflicts of interest concerning any of the items on the meeting agenda. During the meeting, IEC members with conflicts of interest declare that the same before the review of the relevant item begins.

- If the chairperson has a conflict of interest for a particular project, this should be declared and handled like any other member's conflict of interest. An acting chair should be appointed for discussion on such a project.

- When the presence of conflict of interest is uncertain, more information should be gathered from relevant sources and the IEC member should confirm conflict of interest with the help of the Chairperson or Member Secretary.

- The IEC Chairperson has the final authority to determine whether a conflict of interest has been managed or eliminated appropriately for research participant protection.

- The IEC should not approve a research proposal where conflicts of interest have not been managed or eliminated.

3.5.2 Management of conflicts of interest

- In case of a conflict of interest the IEC members will disclose the conflict as detailed above
- The IEC member in question will not serve as a reviewer for the said study
- The IEC members with conflicts of interest will not participate in the discussion and decision making for the concerned study
- The Member Secretary and the IEC Secretariat will record the points related to the conflict of interest disclosure and management in the meeting minutes

3.6 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP03/V1/ANX01 – Conflict of interest declaration form for IEC members
Annexure 2: AIIMS-BLS/IEC-H/SOP03/V1/ANX02 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP03/V1/ANX01
Conflict of interest declaration form for IEC members

Conflict of interest declaration form

I am aware of the policy of the IEC for biomedical and health research, AIIMS, Bilaspur, regarding conflicts of interest, and that no member may participate in the review, deliberation or decision making of any activity in which he/she has actual or potential conflicts of interest except to provide information as and when requested by the IEC.

I declare …… (actual or potential conflict of interest) in relation to the proposal entitled ……
……..
submitted for review to the IEC, AIIMS, Bilaspur. The reason for conflict of interest is ……..
……..
……..
……..

I will refrain from the review process and/or discussion at the IEC meeting, and also will not take part in the ongoing and periodic review and monitoring of this study.

Signature of IEC member: Date:

Signature of Chairperson: Date:

Annexure 2: AIIMS-BLS/IEC-H/SOP03/V1/ANX02
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Chitresh Kumar; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

04

4 Training and assessment of ethics committee members and staff by the Institutional Ethics Committee for biomedical and health research

4.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe how the institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur is to train and assess the performance of the Committee members and Secretariat staff for the efficient functioning of the IEC.

4.2 Scope

This SOP is relevant for the training and assessment of members and staff working for the IEC for biomedical and health research, AIIMS, Bilaspur.

4.3 Responsibility

The IEC Chairperson with the assistance of the Member Secretary will ensure that there is adequate initial and continued training of the IEC members and the Secretariat staff. It is the responsibility of the IEC members to educate themselves and undergo periodic training in biomedical ethics and its various aspects. The Chairperson is responsible for the assessment of all IEC members and complete a self-assessment exercise at prescribed intervals.

4.4 Detailed instructions

4.4.1 Topics for training

A. All IEC members should have thorough knowledge in the following areas:

- Relevant research ethics and regulatory guidelines for biomedical research
- Roles and responsibilities of IEC members

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

- Process and methods for review of research proposals and their related documents, including but not limited to the concepts of risk-benefit assessment, equity in recruitment, autonomy, confidentiality and privacy
- The standard operating procedures laid down for the IEC for biomedical and health research
- Changes and updates in ethics regulations and policies
- The declaration of Helsinki and other international guidelines like the CIOMS and WHO Ethical Issues Guidelines
- The National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), issued by the ICMR
- The Good Clinical Practice: Consolidated Guidance (Apr 1996, ICH –GCP)
- The WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011)
- The Forum for Ethical Review Committees in Asia and the Western Pacific SOPs (2006)
- National Guidelines for Stem Cell Research (2017), issued by the ICMR
- National Ethical Guidelines for Bio-medical Research involving Children (2017), issued by the ICMR
- Relevant regional, national and international laws and regulations
- International issues and cases of ethical concern
- Developments in biomedical science, human health, biomedical technology, environmental health, and safety
- Clinical audit procedures and monitoring practices
- New Drugs and Clinical Trials Rules, 2019
- Any amendments and subsequent or more recent versions of the above documents as and issued by the concerned authorities.

B. The IEC Secretariat staff should have knowledge and skills in the following:

- Competency in working with Microsoft Word, Excel, and IEC office software
- Operation and maintenance of the IEC database
- Good communication skills including both written and verbal
- Knowledge about the IEC SOPs

4.4.2 Training of new IEC members

- Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs. One training every year at the minimum should be provided.

- An individual selected as a new member of the IEC will be required to attend two meetings as an 'Observer' before being inducted as a member of the IEC.

- The Member Secretary or an IEC member will provide introductory training to the new member. New IEC members will be encouraged to undergo online IEC training as well.

- The IEC Member Secretary, members and Chairperson will be encouraged to receive continued training by participating in workshops, conferences, and retraining programs related to research ethics, as a delegate, faculty, facilitator, etc., at least once every year.

- The IEC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the IEC members and to the Institute's faculty members.

4.4.3 Training of the IEC Secretariat

- The Member Secretary along with other IEC members will train the Secretariat on IEC SOPs. There will be initial training and at least one training session per year on the SOPs.

- The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson.

4.4.4 Assessment of IEC members

- The performance of IEC members should be evaluated once a year by the Chairperson, using an assessment form.

- The Chairperson should perform a self-assessment once a year.

4.4.5 Maintenance of training records of IEC members and staff

The Secretariat should maintain copies of the certificates of all training workshops and conferences on research ethics that have been attended by individual IEC members. The copies will be filed in the individual members' files. The records of training of the Secretariat staff will also be maintained in their respective files.

4.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP04/V1/ANX01 – Performance assessment form for the IEC Member Secretary and IEC members
Annexure 2: AIIMS-BLS/IEC-H/SOP04/V1/ANX02 – Self-assessment form for the IEC Chairperson

Annexure 3: AIIMS-BLS/IEC-H/SOP04/V1/ANX03 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP04/V1/ANX01
Performance assessment form for the IEC Member Secretary and IEC members

1. Name:
2. Current tenure:
3. Terms served:
4. Training received:
5. Type of training received:

6. No. of meetings attended:
7. No. of projects reviewed per meeting as primary reviewer:
8. No. of projects reviewed per meeting as secondary reviewer:
9. Participation in SAE report review process (Yes/No):
10. Participation in site monitoring visits (Yes/No):

11. Number and type of continuing training workshops organized for IEC members (applicable to Member Secretary):

12. Number and type of continuing training workshops organised for IEC secretariat staff (applicable to Member Secretary):

13. Any other significant contribution to the field of research ethics:

14. Remarks by the Chairperson on the self-assessment:

IEC member
(Signature, name, date)

IEC Chairperson
(Signature, name, date)

Annexure 2: AIIMS-BLS/IEC-H/SOP04/V1/ANX02
Self-assessment form for the IEC Chairperson

1. Name:
2. Current tenure:
3. Terms served:
4. Training received:
5. Type of training received:
6. No. of meetings held in current year:
7. No. of meetings attended:
8. Whether quorum requirement fulfilled in IEC meetings, as per NDCT Rules, 2019:
9. Whether matters related to conflict of interest considered:
10. Any significant contribution to the field of research ethics:
11. Any other comments:

IEC Chairperson
(Signature, name, date)

Annexure 3: AIIMS-BLS/IEC-H/SOP04/V1/ANX03
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Anurag Negi; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

4.6 Workflow

	Activity	Responsibility
1.	Ensure training of IEC members	Member Secretary, Chairperson
2.	Training of IEC Secretariat staff	Member Secretary, IEC members
3.	Performance assessment of IEC members	Chairperson
4.	Self-assessment of Chairperson's performance	Chairperson

05

5 The selection and responsibilities of independent consultants invited to the Institutional Ethics Committee for biomedical and health research at AIIMS, Bilaspur

5.1 Independent consultant

An Independent consultant is a subject expert in a specific field who provides advice, comments and suggestions on research proposals after review. The consultant is not affiliated to the Institute(s) and investigators who have submitted the proposal. The consultant may be specialized in ethical and legal matters, specific diseases (e.g. genetic disorders), techniques or methodologies (e.g. stem cell research), or might be a representative of pertinent communities, patients or special interest groups.

5.2 Purpose

The purpose of this standard operating procedure (SOP) is to delineate procedures required for selecting and engaging the expertise of professionals as independent consultants for the institutional ethics committee (IEC) for biomedical and health research, AIIMS Bilaspur.

5.3 Scope

This SOP covers the procedures required for selecting and appointing independent consultants, and soliciting their expert opinion for the review of specific research proposals submitted to the IEC for biomedical and health research at AIIMS Bilaspur. If the Chairperson or IEC members agree that a research proposal involves procedures or technicalities that are not within the area of expertise of the committee members, then the Chairperson in consultation with the Member Secretary can suggest competent experts in the relevant subject area to assist in the review of the said research proposal. The SOP further, delineates the responsibilities of the independent consultant.

5.4 Responsibility

It is the responsibility of the Chairperson, Member Secretary, and/or IEC members to nominate the names of one or more independent consultants.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

The Chairperson is responsible for endorsing the choice of independent consultants nominated by the Member Secretary and IEC members. The administrative procedures for the selection, confidentiality agreement and maintenance of list of independent consultants, will be carried out by the IEC Secretariat.

5.5 Detailed instructions

5.5.1 Recommending and preparing a list of independent consultants

- The Chairperson, Member Secretary, and/or IEC members will nominate the names of independent consultants from different specialties.

- The Member Secretary in consultation with the Chairperson will select a panel of independent consultants for the IEC.

- The Member Secretary will issue appointment letters to the independent consultants after confirming their availability and willingness to be independent consultants, through telephonic or electronic communication.

- After receiving a written acceptance from the independent consultants, a list of specialty wise independent consultants will be maintained by the Secretariat in their records. The details of each independent consultant including name, designation, affiliation, contact details and an updated curriculum vitae, will be maintained in the IEC records.

5.5.2 Consulting an independent consultant for an IEC review

- If during the review of a research proposal it is determined that the study involves procedures or technical details that are beyond the collective expertise of the IEC members, then an IEC member, Member Secretary or Chairperson can suggest that the opinion of one or more independent consultants may be sought for the matter. Appropriate independent consultants may be suggested from among the panel of independent consultants available with the IEC. However, an independent consultant from outside the panel can also be suggested.

- The Member Secretary in consultation with the Chairperson, or at a full board meeting (as deemed necessary) will identify and select the independent consultants proposed from outside the panel available with the IEC. The independent consultants should be invited based on their area of expertise, professional independence, and availability.

- The Member Secretary on behalf of the IEC will invite the independent consultants in writing to assist in the review of the research proposal and provide their independent opinion in writing. This may be done after seeking concurrence and confirming the

availability of the independent consultants through telephonic or electronic communication.

5.5.3 Communication with independent consultants for fulfilling administrative requirements

- The IEC Secretariat may request the independent consultants that have been selected from outside the panel available with the IEC, to provide their updated curriculum vitae for IEC's records.

- The Member Secretary will request the independent consultants to declare if they have any conflicts of interest. The independent consultants should declare in writing and sign the stipulated conflicts of interest and confidentiality agreements.

- The IEC Secretariat will send copies of the confidentiality agreement and conflict of interest agreement to the independent consultants, for careful perusal, understanding and signatures.

- The Member Secretary will provide explanations and clarifications (telephonically or in writing) to the independent consultants if any doubts or questions are raised. Any further explanations that might be required can be provided by the Chairperson, legal expert or IEC members.

5.5.4 Conflict of interest and confidentiality agreements

- The independent consultants will thoroughly go through the conflict of interest and confidentiality agreement documents provided to them, and sign, date and return the agreements if they agree.

- The Secretariat will forward the signed agreements received from the independent consultants to the Chairperson.

- The Chairperson will review, sign and date the agreements. The original copies of the agreements will be retained by the Secretariat and photocopies will be sent to the independent consultants.

5.5.5 Review of research proposals

- The Secretariat will provide the research proposal, its related documents, and a study assessment form (customized for independent consultants) to the independent consultants.

- The independent consultants will be requested to review the research proposal and provide their expert comments in the assessment form (duly signed and dated). The consultants will return the assessment forms to the IEC Secretariat within a stipulated period of time or by a scheduled date.

- The assessment report provided by the independent consultants will be incorporated as part of the main study file of the research proposal.

- The assessment report will be reviewed by the Member Secretary in the IEC meeting when the concerned study is being discussed.

- If deemed necessary, the Chairperson or Member Secretary may seek additional information or clarifications from the independent consultant in writing. The additional information provided by the independent consultant will be considered a part of the study assessment report.

- If deemed necessary, the Chairperson or the Member Secretary may invite the independent consultants to attend the IEC meeting for providing additional information or clarifications that may be required by the IEC members or the Chairperson. However, the independent consultants will not participate in the decision making processes related to the research study.

- If deemed necessary, the independent consultants may be reimbursed for the expenses incurred on travel, time spent, documents referred from the library or the internet, and any other incidental expenses.

5.5.6 Tenure of service of independent consultants

The panel of independent consultants maintained by the IEC office will be updated every 5 years or as required. The services and tenure of independent consultants appointed for a particular study, will get automatically terminated once a final decision is taken by the IEC on the concerned study. The IEC will document the termination of the independent consultant's services and send a letter of thanks to the independent consultant for services rendered.

5.5.7 Responsibilities of independent consultants

- If an independent consultant agrees to review a research proposal, he/she should comply with the IEC's requirement of signing the confidentiality and conflict of interest agreements.

- The independent consultant will review the specified research study and complete the study assessment form (duly signed and dated) within a stipulated period of time or by a stipulated date.

- The independent consultant will attend the IEC meeting for providing additional information or clarifications, when invited by the Member Secretary or the Chairperson. However, the independent consultant will not participate in the decision making process on the research study.

- The independent consultant will remain available for telephonic and email communication till the review process of the given research proposal is complete.

5.6 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP05/V1/ANX01 - Confidentiality agreement form for independent consultants
Annexure 2: AIIMS-BLS/IEC-H/SOP05/V1/ANX02 - Conflict of interest agreement for independent consultants
Annexure 3: AIIMS-BLS/IEC-H/SOP05/V1/ANX03 - Study assessment form for independent consultants
Annexure 4: AIIMS-BLS/IEC-H/SOP05/V1/ANX04 - Invitation to attend IEC meeting as an independent consultant
Annexure 5: AIIMS-BLS/IEC-H/SOP06/V1/ANX05 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP05/V1/ANX01
Confidentiality agreement form for independent consultants

Confidentiality agreement for independent consultants

I ……...
(name and designation) as a non-member of the Institutional Ethics Committee (IEC) for biomedical and health research, AIIMS, Bilaspur, understand that the documents pertaining to the IEC and research proposal, provided to me by the IEC are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IEC for biomedical and health research, AIIMS, Bilaspur.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information confidential.

Signature of the independent consultant: Date:

Signature of the Chairperson: Date:

Annexure 2: AIIMS-BLS/IEC-H/SOP05/V1/ANX02
Conflict of interest agreement for independent consultants

Conflict of interest agreement for independent consultants

I understand that it is the policy of the Institutional Ethics Committee (IEC) for biomedical and health research, AIIMS, Bilaspur, that no reviewer may participate in the review, comment or approval of any activity in which he/she has a conflict of interest, except to provide information as requested by the IEC.

I do not have any actual or potential conflicts of interest in relation to the particular research proposal submitted to me for review by the IEC. In the event that I discover any conflict of interest in relation to the particular proposal during the review process, I will declare it to the IEC and refrain from reviewing the research proposal.

I ……. (name) have read and accept the aforementioned terms and conditions as explained in this agreement.

Signature of the independent consultant: Date:

Signature of the Chairperson: Date:

I acknowledge that I have received a copy of this agreement signed by the IEC Chairperson and me.

Signature of the independent consultant: Date:

(The original signed and dated agreement will be kept on file with the IEC. A copy of the original will be handed to the independent consultant you for his/her records.)

Annexure 3: AIIMS-BLS/IEC-H/SOP05/V1/ANX03
Study assessment form for independent consultants

IEC project no:			Date: (dd/mm/yy)
No. of participants at the site		No. of study sites	

Please mark and comment on the items that are applicable to the study.
(Please attach extra sheets where required)

1.	Objectives of the study	Clear	Unclear
	What should be improved?		
2.	Need for human participants	Yes	No
	Comments:		
3.	Methodology	Clear	Unclear
	What should be improved?		
4.	Background information and data	Sufficient	Insufficient
	Comments:		
5.	Risk-benefit assessment	Acceptable	Unacceptable
	Comments:		
6.	Inclusion criteria	Appropriate	Inappropriate
	Comments:		
7.	Exclusion criteria	Appropriate	Inappropriate
	Comments:		
8.	Discontinuation and withdrawal	Appropriate	Inappropriate
	Comments:		
9.	Sufficient number of participants?	Yes	No

	Comments:		
10.	Control arms (placebo, if any)	Yes	No
	Comments:		
11.	Are qualifications and experience of the participating investigators appropriate?	Yes	No
	Comments:		
12.	Facilities and infrastructure of participating sites	Appropriate	Inappropriate
	Comments:		
13.	Contribution to the development of local capacity for research and treatment	Yes	No
	Comments:		
14.	Availability of similar studies / results	Yes	No
	Comments:		

Additional comments:

Independent consultant's signature: Date:

Annexure 4: AIIMS-BLS/IEC-H/SOP05/V1/ANX04
Invitation to attend IEC meeting as an independent consultant

To,
…….
…….
…….

Sub: Invitation to attend Institutional Ethics Committee meeting at AIIMS, Bilaspur

Sir/Madam,

The Chairman of the Institutional Ethics Committee (IEC) for biomedical and health research, AIIMS, Bilaspur, has nominated you as an independent consultant to evaluate a research proposal submitted to the IEC for approval.

You are requested to attend the IEC meeting on …… at ……. and provide written opinion on the assigned research proposal, IEC project no ……. entitled ……
……..
You will not have any voting rights during the meeting and you will have to sign a confidentiality agreement, which is enclosed for your kind perusal. Kindly note that all the documents submitted to you are confidential. These should not be disclosed to anyone and should be returned to the IEC, AIIMS Bilaspur after the meeting.

Yours faithfully,

Member Secretary Date:
(Signature and name)

Enclosures:

1. Research protocol
2. Confidentiality agreement form
3. Conflict of interest agreement form

Annexure 5: AIIMS-BLS/IEC-H/SOP06/V1/ANX05
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Anurag Negi; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

5.7 Workflow

	Activity	**Responsibility**
1.	Recommendation of names of one or more independent consultants	IEC members, Member Secretary, Chairperson
2.	Selection and appointment of independent consultants	Member Secretary in consultation with Chairperson
3.	Invitation to independent consultants on behalf of IEC	Chairperson, Member Secretary
4.	Coordination with independent consultants for completing administrative requirements	IEC Secretariat
5.	Conflict of interest and confidentiality agreements	Independent consultant, Chairperson
6.	Maintenance of a specialty wise list/panel of independent consultants	IEC Secretariat
7.	Reviewing research proposal and related documents	Independent consultant

06

6 Procedures for allowing a guest or observer to visit the Institutional Ethics Committee for biomedical and health research

6.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures that are to be followed by the institutional ethics committee (IEC) for biomedical and health research, at AIIMS Bilaspur, for allowing a guest or observer to visit the IEC office or attending full board IEC meetings, at AIIMS, Bilaspur. The SOP is needed to ensure adequate protection and confidentiality of information related to the IEC and the various research proposals being reviewed by the committee.

6.2 Scope

This SOP covers the procedures for allowing a guest or observer to visit the office of the IEC for biomedical and health research, at AIIMS Bilaspur, and/or observe an IEC meeting in progress.

6.3 Responsibility

- The Member Secretary in consultation with the Chairperson decides whether a guest or observer is to be allowed to visit the IEC office or to attend an IEC meeting.

- The guest or observer planning to attend an IEC meeting or visit the IEC office should read, understand, accept and sign a confidentiality agreement prior to the visit.

- The Secretariat will ensure that the confidentiality form is duly signed and dated by the guest or observer for IEC visit or IEC meeting, and will file it in the IEC records.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

6.4 Detailed instructions

6.4.1 Receiving request from guest or observer to visit the IEC or attend an IEC meeting

On receiving a written or verbal request from a guest or observer to visit the IEC office or observe an IEC meeting, the Member Secretary, IEC member or the Secretariat will obtain permission for the same from the Chairperson.

- The date and time of the visit to the IEC or to an IEC meeting will be informed to the guest or observer preferably in writing or through an email.

- The request letter and/or email will be filed in the IEC records by the Secretariat.

6.4.2 Confidentiality agreement

- The confidentiality agreement form (AIIMS-BLS/IEC-H/SOP06/V1) will be provided to the guest or observer on the day of visit or at the time of the meeting, depending on the purpose of the visit.

- The guest or observer will read and fill up the form carefully before the visit, or before the commencement of the meeting and abide by the agreement.

6.4.3 Clarifications

- In case of any queries or doubts the guest or observer can seek clarifications or additional information from the Secretariat. The Member Secretary will provide the explanations and/or additional information as the case may be.

6.4.4 Signing of the confidentiality agreement

- The guest or observer will sign and date the confidentiality agreement before a member of the IEC Secretariat. He/she will return the signed form to the Secretariat.

- The Secretariat will obtain the signature of the IEC Chairperson on the confidentiality agreement form. Once signed by the Chairperson, the Secretariat will hand the guest or observer a copy of the original for their record, and receive an acknowledgment for the same from the guest or observer. The original copy of the agreement will be saved in the IEC office in secure records under a file entitled “Confidentiality agreements for guests, observers and independent consultants”.

6.4.5 Abiding by the confidentiality agreement

- The guests or observer must abide by the clauses given in the signed confidentiality agreement.

6.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP06/V1/ANX01 - Confidentiality agreement form for a guest or observer visiting the IEC or attending an IEC meeting
Annexure 2: AIIMS-BLS/IEC-H/SOP06/V1/ANX02 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP06/V1/ANX01
Confidentiality agreement form for a guest or observer visiting the IEC or attending an IEC meeting

I …… (name), understand that I am being allowed to visit the institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur, for visiting their office or attending an IEC meeting on …… at …… as a guest/ observer.

The venue of the IEC meeting is …….
I may encounter confidential information during my visit to the IEC office or during the course of the IEC meeting. Upon signing this form, I ensure to take reasonable measures to keep all such information confidential.

Signature of the Guest/Observer Date:

Signature of the IEC Chairperson Date:

I ……. (name) acknowledge that I have received a copy of this agreement signed by the IEC Chairperson and me.

Signature of the Guest/Observer Date:

Annexure 2: AIIMS-BLS/IEC-H/SOP06/V1/ANX02
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Anurag Negi; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

6.6 Workflow

	Activity	**Responsibility**
1.	Receiving a request from a guest or observer	IEC Secretariat, member, Member Secretary
2.	Permitting a guest or observer to visit IEC	Chairperson
3.	Intimate the guest or observer, the visit / meeting date and time	IEC Secretariat
4.	Confidentiality agreement	Guest or observer
5.	Filing of the confidentiality agreement	IEC Secretariat

7 The management of research proposals and study related documents submitted to the Institutional Ethics Committee for biomedical and health research

07

7.1 Purpose

The purpose of the standard operating procedure (SOP) is to lay down various rules and procedures for the institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur, and its Secretariat, for the receipt and management of various research proposals submitted to the IEC for review and approval.

7.2 Scope

This SOP includes detailed procedural instructions on the following research proposal and research studies related activities:

1. Submission of research proposals and related documents for initial review
2. Resubmission of research proposals and study protocols with corrections
3. Submission of research protocol amendments
4. Submission of reports and communications related to continuing review of approved protocols
5. Research study completion, termination, protocol deviations, and protocol violations
6. Reports and communications related to initial, follow-up and final serious adverse event (SAE) reports

7.3 Responsibility

It is the responsibility of the IEC Secretariat to receive, record, and distribute the received research proposals and related documents for review. The Secretariat is also responsible for acting on the instructions given by the concerned IEC member(s) and to ensure that the communication reaches the concerned recipient.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

7.4 Detailed instructions

7.4.1 Receive research proposals and study documents

Principal investigators may submit their research proposals to the IEC office for review and approval under any of the following sections, and as per the stipulated IEC timetable:

- New research proposals for initial review
- Resubmission of research proposals with corrections or modifications
- Amendments in research protocols and related study documents
- Submission of SAE reports (on-site)

The research proposals should be submitted on or before the 5th of the months scheduled for full board IEC meetings, for the consideration of the proposals in the respective meeting. Besides the research proposal, all other study related documents necessary for IEC review and approval at the full board meeting, should be submitted a minimum of 72 hours before the upcoming IEC meeting. However, study documents related to participant safety may be submitted at any time.

7.4.2 Initial review application

A. ***Checking the submitted items*** - the IEC Secretariat will check the print and electronic copies of the following items:

1. Two sets of the research proposal - 1 original and 1 photocopy. An electronic copy of the proposal should also be sent with the print copies.
2. Duly filled IEC project submission application form for initial review
3. A marked checklist
4. A work/duty delegation plan/log of the study team
5. A document receipt form

B. Verification of the contents of the submitted documents

The IEC Secretariat will use the project submission checklist to confirm if all the checked documents have been furnished by the principal investigator with the application. The Secretariat staff will also check if the project submission application is complete, especially with regards to the essential documents required for IEC review. In case any essential documents are missing, an explanation should be sought from the principal investigator on writing, before commencing the proposal review. The following documents should be present with the application:

1. Cover letter to the Member Secretary / Chairperson
2. Original application / project submission form with copy of the research project (AIIMS-BLS/IEC-H/SOP07/V1/ANX01)
3. Case record form/ participant recruitment form
4. Any research protocol amendments, if applicable
5. Consent of principal investigator's head of department (AIIMS-BLS/IEC-H/SOP07/V1/ANX02)
6. Administrative sanction from the head of the Institute
7. Copy of project approval letter from departmental/institutional research review committee, doctoral committee, or MD protocol committee, as appropriate (AIIMS-BLS/IEC-H/SOP07/V1/ANX03)
8. Undertaking by principal investigator (AIIMS-BLS/IEC-H/SOP07/V1/ANX04) and/or student researcher's guide (AIIMS-BLS/IEC-H/SOP07/V1/ANX05)
9. Agreement to comply with national and international ethical guidelines and GCP protocols
10. Conflict of interest declaration by principal investigator (AIIMS-BLS/IEC-H/SOP07/V1/ANX06)
11. Recent signed and dated curriculum vitae of the investigators and student researcher (AIIMS-BLS/IEC-H/SOP07/V1/ANX07)
12. GCP training certificate (from within last 5 years) of principal investigator, co-investigators and study coordinators, if applicable
13. Research methodology training certificate (from within 5 years) of principal investigator, co-investigators, and study coordinators, if applicable
14. List of ongoing research studies currently with the principal investigator
15. Participant information sheet and informed consent forms in English and local vernacular language (AIIMS-BLS/IEC-H/SOP07/V1/ANX08-11)
16. Consent waiver form, if applicable
17. Back translations of the informed consent documents and back translation certificates, if applicable
18. Amendments to the informed consent documents, if any
19. Investigator's brochure (for drug/device trial)
20. Patient recruitment procedures including, project advertisement, information brochure, notices, letters to doctors etc. (for drug/device trial)
21. Clinical Trial Registry of India (CTRI) registration (prerequisite for sponsored clinical trials; for other trials registration can be done after IEC approval)
22. DCGI approval letter with list of approved institutes (for sponsored drug/device trial)
23. Details of the funding agency/ sponsor and grant received for the project (in project submission form and clinical trial agreement)
24. Clinical trial agreement (CTA) between sponsors, investigators, and heads of institutions (for drug/device trial)
25. Insurance policy for study participants indicating conditions of coverage, date of commencement, and date of expiry of risk coverage. It is preferable to have a full insurance policy rather than only an insurance certificate (for drug/device trial)

26. Indemnity policy clearly indicating the conditions of coverage, date of commencement and date of expiry of risk coverage
27. Material transfer agreement (MTA) and Health Ministry's Screening Committee (HMSC) approval (for international transfer of biological materials)
28. Directorate General of Foreign Trade approval (DGFT) (for export of study samples in clinical trials)
29. Genetic Engineering Advisory Committee (MoEF&CC and DBT-GEAC) approval (for proposals involving recombinant DNA technology and/or gene therapy)
30. Bhabha Atomic Research Centre (BARC) approval (for studies involving radioisotopes, or ionizing radiations)
31. Institutional stem cell research committee approval, and NAC-SCRT registration and approval, if applicable
32. Decision of other ethics committees from collaborating institutions
33. Any other MoU or agreement for international collaborations
34. Documentation of clinical trial registration, if available
35. Any additional documents, as required by the IEC
36. Project submission application checklist (AIIMS-BLS/IEC-H/SOP07/V1/ANX12)

C. ***Completing the submission process*** – the IEC Secretariat will:

- Examine the submission checklist and complete the activities to be done by the IEC office
- Stamp the receiving date on the first (and last) page of the cover letter with initials of the IEC official
- Keep copies of the submitted documents with original signatures in the research proposal "Submission" file
- Allot a number to the project file using the notation AIIMS-BLS/IEC-H/(project number)/(year).
- Fill the IEC project receipt form. Store a copy of it with the application and hand a copy to the application submitter to be handed to the principal investigator. (AIIMS-BLS/IEC-H/SOP07/V1/ANX13).

D. Dispatch and store the received documents

- The IEC Secretariat will prepare two sets of the research proposal including the completed application form, the project proposal, all study related documents, and application checklist. One set will be sent to the IEC members along with a copy of the project assessment form for initial review. The set should be sent for review to the IEC members after the last day for submission of applications is over, and at least 5 days before the next full board IEC meeting.

- The original research proposal documents should be appropriately labelled, filed and stored in a designated storage area in the IEC office.

- In case the IEC members prefer to receive and review soft copies of the documents, these may be sent via a compact disc, pen drive or email. An electronic copy of the project assessment form for initial review should also be sent with the proposal documents. The timeline of sending these documents should be the same as for sending print copies, i.e. they should be sent after the last date for submission of projects is over and at least 5 days before the next full board IEC meeting.

7.4.3 Resubmission of research proposals with correction and amendments

- For research proposals which have undergone corrections and amendments after the initial review, the principal investigator is required to submit a print and an electronic copy of the amended proposal and any other study related documents that have been modified or amended.

- The IEC Secretariat will verify if the submitted documents are complete in all respects and contain modifications appropriately highlighted in comparison to the previously submitted original proposal. The justifications of the changes should also be included.

- Project documents that did not require any changes, and have already been submitted to the IEC with the original application, need not be resubmitted.

- After full verification, the IEC Secretariat will present the file to the Member Secretary.

- The Member Secretary will ascertain if the resubmitted proposal needs to undergo all the steps of initial review.

- The Member Secretary will subsequently handle the resubmitted proposal as decided in the IEC meeting. The amended proposal may be reviewed by one or more IEC members selected by the Chairperson. The selected members are usually those who had initially reviewed and recommended the modifications. Alternatively, the review of the resubmitted proposals may be taken up for review in the full IEC board agenda.

7.4.4 Annual continuing review of approved proposals, amended proposals and their related documents, study completion and termination reports, SAE reports, and protocol deviations

- For the above mentioned proposals and reports, the IEC will receive a print copy and an electronic copy of the concerned documents, along with the appropriate forms/application in the stipulated formats given in respective SOPs.

7.4.5 Information of change in funding agency or grant approval status

If there is any change in the funding agency or grant approval status of the project, the principal investigator should intimate the change to the IEC. The principal investigator should send the relevant information along with the project title, IEC project number, date of approval, and if any changes have occurred in the design and mythology of the study. Accordingly, the IEC will issue a fresh approval/status letter for the project, for administrative purposes, if required by the principal investigator.

7.4.6 Clinical trial agreement (CTA) for sponsored drug, device or collaborative trials

- After approval from the IEC the principal investigator will submit 3 signed copies from the sponsor or CRO of clinical trial agreement on Rs. 100 quasi-judicial stamp papers to the institute with counter signatures of the principal investigator. These will be submitted to the Director, AIIMS, Bilaspur for approval and signature.

- CTA/ other agreement and indemnity will safeguard the interest and right of the research participant, investigator and institute.

- As per existing policy of the institute, there would be 25% overhead charges in the financial part to the total cost of the trial/per patient cost.

- The drug trial shall be started by the principal investigator after the agreement is signed by both the parties. Also, DCGI and other required regulatory approvals should be obtained for the concerned trial, and copies of the same should be submitted to the IEC before starting the trial. After approval of the CTA by the CTA screening committee (appointed by the Institute), a copy of the approved and duly signed CTA should be submitted to the IEC before starting the trial.

7.4.7 Material transfer agreement

Any study involving the exchange of biological samples from abroad, including export and/or import, a material transfer agreement has to be obtained by the principal investigator as per ICMR format. The MTA should be submitted to the IEC along with research project. Once approved by the IEC, the principal investigator is required to obtain endorsement from the HMSC, ICMR, before commencing study.

7.4.8 Informed consent process

For biomedical and health research involving human participants the investigator must obtain voluntary, written, informed consent of the prospective participant. It is based on the principle

that competent individuals are entitled to choose freely whether to participate in research or not. Informed consent is a process that provides opportunity to the individual to accept or refuse to participate in the study. It protects the individual's freedom of choice and respects the individual's autonomy.

Essential elements of an informed consent document

- Clear, unambiguous statement mentioning that the study is research.
- The purpose and methods of the study in simple language without technical jargon.
- The expected duration of participation and the frequency of contact with estimated number of participants to be enrolled, type of data to be collected and methods to be employed for the same.
- Benefits that might reasonably be expected as a research outcome for the participant and/or the community.
- Any foreseeable risk, discomfort, or inconvenience to the participant resulting from participation in the study.
- Extent to which confidentiality of the participant's records will be maintained i.e. the limits to which the investigator will be able to safeguard the confidentiality and the anticipated consequences of breach of confidentiality.
- Freedom of the individual to participate and to withdraw from the research at any time without penalty or loss of benefits which the participant would be otherwise entitled to.
- Free treatment and/or compensation that the participant is entitled to in the event of a research related injury or harm.
- The names and contact details including address and phone numbers of the investigators, especially the principal investigator and co-investigators. Names and contact details of the IEC Chairperson and/or Member Secretary for appeal against violations of participant rights.
- Depending on the nature of the study, alternative procedures or treatments that may be more advantageous for the participant as compared to the one the participant will receive.
- Payment or reimbursement of incidental expenses for participation in the study that may be provided depending on the nature of the study.

7.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP07/V1/ANX01 – Project submission form
Annexure 2: AIIMS-BLS/IEC-H/SOP07/V1/ANX02 – Consent of the Principal Investigator's Head of Department
Annexure 3: AIIMS-BLS/IEC-H/SOP07/V1/ANX03 – Research review committee / Departmental research committee / Doctoral committee / Scientific committee / MD-MS protocol review committee approval
Annexure 4: AIIMS-BLS/IEC-H/SOP07/V1/ANX04 – Undertaking by the principal investigator
Annexure 5: AIIMS-BLS/IEC-H/SOP07/V1/ANX05 – Undertaking by the Guide
Annexure 6: AIIMS-BLS/IEC-H/SOP07/V1/ANX06 – Conflict of interest declaration by the principal investigator
Annexure 7: AIIMS-BLS/IEC-H/SOP07/V1/ANX07 – Brief format for curriculum vitae of the principal investigator, co-investigator and/or student researcher
Annexure 8: AIIMS-BLS/IEC-H/SOP07/V1/ANX08 – Guidelines for drafting participant / legally acceptable guardian information documents
Annexure 9: AIIMS-BLS/IEC-H/SOP07/V1/ANX09 – Participant consent form
Annexure 10: AIIMS-BLS/IEC-H/SOP07/V1/ANX10 – Child information document
Annexure 11: AIIMS-BLS/IEC-H/SOP07/V1/ANX11 – Child assent form
Annexure 12: AIIMS-BLS/IEC-H/SOP07/V1/ANX12 – Document checklist
Annexure 13: AIIMS-BLS/IEC-H/SOP07/V1/ANX13 – IEC project receipt form
Annexure 14: AIIMS-BLS/IEC-H/SOP07/V1/ANX14 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP07/V1/ANX01
Project submission form for IEC review

Project submission form

(To be filled by IEC office)
IEC project number:
Date of submission:

A. Project details

1. Project title:
2. Principal investigator:
3. Department and designation:
4. Contact details
   - Telephone number:
   - Email:
   - Fax:
5. Co-investigators:
6. Student researcher:
7. Project funded? Yes / No
8. If funded, funding source and sponsor/CRO
   a. Intramural
   b. Extramural
   c. Clinical trial
9. Budget with details:
10. Student project? Yes / No
    a. Name of the student researcher:
    b. Contact details of student researcher (phone number, email):
    c. Course enrolled in: (e.g. MD, MS, MCh, DM, PhD, MSc, SRF)
    d. Year of admission:
    e. Month and year of appearing for final examination:
    f. Month and year of submitting dissertation:
    g. Guide and co-guides (names, designation, address, phone number and email):
    h. Is the research study intra-departmental or inter-departmental?
    i. If the study is inter-departmental names of the collaborating departments:
    j. Has consent been obtained from the concerned departments?
    k. Total funds required for the study (in Rupees):
    l. Source of funding:
    m. Date of approval by the departmental PG monitoring committee:
11. Is the project collaborative? Yes / No
12. If collaborative, then provided details and names of institutes

a. National:
b. International:

13. Study duration:
14. Study design:
    a. Observational / interventional
    b. Single centre / multicentre
15. Number of research participants:
16. Clearly defined inclusion and exclusion criteria: Yes / No
    a. Inclusion criteria:
    b. Exclusion criteria:
17. Sampling
    a. Sampling population:
    b. Sample size calculation:
    c. Sampling technique:
18. Data collection methods including collection settings and periodicity
19. Any vulnerable subjects: Yes / No
20. Category of vulnerable subjects (please specify): e.g. pregnant, children, elderly, illiterate, handicapped, terminally or seriously ill, mentally challenged, socioeconomically backward, etc.
21. Special group subjects (please specify): e.g. captives, employees, students, nurses, armed forces personnel, healthcare workers, etc.
22. Will advertisement be used for recruitment: Yes / No

B. <u>Specimen collection</u> (to be filled if any specimen will be collected)

1. Please specify the type, frequency and amount of samples that will be collected from the participants e.g. blood, body fluids, tissue, etc.
2. Will foetal tissue or abortus be collected? Yes / No
   - If yes, please provide details.
3. Will pre-existing, stored or left over samples from earlier be used? Yes / No
   - If yes, please provide details.
4. Please specify how biological materials will be disposed?
5. Will any specimens be stored for bio-banking or future research? Yes / No
   - If yes, please give details.
6. Will any participant samples be sent abroad? Yes / No
   - If yes, please give details and the address of the international collaborators.
   - Please specify the reasons for sending samples abroad:
     - Facility unavailable in India
     - Facility inaccessible in India
     - Facility available but not being availed in India
       - Reasons for not being availed?
   - Have necessary clearances been obtained for sending samples abroad?

C. <u>Interventional study</u> (to be filled if applicable)

1. Please specify what all the interventional study involves:
    a. Drugs
    b. Devices
    c. Vaccines
    d. Radiopharmaceuticals
    e. Recombinant DNA/ Gene therapy
    f. Stem cell
    g. Indian/ alternative system of medicine
    h. Other (please specify)
    i. For drugs, devices and vaccines has a copy of the DCGI approval been enclosed? Yes / No
    j. For radiopharmaceuticals, has a copy of the BARC approval been enclosed? Yes / No
2. Are the above items that will be employed in the study, approved and marketed, and in which countries?
    a. India
    b. UK and Europe
    c. USA
    d. Other countries
    e. Please specify approved indications ……
3. Is the drug being employed, an investigational new drug? Yes / No; If yes:
    a. Is the investigator's brochure enclosed? Yes / No
    b. Is preclinical study data available? Yes / No
        i. If yes, please provide summary
    c. Is clinical study data available? Yes / No
        i. If yes, please provide summary
    d. Which phase is the clinical study in?
        i. Phase I
        ii. Phase II
        iii. Phase III
        iv. Phase IV
        v. Not applicable
    e. If study is in phase I-III, will the drug/device be provided free? Yes / No
    f. If study is in phase IV, will the drug/device be provided at a lower cost than hospital pharmacy? Yes / No
    g. Has DCGI permission been obtained? Yes / No
        i. If yes, has a copy of the permission letter been enclosed? Yes / No
4. Data monitoring
    a. Is there a plan for reporting of adverse events? Yes / No
        i. If yes, the reporting will be done to:

- Study sponsor
- IEC
- DCGI

b. Is there a plan for interim analysis of the data? Yes / No
    i. If yes, please describe in brief the data monitoring and analysis plan

5. Methodology and study participants
    a. Inclusion criteria:
    b. Exclusion criteria:
    c. Withdrawal criteria, if relevant, e.g. for trial-related therapy and follow-up, or a prematurely terminated study to ensure safety of participants:
    d. Rescue criteria, if applicable, e.g. starting symptomatic therapy, either to control disease symptoms, or to circumvent the lack of efficacy of the drug under study, or to rescue participants in placebo group:
    e. Number of groups to be studied, with group definitions
    f. Randomization details including, intervention details with standardization techniques for drugs, devices, invasive procedures, non-invasive procedures and other interventions.
6. Is there a provision for travel and treatment of participants due to study-related injuries? Yes / No
    a. If yes, the funds for above will be provided by:
        i. Study sponsor
        ii. Investigators
        iii. Insurance company
        iv. Other source (please specify)
7. Is the study trial registered with the Clinical Trial Registry of India? Yes / No
    a. If yes, is a copy of the registration certificate enclosed? Yes / No

D. <u>Risks and benefits</u>

1. Does this study carry risk for the participant?
    - Minimal risk
    - More than minimal risk
    - High risk
2. Is there any benefit for the participant?
    - Direct
    - Indirect
    - None
3. Is there any benefit to the society?
    - Yes
    - No
4. Is the risk commensurate to the benefits?
    - Yes

- No

E. Privacy and confidentiality

1. What form of identifiers does the study employ?
   - Direct identifiers (participant name, registration number)
   - Indirect identifiers (study identifier)
   - Anonymized identifiers
2. Will the participant and study data be handled confidentially?
   - Yes
   - No

F. Informed consent documents

1. Has the project sought waiver of consent?
   a. If yes, please provide justification for seeking waiver
2. Type of informed consent that will be taken:
   - Written
   - Verbal
   - Audio-visual
3. Language of informed consent:
   - English
   - Hindi
   - Local language (please specify)
4. Does the study include children? Yes / No
5. If yes, which age group? ……
6. Which of the following patient information and informed consent documents have been submitted?
   - For adult patients
   - For adult controls / volunteers
   - For parents / legally acceptable/authorized representative/guardian
   - Assent form for children 7-18 years
7. Who will take the informed consent from participants?

Principal investigator
Co-investigators
Nurse
Counsellor
Research staff
Student
Other (please specify)

G. Project archiving

1. Do the investigators require project documents and records to be archived longer than 5 years after the completion/termination of the project? Yes / No
2. If yes, for how many years? …….
3. Please give reasons for archiving more than 5 years

H. Ethical issues

Please identify and provide details of any ethical issues related to the proposed study.
……..
……..
……..

I. Brief summary of research proposal

Please provided a brief summary of the research proposal including the aim and objectives, methodology, potential risks and benefits, and outcomes (maximum 500 words).

Signature of student researcher (if applicable)
(Name, designation, department, and date)

Signature of Principal investigator / Guide
(Name, designation, department with seal and date)

Signature of Co-investigator / Co-guide
(Name, designation, department with seal and date)

Signature of the Head of Department
(Name, designation, department with seal and date)

Signature of the Head of Department from collaborating institutions
(Name, designation, department with seal and date)

Instructions for submission:

1. Submit two print and one electronic copy of the project, submission form and all other study related documents, as per the submission checklist.
2. Submit the detailed project proposal comprising a short review of literature, study justification, aim, objectives, sample size calculation, methodology, inclusion and exclusion criteria, analysis and expected outcomes. Mention the source of participants, including volunteers and controls.
3. Submit case report form
4. Submit a copy of recent, signed and dated curriculum vitae of the investigators and student who have submitted the project / thesis proposal.
5. The participant information and informed consent documents should be in simple language devoid of technical jargon.
6. Consider including the following in the participant information documents:
    a. Statement that the study involves research
    b. Statement that consent and participation are voluntary
    c. Purpose and procedures
    d. Alternatives to participation
    e. Risk and discomforts
    f. Consent for future use of biological specimens
    g. Confidentiality of records
    h. Right to withdraw from the study
    i. Contact information of investigators
    j. Free supply of drugs/treatment, as applicable
    k. Compensation for study related injuries

Annexure 2: AIIMS-BLS/IEC-H/SOP07/V1/ANX02
Form for consent of the Principal Investigator's Head of Department

Consent of the Principal Investigator's Head of Department

Date: ……

I have reviewed the project entitled "……
……."
submitted by …….., principal investigator from my department. I endorse the project and have no objection on its submission for consideration by the institutional ethics committee. I concur with the investigators included in the study.

Signature and date Name Department

[Note: to avoid conflict of interest, if the head of the department is himself/herself the principal investigator, this form is not be submitted.]

Annexure 3: AIIMS-BLS/IEC-H/SOP07/V1/ANX03
Form for Research review committee / Departmental research committee / Doctoral committee / Scientific committee / MD-MS protocol review committee approval

Research review committee / Departmental research committee / Doctoral committee / Scientific committee / MD-MS protocol review committee approval

The project entitled "…….
……."
with all its accompanying documents was reviewed by the Research review committee / Departmental research committee/ Doctoral committee/ Scientific committee/ MD-MS protocol review committee on (dd/mm/yyyy), at AIIMS, Bilaspur. The committee has granted its approval on the scientific content of the project.

The proposal may now be reviewed by the institutional ethics committee for ethics approval.

Signature of the Committee Chairperson/ Head

Name:

Date:

[Note:
1. This form is not required for sponsor/CRO initiated drug/device trials.
2. Please attach a copy of the minutes of the research review committee / departmental research committee / doctoral committee / scientific committee / MD-MS protocol review committee.]

Annexure 4: AIIMS-BLS/IEC-H/SOP07/V1/ANX04
Form for undertaking by the principal investigator

Undertaking by the principal investigator

Project title:

Name, designation and department of the principal investigator:

Other members of the research team:

Name and address of other institutions collaborating in the study:

Number of ongoing projects / clinical trials with the principal investigator:

- Number of sponsored clinical trials with active enrolments:
- Number of sponsored clinical trials with follow-up only:
- Total number of ongoing projects:

1. I confirm that I will initiate the above study only after obtaining all necessary regulatory clearances.
2. I will not implement any research protocol deviation without prior approval from the sponsor and intimation to the IEC.
3. I confirm that the co-investigators and other members of the study team have been informed about their obligations and are qualified to meet them.
4. I will personally supervise the study and ensure that the requirements of obtaining informed consent and other ethical requirements under national regulatory and ICMR guidelines are adhered to.
5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by the IEC, regulatory authorities, sponsors or their authorized representatives.
6. I will inform the sponsors, IEC, head of Institute, and the Central Licensing Authority of any unexpected or serious adverse event at the earliest and definitely within fourteen calendar days of its occurrence. I will also inform the above authorities about any serious adverse event leading to death at the earliest and within 14 calendar days of the knowledge of its occurrence.
7. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.

8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
9. I will inform the IEC if there is a change in the funding agency/status.
10. I will inform the IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to the IEC Member Secretary within 4 weeks of the due date.

Principal investigator
(Signature, name, designation, department, date)

Annexure 5: AIIMS-BLS/IEC-H/SOP07/V1/ANX05
Form for undertaking by the student researcher's Guide

Undertaking by Guide

Title of the study:

I undertake full responsibility and accountability for the planning and execution of the above study, and for any adverse events that may occur during the course of the study. The data collected during the study and all records pertaining to the study will be kept in my safekeeping for a minimum duration of five years after the completion of the study.

Signature of the Guide
(Name, designation, department, seal, date)

Annexure 6: AIIMS-BLS/IEC-H/SOP07/V1/ANX06
Form for conflict of interest declaration by the principal investigator

Conflict of interest declaration by the principal investigator

The Member Secretary
Institutional Ethics Committee (Biomedical and Health Research),
All India Institute of Medical Sciences,
Bilaspur – 174001, Himachal Pradesh

Project entitled:

Name of principal investigator:

Conflict of interest declaration

[ ] I hereby declare that I have no conflicts of interest related to my project.
[ ] I hereby declare that I have the following conflicts of interest related to my project:

Principal investigator
(Signature, name, date)

Annexure 7: AIIMS-BLS/IEC-H/SOP07/V1/ANX07
Brief format for curriculum vitae of the principal investigator, co-investigator and/or student researcher

Brief format for curriculum vitae of the principal investigator, co-investigator and/or student researcher

1. Name:
2. Date of birth: (dd/mm/yyyy)
3. Study site affiliation: (e.g. principal investigator, co-investigator, coordinator, etc.)
4. Study site and institution address:
5. Phone (office):
6. Phone (mobile):
7. Email address:
8. Academic qualifications (most current first):
9. Professional experience/ academic appointments (most current first):
10. Brief summary of relevant clinical research experience:

Signature
Date:

Annexure 8: AIIMS-BLS/IEC-H/SOP07/V1/ANX08
Guidelines for drafting participant/ legally acceptable guardian information documents

Guidelines for drafting participant / legally acceptable guardian information documents

1. **Study title**
   - Is the title self-explanatory to a lay person? If not, an additional simplified title should be included.
2. **Invitation paragraph**
   - You should explain that the patient is being asked to take part in a research/trial study. "You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part."
3. **What is the purpose of the study?**
   - The background and aim of the study should be given here.
4. **Why have I been chosen?**
   - You should explain how and why the patient/volunteer was chosen and how many other patients will be studied.
5. **Do I have to take part?**
   - You should explain that taking part in the research/trial is entirely voluntary e.g. "It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."
6. **What will happen to me if I take part?**
   - You should say how long the patient will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc.? Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 8.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use, for example:
   - **Randomized trial**: Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then

compared. The groups are selected by a computer, which has no information about the individual – i.e. by chance. Patients in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug/treatment: e.g. a one in four chance.

- **Blind trial**: In a blind trial you will not know which treatment group you are in. If the trial is a double-blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.
- **Cross-over trial**: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

7. What do I have to do?

- Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if necessary) that the patient should take the medication regularly and dangers of non-compliance.

8. What is the drug or procedure that is being tested?

- You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Patients entered into drug trials should preferably be given a card (similar to an identify card) with details of the trial they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

- For therapeutic research/trial the patient should be told what other treatment options are available.

10. What are the side effects of taking part?

- For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the patient will clearly understand (e.g. ‘damage to the heart’ rather than ‘cardiotoxicity’; ‘abnormalities of liver tests’ rather than ‘raised liver enzymes’). For any relatively new drug it should be explained that there may be unknown side effects.

11. What are the possible disadvantages and risks of taking part?

- For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study.

- "It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator."
- Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.
- There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of foetal damage.
- If future insurance status, e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.
- You should clearly state what will happen if you detect or find a condition of which the patient was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV status)?

12. What are the possible benefits of taking part?

- Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.
- It is important not to exaggerate the possible benefits to the patient during the course of the study, e.g. saying they will be given extra attention. For example, "We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better".

13. What if new information becomes available?

- If additional information becomes available during the course of the research/trial you will need to tell the patient about this. For example:
- "Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."

14. What happens when the research/trial study stops?

- If the treatment will not be available after the research/trial finishes this should be explained to the patient. You would also explain to them what treatment will be

available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

15. What if something goes wrong?

- You should inform patients how complaints will be handled and what addresses may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event. You should incorporate following line in PID "In case of study related injury or death, (name of CRO/ company), will provide the complete medical care as well as compensation for the injuries or deaths".

16. Will my taking part in this study be kept confidential?

- You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential.
- "If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analysing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"
- "All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it."

17. What will happen to the results of the research/trial study?

- You should be able to tell the patients what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

18. Who is organizing and funding the research/trial?

- The information should include the organization or company sponsoring or funding the research/trial (e.g. Govt. agency, pharmaceutical company, NGO, academic institution). The patient should be told whether he has to pay for drugs/tests, the doctor conducting the research/trial is being paid for including and looking after the patient in the study. The information regarding payment and compensation should be included in the patient information documents.

19. Will the drug be made available after trial is over? (new drug requires continued use, till it is marketed in India)

- Please explain to participant regarding the query of availability of study drug.

20. Who has reviewed the study?

- You may should mention that the IEC has reviewed and approved the study (you should not however list the members of the committee).

21. Contact for further information

- You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study.
- Include the principal investigator's details including name, address, and telephone numbers; and the name and contact details of the IEC Member Secretary.

Remember to thank the participant for taking part in the study!

The participant information document should be dated and given a version number. It should state that the participant will be given a copy of the information sheet and the signed consent form.

Principal investigator
(Signature, name, date)

Annexure 9: AIIMS-BLS/IEC-H/SOP07/V1/ANX09
Participant consent form

Participant consent form

Study title:
Study number:
Participant's full name:
Participant's father's name:
Date of birth / age:
Address of the participant:
Education level:
Occupation: student/ self-employed/ service/ housewife/ other (please tick appropriate)

1. I confirm that I have read and understood the participant information document dated (dd/mm/yyyy) for the above study and have had the opportunity to ask questions. I have been explained the nature of the study by the investigator.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the clinical trial/study, others working on the sponsor's behalf, the ethics committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study/ trial. However, I understand that my identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tissue/blood) for future research. (Yes / No)
6. I agree to take part in the above study.

Signature (or thumb impression) of the participant / legally acceptable representative
Signatory's name:
Date:

Study investigator
(Signature, name, date)

Signature of the witness
Name of the witness:
Date:

Received a signed copy of the participant information document and consent form.

Signature (or thumb impression) of the participant / legally acceptable representative
Date:

Annexure 10: AIIMS-BLS/IEC-H/SOP07/V1/ANX10
Child information document

Child information document

Study title: ……
……..

1. **Introduction**
   - You have come to meet the doctor as you are suffering from …….....
     You may be having symptoms like ……..
     …….
   - Describe briefly the purpose of this study
   - If this is a randomized trial, details of both arms of the trial/study must be explained in writing to the subject being enrolled.
   - Disclose appropriate alternative treatments available, if any.
   - We invite you to participate in this study.
2. **What will you have to do?**
   - To participate in this research study, you will be examined by your doctor and if found to fulfil pre-specified criteria, you will be eligible to be enrolled in this research study.
   - Since you are in the age group of 7-18 years we ask your accompanying parent / guardian will also sign a similar form called as the parent informed consent form.
   - List all the procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, nontechnical & direct language.
   - In addition, to record the same parameters daily your parent/guardian will also be provided with a diary where they will enter the same findings accordingly. You will have to tell them about your symptom and they will mark accordingly in the diary.
3. **Risks and discomforts**
   - There is no foreseen significant risk/hazard to your health, if you wish to participate in the study. If you follow the directions of the doctors in charge of this study and you are injured due to any substance or procedure given under the study plan, the sponsor will pay for the medical expenses for the treatment of that injury.
4. **Benefits**
   - If you participate in the study you will receive …….
     If you appear to have any acute illness, you will be offered free treatment for those visits in accordance with local standard medical care. You will not be offered free treatment for chronic diseases or conditions not related to study procedures.
   - Your participation in the study may help others, because this participation will help us determine if the study drug/procedure is safe.
5. **Confidentiality**

- Your existing medical records may be accessed; personal health information about you may be collected and processed by study investigators for the purpose of performing the study.
- Information about you will be collected and stored in files with an assigned number, and not directly with your name. All documents related to the study will only be accessed by the study investigator, sponsor, the Ethics Committee and the Regulatory authority.
- Your parent / guardian will have the right to access personal information about you at any time with the study doctor and the right to correct this personal information. Your parent / guardian can take away your authorization to collect process and disclose data about you at any time.

6. Right to refuse or withdraw

- You do not have to take part in this research if you do not wish to do so. Refusing to participate will not affect your treatment. You will still have all the benefits that you would otherwise have got at this clinic/hospital. You may stop participating in the research at any time you wish without losing any of your rights. Your treatment will not be affected in any way.
- The study doctor may decide to withdraw you from the study if he/she considers it is in your best interest.
- You will be informed of important new findings developed during the course of the study so you will be able to consider your participation in the study in light of new information.

7. Parents' responsibilities

- It is the responsibility of your parent / guardian to come along with you to the hospital during the study period for all the visits unless you withdraw or are prematurely discontinued from the study. It is also your responsibility and your parent / guardian to report any expected or unexpected reactions (side effects) that you notice during the study period.
- It is also the responsibility of your parent / guardian to inform the doctor if you consume any other medication apart from the study treatment.
- We expect your co-operation throughout the study.

8. Contact for further information

- You should give the participant a contact address for further information. This can be your name or that of another doctor/nurse involved in the study.
- Include the principal investigator's details including name, address, and telephone numbers; and the name and contact details of the IEC Member Secretary.

Annexure 11: AIIMS-BLS/IEC-H/SOP07/V1/ANX11
Child assent form

Child assent form

Study title:
Study number:
Child's full name:
Child's father's name:
Date of birth / age:
Address of the participant:

I ……., exercising my free power of choice, hereby give my consent for participation in the study entitled ……
…….
I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any study/trial related injury, which has causal relationship with the said study/trial drug. I am also aware of right to opt out of the study/trial, at any time during the course of the study/trial, without having to give reasons for doing so.

Signature of participant
Name of the participant:
Date:

Signature of the witness
Name of the witness:
Date:

Signature of the attending physician
Name of the attending physician:
Date:

Annexure 12: AIIMS-BLS/IEC-H/SOP07/V1/ANX12
Document checklist

Document checklist

Instructions:

1. Please furnish two print copies and one electronic copy of the documents listed below with your research project submission.
2. For non-interventional studies please submit only relevant documents.
3. Please assign page numbers to all the documents and enter the same in the checklist.
4. For drug and device trials please provide version numbers and effective dates for each document.

Project title:

Principal investigator:

Type of project: Intramural/ Extramural / Student project / Investigator initiated / Interventional trial

No.	Document	Yes / No / Not applicable	Page no.
1.	Cover letter to Member Secretary / Chairperson		
2.	Project submission form		
3.	Research proposal		
4.	Amended research proposal, if applicable		
5.	Case report form		
6.	Consent of Principal Investigator's Head of Department		
7.	Administrative sanction from the head of the Institute		
8.	Approval letter from research review committee, doctoral committee, departmental research committee, MD protocol review committee or other scientific committee		
9.	Undertaking by principal investigator		
10.	Conflict of interest declaration by principal investigator		
11.	Recent signed and dated curriculum vitae of the investigators and student researcher		

No.	Document	Yes / No / Not applicable	Page no.
12.	GCP training certificate (from within last 5 years) of principal investigator, co-investigators and study coordinators, if applicable		
13.	Research methodology training certificate (from within 5 years) of principal investigator, co-investigators, and study coordinators, if applicable		
14.	List of ongoing research studies currently with the principal investigator		
15.	Participant information sheet and informed consent forms in English and local vernacular language		
16.	Consent waiver form, if applicable		
17.	Back translations of the informed consent documents and back translation certificates, if applicable		
18.	Amendments to the informed consent documents, if any		
19.	Investigator's brochure (for drug/device trial)		
20.	Patient recruitment procedures including, project advertisement, information brochure, notices, letters to doctors etc. (for drug/device trial)		
21.	Clinical Trial Registry of India (CTRI) registration (prerequisite for sponsored clinical trials; for other trials registration can be done after IEC approval)		
22.	DCGI approval letter with list of approved institutes (for sponsored drug/device trial)		
23.	Details of the funding agency/ sponsor and grant received for the project (in project submission form and clinical trial agreement)		
24.	Clinical trial agreement (CTA) between sponsors, investigators, and heads of institutions (for drug/device trial)		
25.	Insurance policy for study participants indicating conditions of coverage, date of commencement, and date of expiry of risk coverage. It is preferable to have a full insurance policy rather than only an insurance certificate (for drug/device trial)		
26.	Indemnity policy clearly indicating the conditions of coverage, date of commencement and date of expiry of risk coverage (for drug/device trial)		
27.	Material transfer agreement (MTA) and Health Ministry's Screening Committee (HMSC) approval (for international transfer of biological materials)		
28.	Directorate General of Foreign Trade approval (DGFT) (for export of study samples in clinical trials)		

No.	Document	Yes / No / Not applicable	Page no.
29.	Genetic Engineering Advisory Committee (MoEF&CC and DBT-GEAC) approval (for proposals involving recombinant DNA technology and/or gene therapy)		
30.	Bhabha Atomic Research Centre (BARC) approval (for studies involving radioisotopes, or ionizing radiations)		
31.	Institutional stem cell research committee approval, and NAC-SCRT registration and approval, if applicable		
32.	Decision of other ethics committees from collaborating institutions		
33.	Any other MoU or agreement for international collaborations		
34.	Documentation of clinical trial registration, if available		
35.	Any additional documents, as required by the IEC		
36.	Document checklist		
37.	IEC document receipt form		

Principal investigator
(Signature, name, date)

Annexure 13: AIIMS-BLS/IEC-H/SOP07/V1/ANX13
IEC project receipt form

IEC project receipt form
(Please submit in duplicate)

1. Type of submission: new / revised proposal
2. Project title:
3. Principal investigator:
4. Type of project: Intramural/ extramural/ student project/ investigator initiated/ interventional
5. Are documents submitted complete? Yes / No
    a. If incomplete, list the documents not submitted and expected date by which they will be submitted

6. Comments from IEC

Receiver's name, signature and date

Submitter's name, signature and date

Annexure 14: AIIMS-BLS/IEC-H/SOP07/V1/ANX14
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

7.6 Workflow

	Activity	**Responsibility**
1.	Receive research proposal submission and verify documents as per submission checklist	IEC Secretariat
2.	Fill receipt form and stamp the receipt of documents	IEC Secretariat
3.	Allot an IEC project number to the submission	IEC Secretariat
4.	File and store the print and electronic copies of the application and proposal	IEC Secretariat

8 Categorization of new research protocols by the Institutional Ethics Committee for biomedical and health research

08

8.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for categorizing new research proposals submitted by investigators for initial review, into those requiring full board review, expedited review or exemption from review by the Institutional Ethics Committee (IEC) for biomedical and health research, AIIMS, Bilaspur.

8.2 Scope

This SOP covers the process of categorisation of new research study protocols submitted to the IEC for biomedical and health research for initial review. It does not cover the processes required for subsequent submissions.

8.3 Responsibility

It is the responsibility of the Member Secretary, in consultation with the Chairperson (as applicable), to categorize the research studies into one of the three review categories. This categorization is to be carried out depending on the risks involved for prospective research participants. The three categories include: full board review, expedited review, and exemption from review.

8.4 Detailed instructions

8.4.1 New proposals received for initial review

New research study proposal received by the 5th of the month scheduled for full board IEC meeting will be considered for review in the respective monthly IEC meeting. The Secretariat will ensure that the research proposal applications are complete in all regards and include all necessary documents, and make a note if any essential documents are missing. For the latter, an explanation should be sought in writing from the principal investigator prior to IEC review.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

8.4.2 New proposals forwarded to the Member Secretary

The Secretariat will forward the copy of the research proposal to the Member Secretary for initial screening within two working days of receiving the proposal. The Member Secretary will screen the research proposals and categorize them as elaborated in section 8.4.3 within two working days of their receipt.

8.4.3 Categorization of new proposals for review by the IEC

The Member Secretary, in consultation with the Chairperson (as applicable), will categorize the proposals into three types. The type of review processes and the criteria to decide the type of review are explained below, and are also available from the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Indian Council of Medical Research, 2017. Recent amendments are also available in the New Drugs and Clinical Trials Rules, 2019.

- **Full board review**: when new research proposals and their related documents are tabled in a formally convened meeting of the IEC for detailed discussion and decision. The following types of research proposals will require a full board review:
    - Research studies involving more than minimal risk to human participants, are required by national and international regulations to be reviewed by the full board of the IEC.
    - Research that is considered to pose minimal risk but involves vulnerable populations, may be referred for a full board review.
    - Research proposals that have undergone an expedited review and are referred to the full IEC board because no decision could be reached.
- **Expedited review**: when new research proposals and their related documents undergo a speedy review process only by 2-3 IEC members, designated by the IEC Chairperson. The following types of research proposals can be considered for expedited review:
    - Proposals involving instructional techniques, curricula or class room management methods.
    - Minor modifications of proposals that have already been approved by a full board review by the IEC.
    - Change in the name, address of sponsor / principal investigator, contact details of the principal investigator, IEC Chairperson, or the IEC Member Secretary.

- A request for change in the principal investigator, co-investigator, and/or a change in any member involved in the research.
- When adverse events (AE) or unexpected adverse drug reactions (ADR) of minor nature are reported.
- Minor corrections in the budget.
- Other administrative changes in the investigator's brochure, and/or informed consent documents.
- Proposals involving clinical materials that have been collected for non-research or clinical purposes, i.e. patient care records and specimens.
- Proposals involving pilot studies during and/or pertaining to emergency outbreaks and disasters, especially when a full IEC review is not possible.
- Proposals NOT involving therapeutic, diagnostic, prophylactic and screening interventions.
- Proposals NOT involving vulnerable and special groups.
- Collection of data for research purposes through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for clinical use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using Doppler principle, non-invasive blood pressure, routine clinical measurements, exercise tolerance, etc. However, procedures involving the use of X-rays or microwaves are NOT recommended for expedited review.
- Clinical studies of drugs and medical devices only when research is proposed on already approved drugs, except when studying drug interactions, conducting trials on vulnerable populations, or research involving disaster management.

- **Exemption from review**: when a research proposal involves less than minimal risk, where there are no linked identifiers (Table 4.2, ICMR Guidelines 2017), and which fulfils the following criteria, the IEC may grant an exemption from review:
  - The research does not involved live human participants, and involves data that are already available in the public domain. Alternatively, the data comprise anonymised information derived from participants, and the research poses less than minimal risk to the participants. In such scenarios an exemption from IEC review may be considered.

- Examples that may be eligible for exemption from review include:
  - Research conducted on data available in public domain for systematic review or meta-analysis
  - Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed persons
  - Quality control and quality assurance audits in the institution
  - Comparison of instructional techniques, curricula, or classroom management methods
  - Consumer acceptance studies related to taste and food quality
  - Public health programmes by government agencies, such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)
  - Audits of educational practices
  - Research on microbes cultured in the laboratory
  - Research on immortalized cell lines
  - Research on cadavers or death certificates, provided that the study will not reveal any identifiable personal data
  - Analysis of data freely available in the public domain

- The principal investigator may also apply to the IEC for exemption from review if she/he finds that the proposed research satisfies the criteria for exemption.

8.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP08/V1/ANX01 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP08/V1/ANX01
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

8.6 Workflow

	Activity	Responsibility
1.	Receiving new research proposals and their related documents by a fixed date of the month.	IEC Secretariat
2.	Verifying that the submitted research proposal documents are complete in all respects.	IEC Secretariat
3.	Forwarding new proposals to the IEC Member Secretary.	IEC Secretariat
4.	Categorization of the proposals into 3 categories: full board review, expedited review, and exemption from review.	Member Secretary

09

9 Initial full committee review of new research proposals by the Institutional Ethics Committee for biomedical and health research

9.1 Purpose

The purpose of the standard operating procedure (SOP) is to describe how the members of the Institutional Ethics Committee (IEC) for biomedical and health research, at AIIMS, Bilaspur, will perform an initial review of new research proposals submitted to the committee.

9.2 Scope

This SOP applies to the initial review and assessment of all research study protocols submitted to the IEC for review and approval. All research studies carrying more than minimal risk and those not qualifying for exemption or expedited review are covered in this SOP.

9.3 Responsibility

- The Member Secretary is responsible, after categorization of the research proposals, to forward them to the IEC Secretariat.
- The IEC Secretariat is responsible for the creation of a file for the study, allotting a unique IEC identifier, and distribution of the proposal packages along with the study assessment forms, to the IEC members for review (if the study is categorized for full board review), and communicate the review results to the investigators.
- IEC members, including the Member Secretary, will be responsible for reviewing the research protocols and their related documents within the allotted time frames.
- The IEC members are responsible or attending and participating actively in the discussion at the full board meeting.
- The Member Secretary is responsible for setting up the full board meeting.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

- The IEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.

- The Member Secretary is responsible for ratifying the decision (with signature and date) in the IEC decision form (AIIMS-BLS/IEC-H/SOP09/V1/ANX03).

9.4 Detailed instructions

9.4.1 Appointment of primary reviewers

The Chairperson / Member Secretary will appoint two or more primary reviewers for each study on the basis of their expertise and experience in the related field. They will include one clinician and one non-technical person as applicable. More than two reviewers may also be appointed if necessary.

9.4.2 Distribute the protocol package

- The Secretariat will fill in the required details in the cover letter to the IEC members requesting initial review along with the study assessment form (AIIMS-BLS/IEC-H/SOP09/V1/ANX02). The Secretariat will send a packet (hard or soft copy) to the IEC members.

- Letter to the IEC members requesting initial review

- Study assessment form

- Study submission application form

- Protocol and related documents

9.4.3 Receive the distributed protocol package

- IEC members will receive the protocol package with the study application form as a hard copy or through email (if desired).

- Designated primary reviewers will also receive the study assessment form for initial review.

9.4.4 Verify the contents of the package

- The IEC member will verify the contents of the received package.

- The IEC member will check the meeting date to see if it is convenient for the member to attend the meeting.

- The IEC member will notify the IEC Secretariat if any documents are missing or if the specified date of the IEC meeting is not convenient for the member.

9.4.5 Review by the IEC members

- The protocol will be reviewed by each member as per the guidelines for reviewing study proposals.

- The IEC member will consider the following criteria while reviewing the study proposals and its related documents:

    - Scientific design and conduct of the study
    - Risks and potential benefits
    - Selection of the study population and recruitment of research participants
    - Inducements, financial benefits and costs involved
    - Protection of research participants' privacy and confidentiality
    - Community considerations
    - Qualifications of the investigators and adequacy of the study site(s)
    - Disclosure or declaration of potential conflicts of interest

- The IEC member will consider the following criteria when performing the review of the informed consent documents:

    - Voluntary, non-coercive recruitment, participation and withdrawal
    - Procedures for obtaining informed consent
    - Contents of the patient information sheet – title, objective, study design, and procedures
    - Content and language of the informed consent documents
    - Translation of the informed consent documents in local languages
    - Language used should be simple and easy to understand by the general population
    - Contact persons with address and phone numbers for queries from research participants regarding the study, their rights or injuries and any other concerns.
    - Privacy and confidentiality
    - Risks and discomforts – physical, mental, social or alternative treatment
    - Benefits to the participants, community, institution and society
    - Compensation for participation: whether it will act as an undue inducement, especially of vulnerable participants

- Provisions for medical and/or psychosocial support and treatment of study related injuries.
- Compensation for study-related injuries: as per applicable local regulations on use of biological materials
- Check for provisions that signatures and dates will be recorded for the participants, the researcher discussing and taking the informed consent, the principal / co-investigator, and a witness.
- Provision for audio-visual recording of the consent process in case of regulatory drug trials.
- Use of study assessment forms for reviewers
- The assessment form is designed to standardize the review process
- All reviewers will fill out the form (AIIMS-BLS/IEC-H/SOP09/V1/ANX01-02 – letter to the IEC members requesting initial review with study assessment form) and write their comments pertaining the review of the research proposal.
- In addition, primary reviewers will use the study assessment form.
- Ensure that all the elements of the research proposal are reviewed and are accordingly documented during the discussion / meeting.
- The duly filled, signed and dated assessment forms will be submitted to the Secretariat a minimum of five working days prior to the meeting.

9.4.6 Gather assessment reports

The IEC Secretariat will collect the assessment forms, comments from each reviewer; file them in the original study file; and also convert them into soft copies for discussion at the EIC meeting. If the comments are sent by the reviewer as a soft copy, they will be collated for discussion at the meeting.

9.4.7 IEC meeting

- During the discussion in the IEC meeting, the primary reviewer shall brief the members about the summary of the study protocol and read out the comments and evaluation provided on the assessment form.

- The comments of an independent consultant, if applicable, will be discussed by the Member Secretary.

- The other IEC members shall give their comments right after the presentation.

- The principal investigator / co-investigators may be called in to provide further clarification on the study protocols that had been submitted to the IEC for review.

- The IEC members will discuss and clarify the comments and suggestions.

- The Member Secretary, assisted by the Secretarial staff, shall record the discussion.

- The final decision on the study will be recorded as: “approved”, “disapproved", “suggested recommendations”, or “any other” (as per IEC policy). The final decision will be made by voting or by majority consensus (as per IEC policy) and will be recorded in the IEC decision form by the Member Secretary.

- A majority vote for approval, disapproval or request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the voting members present at the meeting.

- The following will not be eligible to vote:
    - Members of the committee who are listed as investigators on a research proposal
    - An investigator or study team member invited for the meeting
    - An independent consultant invited for the meeting to provide an opinion
    - Specific patient groups invited for the meeting will not vote or participate in the decision making process of the committee

- The committee will decide whether the query responses, and if applicable, revised protocol will go only to the Member Secretary, to the primary reviewers, or to the full board, before final approval.

- The response and changes carried out may be considered for discussion at a future IEC meeting.

- If the IEC decision is “Disapproved” or “Any other”, then the decision should be made on the basis of specific reasons which are communicated by the IEC to the principal investigator, in the letter of notification.

- The Secretariat will obtain the signature of all the members and the Chairperson of the IEC on the IEC decision form.

- If the study is approved, the committee will recommend monitoring of a study if it is so deemed at the meeting, depending on factors like risk to the participants is high, the principal investigator has a history of repeated protocol violations, the principal investigator has many research proposals, or any other reason so deemed.

- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members.

- With the study protocol, the study assessment form from all the members and the IEC decision form will be filed in the study file by the IEC administrative officer.

- The IEC administrative officer will return the file and the protocol to the appropriate storage areas.

9.4.8 Final communication of the IEC decision to the principal investigator

- The Secretariat will prepare an approval letter to be sent to the principal investigator when the study is approved at an IEC meeting.

- The letter will contain:

    - Study reference number
    - Study title
    - A listing of each document approved
    - The date set by the committee for frequency of continuing review
    - Other obligations and expectations from the investigators throughout the course of the study
    - List of IEC members present at the meeting when the study was approved
    - The Chairperson / Member Secretary will sign the approval letter and the Secretariat will send it to the principal investigator within 14 days.

- If the committee disapproves a study, the Secretariat will notify the principal investigator in writing about the decision and the reasons for not approving the study, within 7 working days.

- A notifying letter to the investigator should state the following:

    - If you wish to appeal this decision, please contact the IEC and submit your appeal in writing within 12 weeks of the receipt of the committee's decision, addressed to the IEC Chairperson with justification as to why the appeal should be granted. In the absence of an appeal, the study will be declared closed in the official IEC records.

- If the committee recommends any modifications to the study documents, the Secretariat will send a written request to the principal investigator for carrying out the specified changes and resubmit the documents to the IEC. The principal investigator will be asked to respond to the letter of comments and queries within 60 days of the receipt of the letter. In the absence of a response, the study will be declared closed in the official IEC records.

- The Secretariat will verify the accuracy of the wordings and spellings in all the letters and processes described above, within 14 days of the meeting.

9.4.9 Final communication of the IEC approval to the Central Licensing Authority

- In case a clinical trial, bioavailability study, or a bioequivalence study is approved by the IEC, the IEC should inform the Central Licencing Authority within 15 working days of granting such an approval.

9.4.10 Storage of documents

The Secretariat will keep a copy of the approval letter, query letter, or disapproval letter in the study file along with all the reviewed documents. The IEC administrative officer will store the file in a designated storage area.

9.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP09/V1/ANX01 – Letter to IEC members requesting initial review with study assessment form
Annexure 2: AIIMS-BLS/IEC-H/SOP09/V1/ANX02 – Study assessment form for primary reviewer
Annexure 3: AIIMS-BLS/IEC-H/SOP09/V1/ANX03 – IEC decision form
Annexure 4: AIIMS-BLS/IEC-H/SOP09/V1/ANX04 – Format of study approval letter
Annexure 5: AIIMS-BLS/IEC-H/SOP09/V1/ANX05 – Guidelines for reviewing a study protocol
Annexure 6: AIIMS-BLS/IEC-H/SOP09/V1/ANX06 – Intimation of start of study
Annexure 7: AIIMS-BLS/IEC-H/SOP09/V1/ANX07 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP09/V1/ANX01
Letter to IEC members requesting initial review with study assessment form

Dear Member,

The next meeting of the IEC will be held on …… at …… in ……

Please note that the package of research proposals is to be circulated in the following order. You are requested to review the same preferably within 14 days of receiving the package. Please review the protocol and related documents as per the guidelines attached, provide your comments below, and fill the study assessment form (for primary reviewers only) provided with the package. Kindly confirm your availability for the meeting.

Name of the Member	Date of receipt	Signature	Attending meeting (Y/N)

1. Protocol number (as per IEC records):
2. Date of receipt at the IEC office after review by member (dd/mm/yy):
3. Protocol title:

4. Name of the principal investigator:
5. Designation:
6. Department:
7. Name of the reviewer:
8. Comments:

Member Secretary
(Signature with date)

Annexure 2: AIIMS-BLS/IEC-H/SOP09/V1/ANX02
Study assessment form for primary reviewer

Protocol number:		Date (dd/mm/yy):	
Protocol title:			
Principal investigator:			
Department:			
Number of participants at the study site:		Number of study sites:	

Please mark and comment on the items that are applicable to the study.
(Please attach extra sheets where required)

1.	Objectives of the study	Clear	Unclear
	What should be improved?		
2.	Need for human participants	Yes	No
	Comments:		
3.	Methodology	Clear	Unclear
	What should be improved?		
4.	Background information and data	Sufficient	Insufficient
	Comments:		
5.	Risk-benefit assessment	Acceptable	Unacceptable
	Comments:		
6.	Inclusion criteria	Appropriate	Inappropriate
	Comments:		
7.	Exclusion criteria	Appropriate	Inappropriate
	Comments:		

8.	Discontinuation and withdrawal	Appropriate	Inappropriate
	Comments:		
9.	Involvement of vulnerable participants	Yes	No
	Comments:		
10.	Voluntary, non-coercive recruitment of participants	Yes	No
	Comments:		
11.	Sufficient number of participants?	Yes	No
	Comments:		
12.	Control arms (placebo, if any)	Yes	No
	Comments:		
13.	Are qualifications and experience of the participating investigators appropriate?	Yes	No
	Comments:		
14.	Disclosure or declaration of potential conflicts of interest	Yes	No
	Comments:		
15.	Facilities and infrastructure of participating sites	Appropriate	Inappropriate
	Comments:		
16.	Community consultation	Yes	No NA
	Comments:		
17.	Benefits to local communities	Yes	No
	Comments:		
18.	Contribution to the development of local capacity for research and treatment	Yes	No

	Comments:		
19.	Availability of similar studies / results	Yes	No
	Comments:		
20.	Are blood / tissue samples send abroad?	Yes	No
	Comments:		
21.	Are the procedures for obtaining informed consent appropriate?	Yes	No
	Comments:		
22.	Contents of the informed consent documents	Yes	No
	Comments:		
23.	Language of the informed consent documents	Clear	Unclear
	Comments:		
24.	Contact person for participants	Yes	No
	Comments:		
25.	Privacy and confidentiality	Yes	No
	Comments:		
26.	Inducement for participation	Unlikely	Likely
	Comments:		
27.	Provision for compensation for participation	Appropriate	Inappropriate
	Comments:		
28.	Provision for treatment for study-related injuries	Appropriate	Inappropriate
	Comments:		

29.	Provision for compensation for study related injuries	Appropriate	Inappropriate
	Comments:		

Reviewer's signature with date: _____

Annexure 3: AIIMS-BLS/IEC-H/SOP09/V1/ANX03
IEC decision form

Date of IEC meeting: _____

Protocol number: _____

IEC protocol number and title:	
Principal investigator:	
Department:	
Final decision at the IEC meeting	• Approved – with or without suggestions or comments • Revision with minor modifications / amendments • Revision with major modifications and resubmission • Not approved Reason(s):

Member Secretary
(Signature and date)

Annexure 4: AIIMS-BLS/IEC-H/SOP09/V1/ANX04
Format of study approval letter

Date: (dd/mm/yyyy)

Dr.
Principal Investigator,
Department of
All India Institute of Medical Sciences,
Bilaspur – 147001, Himachal Pradesh

Ref: Your project number …… entitled ……...
……..
……..

Dear Dr.

The Institutional Ethics Committee for studies involving human participants, at AIIMS, Bilaspur, reviewed and discussed your above mentioned research proposal and ethics application in the IEC meeting held on (dd/mm/yyyy).

The following documents of the above mentioned proposal were reviewed and approved:

1. IEC project submission form
2. Research proposal (dated: dd/mm/yyyy)
3. Approval from research committee, concerned department, funding agency, doctoral committee, and/or relevant scientific committee
4. Patient information documents and informed consent form in English and vernacular language
5. Investigator's brochure (dated: dd/mm/yyyy)
6. Proposed methods for patient recruitment including advertisements proposed for the purpose
7. A recent signed and dated curriculum vitae of the principal investigator and co-investigators, including those not affiliated with AIIMS, Bilaspur, or that of student (MD, MS, DM, MCh, PhD) in case of a thesis proposal
8. Insurance policy or compensation mechanism for research participants and for serious adverse events that may occur during the study
9. Principal investigator's agreement with the sponsor
10. Principal investigator's undertaking
11. DCGI/ DGFT approval
12. Clinical trial agreement (CTA), memorandum of understanding (MoU), material transfer agreement (MTA), if applicable

13. Clinical trial registry of India (CTRI) approval at the time of proposal submission in case of a drug trial. In other studies this approval can be sought after the approval of the study itself, but before commencing the study.

The following members of the IEC were present in the meeting held on ……..
at the following venue …….

1. Chairperson, IEC-H, AIIMS, Bilaspur: Prof./Dr.
2. Member Secretary, IEC-H, AIIMS, Bilaspur: Dr.
3. Names of all IEC members present in the meeting
4.
5.

The above mentioned study is approved in its current form and it is understood that the study will be conducted under your direction, in a total of …….. research participants, as per the submitted protocol. The IEC approval of the study is valid for the entire duration of the study.

The investigators must note the following:

1. Please inform the IEC when you commence the study and furnish annual progress reports.

2. The approval of the above mentioned study is for the recruitment of ……. number of patients.

3. The IEC may monitor the study site from time to time, and the investigators and study team should cooperate with the IEC.

4. The decision to approve the above study was reached through consensus, and neither the principal investigator, co-investigators, nor any other study team member were present during the decision making process of the IEC.

5. In case the principal investigator retires or leaves the Institute, the responsibility of the study should be transferred to a colleague in the Institute after obtaining clearance from the head of the concerned department, concurrence from the IEC, and submitting a status report including the financial status of the project. These documents should be furnished to the head of the department, the IEC and the extramural sponsor.

6. The IEC functions in accordance with the GCP-CDSCO, ICMR, NDCT 2019, and ICH-GCP norms.

7. In case of injury or death of the participant(s) occurring during the research, the sponsor (whether a pharmaceutical company or an institution) or their representative, whosoever had obtained permission from the Licensing Authority for the conduct of the clinical research shall make payments for the medical management of the subject and also provide financial compensation for the clinical research related injury or death.

8. The investigators are advised to inform the IEC of any on-site serious adverse events or any unexpected adverse events within 24 hours as per the formats specified in SOP16 or by email if the said date is a holiday. The report of SAE or death, after due analysis, shall be forwarded by the principal investigator to the IEC Chairperson, the Head of the Institute where the research is being conducted, and the Central Licencing Authority within 14 calendar days of the SAE's occurrence. In case of a serious adverse event of death the principal investigator should forward their report on the event after due analysis to the above authorities within 14 days of the knowledge of the occurrence of serious adverse event of death.

9. Any new information that emerges and affects the study and the safety and well-being of the research participants, should be intimated to the IEC.

10. In the events of any protocol amendments, the IEC must be informed and the amendments should be highlighted in clear terms as follows:

    - The IEC expects that the investigator should promptly report to the IEC any changes to the protocol to eliminate immediate hazards to the research participants and about any new information that may adversely affect the safety of the research participants or the conduct of the research.
    - The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project e.g. page no., clause no. etc.
    - The principal investigator must comment how the proposed amendments will affect the ongoing trial.
    - Alterations in the budget and staff requirements should be clearly indicated and the revised budget should be submitted.
    - If the amendments require a change in the consent form, the copy of revised informed consent form should be submitted to the IEC for approval.
    - If the amendment demands a re-examination of the risks of toxicity and side effects to the participating patients, the same should be documented.
    - If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted to the IEC for approval, and only after the approval can they be implemented.
    - Approval of amendments must be obtained prior to the implementation of the changes. The amendment is unlikely to be approved by the IEC unless all the above information is provided.

11. Any deviations and violations in the research protocols must be promptly informed to the IEC as per the procedures detailed in AIIMS-BLS/IEC-H/SOP13/V1.

12. If the research study or trial is not initiated over the next 6 months from the date of IEC approval, a further extension will not be granted and it will require a resubmission of the research proposal to the IEC.

13. For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date, i.e. 11 months from the date of approval) on or before (dd/mm/yyyy).

14. A copy of the final project report should be submitted to the IEC for review.

Thanking you,
Yours sincerely,

Member Secretary
(Signature and name)

Date:

Date of approval of the study:

Annexure 5: AIIMS-BLS/IEC-H/SOP09/V1/ANX05
Guidelines for reviewing a study protocol

Guidelines for reviewing a study protocol

Reviewers should make use of the following points while reviewing research studies. These guidelines relate to various aspects of the proposed research including, the scientific validity, informed consent documents, placebo justification, suitability and feasibility of the study, advertisements review.

1. How will the knowledge, results or outcome of the study contribute to the human well-being?
    a. Knowledge from the basic research may possibly benefit.
    b. A new choice of method, drug or device that benefits the research participants during the study and others in the future.
    c. Provide safety data or more competitive choices

2. Will the study design be able to answer the objectives? Whether
    a. The end points have been appropriately selected
    b. The duration of a study subject's participation is adequate to allow sufficient change in the endpoints
    c. The control arm is appropriately selected for best comparison.
    d. The placebo is justified
    e. The number of study participants is adequate to allow the measurement of sufficient change in the end points.
    f. Unbiased assignment (e.g. randomization) is being used
    g. The inclusion and exclusion criteria have been carefully selected to eliminate confounding factors as far as possible.
    h. The sample size of various study cohorts is adequate within appropriate statistical assumptions.
    i. Predictable risks are minimized
        i. The tests and procedures that carry more than minimal risk are being cautiously used
        ii. Deception of research participants is avoided
        iii. If required, the instructions and counselling for study participants are included when deception is integral to the study design
        iv. The study participants will be adequately assessed and provided follow-up care, if required.

3. Who will be the participants in the study? Whether
    a. The described population is appropriate for the study
    b. Predictable vulnerabilities have been considered
    c. It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
    d. There will be secondary participants

4. Do the inclusion and exclusion criteria

a. Selectively include participants most likely to serve the objectives of the study?
b. Equitably include participants?
c. Properly exclude participants who can predictably confound the results?
d. Properly exclude participants who may predictably be at an increased risk in the study due to coexisting conditions or circumstances?

5. Does the study design have adequate built-in safeguards for risks?
    a. Appropriate screening of potential participants?
    b. Use of a stepwise dose escalation with analysis of the results before proceeding?
    c. Does the frequency of visits and biological samplings reasonably monitor the expected effects?
    d. Are there defined stopping (discontinuation) / withdrawal criteria for the participants with worsening conditions?
    e. Is there minimized use of medication withdrawal and placebo whenever possible?
    f. Will rescue medications and procedures be allowed when appropriate?
    g. Is there a defined safety committee to perform interim assessments, when appropriate?
    h. Is appropriate follow-up designed into the study? For instance, gene transfer research may require follow-up of the participants for years or for their entire lifetime after they receive the gene transfer agent.

6. Have appropriate pre-clinical and/or early clinical studies been performed before this study?
    a. The animal study and in vitro testing results?
    b. Previous clinical results, if available?
    c. Whether the proposed study is appropriately built on the pre-clinical and / or early clinical results.
    d. The selected dose based on adequate prior results?
    e. Monitoring tests designed to detect expected possible risks and side effects?

7. Does the study and the informed consent process include issues of special concern, such as:
    a. Waiver or alteration of consent?
    b. Delayed consent e.g. emergency treatment, etc.?
    c. Deception?
    d. Sensitive information of participants that may require a confidentiality statement?

Guidelines for reviewing informed consent documents and patient information sheet

The actual process of informed consent should:

1. Give the participants significant information about the study
2. Make sure that the participants have enough time to carefully read and consider all options
3. Answer all questions of the participants before making decision to participate.
4. Explain risks or concerns to the participants.
5. Make sure that all the information is understood and satisfied by the participants.
6. Make sure the participants understand the study and the consent process.

7. Obtain voluntary informed consent for participation.
8. Make sure the participants can freely consent without coercion, pressure or other undue influences.
9. Consent should be informally verified on a continuing basis.
10. Continue to inform the participants throughout the study.
11. Continue to re-affirm the consent to participate throughout the study.

Guidelines for placebo justification

Background conditions such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered.

1. Benefits of standard treatment

a. Is there a standard treatment?
b. Is the standard treatment widely accepted?
c. Has efficacy of the treatment been consistently proven?
d. Are all newly diagnosed patients with this condition put in standard treatment, (versus observed or other)?
e. Does the treatment act on the basic mechanism of the disease (versus symptoms)?
f. Are most (≥ 85%) of the patients with this condition responsive to standard treatment alternatives (versus resistant or refractory)?

If the answers of above (a.) to (f.) are "yes", then placebo is not recommended. If any of the answers is "no", then placebo may be considered.

g. Are the side effects of the standard treatment severe?
h. Does standard treatment have many uncomfortable side effects?
i. Does standard treatment have contraindications that prevent some research participants from being treated?
j. Is there substantial (≥ 25%) placebo response in this disease or symptom?

If the answers to (g.) to (k.) are "no", then placebo is not recommended. If any of the answers is "yes", then placebo may be considered.

2. Risk of placebo

a. Is the risk of using placebo instead of treatment, life threatening?
   If yes, then placebo is not acceptable.
b. Is the use of placebo instead of treatment likely to lead to permanent damage?
   If yes, then placebo is not acceptable.
c. Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?
   If yes, then placebo is not acceptable.
d. Can the use of placebo instead of treatment lead to an acute emergency?

e. Does the risk of using placebo instead of treatment involve persistence of distressing symptoms?
f. Does the risk of using placebo instead of treatment involve severe physical discomfort or pain?

If the answers to (d.) to (f.) are "yes", then placebo is not acceptable unless the risk management is adequate.

3. Risk management

a. Is there benefit in the overall management of the research participants?
    i. Yes, consider placebo
    ii. No, placebo not recommended
b. Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?
    i. No, consider placebo
    ii. Yes, placebo not recommended
c. Are research participants at high risk for the use of placebo excluded?
    i. Yes, consider placebo
    ii. No, placebo not recommended
d. Does the study duration include the minimum necessary time required for the action of the drug?
    i. Yes, consider placebo
    ii. No, placebo not recommended
e. Are there clearly defined rules to stop and withdraw the research participants in case they do not improve?
    i. Yes, consider placebo
    ii. No, placebo not recommended
f. Is risk monitoring adequate to identify progression of the disease before the research participants experience severe consequences?
    i. Not applicable
    ii. Yes, consider placebo
    iii. No, placebo not recommended
g. Are there clearly defined stopping rules to withdraw the research participants before severe disease progression sets in?
    i. Yes, consider placebo
    ii. No, placebo not recommended
h. If the risk of placebo is an acute emergency, are rescue medications and emergency treatment available?
    i. Not applicable
    ii. Yes, consider placebo
    iii. No, placebo not recommended
i. If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?
    i. Not applicable
    ii. Yes, consider placebo
    iii. No, placebo not recommended
j. If the risk of placebo is severe physical discomfort or pain, is there rescue medication?

i. Not applicable
ii. Yes, consider placebo
iii. No, placebo not recommended

4. Risk disclosure in the consent form

a. Have the risks of receiving a placebo instead of active treatment been fully disclosed?
   i. Yes, consider placebo
b. Have the risks of the test drug been disclosed?
   i. Yes, consider placebo
c. Have the advantages of alternative treatments been explained?
   i. Yes, consider placebo

Conclusions

The use of placebo is ethically acceptable when:

- Research participants are not exposed to severe or permanent harm by the use of placebo.
- Research participants under placebo will benefit from the overall treatment of the disease.
- Risks of the use of placebo are minimized.
- Risks are adequately disclosed in the consent form.

Guidelines to review advertisements

1. Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:

   a. The name and address of the researcher or research facility
   b. The purpose of the research or the condition under study
   c. In summary form, the criteria that will be used to determine eligibility for the study
   d. A brief list of benefits to the participants, if any
   e. The time or other commitment required of the participants
   f. The location of the research and the person or office to contact for further information

2. The IEC should review research advertising to ensure that the advertisements DO NOT:

   a. State or imply a certainty of a favourable outcome or other benefits beyond what is outlined in the consent document and study protocol.
   b. Include exculpatory language
   c. Emphasize the payment or the amount to be paid, by such means as larger or bold type
   d. Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.

Annexure 6: AIIMS-BLS/IEC-H/SOP09/V1/ANX06
Intimation of start of study

IEC project number:
Study protocol number (for drug/device trial):
Project title:
Name of principal investigator:
Department of principal investigator:
Sponsor:
Contract research organization, if any:
Date of sanction by the IEC:
Date of start of the study:

Principal investigator
(Signature and date)

Annexure 7: AIIMS-BLS/IEC-H/SOP09/V1/ANX07
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

9.6 Workflow

	Activity	**Responsibility**
1.	Receive package or research proposal and research related documents	IEC Secretariat
2.	Verify contents and distribute	IEC Secretariat
3.	Appointment of primary reviewers	Chairperson / Member Secretary
4.	Initial review of documents, fill review assessment form	IEC members
5.	IEC board meeting, discussion and decision	Chairperson, Member Secretary, IEC members
6.	IEC decision communicated to the principal investigator	IEC Secretariat
7.	Storage of study related documents with relevant correspondence	IEC Secretariat

10 Expedited review of research study protocols by the Institutional Ethics Committee for biomedical and health research

10.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) members will perform an expedited review on a new research proposal using appropriate assessment forms.

10.2 Scope

This SOP applies to the review and approval of research studies and documents which qualify for expedited review by the IEC. Any protocol that carries no more than minimal risk and fulfils the criteria for expedited review is covered in this SOP.

10.3 Responsibility

- The Member Secretary is responsible after categorization of the projects to forward them to the Secretariat.

- The IEC Secretariat is responsible for the creation of a study specific file, allotment of a unique IEC identifier, distribution of the packages along with study assessment forms to the designated IEC members for the review (if he study has been categorized for expedited review) and communicate the review results to the investigators.

- Designated IEC members, including the Chairperson and/or the Member Secretary will be responsible for reviewing the research proposals and their related documents within allotted time frames.

- It is the responsibility of all the designated IEC members to fill the assessment form along with comments and recommendations after reviewing the study protocol.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

- The IEC Secretariat is responsible for recording and filing the decision, relevant points and deliberations about a specific study protocol, including the reasons for that decision.

- The Chairperson is responsible for signing (with date) the decision in the IEC decision form.

10.4 Detailed instructions

10.4.1 Appointment of reviewers

After determining that the protocol / project qualifies for an expedited review, the Member Secretary, in consultation with the Chairperson, will nominate two or more IEC members to review the amended protocol.

10.4.2 Distribute the protocol package

- The Secretariat will fill in the required details on the nomination form to the IEC members requesting initial review and in the study assessment form.

- The Secretariat will send a packet (hard or soft copy) to the designated IEC members.

- Nomination letter to IEC members requesting an initial review.

- Study assessment form

- Project submission application form

- Protocol and related documents

10.4.3 Receive the distributed protocol package

Designated IEC members will receive the protocol package with the project application form as hard copy or through email (if desired).

10.4.4 Verify the contents of the package

- The IEC member will verify all the contents.
- The member will notify the IEC Secretariat if any of the documents are missing.

10.4.5 Review by the IEC members

- IEC members will review the protocol within the stipulated time.
- The comments of the IEC members will be recorded.

10.4.6 Gather the assessment reports

The IEC Secretariat will collect the assessment forms with the comments from the designated reviewers and file them in the original study file.

10.4.7 Decision and communication of the decision to principal investigator and full IEC board

- The Member Secretary will discuss the comments of the members with the Chairperson and a decision about the protocol will be taken.

- If there are queries, these will be sent to the principal investigator within one working day after they are received by the Secretariat, in consultation with the Member Secretary.

- The reply from the principal investigator will be discussed by the Member Secretary with the Chairperson or the designated IEC members and a decision will be reached.

- The final decision will be recorded on the study assessment form for expedited review.

- The decision will be informed to the IEC members at the next full board meeting.

- If deemed necessary by the Chairperson, Member Secretary or the reviewers, the project shall be discussed at the forthcoming full board meeting before a final decision is reached. The final decision by the Chairperson is recorded on the study assessment form for expedited review.

- The Secretariat will send the study approval letter to the principal investigator. If the project has been disapproved or requires further modifications and resubmission, this will also be informed to the principal investigator in writing. The reasons for disapproval of a project will be specified in the letter sent to the principal investigator. The expedited review process should be completed within 14 working days.

10.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP10/V1/ANX01 – Form for nomination of IEC members for expedited review

Annexure 2: AIIMS-BLS/IEC-H/SOP10/V1/ANX02 – Study assessment form for expedited review

Annexure 3: AIIMS-BLS/IEC-H/SOP10/V1/ANX03 – Approval letter format in case of expedited review

Annexure 4: AIIMS-BLS/IEC-H/SOP10/V1/ANX04 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP10/V1/ANX01
Form for nomination of IEC members for expedited review

Date:

Dr.
Member, Institutional Ethics Committee,
All India Institute of Medical Sciences
Bilaspur – 174001, Himachal Pradesh

Ref: IEC project number: _____ entitled _____
_____

Subject: Review of _____

Dear Dr.

The following documents have been submitted to the IEC for review:
1.
2.
3.

The following members are nominated to review / carry out an expedited review of the above mentioned documents.

1.
2.
3.

For expedited review, you are requested to fill the enclosed study assessment form (annexure AIIMS-BLS/IEC-H/SOP10/V1/ANX02) and send it to the IEC office within 7 working days.

Chairperson / Member Secretary
(Signature with date)

Annexure 2: AIIMS-BLS/IEC-H/SOP10/V1/ANX02
Study assessment form for expedited review

IEC protocol number:		Date of receipt at IEC office (dd/mm/yy):
Project title:		
Name of the Principal Investigator	Department	Contact number
Total number of participants at the study site:		
Number of study sites:		
Sponsor:		

Duration of the study:

Reviewer's name:			
Type of study:	Intervention	Epidemiology	Observation
	Document based	Genetic	Social survey
	Other, please specify		
Description of the study in brief (mark whichever is applicable to the study):			
Randomized	Open-labelled	Double blinded	Placebo controlled
Treatment controlled	Cross-over	Parallel	Interim analysis
Use of tissue samples	Use of blood samples	Use of genetic material	
Comments:			

(Review the protocol and its related documents as per the guidelines given in AIIMB-BLS/IEC-H/SOP09/V1/ANX05)

Provisional decision:

- Approved
- Resubmission
- Disapproved
- Full board review
- Approved with modifications

Reasons for disapproval:

Name and Signature of the IEC member, with date

Final decision

Approved Yes No

If disapproved, reasons for disapproval:

Further revision or modifications required with resubmission:

Any other remarks:

Chairperson
(Signature with date)

Annexure 3: AIIMS-BLS/IEC-H/SOP10/V1/ANX03
Approval letter format for an expedited review

Date:

Dr.
Department of
All India Institute of Medical Sciences,
Bilaspur – 174001, Himachal Pradesh

Ref: IEC project number _____ entitled _____
_____

Dear Dr.

The following documents of the above mentioned project were reviewed and approved through an expedited review process.
1.
2.
3.

It is understood that the study will be conducted under your direction, in a total of _____ research participants, as per the submitted protocol.

The IEC approves the above mentioned study. This approval is valid for the entire duration of the study.

It is our policy that the IEC be informed about any on-site serious adverse events or any unexpected adverse events report within 24 hours, as per the formats specified in SOP16 or by email if the said date is a holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the IEC Chairperson, the Head of the Institute where the trial is being conducted, and the Central Licensing Authority within 14 calendar days of the SAE's occurrence. In case of serious adverse event of death the principal investigator should forward their report on the event after due analysis to the above authorities within 14 days of the knowledge of the occurrence of serious adverse event of death.

In case of injury or death of participant(s) occurring during the trial, the sponsor (whether a pharmaceutical company or an institution) or the sponsor's representative, whosoever had obtained the permission from the Licensing Authority for the conduct of the clinical trial shall

make payments for the medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

No deviations or changes to the study protocols and informed consent documents should be initiated without the prior written approval of the IEC. The IEC expects that the investigator should promptly report to the IEC any deviations or changes made to the study protocol to rule out immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before _____

A copy of the final report should be submitted to the IEC for review.

Yours sincerely,

Chairperson / Member Secretary

Date of approval of the study:

Annexure 4: AIIMS-BLS/IEC-H/SOP10/V1/ANX04
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

10.6 Workflow

	Activity	**Responsibility**
1.	Receive the submitted documents	IEC Secretariat
2.	Determine protocols for expedited review	Member Secretary
3.	Approve Member Secretary's recommendation regarding the protocol's expedited review	Chairperson
4.	Expedited review process	Chairperson / IEC members
5.	Decision of the IEC	Chairperson
6.	Communicate with the IEC and the principal investigator	Member Secretary / IEC Secretariat

11 Exemption from ethical review of research study protocols by the Institutional Ethics Committee for biomedical and health research

11.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures to be followed by the members of the Institutional Ethics Committee (IEC) for biomedical and health research, at AIIMS, Bilaspur, for assessing and granting exemption from ethical review to any research proposal submitted to the committee.

11.2 Scope

This SOP is applicable to research proposals that are submitted to the IEC for exemption from ethical review. The SOP describes the type of research proposals that can be exempted from ethical review and can be carried out without the approval of the IEC. The exemption forms listed in the annexure have been designed to standardize the exemption process.

11.3 Types of protocols for exemption from review

11.3.1 An exemption from ethical review may be considered in following situations:

- Research proposals with less than minimal risk, and where there are no linked identifiers, for example (Table 4.2, ICMR Guidelines 2017):
    - Research conducted on data available in the public domain for systematic review or meta-analysis
    - Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed persons
    - Quality control and quality assurance audits in the institution
    - Comparison of instructional techniques, curricula, or classroom management methods
    - Consumer acceptance studies related to taste and food quality

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

- Public health programmes by government agencies, such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)

- Research on educational practices such as instructional strategies, their effectiveness and their comparison across different techniques, curricula and classroom management methods.

- Exceptions to the above include:

  - Any research involving the use of educational tests, surveys, interview procedures and/or observation of public behaviour that can identify the participants directly or indirectly. The disclosure of such information outside the research project can subject the participants to various risks of civil, criminal or financial liability and psychosocial harm.

  - Similarly, research interviews with direct access to private information of the participants should not be exempted from ethical review.

- Proposals which do not involve human participants or any data derived from them are also exempt from ethical review by the IEC for biomedical and health research.

- Examples of such research include:
  - Audit of educational practices
  - Research on microbes cultured in the laboratory
  - Research on immortalized cell lines
  - Research on cadavers or death certificate data, provided such research does not reveal any identifiable personal data of the research subjects
  - Analysis of data freely available in the public domain

- However, in certain circumstances research that falls under the above categories may still need to be reviewed by the IEC. This may be required because of the following reasons:

  - The organization sponsoring / funding the research, providing the resources, data or access to participants may require the proposal to be reviewed.

  - The organization publishing the research may require the research proposal to be reviewed

11.4 Responsibility

The Member Secretary will record the decision in the accompanying review exemption form and cite reasons for the exemption. The Secretariat will be responsible for recording and filing the decision and its reasons as per the annexure listed in AIIMS-BLS/IEC-H/SOP11 /V1/ANX02.

11.5 Detailed instructions

11.5.1 Receive the submitted documents

- The IEC Secretariat will receive the review exemption application submitted by the principal investigator as per the format listed in annexure AIIMS-BLS/IEC-H/SOP11/V1/ANX01, along with the project proposal and its related documents submitted as per the formats given in SOP07.

- The Secretariat will acknowledge the receipt of the submitted documents.

- The application will be put up before the IEC members in the upcoming full board meeting.

11.5.2 Exemption process

- The IEC Chairperson, Member Secretary and IEC members will weigh the research proposal and reach a conclusion if it merits review exemption.

- The Member Secretary will record the decision on the exemption form.

- The decision taken by the IEC should be intimated to the principal investigator in 7 working days as per the format given in annexure AIIMS-BLS/IEC-H/SOP11/V1/ANX02.

11.6 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP11/V1/ANX01 – Application form for the exemption of ethical review
Annexure 2: AIIMS-BLS/IEC-H/SOP11/V1/ANX02 – Decision letter from the IEC regarding exemption from ethical review
Annexure 3: AIIMS-BLS/IEC-H/SOP11/V1/ANX03 – Investigational new drug application exemption checklist
Annexure 4: AIIMS-BLS/IEC-H/SOP11/V1/ANX04 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP11/V1/ANX01
Application form for the exemption of ethical review

IEC no: _____ (to be filled in by the IEC Secretariat)
Principal Investigator:
Department:
Title of the project:

Name of other participating investigators, staff and students:

Brief description of the project:

[Please provide a brief (300 words) summary of the research proposal covering the nature of the research, aims, objectives, hypothesis, rationale, type of participants, procedures and methods to be employed in the project. Please also complete and append the project submission form (given in SOP07), project proposal and its related documents, along with this application.]

Please state the reasons why an exemption from ethical review is requested. Does your research fall under the following categories or any other that allow a review exemption?

- Research conducted on data available in the public domain for systematic review or meta-analysis
- Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed persons
- Quality control and quality assurance audits in the institution
- Comparison of instructional techniques, curricula, or classroom management methods
- Consumer acceptance studies related to taste and food quality
- Public health programmes by government agencies, such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)
- Audits of educational practices
- Research on microbes cultured in the laboratory
- Research on immortalized cell lines
- Research on cadavers or death certificate data, provided the research does not reveal any personal identifiable data
- Research involving the analysis of data available in the public domain
- Any other

(Please include a detailed justification for the exemption request, e.g. the study does not involve human participants, or if the exemption is being requested on the basis of low risk involved in the study. In case of the latter please refer to AIIMS-BLS/IEC-H/SOP11/V1/ANX03).

Principal Investigator
(Signature with date)

Forwarded by the Head of the Department

Signature:
Name:
Date:

Annexure 2: AIIMS-BLS/IEC-H/SOP11/V1/ANX02
Decision letter from the IEC regarding exemption from ethical review

To,
Dr.
Principal Investigator,
Department of
All India Institute of Medical Sciences,
Bilaspur – 174001, Himachal Pradesh

Ref: IEC number _____ project entitled _____
_____

Dear Dr.

The Institutional Ethics Committee for research projects involving human participants has reviewed your application (dated: _____) for an exemption from ethical review. Your application was discussed by the IEC during its meeting (number: _____), dated _____.

The IEC has decided:

Exemption granted: Yes [ ] No [ ]
Cannot be exempted for the following reasons:

Thanking you,
Yours sincerely,

Signature of the Member Secretary
Name:
Date:

Annexure 3: AIIMS-BLS/IEC-H/SOP11/V1/ANX03
Investigational new drug application exemption checklist

This checklist is intended to be used by the investigator as a preliminary test of whether an investigational new drug application needs to be submitted to the DCGI for studies involving DCGI/RA-approved drugs.

If any of the questions receives a "yes" as an answer, an investigational new drug application must be submitted to the DCGI. If the answers to all the questions are "no", then the study may meet the criteria for an exemption.

1. Name of the drug, dosage, route of administration

2. Does the study involve a different route of administration of the marketed drug than already approved?

   Yes / No

3. Does the study involve the administration of different drug dosage levels that significantly increase the risk or decrease the acceptability of risk for the study subjects?

   Yes / No

4. Does the study involve the administration of the drug to a different patient population for whom there may be increased or decreased acceptability risk?

   Yes / No

5. Does the study entail any other factor that significantly increases the risk or decreases the acceptability of risk to the study subjects?

   Yes / No

6. Are the results of the study intended to be reported to the DCGI-RA in support of any significant change in the labelling or advertising of the drug (only for corporate sponsored studies)?

   Yes / No

Principal investigator
(Signature, name, department, date)

Annexure 4: AIIMS-BLS/IEC-H/SOP11/V1/ANX04
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

11.7 Workflow

	Activity	**Responsibility**
1.	Receive application for review exemption with research proposal and its related documents	IEC Secretariat
2.	Review of application and research protocol	Member Secretary / Chairperson
3.	Informing and discussing the application with IEC members in upcoming full board meeting	IEC Secretariat/ Member Secretary / Chairperson
4.	Decision on exemption in consultation with the IEC Chairperson	Member Secretary / Chairperson
5.	Communicate decision to the principal investigator	IEC Secretariat
6.	Recording and filing the decision and related documents	IEC Secretariat

12

12 Agenda preparation, meeting procedures and recording of minutes by the Institutional Ethics Committee for biomedical and health research

12.1 Purpose

The purpose of this standard operating procedure (SOP) is to delineate the administrative processes required for planning and preparing the agenda of meetings, distributing the meeting agenda, conducting the meetings, and recording the minutes of the meetings by the institutional ethics committee (IEC) for biomedical and health research at AIIMS, Bilaspur.

12.2 Scope

This SOP applies to administrative processes pertinent to the preparation of agenda, various meeting procedures, and recording of minutes of IEC meetings, conducted by the IEC for biomedical and health research at AIIMS, Bilaspur. This SOP covers the relevant processes required to be followed before, during and after an IEC meeting.

12.3 Responsibility

It is the responsibility of the Member Secretary assisted by Secretariat staff to prepare the agenda for IEC meetings. The agenda will be subsequently reviewed and approved by the Chairperson. The Member Secretary will ensure proper recording and dissemination of the minutes after the meeting. It is the responsibility of all members to read and approve the minutes sent to them. The Chairperson will review and issue the final approval of the minutes.

12.4 Detailed instructions

12.4.1 Procedures to be carried out before an IEC meeting

A full board meeting of the IEC will be regularly scheduled once every three months and the dates will be decided by the Member Secretary with the help of the IEC Secretariat at the beginning of the year. The frequency of full board meetings may be amended depending on the

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

number of research proposals being managed by the IEC. After discussing and ratifying in the IEC meeting, the approved dates will be communicated to the AIIMS, Bilaspur research calendar and the meetings will be held on the stipulated dates.

12.4.2 Preparation of meeting agenda

- The Member Secretary assisted by the IEC Secretariat will prepare the meeting agenda according to the format given in annexure 1: AIIMS-BLS/IEC-H/SOP12/V1/ANX01. The meeting agenda shall include:

    - Welcome of all members by the Chairperson
    - The Chairperson will confirm quorum
    - Reading and approving minutes of the previous meeting
    - Consideration of projects submitted for initial review
    - Consideration of resubmitted protocols for full board review
    - Review of amended research protocols and protocol-related documents submitted for full board review
    - Continuing review of study protocols
    - Review of study completion reports
    - Review of studies that have been prematurely terminated
    - Review of site monitoring visit reports
    - Consideration of serious adverse event (SAE) reports submitted to the IEC
    - Review of the minutes of the SAE sub-committee
    - IEC issues to be discussed including, but not limited to, emergency concerns, IEC policies, training of members, revision of IEC SOPs, or any other issue that is raised by the IEC members.
    - Any other matter that has been referred to the IEC for the latter's opinion, or issues that need to be intimated to the members
    - Report of any other sub-committee or group appointed or designated by the Chairperson for a specific or general purpose
    - Any other matter besides the above list

- The IEC Secretariat will collect and organise the documents required for the scheduled meeting, and will verify if the documents are complete in all respects.

- The IEC Secretariat will schedule the research proposals received for review on a first come first serve basis. Accordingly, the research proposals will be include in the meeting agenda as per their date of receipt.

- Study related documents including research proposals, informed consent documents, CRF and IB; amended study related documents; and investigators' answers to IEC queries will be included in the agenda of the upcoming IEC meeting, provided these are received a

minimum 14 days before the meeting. Documents other than these can be scheduled for the impending IEC meeting if they are received at least 10 days before the meeting.

- The meeting agenda will be prepared at least 3 working days before the date of the meeting.

- The study related documents that are received in the 3 days preceding the IEC meeting will not be considered for the impending meeting, unless they are related to the safety of research participants, are SAE reports, pertain to research protocol violations, or are related to urgent matters that have direct bearing on the safety and rights of research participants. Documents pertaining to such matters are to be vetted by the Member Secretary or Chairperson.

12.4.3 Distribution of research proposals and documents to the IEC members

- The date, time, venue, and documents relevant to the upcoming meeting should be communicated to the IEC members preferably 14 days before the meeting, and the final agenda of the meeting should be sent to the attending IEC members a minimum of three working days before the meeting.

- The Secretariat staff will confirm with the IEC members, either verbally, via email, or telephonically if they have received all the relevant documents.

- It is the responsibility of the IEC member to verify on receipt if all relevant items have been provided. In case any items are missing the member should inform the IEC immediately so that the relevant documents can be sent to the members before the meeting.

- The meeting notice and its agenda should be circulated to the relevant investigators via email. The investigators should be informed and requested to be available for the meeting date, if required.

- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the IEC members via email. The Secretariat will make sure that the meeting venue, equipment and facilities are available for the meeting day, and the members have been intimated at least one day prior to the meeting.

12.4.4 Conditions to be fulfilled for conducting the meeting

- For an IEC meeting, besides the Member Secretary and the Chairperson, the quorum should consist of 5 members as given below:

    - One basic medical scientist (preferably a clinical pharmacologist)
    - One clinician

- One social worker (or a social scientist, theologian, ethicist, philosopher, member or representative of a non-governmental voluntary agency, or a similar person)
- A lay person from the community
- A legal expert

- The quorum should include both medical, non-medical, and technical and non-technical members. A minimum of one non-affiliated member should be part of the quorum. A lay person should also preferably be part of the quorum.

- Medical members should be clinicians with appropriate medical qualifications.

- Technical individuals should be members with qualifications in specific fields that are relevant to the studies being discussed.

12.4.5 Procedures to be carried out during the meeting

- The Chairperson will initiate the meeting after ensuring that quorum has been achieved. The Chairperson at his/her discretion may delegate the responsibility of conducting the meeting to the Member Secretary, as per the agenda laid down for the meeting.

- The Chairperson will ask the members if anyone has any conflicts of interest with the research projects tabled for the meeting and if so, to declare the conflicts.

- The Secretariat staff will obtain the signatures of the members on the conflict of interest form. IEC members who happen to be principal investigators or co-investigators in tabled research proposals should declare their conflicts of interest prior to the start of the meeting.

- If a conflict of interest has been declared by a member, the Chairperson will ask the concerned member to leave the meeting room when the concerned issue is being discussed.

- The Secretariat staff will obtain the signatures of attending IEC members on the attendance register.

- At the discretion of the Chairman, guests may be allowed to observe the board meeting. These guests may include students, inspectors, auditors, members of other ethics committees, surveyors, regulators, members of regulatory agencies, representatives of patient groups, representatives of special interest groups, representatives of accrediting organizations, or members of general public.

- All guests are required to sign a confidentiality agreement prior to attending the meeting.

- The Secretariat will obtain the signatures of the guests, observers, and/or independent consultants, prior to the start of the meeting on the confidentiality agreement.

- The Member Secretary will ask the members whether any points need to be discussed regarding the minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.

- The Member Secretary will present the agenda of the meeting for discussion.

- The meeting shall generally proceed in the order detailed in the agenda. However, the Chairperson may allow alterations to the order of issues depending on the situation.

- Investigators who have been asked by IEC secretariat to provide additional information or clarifications related to their projects may do so by attending the IEC meeting. However, no discussion will be carried out between the IEC members while the investigator is present in the meeting room.

- For other points in the agenda, the Member Secretary will present the gist of the matter, read the relevant letters from the investigator (if deemed necessary), and request the IEC members to give their comments. The Member Secretary assisted by the Secretariat staff will also record a gist of the discussions and decisions made on these issues in the meeting.

12.4.6 Decision making processes

- The final decision on each proposal or issue discussed in the meeting shall be through consensus. When a consensus is not possible, the IEC will vote. In case of a tie the Chairperson can cast a vote. A majority vote is defined as 2/3rd of the members who have reviewed the project, are present in the meeting, and have voted.

- The following individuals will not vote in an IEC meeting:
    - Members of the committee who are listed as investigators on a research proposal
    - An investigator or study team member who has been invited to the meeting
    - An independent consultant invited to the meeting to provide expert opinion
    - Specific patient groups that might be have been invited to the meeting

- Decision will include approvals, disapprovals, request for study modifications, and suspension or termination of an ongoing study.

- If the full board approves a research proposal in principle subject to minor modifications, the revised project proposal will be reviewed and approved by the Member Secretary, IEC or a sub-committee of the IEC, on behalf of the full board. The Member Secretary will report the decision in the next full board IEC meeting. Such revised proposals will not be

taken up for a full board review, unless there are major changes in the revised documents. In the latter situation the revised proposal will be discussed by a 3-member sub-committee, or by the full IEC board in their next meeting.

- The IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk-benefit ratio of the study.

- In case of conditional decisions, clear recommendations for the revision of the study, and its resubmission for review should be provided.

- A negative decision on an application will be clearly explained with appropriate reasons. If the investigator wishes to appeal against the decision, he/she may do so.

- The discontinuation of a study will be recommended if the IEC finds that the goals of the trial have already been achieved midway, if unequivocal results have been obtained, or if SAE have been observed.

12.4.7 After the IEC board meeting

- The IEC Secretariat will draft a concise and easy-to-read summary of the discussions and decisions taken in the meeting within 7 working days after the meeting.

- The Secretariat will ensure that each section of the summary carries the following details as and where appropriate:

    - Name of person preparing the minutes
    - Location where the meeting was held (including city and state)
    - Meeting number, date and duration of the meeting (including the time of commencement and end)
    - Names of the IEC members and guests who attended the meeting
    - Name of the Chairperson or his/her representative who presided over the meeting
    - Confirmation that a quorum was constituted for the meeting by the Chairperson

- **Requirements for research studies or activities requesting approval:**

    - Sponsor's name, if applicable
    - Research project number, date, version, as applicable
    - Principal investigator's name
    - Names of the primary reviewers who presented their findings
    - Discussion as deemed appropriate by the Chairperson
    - Follow-up action decided
    - Reference to the approval letter for the principal investigator that lists the changes requested by the IEC board

- Determination of the next continuing review

- **Requirements for research proposals or activities requesting expedited review:**
  - Sponsor's name, if applicable
  - Research project number, date
  - Principal investigator's name
  - Details of the expedited approval requests and outcomes

- **Requirements for continuing reviews:**
  - Sponsor's name, if applicable
  - Research project number
  - Principal investigator's name
  - IEC board's decision to continue, terminate, or amend the study
  - List of recommendations or actions to be implemented by the principal investigator, if applicable

- **Requirements for adverse event notifications and reports:**
  - Sponsor's name, if applicable
  - Research project number
  - Principal investigator's name
  - Report or summary provided by the SAE sub-committee
  - Action deemed appropriate by the IEC board after review

- **Requirements for terminating study approval:**
  - Sponsor's name, if applicable
  - Research project number
  - Principal investigator's name
  - Reasons for termination

12.4.8 Approval of meeting minutes

- The IEC Secretariat will check the correctness and completeness of the minutes and present the minutes to the Chairperson for review and approval within 7 working days of the meeting.

- The Secretariat will email the minutes of the meeting to the IEC members.

- The Chairperson will give his/her final approval by signing and dating the minutes, after the approval from all IEC members in the next meeting.

12.4.9 Filing the minutes

- The Secretariat will place the original version of the minutes in the "Minutes" file.

- The Secretariat will file the IEC decision forms in the respective project files and place all the correspondence in the appropriate files.

- The Secretariat will send a list of the studies approved and rejected by the IEC at the regular full board meetings to the head of the Institute within 21 days of the IEC meeting. The list should contain the title of the study, name of the principal investigator and the final decision.

12.4.10 Calling an emergency IEC meeting

The Member Secretary in consultation with the Chairperson may decide to call an emergency meeting for any one or more of the following reasons:

- Urgent issues, which, if not decided upon early could adversely affect or have adverse impact on patient safety, public safety, or national economy etc.

- Occurrence of unexpected serious adverse events in a study.

- Other reasons, as deemed appropriate by the Member Secretary and Chairperson.

- The Secretariat will endeavour to contact every IEC member and inform them about the date, time and venue of the emergency meeting, as well as the reason for calling the meeting.

- The IEC administrative officer will prepare packets for distribution to the members containing the information and documents about the matters going to be discussed in the emergency meeting. The details may also be sent via email.

- During the meeting, the Chairperson or Member Secretary will ascertain if quorum has been attained. If a quorum is not achieved, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes, the meeting will be held without a quorum provided at least four members (including at least one scientific and one non-scientific member) are present, given the urgency of the matter under consideration.

- The IEC members will act according to the relevant IEC SOPs (expedited review, SAE review, review of protocol deviations and violations etc.) for discussion and taking decisions on the matters under consideration.

- The minutes of the emergency meeting will be prepared, distributed, approved and filed as described in the steps above for a regular full board meeting.

12.4.11 Communicating decisions

- The decisions taken by the IEC will be communicated in writing by the Member Secretary to the principal investigators, preferably within a period of 2 weeks after the IEC meeting during which the decisions were made. The communication of the decisions will include, but is not limited to, the following:

    - The IEC code of the project and the title of the research proposal
    - The name of the principal investigator
    - Clear identification of the proposed research and/or amendments
    - The documents reviewed including participant information sheet and informed consent form
    - The date and place of the decision
    - A clear statement of the decision reached
    - Any suggestions/recommendations proffered by the IEC
    - When seeking clarifications, a deadline of 4 week will be given to the principal investigator. If the clarifications are received after the deadline, then the project may not be put up in next meeting for approval. Conditional approval pending clarification will not be given. If the principal investigator fails to provide clarifications, a reminder will be sent by the IEC stating that a repeated failure to respond will lead to the closure of the project file.

- In the case of a positive decision, the principal investigator will be notified of the following requirements through an approval letter (AIIMS-BLS/IEC-H/SOP09/V1/ANX04).

    - A statement of the responsibilities of the principal investigator including, the confirmation of the acceptance of any requirements recommended by the IEC
    - Registration with CTRI if applicable
    - Communicate date of start of study to the IEC (AIIMS-BLS/IEC-H/SOP09/ V1/ANX06)
    - Submission of annual progress reports
    - The need to notify the IEC in cases of protocol amendments, other than amendments involving only logistical or administrative aspects of the study

- The need to notify the IEC in the case of amendments to the recruitment like the research participant information, the informed consent documents, or the number of participants.
- The need to report serious and unexpected adverse events related to the conduct of the study
- The need to report unforeseen circumstances, withdrawal and termination of the study, or significant decisions taken by another IEC
- The information the IEC expects to receive in order to perform ongoing review
- The final report on study completion
- The schedule/plan of ongoing review of sponsored trials

- In the case of a negative decision, the reasons should be clearly stated in the communication to the principal investigator

- All decisions and approval letters will be signed by the IEC Member Secretary and/or the Chairperson

12.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP12/V1/ANX01 – Format for setting up IEC meeting agenda
Annexure 2: AIIMS-BLS/IEC-H/SOP12/V1/ANX02 – Conflict of interest form to be signed by IEC members before board meeting
Annexure 3: AIIMS-BLS/IEC-H/SOP12/V1/ANX03 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP12/V1/ANX01
Format for setting up IEC meeting agenda

IEC Meeting Agenda

IEC meeting number: (yyyy/nn)
Venue of meeting:
Date and time of meeting:

The board meeting will proceed in the following order:

Period 1

- Discussion of the points arising from the minutes of the previous meeting
- Presentation of the agenda of the day's meeting
- Declaration of conflicts of interest.

Period 2

- Presentation, review, discussion and decisions on of new research proposals. Decisions to be reached by consensus or by voting on various approvals and queries
- Review of clarifications and responses submitted by principal investigators to the queries communicated by the IEC regarding respective research proposals
- Review, discussion and approval of research protocol amendments and related documents
- Review continuing review reports, study completion reports, final clinical trial reports, annual study reports, and/or study termination reports
- Review study protocol deviations and violations
- Review other letters and correspondence related to research projects
- Review site monitoring reports
- Inform about the other IEC meetings (meetings other than full board meetings) and to review the policy decisions taken
- Inform about SAE sub-committee meetings and review SAE and safety reports
- Any other points for discussion

Period 3

- Issues which have been reviewed and approved by the IEC Member Secretary and Chairperson, and are to be reported to the full IEC board for consideration

Period 4

- Issues that have been already approved by the IEC Member Secretary and Chairperson, and letters of which have already been sent to the principal investigator, but need to be informed to the full IEC board.

Period 5

- Other issues that may be of interest or may require discussion with the IEC members.

Annexure 2: AIIMS-BLS/IEC-H/SOP12/V1/ANX02
Conflict of interest form to be signed by IEC members before board meeting

Date: (dd/mm/yyyy)

The Chairperson,
Institutional Ethics Committee (IEC-H),
All India Institute of Medical Sciences,
Bilaspur – 174001, Himachal Pradesh

I hereby declare the conflicts of interest for the IEC project no: ……
entitled ……
…… as under:

- I am the principal investigator/co-investigator/study team member/author
- I have financial interests that conflict with the above study
- ……
- ……
- ……

The project will be discussed in today's IEC meeting on (dd/mm/yyyy).

IEC member
(Signature and name)

IEC Chairperson
(Signature and name)

Annexure 3: AIIMS-BLS/IEC-H/SOP12/V1/ANX03
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Anurag Negi; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

12.6 Workflow

	Activity	**Responsibility**
1.	Preparation of meeting agenda prior to IEC board meeting	IEC Secretariat
2.	Procedures during the IEC meeting	IEC Secretariat, IEC members, Chairperson
3.	Procedures after the IEC meeting including the preparation of minutes	IEC Secretariat, Member Secretary
4.	Approval of meeting minutes	IEC members, Chairperson
5.	Filing of minutes	IEC Secretariat
6.	Calling an emergency IEC meeting	Member Secretary in consultation with the Chairperson

13 Review of resubmitted and amended protocols and protocol-related documents by the Institutional Ethics Committee for biomedical and health research

13.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) for biomedical and health research, AIIMS, Bilaspur will manage resubmitted and amended study protocols.

13.2 Scope

This SOP applies to the review of:

- Study protocols and their related documents that have been resubmitted to the IEC by the principal investigator with clarifications and modifications sought by the IEC in the initial review.

- Amendments to the study protocols and related documents that have been approved earlier by the IEC.

13.3 Responsibility

It is the responsibility of the IEC Secretariat to ensure the completeness of the documents submitted to the IEC.

A re-submitted protocol and its related documents will be reviewed by two IEC members designated by the Member Secretary as per the IEC decision at the time of the initial review of the project during the full board meeting, or the expedited review meeting, as the case may be. This information shall be recorded (during the meeting) in the IEC decision form.

In the case of an amended study protocol and related documents, Chairperson / Member Secretary will decide whether the proposed protocol amendments need to undergo a full board review or an expedited review.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

If the amendments are of an administrative nature, the Chairperson / Member Secretary can recommend an expedited review, whereas if the amendments are related to participant safety or data collection, a full board review should be recommended. Additionally, the primary reviewers who had reviewed the initial submission may be asked to review the resubmitted protocol.

13.4 Detailed instructions

13.4.1 Receipt of the resubmitted protocol and its distribution

- The Secretariat will verify if the principal investigator has responded to the queries posed by the IEC, within 60 days of the receipt of the letter of comments from the IEC.

- The Secretariat will check the resubmitted protocol and its related documents (both hard and soft copies) for the following items:

    - Reply to the IEC letter of comments / queries

    - Revised version of the study protocol, informed consent documents, and/or any other related documents, such as, case report forms, diary sheets, etc., with appropriate changes underlined or highlighted in the revised documents.

- The Secretariat will refer to the IEC decision form on the given protocol and distribute the documents containing the reply to the IEC query letter, revised study protocol and its related comments, along with the assessment form for the resubmitted protocol to the:

    - Member Secretary for summarizing and including it in the agenda for a full board discussion in the forthcoming meeting, if the decision on the protocol was – "to be discussed at full board meeting".

    - Designated IEC members, if the decision on the protocol was – "to be reviewed by two or more IEC members".

    - Chairperson / Member Secretary, if the decision on the protocol was – "Approved with recommendations subject to review by the Chairperson / Member Secretary only", as per the IEC decision form.

13.4.2 Review of revised protocol by Chairperson / Member Secretary / IEC members:

- The Chairperson / Member Secretary / IEC members will refer to the IEC query letter and comments for guidance for the review of the resubmitted protocol. They will review if the recommendations of the IEC have been followed or have been adequately addressed.

- Where required, the Chairperson / Member Secretary / IEC members will further issue comments in the assessment form for the resubmitted protocol AIIMS-BLS/IEC-H/SOP13/V1/ANX01.

- The Secretariat will retrieve the assessment form for the resubmitted protocol (AIIMS-BLS/IEC-H/SOP13/V1/ANX01) from the Chairperson / Member Secretary / IEC members.

- In case the decision is to discuss the revised protocol at the upcoming full board meeting, then the Member Secretary will present a brief oral summary of the study design and the comments issued by the Chairperson / IEC members in the full IEC board meeting.

- The Chairperson shall entertain a discussion on the protocol revision, involving all the IEC members.

- The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:

    a) Approved

    b) Modifications to the items noted in the convened meeting follow-up by the Chairperson / Member Secretary / IEC members, after the receipt of the requested modifications.

    c) Disapproved giving reasons for the disapproval

- In case the revised protocol is already approved through an expedited review, the decision is informed to the members at the full board meeting.

13.4.3 Receipt of the protocol for amendments

- The documents for amendments (both hard and soft copies) forwarded by the principal investigator will be received and verified by the Secretariat.

- The Secretariat will confirm the request for review of the amended protocol and its related documents received from the principal investigator on the previously approved protocols and its related documents as per the form AIIMS-BLS/IEC-H/SOP13/V1/ANX02.

- The administrative staff will confirm that the amended version of the protocol and related documents are attached with the application and that the changes or modifications in the protocol are underlined or highlighted in the amended version.

13.4.4 Notify Member Secretary

The Secretariat will inform the Member Secretary of the receipt of the amended protocol.

13.4.5 Full review or review by designated members

- After review of the materials, the Member Secretary will determine whether the protocol requires a full board review or an expedited review. The Member Secretary will indicate this decision on the protocol amendment assessment form (AIIMS-BLS/IEC-H/SOP13/V1/ANX02).

- The amended protocol and its related documents will require a full board review if any of the following criteria are met:

    - The protocol amendments include risk-benefit assessments such as:
        - A change in the study design
        - Addition or removal of treatments
        - Changes in the inclusion and/or exclusion criteria
        - Change in the method of dosage or formulation, such as, oral formulation changed to intravenous
        - A significant change in the number of research participants (if a decrease or increase in the number of research participants alters the fundamental characteristics of the study).

- For regulatory studies, a protocol amendment with the above changes would require a DCGI approval.

- For an expedited review, the form in AIIMS-BLS/IEC-H/SOP13/V1/ANX02 will be used to nominate members by the Chairperson / Member Secretary.

13.4.6 Distribution to the IEC members

- The following documents will be distributed to the designated IEC members as per the decision regarding the review

    - The revised and amended documents should clearly identify each change made.
    - The protocol amendment assessment form AIIMS-BLS/IEC-H/SOP13/V1/ANX01 should be accompanied.

- Whenever the decision is a full board review, the Secretariat will summarize the points for discussion regarding the amended protocol and its related documents, and shall place the

protocol amendment request on the agenda for discussion in the next convened full board meeting.

13.4.7 Protocol Amendment Review Process

- The IEC members will review the amended documents and write their comments in the form AIIMS-BLS/IEC-H/SOP13/V1/ANX01.

- The reviewer may request the Secretariat to keep the documents for a full board discussion after completing the review.

- The IEC members performing the review must sign and date the form AIIMS-BLS/IEC-H/SOP13/V1/ANX02, and return this to the Secretariat after the review.

13.4.8 IEC decision on amended protocols

- In case the project is earmarked for a full board review, the Member Secretary / designated IEC member(s) will present a brief oral summary of the study design and read the comments on the amended protocol and protocol related documents, in the meeting.

- The decision by the designated reviewers may be:

    - Approved
    - Disapproved
    - Suggested recommendations
    - Full board discussion in next meeting

- The final decision regarding the research project will be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:

    - Approve the protocol amendment
    - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IEC review.
    - Disapprove the amendment requested, stating the reasons, but allow the study to continue as previously approved.
    - Suspend the study, until further information is obtained.

13.4.9 Recording of the decision

The IEC decision will be recorded by the Secretariat in the IEC decision form.

13.4.10 Communication of the decision to the Principal Investigator

- If the IEC approves the amendments in the protocol and its informed consent documents, the Secretariat staff will send a signed and dated amendment approval letter, i.e. AIIMS-BLS/IEC-H/SOP13/V1/ANX03 to the principal investigator within 14 working days of the meeting. The decision regarding disapproval with reasons, or a request for modifications, stating specific changes needed, will be communicated in writing to the principal investigator within 14 working days of the meeting.

- The letter of comments sent to the principal investigator shall state that the reply to the letter is expected within 60 days from the date of receipt of the letter, and in the absence of a response, the project will be declared closed in the IEC office records.

- The Member Secretary shall inform other members about the decision taken on the amended documents at the next full board meeting.

13.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP13/V1/ANX01 – Assessment of resubmitted protocol
Annexure 2: AIIMS-BLS/IEC-H/SOP13/V1/ANX02 – Protocol amendment request and assessment form
Annexure 3: AIIMS-BLS/IEC-H/SOP13/V1/ANX03 – Protocol amendment / document amendment approval letter
Annexure 4: AIIMS-BLS/IEC-H/SOP13/V1/ANX04 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP13/V1/ANX01
Assessment of resubmitted protocol

Protocol number:
Protocol title:

Number of review:	2nd review	3rd review	4th review
Principal Investigator:			
Department:			
Date of initial review by the IEC:			
Date of last review:			
IEC decision recorded in the meeting minutes (held on _____):			

Opinion of the reviewer:

Revision or modification according to the recommendation:	Yes	No Please provide explanation:
Approved:	Yes	No
If disapproved, reasons for disapproval:		
Further revision or modification required:		
To be discussed at the forthcoming full board meeting:		
Any other comments:		

Reviewer 1
(Name, signature, date)

Reviewer 2
(Name, signature, date)

Final decision

- Approved: Yes / No
- If disapproved, reasons for disapproval:
- Further revision, modification or resubmission required:
- Any other reasons:

Signature of the Chairperson / Member Secretary Date:

Annexure 2: AIIMS-BLS/IEC-H/SOP13/V1/ANX02
Protocol amendment request and assessment form

IEC protocol number:

a) Protocol title:

b) Principal Investigator:
c) Department:
d) Approval date:
e) Number of amendments:
f) State / describe the amendments:

g) Type of document and part of document amended:

h) Reasons for the amendment:

i) Impact of the amendment on the present study at this study site: (such as, but not limited to, modifications to the informed consent documents, re-consent of enrolled research participants, untoward effects likely to occur because of the amendments, and any other):

j) Have the changes/modifications in the amended versions been highlighted / underlined?
Yes …….. No ……..

Principal Investigator
(Name, signature, date)

Type of review: (Decision by the Chairperson / Member Secretary)

- Review by the Chairperson / Member Secretary
- Review by the designated IEC members
- Full board review and discussion

13

Comments of the reviewer:

- Decision
  - Approved
  - Disapproved
  - Next full board discussion
  - Suggested recommendations

Name(s) of the Chairperson / Member Secretary / IEC members reviewing the project:

Signatures with date:

Final decision:

- Approved: Yes …….. No ……..
- If disapproved, reasons for disapproval:
- Further revision or modifications required:
- Any other remarks:

Signature of the Member Secretary Date:

Annexure 3: AIIMS-BLS/IEC-H/SOP13/V1/ANX03
Protocol amendment / document amendment approval letter

To,
(Name of the PI)
Department
All India Institute of Medical Sciences,
Bilaspur – 174001, Himachal Pradesh

Ref: IEC number _____; project entitled _____
_____

Dear Dr.

We have received from you the following documents.
1.
2.

At the Institute review board meeting held on _____ the above mentioned documents were reviewed.

After consideration, the IEC has decided to approve:
The aforementioned study-related documents OR the following documents:
1.
2.

The members who attended this meeting held on _____ at which the above mentioned documents were reviewed and discussed, are listed below:
1.
2.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Review Board.
OR
After reviewing the documents, the IEC has decided to approve the aforementioned study-related documents.

Yours truly,

Member Secretary
(Signature with date)

Annexure 4: AIIMS-BLS/IEC-H/SOP13/V1/ANX04
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

13.6 Workflow

	Activity	**Responsibility**
1.	Receive the protocol amendment / resubmitted protocol	IEC Secretariat
2.	Notify the Chairperson / Member Secretary of the IEC	IEC Secretariat
3.	Determine if a full board review or review by designated IEC members is needed	IEC Chairperson / Member Secretary
4.	Nomination of IEC members for review	IEC Chairperson
5.	Distribution to the IEC members	IEC Secretariat
6.	Protocol Amendment / revised document review	Chairperson / Member Secretary/ IEC members
7.	IEC decision	IEC Chairperson / Member Secretary
8.	Communication of the decision to the principal investigator	IEC Secretariat
9.	Store documents	IEC Secretariat

14 The review of protocol deviations and violations by the Institutional Ethics Committee for biomedical and health research

14.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the actions to be taken by the institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur, when research investigators and trial sites: a) fail to follow the research protocols approved by the IEC, b) fail to comply with national and international guidelines, statutory provisions, institutional guidelines, rule and procedures mandated by the IEC for conduct of research involving human participants, and/or c) fail to respond to the IEC requests regarding statutory, ethical, scientific or administrative matters.

14.2 Scope

This SOP covers various procedures that the IEC needs to follow while assessing and acting upon violations and deviations from approved research protocols, and national/international rules and guidelines. The procedures delineated in this SOP have been laid down for research proposal involving human participants approved by the IEC for biomedical and health research, AIIMS, Bilaspur.

14.3 Responsibility

The IEC Secretariat is responsible for receiving deviation and violation reports submitted either by the principal investigator, other investigators, Institute faculty or other members of the Institute or research trial site. Deviation and violation reports must be submitted using the format provided by the IEC. The Secretariat will schedule deviation and violation reports in the agenda for the next full board IEC meeting. The IEC members should review and act on such reports.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

14.4 Definitions

14.4.1 Protocol deviation

A protocol deviation is any change, divergence, or departure from the study design or procedures of a research study that have not been approved by the IEC. Upon discovery, the principal investigator is responsible for reporting the deviations to the IEC using the reporting form stipulated by the committee.

14.4.2 Protocol violation

A protocol violation is a deviation from the IEC approved research protocol that may affect the participant's rights, safety, and wellbeing, and/or the completeness, accuracy and reliability of the study data. If a study deviation meets any of the following criteria, it is considered a protocol violation:

1. The deviation has harmed or posed a significant risk of harm to the research participants.
    - A research participant received the wrong treatment of incorrect dose
    - A research participant met the study withdrawal criteria during the study, but was not withdrawn
    - A research participant received an excluded concomitant medication

2. The deviation compromises the scientific integrity of the data collected in the study.
    - A research participant was enrolled but did not meet the study's eligibility criteria
    - A failure to treat research participants according to the study protocols that specifically relate to the efficacy outcomes
    - Changing study protocols without a prior IEC approval
    - Inadvertent loss of samples or data

3. The deviation is a wilful breach of regulations, policies and/or procedures meant for the protection of human participants, by the study investigators.
    - Failure to obtain informed consent before commencing study related procedures
    - Falsifying research or medical records
    - Performing tests or procedures beyond the individual's professional scope or privilege status

4. The deviation involves a serious or continuing non-compliance of federal, state, local or institutional human subject protection regulations, policies, or procedures.
    - Working under an expired professional license or certification
    - Failure to follow the federal and local regulations, and/or intramural research policies
    - Repeated minor deviations in the research study

5. The deviation is inconsistent with the NIH Human Research Protection Program's research, medical, and ethical principles.
    - A deviation that involves a breach of confidentiality
    - Inadequate or improper informed consent procedure

14.4.3 Minor protocol deviation

A minor protocol deviation is any change, divergence or departure from the study design or research procedures that have not been approved by the IEC, but which do not pose a major impact on the research participant's rights, safety, and wellbeing, or on the completeness, accuracy, and reliability of the study data.

14.5 Detailed instructions

14.5.1 Detecting research protocol deviations and violations

Any one of the following ways (but not limited to) may be employed to identifying research protocol deviations and violations. A protocol deviation or violation may be reported to the IEC by:

a) The principal investigator, trial site, study sponsor, or the contract research organization involved with the study.

b) The IEC members who are monitoring a research project at the trial site. If the members detect that the research is not being carried out as per the IEC approved protocols, they should report such deviations and violations to the IEC.

c) The IEC Secretariat may report protocol deviations or violations based on the failure of the research investigators to comply with statutory requirements; and/or failure to respond to IEC's requests within a reasonable time frame.

d) IEC members may detect research protocol deviations and violations while scrutinizing annual, periodic, SAE or other reports and communications submitted by the principal investigator, trial site, study sponsor, or the contract research organization involved with the study.

e) The IEC may receive a communication, complaint or information from a research participant who has been enrolled or has been approached for enrolment by a research study.

f) Any report or communication from an independent person brought to the attention of the Member Secretary or Chairperson of the IEC.

g) A communication received from the Head of the Institute, informing the IEC about an alleged research protocol deviation or violation.

14.5.2 Receipt of research protocol deviation or violation report

- The principal investigator will report the research protocol deviation or violation to the IEC as per the format given in annexure AIIMS-BLS/IEC-H/SOP14/V1/ANX01.

- In case a protocol deviation or violation is detected by a person other than the principal investigator, the deviation or violation may be reported to the IEC in any format. Upon receipt of such a report, the Member Secretary will write to the principal investigator to submit a protocol deviation or violation report as per the format provided in AIIMS-BLS/IEC-H/SOP14/V1/ANX01.

- The Secretariat will notify the Member Secretary if any research protocol deviation or violation report is received from a principal investigator and any other source, within 2 working days of the receipt of the report.

14.5.3 Actions to be taken

a) The action taken by the IEC will be based on:

  - The nature and seriousness of the deviation or violation
  - The frequency of past deviation and violations carried out by the study
  - The frequency of deviations and violations carried out in previous research studies by the same principal investigator, team of co-investigators or department.

b) The Member Secretary will ascertain the impact of the protocol deviation or violation. Depending on the seriousness of the deviation or violation, the IEC shall do the following (but may not be limited to these actions):

  - Ask the principal investigator for written clarification as soon as the deviation or violation report is received

  - If the impact of the deviation or violation is serious, the report will be shared with the Chairperson and two other IEC members designated by the Chairperson.

  - If the impact of the protocol deviation or violation is serious, the Member Secretary will instruct the Secretariat to schedule and call a full board IEC meeting specifically

for discussing the deviation or violation report within 7 working days of the initial scrutiny.

- The IEC Secretariat will put up the information and communication at the scheduled full board meeting for discussion.

c) The Member Secretary in consultation with the IEC members will review and discuss the deviation or violation report and related information.

d) The Chairperson will take the final decision depending on the seriousness of the deviation or violation. The decision will be taken to ensure that the safety and rights of the research participants are protected. The decision will be taken by voting. A majority vote for approval, disapproval, study modifications, study suspension, or study termination will be defined as 2/3rd majority of all the members present and voted in the meeting.

e) The decision taken by the IEC could include one or more of the following:

- Decide that no further action is required.
- Inform the principal investigator that the IEC has noted the deviation or violations that have occurred in the research study, and instruct the principal investigator to ensure that further deviations or violations do not occur and only IEC approved protocols and recommendations be followed for the study.
- Delineate the measures that the principal investigator should undertake to ensure that no further deviations or violations occur in the study.
- Depending on the nature and frequency of the protocol deviations or violations, the IEC may further monitor the research procedures and consent processes being employed in the study.
- The IEC may suggest modifications to the research protocol.
- The IEC may alter the interval for submission of continuing review and project status reports of the offending research study.
- The IEC may ask the principal investigator to provide additional training to the investigators and study team.

- The IEC may reprimand the principal investigator and/or:
    - Seek additional information from the principal investigator
    - Conduct an audit of the research trial/study
    - Suspend the research study till further information is made available and scrutinized
    - Suspend the research study till the recommendations issued by the IEC have been implemented by the principal investigator and have been checked and found satisfactory by the IEC.
    - Suspend the research study for a fixed duration of time.
    - Suspend or terminate the research study completely.
    - Revoke the approval of the offending research study.
    - Inform the DCGI or other relevant regulatory authorities.
    - Keep other research proposals from the principal investigator and co-investigators in abeyance.
    - Review and inspect other research studies carried out by the principal investigator and co-investigators.

f) The final decision will be recorded by the Member Secretary on the relevant AIIMS-BLS/IEC-H/SOP14/V1/ANX01 form.

14.5.4 Procedure for notifying the principal investigator and concerned authorities

- The Member Secretary will draft a notification letter.
- The signed letter from the Member Secretary will be sent to the principal investigator, the department heads, and the Institute officials (as required depending on the case).
- The IEC Secretariat will send a copy of the notification to the relevant national authorities (as required depending on the case) and other participating institutes (in case of multicentre studies).

14.5.5 IEC Secretariat records

- The IEC Secretariat will keep a copy of the notification letter in the respective research project file.

14.6 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP14/V1/ANX01 – Research protocol deviation / violation record
Annexure 2: AIIMS-BLS/IEC-H/SOP14/V1/ANX02 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP14/V1/ANX01
Research protocol deviation / violation record

IEC project no:
Study title:
Principal investigator:
Department:

Deviation from research protocol:
Violation of research protocol:
Description of the deviation / violation:

Corrective actions taken by the principal investigator:

Reported by (Name of the Principal investigator/ Study team member / other):

Signature with date:

Provisional decision by the reviewer (Member Secretary, Chairperson, and/or IEC members)

- Noted
- Request the principal investigator to avoid future deviations, non-compliance or violations
- Specific recommendation listed below should be implemented

Specific recommendations to be implemented:

- Suspend the study till the recommendations of IEC are implemented
- Suspend the study till further information is available
- Revoke the IEC approval and terminate the study
- Reasons for termination of the study
- Decline future research applications from the principal investigator
- Discuss the matter in full board meeting
- Any other

Deviation/violation report reviewed by
Name(s):
Signature(s) with date:

Discussion of the research protocol deviation or violation at

- Emergency meeting on
- Next scheduled full board meeting on
- Final decision at the full board meeting held on:

IEC Member Secretary
(Signature with date)

Annexure 2: AIIMS-BLS/IEC-H/SOP14/V1/ANX02
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

14.7 Workflow

	Activity	**Responsibility**
1.	Identification and reporting of research protocol deviation or violation	Principal investigator, IEC members, IEC Secretariat
2.	Receipt of research protocol deviation or violation report	IEC Secretariat
3.	Review, board discussion, decision and action	Chairperson, Member Secretary, IEC members
4.	Notify the principal investigator and concerned authorities of the action taken by the IEC	IEC Secretariat
5.	Store decision and notification in IEC records	IEC Secretariat

15 Continuing review of study protocols by the Institutional Ethics Committee for biomedical and health research

15.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe how continuing review of previously approved study protocols should be managed by the Institutional Ethics Committee (IEC) for biomedical and health research, AIIMS, Bilaspur. The purpose of continuing review is to periodically monitor the progress of study, to ensure continuous protection of the rights and welfare of involved research participants.

15.2 Scope

The SOP applies to conducting any continuing review of already approved study protocols at pre-specified intervals by the IEC for biomedical and health research, AIIMS, Bilaspur. All the projects approved by the IEC will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants, and the duration of the study, the IEC may choose to review or monitor the protocols more frequently.

15.3 Responsibility

It is the responsibility of the IEC Secretariat to remind the principal investigator and the Member Secretary about the continued review of protocols at correct intervals. All approved study protocols will be reviewed annually. It is the responsibility of the Member Secretary to decide whether a research project needs to be reviewed more frequently and such matter is taken up during the IEC meeting in which the project is finally approved. This must be recorded in the minutes. A fresh decision to increase the frequency of review may be subsequently taken, if required, based on the SAE reports, monitoring reports, and/or safety concerns. This is the responsibility of the SAE sub-committee and Member Secretary.

The IEC is responsible for reviewing the progress made in the study protocol (including the number of participants recruited, dropped out, and reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator with regards to the communication with the IEC.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

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15.4 Detailed Instructions

15.4.1 Determining the date of continuing review

- A minimum of one date of continuing review for a project will be earmarked in a year
- The IEC may recommend more reviews per year, during the approval process depending on the level of risk involved in the study. This will be documented in the minutes.
- The Secretariat will inspect the minutes of meeting to set a timetable for continuing review.
- The Secretariat will identify and record the due dates for each project.

15.4.2 Notifying the principal investigator or the study team

The Secretariat will send a reminder to the principal investigator as per the format AIIMS-BLS/IEC-H/SOP15/V1/ANX01 one month prior (if an annual review) or less (as appropriate, if any special additional reviews are required) to the due date of the continuing review.

15.4.3 Managing the continuing review package upon receipt

The Secretariat will receive a package (a soft and a hard copy) submitted by the principal investigator for continuing review of each approved protocol. Only one set (of soft and hard copies) of the continuing review report shall be submitted by the principal investigator to the IEC, as per the format of the continuing review application form (AIIMS-BLS/IEC-H/SOP15/V1/ANX02).

15.4.4 Verifying the contents of the package

- The Secretariat will ensure that the contents of the package include the following documents:
    - The continuing review application form (AIIMS-BLS/IEC-H/SOP15/V1/ ANX02).
    - The continuing review application form duly filled with an explanation for any answers that have been marked “yes” in the continuing review application form (AIIMS-BLS/IEC-H/SOP15/V1/ANX02), along with a discussion of the

scientific developments, either during the conduct of this study or similar research that may alter the risk to the study participants. The changes in the selection criteria of the participants, study protocol, informed consent documents, study team, and/or any unexpected complications during the study must have been discussed in the attached narrative.

- The Secretariat will confirm that complete information has been appended along with the required signatures of the principal investigator in the continuing review application form (AIIMS-BLS/IEC-H/SOP15/V1/ANX02).

15.4.5 Review process

- The continuing review submission may undergo an expedited review or a full board review as deemed appropriate by the IEC Member Secretary.

- The IEC Member Secretary and the IEC members will use the continuing review application form (AIIMB-BLS/IEC-H/SOP15/V1/ANX02) to guide the review and deliberation process.

- The Secretariat will send the continuing review application form (AIIMS-BLS/IEC-H/SOP15/V1/ANX02) to the designated IEC members.

- The IEC Chairperson / Member Secretary / Members could reach one of the following decisions after review:

    - **Noted**: The IEC approves the continuation of the project without any modifications.

    - **Modifications recommended**: the study protocols that are advised modifications by the IEC may not proceed further until the conditions set by the IEC in their decision are met. The amendments and the required documents should be amended and resubmitted to the IEC within one month for review.

    - **Project cannot be continued**: the reasons for the discontinuation of the project should be mentioned in the letter notifying the decision to the principal investigator. This decision shall be recorded by the Member Secretary on the AIIMS-BLS/IEC-H/SOP15/V1/ANX02 form. The IEC Chairperson will sign and date the IEC decision on the continuing review report after a decision has been reached. The decision on the continuing review taken by the Chairperson / Member Secretary / Members will be informed to all the IEC members in the next full board meeting. The continuing review report may be discussed by the full board if deemed necessary by the Chairperson / Member Secretary.

- The IEC Secretariat will maintain and keep the IEC decision forms and minutes of the meeting, relevant to the continuing review, as part of the official record of the review process in the project file.

15.4.6 Communicating the IEC decision to the principal investigator

The Secretariat will notify the principal investigator of the decision within 14 days of the meeting at which the report was discussed or of the date of review by the Chairperson / Member Secretary / IEC Members.

15.4.7 Non-submission of continuing review report by the principal investigator before the due date

- If a principal investigator fails to submit the continuing review report with one month of the due date, i.e. 11 months from the date of approval, or earlier, on the dates as specified, then the Secretariat will send an email reminder to the principal investigator, at least 15 days prior to the due date of the review.

- If there is no response from the principal investigator, the IEC Secretariat will put up the matter for discussion in the forthcoming full board meeting for appropriate action, which may consist of, but not limited to sending:

    - A reminder letter again
    - A letter asking the principal investigator for an explanation for the non-submission
    - A letter asking the principal investigator to put the recruitment of new participants on hold until the report is submitted
    - Any other action as deemed appropriate by the IEC

15.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP15/V1/ANX01 – Reminder letter from the IEC to the principal investigator
Annexure 2: AIIMS-BLS/IEC-H/SOP15/V1/ANX02 – Continuing review application form
Annexure 3: AIIMS-BLS/IEC-H/SOP15/V1/ANX03 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP15/V1/ANX01
Reminder letter from the IEC to the principal investigator

Date:
Name of the Principal Investigator:
Department
All India Institute of Medical Sciences,
Bilaspur – 174001, Himachal Pradesh

Ref: Project No:
Title:

The above referenced project was approved by the IEC on …… and is due for continuing annual / period review by the IEC. You are requested to submit an annual / periodic status report in the prescribed format which is enclosed (Continuing Review Application Form) at the earliest, on or before …….. (one month period).

Member Secretary
(Signature with date)

Annexure 2: AIIMS-BLS/IEC-H/SOP15/V1/ANX02
Continuing review application from

Summary of protocol participants:

- Number of participants screened:
- Number of participants approved by the IEC:
- Number of recruited participants:
- Number of ongoing participants:
- Number of completed participants:
- Number of participants that refused consent:

- Have any participants been withdrawn from this study?
  Yes …….. No ……..
  If yes, state the number and reasons for the drop-outs, for each participant. Attach separate sheet if needed.

- Have there been any amendments in the study protocol / informed consent documents, since the last review?
  Yes …….. No ……..

- Were these protocol / informed consent document amendments approved by the IEC?
  Yes …….. No ……..
  If no, then mention the amendments that have not been approved.

- Which protocol amendment is the study site following at present?

- Has any information appeared in the literature, or has emerged from this or similar research that might affect the evaluation of the risk-benefit analysis of the participants involved in this study protocol?
  Yes …….. No ……..
  If yes, attach evidence. Use separate sheet, if needed.

- Whether the reports of the SAE encountered so far have been reviewed by the IEC?

- Whether reports of the SAE at other sites have been submitted to the IEC?

- Have any participating investigators been added or withdrawn since the last IEC review?
  Yes …….. No ……..
  If yes, please identify all changes in the attached narrative.

- Is a report of the interim data analysis available?
  Yes …….. No ……..
  If yes, please submit as an attachment.

- Is a report of the data safety and monitoring board available?
  Yes …….. No ……..
  If yes, please submit as an attachment.

- Has any study investigator developed a consultative relationship with, or has acquired equity / shares from a source related to this study protocol, which might be considered a conflict of interest?
  Yes …….. No ……..
  If yes, please submit details as an attachment.

Signature of the Principal Investigator with date: _____

Assessment of the continuing review report by the IEC to be reviewed by:

- The Chairperson / Member Secretary only, and informed to the IEC members at the full board meeting
- The full IEC board
- Any 2 IEC members and informed to the IEC members at the full board meeting

Names of the IEC members:

Member Secretary
(Signature with date)

IEC decision on the Continuing Review Report

Date:

Decision:

- Approved - the project can be continued without any modifications
- Modifications recommended – requires protocol resubmission
    - Recommendations

- Protocols should be discontinued
    - Reasons for discontinuation

Date of full board discussion:

Signature of the reviewer(s) with date:

Member Secretary
(Signature with date)

Annexure 3: AIIMS-BLS/IEC-H/SOP15/V1/ANX03
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

15.6 Workflow

	Activity	**Responsibility**
1.	Determine the date of continuing review	IEC Secretariat
2.	Notify the principal investigator or study team	IEC Secretariat
3.	Manage the continuing review package upon receipt and verify its contents	IEC Secretariat
4.	Notify the members of the IEC	IEC Secretariat
5.	Review of the Continuing Review Report	IEC Secretariat, Members and Chairperson
6.	Prepare meeting agenda	IEC Secretariat
7.	Communicate the IEC decision to the principal investigator	IEC Secretariat

16 The review of serious adverse event reports by the Institutional Ethics Committee for biomedical and health research

16.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) and unexpected events occurring in any study under the oversight of the institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur.

16.2 Scope

This SOP applies to the review of SAE reports including, adverse events and serious adverse events occurring onsite as well as those occurring at other collaborating sites in a multicentre study. Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the IEC or SAE monitoring sub-committee (formed by IEC) to ensure adequate protection of the welfare of the study participants. The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, welfare or safety of participants in the study.

16.3 Responsibility

- It is the responsibility of the principal investigator to report any adverse events or serious adverse events, both onsite and offsite, that occur in the enrolled participants, as per rules laid down by the government of India.

- It is the responsibility of the IEC to review all SAE reports in a timely manner. The IEC should also make sure that the researchers are made aware of the policies and procedures concerning the reporting and continuing review of SAE.

- In case, the investigator fails to report any SAE within the stipulated period, the investigator will have to furnish reasons for the delay to the satisfaction of DCGI along with the report of the SAE.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

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16.4 Definitions

16.4.1 Serious adverse event

Any untoward occurrence, at any dose, which results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly or birth defect, is classified as a serious adverse event.

16.4.2 Serious adverse event or serious adverse drug reaction

An adverse event or adverse drug reaction that is associated with death, inpatient hospitalization (in case the study is being conducted on out-patients), prolongation of hospitalization (in case the study is being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.

16.4.3 Adverse event

An AE is any untoward medical occurrence in a patient or in a subject under clinical investigation who has been administered a pharmaceutical product, which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the product.

16.5 Detailed instructions

16.5.1 SAE sub-committee

- The Serious Adverse Event (SAE) sub-committee of the IEC AIIMS, Bilaspur will review all serious adverse events (SAE) occurring onsite or at other sites in studies involving human participants that have been approved by the IEC.

- The sub-committee will consist of IEC members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.

16.5.2 Composition of the SAE sub-committee

- The SAE sub-committee will be appointed by the IEC Chairperson.
- The SAE sub-committee will be multidisciplinary and multi-sectoral in composition.

- The SAE sub-committee will be composed of at least 5 and a maximum of 10 members of the IEC.
- The composition shall be as follows:
    - Chairperson of the SAE sub-committee
    - An Executive Secretary
    - At least one member with postgraduate qualifications in the discipline of internal medicine, clinical pharmacology, and other relevant clinical specialties available in the institution.

- The SAE sub-committee may invite the legal expert of the IEC to provide opinion on legal implications of any adverse event.

- The head of the SAE sub-committee will be responsible for conducting SAE sub-committee meetings, and will lead all discussions and deliberations pertinent to the review of adverse event reports.

- The head of the SAE sub-committee or the Executive Secretary will sign the minutes of the SAE sub-committee meetings.

- In case of anticipated absence, the head of the SAE sub-committee will nominate a SAE sub-committee member as the acting head. The acting head will have all the powers of the head of SAE sub-committee for that meeting.

- For a SAE sub-committee meeting, a quorum will consist of at least 4 members as follows: one member (preferably from clinical pharmacology), one member (preferably a clinician), the executive secretary, and the head or acting head of the SAE sub-committee.

- SAE subcommittee will meet at least once in a month (or as often as required)

16.5.3 Membership requirements

- IEC members will be appointed to the SAE sub-committee if they show willingness and commitment with respect to the time required to perform the roles and responsibilities of the SAE sub-committee.

- The Head of the Institute is responsible for appointing the SAE sub-committee members. The names of new members to be appointed may be suggested by the Chairperson and IEC members to the Head of the Institution.

- The tenure of SAE sub-committee will be for a continuous period of two years from the date of appointment.

- A retiring member will be eligible for reappointment for a repeat tenure, consecutively for four times.

- A SAE sub-committee member may resign from the membership by submitting a letter of resignation to the Executive Secretary of the SAE sub-committee. The member may or may not assign reasons for the resignation.

- A SAE sub-committee member may be disqualified from the membership if the member fails to attend more than 5 consecutive regular SAE sub-committee meetings without prior intimation. The head of SAE sub-committee will inform the Chairperson, in writing, if a member has not attended more than five consecutive regular meetings of the SAE sub-committee. The Chairperson will take up the issue of disqualification for discussion at the full board IEC meeting and allow the concerned SAE sub-committee member to state his/her reasons for the unauthorized absence.

16.5.4 Functions of the Executive Secretary of the SAE sub-committee

- To schedule and organize the SAE sub-committee meetings
- To prepare and maintain meeting agenda and minutes
- To conduct SAE sub-committee meetings
- To prepare the communication letters related to the adverse event reports
- To communicate with other IEC members, regulatory authorities, and the investigators in a timely manner
- To provide necessary administrative support for related SAE sub-committee activities
- To ensure adherence of the SAE sub-committee functioning as per appropriate SOPs

16.5.5 Onsite SAE

16.5.5.1 Receipt of SAE report

- The IEC Secretariat will receive the following documents within the specified time frame if a SAE occurs in a research participant:

    - Initial SAE report submitted by the principal investigator within 24 hours of the SAE occurrence in the format specified for submitting SAE reports.

    - Due analysis of the SAE should be submitted by the principal investigator within 14 days of SAE occurrence, or within 14 days of the knowledge of occurrence of SAE of death, in the specified format.

- Due analysis will also be submitted by the sponsor within 14 days of the SAE occurrence, or within 14 days of the knowledge of occurrence of SAE of death, in the specified format.

- Follow-up reports of an onsite SAE until the event is resolved.

- The IEC Secretariat will verify that the SAE report is complete in all respects and that it has been received at the IEC office within the specified timeline. If the report has been received after the specified time, it will be considered as a protocol violation and action will be taken.

- The IEC Secretariat will sign and write the date on which the report is received.

- The IEC Secretariat will forward the SAE report to the IEC Member Secretary or to the SAE sub-committee Executive Secretary (if constituted), within two working days.

- If the principal investigator has not adhered to the above stipulated timeline, the IEC will notify the discrepancies in the reporting time, and the time of occurrence of the SAE to the principal investigator.

16.5.5.2 Review and decision on SAE reports and communication to the principal investigator and appropriate regulatory authority

- The IEC Member Secretary or the SAE sub-committee Executive Secretary will review the SAE report and present it to the full IEC board or the SAE sub-committee (as applicable) for review and opinion.

- At the IEC or SAE sub-committee meeting, the SAE reports will be reviewed with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participants. The applicable formulae and guidelines from the regulatory authority will be used during this discussion.

- If deemed necessary, a decision to hold an emergency IEC meeting may be taken to discuss about financial compensation. An emergency IEC meeting will be scheduled within 7 days for the same.

- The Executive Secretary of the SAE sub-committee may refer the SAE report to the full IEC board for review, if deemed necessary.

- The minutes of the SAE sub-committee and/or IEC meeting will include the following information on the SAE at the site along with the opinion on the following points:
  - Research participant ID
  - SAE letter number and date of reporting

- Initial SAE report or follow-up SAE report
- Date of SAE onset
- Whether the drug under study has been withheld
- SAE outcome
- Causality in the opinion of the principal investigator
- Recommendations given by the SAE sub-committee

- The minutes will be circulated among the IEC members via email and an approval or objections, if any, will be sought from the members within a period of 5 working days.

- The IEC Secretariat will draft a formal letter to the concerned principal investigator informing about the IEC decision. This letter will be signed and dated by the Member Secretary or the Chairperson. It should be sent to the principal investigator within a period of 7 days from the date of the SAE sub-committee meeting.

- The principal investigator will be requested to reply to any queries that the IEC communicates in the letter within 7 working days.

- In case of regulatory clinical trials, the opinions on whether the SAE is related to the drug/intervention under study, the medical management of the SAE, and the compensation to be provided for research related injury will be communicated to the Central Licensing Authority (DCGI) within 30 calendar days of receiving the report of SAE from the principal investigator.

- The IEC administrative officer will file a copy of these letters in the study file.

16.5.6 SAE reports occurring at other sites

- In case of offsite SAE, where adverse event reports that are serious, unexpected, and related (definitely, probably, or possibly) to the drug need prompt reporting to the IEC with reporting of centre-wise SAEs.

- The SAE that are expected (if listed in the informed consent), or are unexpected and unrelated to the drug (classified as per the Offsite Safety Report Classification form) have to be logged and submitted by the principal investigator every 3 months and/or are to be submitted along with the continuing review report. The log has to be maintained continuously until the end of the study.

- If a trend of SAEs is observed by the principal investigator, such a trend will be reported to the IEC, and action on such reports will be taken by the Member Secretary.

- The investigator will need to submit the SAE reports occurring at other study sites to the IEC. The SAE reports may be submitted as electronic copies along with a cover letter in print, mentioning the total number of SAE reports and their details in the following format:

No.	Study site (city, country)	Initial / follow-up SAE report	SAE event	Date of onset	Date of report	Outcome	Causality	
							Investigator	Sponsor

- For every SAE term, a separate row of the above table is to be used (different SAE terms should not be combined).

- Causality should be stated as related (R) or not related (NR).

- The SAEs occurring at other sites will be reviewed by the IEC Member Secretary and/or the SAE sub-committee (as applicable) and will be informed to the other IEC members and taken up for discussion in the forthcoming IEC full board meeting. The agenda and minutes of the meeting will include the information on SAEs recorded at other sites.

- The principal investigator must comment on the possible effects of previously reported and current SAEs on the ongoing study while submitting the documents.

16.5.7 Onsite adverse events (AE)

- The IEC Secretariat will receive the following documents pertaining to the adverse events experienced by the research participants enrolled in approved research studies under the oversight of IEC AIIMS, Bilaspur:

    - Onsite adverse event report submitted by the principal investigator annually in the continuing review report.

    - In view of the risk assessment of a given research proposal the IEC can request adverse events to be reported earlier, if deemed necessary, at specified timelines in the project approval letter.

- The IEC Secretariat will verify that the report is complete in all respects, and is signed and dated by the principal investigator, and that it has been received at the IEC office within the stipulated timeline. If the report has been received beyond the specified time, it will be considered as a protocol deviation.

- All onsite AE reports received at the IEC office will forward to the IEC Member Secretary for review, by the IEC Secretariat.

- If the Member Secretary deems necessary an AE report may be tabled in the forthcoming full IEC board meeting for discussion. IEC queries on the report will be communicated to the principal investigator by the Member Secretary after the full board meeting.

- The IEC Secretariat will file a copy of these letters in the study file.

16.5.8 Review during the full board IEC meeting

- The IEC Member Secretary will read out the minutes of all the weekly SAE sub-committee meetings including the recommendations and decisions made by the SAE sub-committee (if constituted).

- In case of SAE reports to be discussed at the full board IEC meeting, the Member Secretary will provide relevant information and updates on the SAE that have already occurred at the study site. The Chairperson will invite members to voice their opinions and ensure a free and frank discussion.

- A decision on a SAE report can be arrived by consensus. However, if a consensus is not reached, the issue will be put for voting. A majority vote for a decision will comprise 2/3rd majority of the members present and voting.

16.5.9 IEC decisions on SAE reports

The IEC and the SAE sub-committee may take one or more of the following decisions after review of a SAE:

- Note the SAE information in IEC records for future reference
- Request further information
- Ask for periodic follow-up of the research participant till the SAE is resolved
- Depending on the complexity of the issue, the IEC and/or the SAE sub-committee may decide to seek opinion of an external expert consultant, who is requested to respond within 14 working days.
- Provide recommendations and/or raise queries related to compensation for study related injury and death.

16.5.10 Type of actions taken by the IEC following a full board review

The IEC Chairperson, based on the information and comments received from the Member Secretary and the SAE sub-committee, may direct the IEC to implement any one or more of the actions listed below (but not limited to):

- Suggest changes and amendments in study protocol, patient information sheet, informed consent documents, the investigator's brochure and/or any other study-related documents.
- Suspend the study till additional information is available.
- Suspend all study related procedures till SAE review is completed. However, study procedures pertaining to the monitoring of safety and wellbeing of currently enrolled participants should be continued.
- Suspend the study till the amendments recommended by the IEC are addressed
- Suspend enrolment of new participants
- Suspend specific activities under the study protocol
- Direct the principal investigator to inform the participants that are already enrolled in the study about the adverse effects and if required obtain their consent again for continuing their participation in the research trial
- Direct the principal investigator to inform the participants already enrolled in the study about the adverse effects and request them to undertake additional visits, undergo additional procedures and investigations for monitoring their safety and wellbeing
- Terminate the study
- Recommend for compensation and send the report to DCGI.
- Any other action (as per New Drugs and Clinical Trials Rules 2019).
- The decisions taken shall be recorded in the minutes of the full board IEC meeting.

If the recommendations from the IEC include suspension of the study, suspension of any one or more of study-related procedures or activities, amendments in the study protocol and in study-related documents (excluding investigator's brochure), and/or re-consenting of research participants, the decisions will be conveyed to the principal investigator through telephone, fax or email within 24 hours. Such communication will be documented by the IEC Member Secretary in the study file. A formal letter to the principal investigator informing about the IEC recommendations will be subsequently sent within 5 working days after the IEC meeting.

16.6 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP16/V1/ANX01 – Data elements for reporting adverse events occurring in a clinical trial
Annexure 2: AIIMS-BLS/IEC-H/SOP16/V1/ANX02 – Checklist for onsite serious adverse event reporting
Annexure 3: AIIMS-BLS/IEC-H/SOP16/V1/ANX03 – Onsite serious adverse event analysis report
Annexure 4: AIIMS-BLS/IEC-H/SOP16/V1/ANX04 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP16/V1/ANX01
Data elements for reporting adverse events occurring in a clinical trial

Proforma for reporting serious adverse events occurring in a clinical trial

1. **Patient details**

- Initials and other relevant identifiers (hospital/OPD record number etc.):
- Gender:
- Age and/or date of birth:
- Weight:
- Height:

2. **Suspected drug(s)**

- Generic name of the drug:
- Indications for which the suspected drug was prescribed or tested:
- Dosage form and strength:
- Daily dose and regimen (specify units e.g., mg, ml, mg/kg):
- Route of administration:
- Starting date and time of day:
- Stopping date and time; duration of treatment:

3. **Other treatments**

- Provide the same information for concomitant drugs (including non-prescription/ over-the-counter drugs), and non-drug therapies, as for the suspected drug(s).

4. **Details of suspected adverse drug reaction**

- Full description of the reaction including body site, severity, and the criteria for regarding it as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.
- Start date (and time) of onset of reaction:
- Stop date (and time) or duration of reaction:
- De-challenge and re-challenge information:
- Setting (e.g. hospital, out-patient clinic, home, nursing home):

5. **Outcome**

- Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.
- For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post mortem findings.
- Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse, family history, findings from special investigations etc.

6. **Details about the Investigator**

- Name:
- Specialty:
- Address:
- Telephone number:
- Date of reporting of the SAE to the licensing authority:
- Date of reporting of the SAE to the IEC overseeing the site:

Principal investigator
(Signature, name, designation, department, and date with seal)

Annexure 2: AIIMS-BLS/IEC-H/SOP16/V1/ANX02
Checklist for onsite serious adverse event reporting

1.	Country (name of the country should be specified)		
2.	SAE report of death or other than death	Death	Other than death
Please tick (✓)		**Yes / No**	**Page no.**
3.	In case of serious adverse event (SAE), please specify (Yes/No) if there is any injury to the participant		
4.	Project title		
5.	Project No./ ID/ Code		
6.	Copy of clinical trial permission obtained from CDSCO		
7.	CTRI Registration no.		
8.	Sponsor (address with phone no, email)		
9.	CRO (address with phone no, email)		
10.	Initial / follow-up report		
11.	In case of follow-up, date and diary number of the initial/ last submitted report		
12.	Patient details		
a.	Initials and other relevant identifier (hospital/ OPD record number etc.)		
b.	Gender		
c.	Age and/or date of birth		
d.	Weight		
e.	Height		
13.	Suspected drugs		
a.	Generic name of the drug		
b.	Indication(s) for which suspect drug was prescribed or tested		
c.	Dosage form and strength		
d.	Daily dose and regimen (specify units e.g., mg, ml, mg/kg)		
e.	Route of administration		
f.	Starting date and time of day		
g.	Stopping date and time, or duration of treatment		
14.	Other treatment		
	Provide the same information for concomitant drugs (including non-prescription/OTC drugs) and non-drug therapies, as for suspected drug(s)		
15.	Details of the events		
a.	Full description of the SAE including body site and severity, as well as the criteria for regarding the report as serious.		

b.	In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
c.	Start date (and time) of onset of reaction		
d.	Stop date (and time) or duration of reaction		
e.	De-challenge and re-challenge information		
f.	Setting (e.g., hospital, out-patient clinic, home, nursing home)		
16.	Outcome		
a.	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted		
b.	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings		
c.	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		
17.	Details about the Investigator		
a.	Clinical trial site number, if any		
b.	Name		
c.	Address		
d.	Telephone/mobile number; email		
e.	Profession (specialty)		
f.	Date of reporting the event to licensing authority		
g.	Date of reporting the event to IEC overseeing the site		
h.	Signature of the investigator		
18.	Details about the Ethics Committee		
a.	Name and address		
b.	Name of Chairperson and address		
c.	Telephone/mobile number		
d.	Email		
19.	Adverse event term/ Details of SAE		
20.	Causality assessment (related/ unrelated) by Investigator		
21.	Causality assessment (related/ unrelated) by sponsor/ CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reasons for the same		
23.	Duly filled SAE form as per NDCT Rules 2019		
24.	Laboratory investigation reports/ discharge summary (if available and applicable)		
25.	Post-mortem report (if applicable)/ any additional documents		

Note: Information not relevant to a particular SAE should be marked NA

Annexure 3: AIIMS-BLS/IEC-H/SOP16/V1/ANX03
Onsite serious adverse event analysis report

No.	Details		
1.	Country (name of the country should be specified)		
2.	SAE report of death or other than death	Death	Other than death
Please tick (✓)		**Yes / No**	**Page no.**
3.	In case of serious adverse event (SAE), please specify (Yes/No) if there is any injury to the participant		
4.	Project title		
5.	Project No./ ID/ Code		
6.	Copy of clinical trial permission obtained from CDSCO		
7.	CTRI registration no.		
8.	Sponsor (address with phone number, email)		
9.	CRO (address with phone number, email)		
10.	Initial / follow-up report		
11.	In case of follow-up: date and diary number of initial or last submitted report		
12.	Patient details		
a.	Initials and other relevant identifier (hospital/ OPD record number etc.)		
b.	Gender		
c.	Age and/or date of birth		
d.	Weight		
e.	Height		
13.	Suspected drugs		
a.	Generic name of the drug		
b.	Indication(s) for which suspect drug was prescribed or tested		
c.	Dosage form and strength		
d.	Daily dose and regimen (specify units e.g., mg, ml, mg/kg)		
e.	Route of administration		
f.	Starting date and time of day		
g.	Stopping date and time, or duration of treatment		
14.	Other treatment		
	Provide the same information for concomitant drugs (including non-prescription/OTC drugs) and non-drug therapies, as for suspected drug(s)		
15.	Details of the events		
a.	Full description of the SAE including body site and severity, as well as the criteria for regarding the report as serious		

b.	In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction		
c.	Start date (and time) of onset of reaction		
d.	Stop date (and time) or duration of reaction		
e.	De-challenge and re-challenge information		
f.	Setting (e.g., hospital, out-patient clinic, home, nursing home)		
16.	Outcome		
a.	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted		
b.	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c.	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		
17.	Details about the Investigator		
a.	Clinical trial site number, if any		
b.	Name		
c.	Address		
d.	Telephone/mobile number; email		
e.	Profession (specialty)		
f.	Date of reporting the event to licensing authority		
g.	Date of reporting the event to IEC overseeing the site		
h.	Signature of the investigator		
18.	Details about the Ethics Committee		
a.	Name and address		
b.	Name of Chairperson and address		
c.	Telephone/mobile number		
d.	Email		
19.	Adverse event term/ details of SAE		
20.	Causality assessment (related/ unrelated) by investigator		
21.	Causality assessment (related/ unrelated) by sponsor/ CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same		
23.	Duly filled SAE form as per NDCT Rules 2019		
24.	Laboratory investigation reports/ discharge summary (if available and applicable)		
25.	Post-mortem report (if applicable)/ any additional documents)		

Details of payment for medical management of SAE? (please give information who paid, how much was paid, to whom, with evidence of the same)		
What is the investigator's assessment for the amount of the compensation to be paid?		
What is the sponsor's assessment for the amount of compensation to be paid?		
Has the participant made a claim?	Yes	No
If yes, for how much amount?		
If no, please ensure that the participant/ nominee have been made aware of his/her rights regarding compensation. Please submit documentation regarding the same		
Principal investigator (Signature, name, designation, department, and date with seal)		Date

Annexure 4: AIIMS-BLS/IEC-H/SOP16/V1/ANX04
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Jasbir Singh; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

16.7 Workflow

	Activity	**Responsibility**
1.	Receipt of a SAE report	IEC Secretariat
2.	Submission of SAE report to SAE sub-committee	Executive Secretary of SAE sub-committee
3.	Agenda and minutes of the sub-committee	Executive Secretary of SAE sub-committee
4.	Review and discussion of SAE report at sub-committee meeting	SAE sub-committee members
5.	Review and discussion of SAE report at full board IEC meeting	Member Secretary
6.	Communication of the IEC decision to the licensing authority, after SAE review	Executive Secretary of the SAE sub-committee
7.	Communication of the IEC decision to the principal investigator, after SAE review	Executive Secretary of the SAE sub-committee

17 Review of study completion reports by the Institutional Ethics Committee for biomedical and health research

17.1 Purpose

The purpose of this standard operating procedure (SOP) is to provide instructions on how to review the study completion reports submitted to the institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur, by the principal investigators for their respective studies.

17.2 Scope

This SOP applies to the review of study completion report of various completed research studies at AIIMS, Bilaspur. The review of the study completion report is an obligatory part of the assessment of each investigator's activities in the research projects carried out by them.

17.3 Responsibility

It is the responsibility of the principal investigator to submit the study completion report for their research project to the IEC within one month of the completion of the study. The investigator should submit the study completion report as per the appropriate format given in the annexures of this SOP. An alternate form provided by the study sponsor for pharmaceutical company driven trials may also be used, provided the information submitted covers all the points mentioned in the appropriate study completion report forms given in the annexures. Site closure information for pharmaceutical company driven trials should also be submitted.

Upon receipt of the study completion report, it is the responsibility of the IEC Chairperson, Member Secretary, and IEC members to review the study report, notify their approval, or request further information as deemed necessary.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

17.4 Detailed instructions

A. Before the board meeting

17.4.1 Receipt of study completion report

- The Secretariat will receive 6 print copies and one electronic copy of the study completion report, filled-in by the principal investigator as per the format relevant for their study given in annexures of this SOP. The study completion report is expected from the principal investigator within one month of the completion of the study at the site. The Secretariat will check if the submitted documents are complete in all respects, as per the instructions given in the SOP07 on management of protocol submission for receiving and checking the study report package. After verifying the study completion report and its related documents the Secretariat will forward it to the Member Secretary within 7 working days of its receipt.

- The Member Secretary will review the study completion report, confirm that it is complete, and present it at the next full board meeting. If any protocol deviation or violation are noted then the Member Secretary should handle it as per SOP14.

- The Secretariat will include the study completion report in the agenda of the upcoming full board meeting.

B. During the board meeting

- The Member Secretary will present the report and the IEC members will discuss as needed. If appropriate to the discussion, the Chairperson may call for a consensus for accepting the report, requesting further information from the principal investigator, or take any other action as suggested by IEC.

- Following the discussion, the Chairperson may take one of the following decisions:

    - Noted and approved
    - Request for additional information / clarification

- The Secretariat will note the decision in the meeting minutes. The Member Secretary will draft a letter to the principal investigator conveying the decision on the study completion report.

C. After the board meeting

- The Secretariat will note the decision in the meeting minutes.

- In case further information or action is requested from the principal investigator, the information should be provided to the IEC Secretariat within 4 weeks. The final IEC decision will then be communicated to the principal investigator by the Member Secretary as per the format given in AIIMS-BLS/IEC-H/SOP17/V1/ANX03.

- The study shall be considered closed if the IEC gives the verdict of "Noted" or "Approved". The Secretariat will accept and file the report and get the study completion report form signed by the Chairperson. The final report will be placed in the master file of the research project and stored in the IEC archives. Once the IEC gives the verdict of "Noted and Closed", the IEC administrative officer will archive the entire study for a period of 5 years from the date of completion of the project.

17.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP17/V1/ANX01 – Study completion report form for interventional studies
Annexure 2: AIIMS-BLS/IEC-H/SOP17/V1/ANX02 – Study completion report form for non-interventional studies
Annexure 3: AIIMS-BLS/IEC-H/SOP17/V1/ANX03 – Notification of acceptance of study completion report
Annexure 4: AIIMS-BLS/IEC-H/SOP17/V1/ANX04 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP17/V1/ANX01
Study completion report form for interventional studies
(To be filled by the principal investigator. Please attach extra sheets where necessary.)

A.

1. IEC project number:
2. Study protocol number (for drug/device/any other trial):
3. Project title:
4. Principal Investigator:
5. Department:
6. Phone number and email:
7. Study sponsor:
8. Address of study sponsor:
9. Phone and email of study sponsor:

B.

10. Study initiation date:
11. Study completion date:
12. Target number of participants required:
13. Number of participants approved by the IEC:
14. Number of participants screened:
15. Number of participants enrolled:
16. Date when first participant enrolled:
17. Date when last participant enrolled:
18. Date when first participant completed study:
19. Date when last participant completed study:
20. Number of study arms:
21. Duration of study:
22. Study objectives:

C.

23. SAEs at the centre
24. Total number and type of SAEs at the centre:
25. Whether all the SAEs intimated to the IEC (Yes / No):
26. If no, then the reasons for not intimating:

D.

27. Number of patients withdrawn / lost to follow-up/ dropped out:
28. Reasons for withdrawal:
29. Protocol deviations / violations (number and nature):
30. Storage of documents for more than 5 years (Yes / No):
31. If yes, storage required for how many years?

E.

32. **Results of the study** (please attach extra sheets as per requirement). If the study was a sponsored clinical trial and the final report is unavailable from the sponsor, then the principal investigator is requested to submit it when available:

33. **Conclusions of the study**:

Principal Investigator
(Signature, name and date)

(To be completed by the IEC Secretariat)

1. IEC meeting date (if reviewed in meeting):
2. Review conclusions:

3. Noted and action taken:

4. Requires more information/ further action:

5. Final decision:

Annexure 2: AIIMS-BLS/IEC-H/SOP17/V1/ANX02

Study completion report form for non-interventional studies

(To be completed by the Principal Investigator. Please attach extra sheets where necessary.)

A.

1. IEC project number:
2. Title of the project:
3. Principal Investigator:
4. Department:
5. Sponsor:

B.

6. Date of sanction by the IEC:
7. Date of start of the project:
8. Date of completion of the study:
9. Duration of the study:
10. Objectives of the study:
11. Target number of participants required:
12. Number of participants enrolled:
13. Protocol deviations/ violations (number and nature):
14. Storage of documents for more than 5 years (Yes / No):
15. If yes, storage required for how many years:

C.

16. **Results of the study** (please attach extra sheet as required):

17. **Conclusions of the study**:

Principal Investigator
(Signature, name and date)

(To be completed by the IEC Secretariat)

1. IEC meeting date (if reviewed in meeting):
2. Review conclusions:

3. Noted and action taken:

4. Requires more information/ further action:

5. Final decision:

Annexure 3: AIIMS-BLS/IEC-H/SOP17/V1/ANX03
Notification of acceptance of study completion report

1. Full IEC board meeting held on:
2. Comments (if any):

3. Action taken
    a. Noted
    b. Requires more information/ further action as under:

Member Secretary
(Signature, name and date)

Annexure 4: AIIMS-BLS/IEC-H/SOP17/V1/ANX04
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Jasbir Singh; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

17.6 Workflow

	Activity	**Responsibility**
1.	Receipt of the study completion report	IEC Secretariat
2.	Check the contents of the report package and assess the adequacy of the contents	IEC Secretariat
3.	Verification of the study completion report, preparation of the study completion statement and sending them to the Member Secretary	IEC Secretariat
4.	Review of study completion report for completeness and informing IEC members at the full board meeting	Member Secretary/ Chairperson
5.	Inclusion of report/ review at full board meeting	IEC Secretariat
6.	Discussion and decision at the full board meeting	Member Secretary/ Chairperson
7.	Noting the decision in the minutes of the meeting	IEC Secretariat
8.	Conveying decision to the principal investigator	IEC Secretariat
9.	Archiving all the study related documents along with the study completion report	IEC Administrative Officer

18 The management of premature termination, suspension and discontinuation of research projects by the Institutional Ethics Committee for biomedical and health research

18.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the how the institutional ethics committee (IEC) manages the premature termination, suspension, and discontinuation of a research study. A research project may be terminated, suspended or discontinued at the recommendation of the IEC, Data Safety Monitoring Board (DSMB), Principal Investigator, sponsor, regulator, or other authorized bodies, whereby participant enrolment and follow-up are discontinued before the scheduled end of the study.

18.2 Scope

This SOP applies to any study previously approved by the IEC for biomedical and health research, at AIIMS, Bilaspur, that has been now recommended for termination, suspension or discontinuation before its scheduled completion.

18.3 Responsibility

It is responsibility of the IEC to manage the termination, suspension or discontinuation of a study that has been recommended for such action by the IEC, Data Safety and Monitoring Board, the principal investigator, sponsor or other authorized body. Such action is recommended when the safety or benefit of the study participants is doubtful or at risk.

18.4 Recommendation for the premature termination, suspension or discontinuation of a study

18.4.1 By the Principal Investigator or Sponsor

A principal investigator or sponsor may put on hold a previously approved research project when they adjudge that such action is appropriate for protecting the rights and welfare of participants, or when new safety information emerges in the literature or from similar research

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

that raises concerns or provides evidence regarding the rights, benefits and welfare of the participants.

18.4.2 By the Institutional Ethics Committee

The IEC Chairperson or members can prematurely terminate, suspend or discontinue a research study in following situations:

- If protocol non-compliance or violation is detected by the IEC following which the full IEC board decides to terminate, suspend or discontinue the study.
- When SAEs occur at the trial site that require the study to be prematurely terminated for the safety of the participants.
- When research is not conducted in accordance with the IEC policies, does not comply with the local regulations, or has led to unexpected serious harm to the participants.
- When a study has had zero accrual for 1-2 years or over a longer period, or is witnessing low accrual.
- Suspended protocols remain open and require continuing review.
- The IEC may revoke a previously granted approval and recommend permanent termination of all activities in a previously approved research study. Terminated protocols are considered closed and no longer require continuing review.

18.5 Detailed instructions

18.5.1 Receipt of recommendation for study termination:

The IEC Secretariat will receive a study report and recommendation for the termination, suspension, or discontinuation of a research study, from the principal investigator or other competent authority. The Secretariat will verify if the contents of the submitted report and recommendation are complete and in the correct format as given in AIIMS-BLS/IEC-H/SOP18/V1/ANX01. The submission may also include a letter / report from the study sponsor.

18.5.2 Review by the Institutional Ethics Committee

- The IEC Secretariat will inform the Chairperson and Member Secretary regarding the recommendation and study report for the premature termination, suspension or discontinuation of the research study, within 3 working days of the receipt of report.

- The Member Secretary or Chairperson shall review the report and may either call for an emergency meeting or discuss the report at the upcoming regular full board meeting.

- The Secretariat will arrange for an emergency meeting or table the matter for discussion at the next full board meeting.

- In the meeting, the Member Secretary will inform the IEC members about the premature termination, suspension or discontinuation of the project and the reasons for the same.

- If the premature termination, suspension or discontinuation report is unclear or requires further information from the principal investigator, then the Chairperson shall instruct the Secretariat to seek clarifications and/or additional information from the principal investigator.

- The Chairperson shall sign and date the study termination, suspension or discontinuation report in acknowledgement.

- If the IEC has revoked the approval or suspended a study, then relevant regulatory authorities and the Head of the Institution must be informed within 14 working days of the full board meeting.

18.5.3 Notifying the Principal Investigator

- The Secretariat will prepare a notification letter and send it to the principal investigator within 14 working days of the meeting, acknowledging the approval of termination and the letter seeking clarifications and information regarding the premature termination.

- In case a letter is sent seeking clarifications or more information regarding the premature termination, suspension or discontinuation, the principal investigator shall send a written response within 60 days of receiving the letter.

- If the principal investigator does not comply, the matter will be put to the full board meeting for discussion.

- The investigator may appeal or respond to the convened IEC in writing.

18.5.4 Notifying the Central Licensing Authority

In case a clinical trial, bioavailability study, or bioequivalence study is terminated prematurely, the detailed reasons for such termination should be communicated to the Central Licencing Authority within 30 working days of such termination.

18.5.5 Store the protocol documents

- The Secretariat will keep the original version of the premature termination report in the research project file and store it in the IEC archives.

- The protocol documents will be stored for a period of 5 years from the date of project termination.

18.6 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP18/V1/ANX01 – Premature study termination, suspension or discontinuation report
Annexure 2: AIIMS-BLS/IEC-H/SOP18/V1/ANX02 – IEC notification the premature termination, suspension or discontinuation of a research project
Annexure 3: AIIMS-BLS/IEC-H/SOP18/V1/ANX03 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP18/V1/ANX01

Premature study termination, suspension or discontinuation report

(Please attach extra sheets as and where required)

A.

1. IEC project number:
2. Study protocol number (for drug, device or any other trial):
3. Project title:
4. Principal Investigator:
5. Department:
6. Study sponsor:

B.

7. IEC approval date:
8. Date of last annual/ periodic status report submitted to the IEC:
9. Date of initiation of the study:
10. Date of termination/ suspension/ discontinuation of the study:
11. Number of participants enrolled:
12. Number of participants that have completed the study:
13. Number of participants currently undergoing study:

C.

14. Number of drop-outs:
15. Reasons for each drop-out:
16. Total number of SAE:
17. Whether SAE were reported to the IEC (Yes / No):
18. Storage of documents for more than 5 years (Yes / No):
19. If yes, storage required for how many years:

D.

20. Brief summary of study results (please attach extra sheets as required):

21. Reasons for terminating, suspending, discontinuing the study:

Principal Investigator
(Signature, name and date)

(To be completed by the IEC Secretariat)

- Discussed at the IEC meeting held on:
- Action taken
    - Approval of the premature termination, suspension or discontinuation of the research project
    - Requires more information and further action as follows:

Chairperson
(Signature, name and date)

Annexure 2: AIIMS-BLS/IEC-H/SOP18/V1/ANX02
IEC notification for the premature termination, suspension or discontinuation of a research project

Dr.
Department of
All India Institute of Medical Sciences,
Bilaspur – 174001, Himachal Pradesh

Ref: IEC project number: …….. project entitled ……..
……..

Dear Dr.

The IEC had received project termination/ suspension/ discontinuation recommendation and study report for the above mentioned research project. The IEC took up the matter in its full board meeting held on (dd/mm/yy). After deliberation, the IEC has reached to following decision:

- Action taken
    - Approval of the premature termination of the project
    - Requires more information and further action as follows:

Yours faithfully,

Member Secretary
(Signature, name and date)

Annexure 3: AIIMS-BLS/IEC-H/SOP18/V1/ANX03
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Jasbir Singh; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

18.7 Workflow

	Activity	Responsibility
1.	Receive recommendation for study termination, suspension or discontinuation	IEC Secretariat
2.	Review and discuss the termination, suspension or discontinuation report	Chairperson, Member Secretary, IEC Members
3.	Notify the principal investigator	IEC Secretariat
4.	Store the protocol documents	IEC Secretariat

19 Waiver of written or verbal informed consent by the Institutional Ethics Committee for biomedical and health research

19.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the type of research projects for which the institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur may grant a waiver for obtaining written or verbal consent. The SOP also specifies the procedures and application format to be used by the investigators and the IEC.

19.2 Scope

This SOP applies to the research studies which submit a request to the IEC, AIIMS Bilaspur for a waiver of written or verbal consent. The decision for waiver will be taken by the IEC either at an expedited sub-committee meeting or at the next full board meeting.

19.3 Responsibility

It is the responsibility of the IEC Member Secretary to table the waiver request along with the study protocol, and to record the decision taken on the matter at the full board meeting or expedited sub-committee meeting. The Chairperson must sign and date the letter conveying the decision to the principal investigator.

19.4 Detailed instructions

When a request for waiver of consent is submitted by a principal investigator in the prescribed format (AIIMS-BLS/IEC-H/SOP19/V1/ANX01) to the IEC Secretariat along with the study protocol, along with the reasons for seeking a consent waiver, the following steps are to be taken:

- The IEC Secretariat will check if all requisite documents are enclosed and are complete in all respects.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

- The IEC members will review the request taking into consideration the type of studies for which a waiver of consent may be given.

- The IEC will ensure that there are adequate mechanisms described in the study protocol to protect the identity of the study participants and to maintain confidentiality of the study data. This is necessary as the participants cannot be assured of confidentiality of data through formal informed consent once a waiver of consent is granted.

- The decision whether to grant the waiver is taken at a full board meeting or an expedited sub-committee meeting.

- The decision regarding the approval or disapproval of waiver is informed to the principal investigator in writing. If the waiver is not granted then the reasons for it will also be intimated.

19.4.1 Type of research projects which may qualify for consent waiver

A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding the protection of research participants' identity and maintenance of confidentiality of their data. The following criteria (National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017) must be met for a research project so that it can qualify for a waiver of both written and verbal consent.

1. The proposed research presents no more than minimal risk to subjects e.g., a retrospective review of patient case records to determine the incidence of disease or recurrence of disease. Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as a part of current everyday life.

2. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout the research as may be required due to the sensitivity of the research objectives, e.g., conducting interviews with citizens about their religious beliefs, people with HIV and AIDS, or conducting phone interviews with the members of the LGBTQ community. The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they may be

identified as such by signing the consent form, the requirement for obtaining consent may be waived off by the IEC. In case of telephonic interviews, waiver of written informed consent may be requested but verbal consent is mandatory.

Documents to be submitted to the IEC for waiver of verbal consent:

- A script for verbal consent: a verbal consent script provides all the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact numbers and names.

- The interview schedule (questions to be asked) will confirm that the interview is a simple 5 minute call and that no questions will be asked that compromise a person's confidentiality or position.

- The investigators will be asked to keep a log of those who were approached for the study and offered verbal consent. A simple chart can indicate the subjects as anonymised participants 1, participant 2, participant 3, and so on. A column can indicate that verbal consent was taken along with the date of recruitment. Since a specific number of study participants are to be recruited, it is important that the investigators maintain a record to indicate that they are not enrolling more subjects than originally planned.

3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs and consumer acceptance studies.

4. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell-free derivatives like viral isolates, DNA or RNA from recognised institutions or qualified investigators, samples or data from repositories or registries etc.

5. In emergency situations, when no surrogate consent can be taken when consent of the person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IEC can allow waiver of consent for recruiting participants in such a study. However, information about intervention should be given to the patient whenever the patient regains consciousness or to the relative or legal guardian when later available.

6. The IEC may approve a consent procedure which does not include, or which alters some or all elements of informed consent set forth or waive the requirement to obtain informed consent, provided the IEC finds and documents that:

- The research or demonstration project is to be conducted by or subject to approval of state or local government officials and is designed to study, evaluate or otherwise or examine:
    - Public benefit or service programs
    - Procedures for obtaining benefits or services under those programs
    - Possible changes in or alternatives to those programs or procedures
    - Possible changes in methods or levels of payment for benefits or services under those programs
- The research could not practicably be carried out without the waiver or alteration.
- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

7. The informed consent requirements in this policy are not intended to pre-empt any applicable national, state or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

8. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care.

9. In cases in which the documentation requirement is waived, the IEC may require the investigator to provide subjects with a written statement regarding the research.

19.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP19/V1/ANX01 – Application form for requesting waiver of consent
Annexure 2: AIIMS-BLS/IEC-H/SOP19/V1/ANX02 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP19/V1/ANX01
Application form for requesting waiver of consent

1. Principal Investigator's Name:

2. Department:

3. Title of the project:

4. Names of Co-investigators and Departments:

5. Reasons for request for waiver of informed consent (please tick). Please refer to the criteria detailed in the SOP that will be used to consider the waiver request:

    a. Research involves no more than minimal risk
    b. There is no direct contact between the researcher and participant
    c. Emergency situations as described in ICMR guidelines
    d. Any other (please specify)

6. Statement assuring that the rights of the participants are not violated

7. State the measures described in the protocol for protecting confidentiality of data and privacy of research participant.

Principal Investigator
(Signature with date)

Final decision at the full board / expedited sub-committee meeting held on (dd/mm/yy)
Waiver granted: Yes …… No ……
If not granted, reasons:

IEC Chairperson
(Signature with date)

Annexure 2: AIIMS-BLS/IEC-H/SOP19/V1/ANX02
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Sushruti Kaushal; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

19.6 Workflow

	Activity	**Responsibility**
1.	Receive the submitted documents	IEC Secretariat
2.	Review of study protocol and application for consent waiver	IEC Members
3.	Decision regarding waiver of consent	IEC Members, Member Secretary, Chairperson
4.	Communicate the decision to the principal investigator	IEC Secretariat
5.	Recording and filing the decision	IEC Secretariat

20 Audio-visual recording of the informed consent process for studies approved by the Institutional Ethics Committee for biomedical and health research

20.1 Purpose

The purpose of this standard operating procedure (SOP) is to delineate the procedures required to be followed by the investigators and institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur, for audio-visual recording, review, storage, and archival of the informed consent and assent process for regulatory studies.

20.2 Scope

- This SOP applies to all those regulatory clinical trials that are approved by the DCGI and which require documenting the written informed consent and assent process.

- The audio-visual recording of the entire informed consent process is mandatory for all clinical trials approved by the DCGI, provided they come under the following categories:

    - Informed consent of vulnerable subjects in clinical trials of new chemical entities or new molecular entities, including the procedure of providing information to the participants and their understanding of the consent.

    - Clinical trial of anti-HIV and anti-leprosy drugs, require only audio recording of the informed consent process including, the procedure of providing information to the participants and their understanding of the consent.

20.3 Responsibility

The principal investigator, co-investigators and any other suitably qualified and trained member of the research team delegated by the principal investigator for taking informed consent from the study participants, will also be responsible for ensuring that the audio-visual recording of the informed consent process is properly done and securely stored and archived thereafter without violating the participant's confidentiality.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

20.3.1 Applicable rules, regulations and guidelines

- Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), F. No. GCT/ 20/SC/Clin./2013 DCGI dated 19th November 2013.
- Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), F. No. X.11014/1/2012 – DFQC dated 31st July 2015.
- Drugs and Cosmetics Act, 1940; amended in 2019 to New Drugs and Clinical Trials Rules 2019.
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR 2006.
- International Conference on Harmonization; Good Clinical Practice Guidelines: May 1996
- Indian GCP 2001.
- National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017.
- Any subsequent versions and amendments to the above guidelines, issued by competent authorities.

20.4 Detailed instructions

- All the basic principles and procedures for the administration and documentation of the informed consent process are to be followed as have been delineated in this compendium elsewhere.

- If the participant is unable to give consent for medical or legal reasons, then the consent should be taken from the legally acceptable representative (LAR) and the process should be recorded.

- If the participant/LAR is illiterate, then an impartial witness is needed, this person should also be in the frame for the entire duration of the consent process.

- The audio-visual recording should be done for the assent process as well, wherever applicable.

- Ensure that the following infrastructure is available prior to counselling a potential participant:

    - A designated area for carrying out the informed consent process which should be:

        - Free from disturbance
        - Well lit

- Provide adequate privacy for the participant
- Should be comfortable for the participant
- The camera to be used for the recording should have a video recording feature with:
- Good resolution, minimum 1280 x 720 pixels
- Sufficient memory, minimum 4 GB
- Sufficient battery back-up, minimum 2 hours
- Display non-editable date and time on the video

  - The recording paraphernalia should also contain:

    - A good quality microphone
    - A computer or laptop with a CD/DVD write or a USB port
    - Blank CD/DVD or USB flash drive
    - External hard drive of minimum 500 GB or 1 TB capacity

- Before starting the informed consent process and the audio-visual recording ensure:

  - All the above mentioned equipment is in working order

  - The potential participant/LAR has been informed of the whole process that will be undertaken for taking his/her informed consent, and that the process if being recorded as per the government of India rules and notification. The participant should be explained that these processes are being carried out to ensure his/her safety and wellbeing, and to ensure that he/she has fully understood the details and purpose of the research, the potential risks and benefits involved, and his/her rights. The recording is a means of documentation and securing the participant's confidentiality and rights.

  - The potential participant/LAR/impartial witness should be made aware that his/her recording may be shown to government agencies, members of the IEC and independent auditors, and will be kept secure and confidential at all times.

  - The participant's consent should be documented in a separate informed consent document that states the above.

- The process of obtaining signatures of the potential participant/LAR/impartial witness and principal investigator or his/her designee on the audio-visual consent form should also be recorded.

20.4.1 Audio-visual recording process

- The principal investigator, co-investigator, or any other suitably qualified person delegated by the principal investigator, and the potential participant/LAR, and if needed the impartial witness should sit comfortably facing each other or side-by-side in such a way that their faces can be captured in a single frame simultaneously.

- The principal investigator, co-investigator, or a medically qualified person delegated by the principal investigator should introduce himself/herself by name, designation and his/her role in the research study, and state the current date and time.

- The participant/LAR should be requested to introduce his/her name, age and address and in case of LAR, he/she should clearly state the relation to the actual participant, as well as the reason why the participant cannot give consent. The participant/LAR should also state the language he/she understands best and is literate in. The principal investigator, co-investigator, and/or the medically qualified person delegated by the principal investigator may facilitate the process to ensure all the above points are captured in the recording.

- In case the participant/LAR is illiterate and an impartial witness is needed, the impartial witness should be requested to introduce himself/herself, give his/her address, and state the language that he/she is literate in.

- The participant/LAR should state that he/she has been informed about the fact that the entire consent process is being recorded and that he/she has agreed for the same.

- The informed consent process should be carried out as per the relevant SOP on administering and documenting informed consent.

- The participant should be allowed to read the patient information and consent documents, and this process should be recorded.

- The principal investigator, co-investigator and/or the medically qualified person delegated by the principal investigator should explain all the elements of the approved informed consent form and patient information documents, in the language best understood by the potential participant.

- The explanation or narration given by the principal investigator, co-investigator and/or the medically qualified person delegated by the principal investigator, all the questions asked by the potential participant/LAR, and the answers given to them should be clearly audible and recorded.

- At any point during the consent process, if the participant wishes to take more time to read and understand the consent documents including, for example, take it home to discuss with relatives, the recording shall be stopped mentioning the time of stopping. When he/she returns, the recording will be restarted from the point where it was stopped while clearly stating again the date and time of recording.

- The participant/LAR (wherever applicable) should be invited to sign the consent form only after satisfactory answers (in the investigator's judgement) have been given by the participant/ LAR to all the above mentioned questions.

- The participant/LAR should read out all the statements mentioned in informed consent form, as per the Drugs and Cosmetics Act., amended in 2019, and state whether he/she agrees or not for each statement and affix signature/thumb print at the end.

- The actual signing process should be recorded.

- The impartial witness should be requested to enter the name and details of the participant and the date of the consent. The impartial witness will also be requested to sign and date the consent form.

- The principal investigator, co-investigator and/or the medically qualified person delegated by the principal investigator will also sign and date the consent form at the end of the process.

- The recording will be stopped after thanking the participant.

20.4.2 After the audio-visual recording process

- The recording should be checked for completeness and clarity of both audio and video recording.

- No editing should be done on the recording so as to maintain authenticity.

- The computer/laptop should be password protected. The password will be known only to the principal investigator and members of the study team designated by the principal investigator.

- A register should be maintained wherein, each time the data is accessed, the details of who accessed the data, the date and reasons for the same should be entered into the designated register.

- The recording should be transferred to a CD/USB drive/external hard drive and labelled with the study name and identifier, and a unique identifier assigned to the participant, with date and time of the recording, number of recordings (applicable for re-consenting), and archival date.

- The study participants should be informed that there is a possibility of failure of the investigational product in providing the intended therapeutic effect.

- In case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

20.4.3 Archival

- If every participant's audio-visual recording has been maintained on separate CDs, the same will be archived with each participant's file.

- The electronic copies of the recordings will also be stored in a password protected external hard drive.

- The original recording in the computer/laptop will be deleted when study is completed.

20.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP20/V1/ANX01 – Checklist for monitoring the audio-visual recording of the informed consent process
Annexure 2: AIIMS-BLS/IEC-H/SOP20/V1/ANX02 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP20/V1/ANX01
Checklist for monitoring the audio-visual recording of the informed consent process

1. Is the facility where the informed consent process will be carried out, well lit, free from noise, provides adequate privacy, is a dedicated room, with a permanently or temporarily arranged camera set-up, and where voice recording has been tested beforehand?

    - Yes / No
    - Remarks:

2. Whether the consent for audio-visual recording was already taken before starting the recording or if it was taken in front of the camera?

    - Yes / No
    - Remarks:

3. Whether all the relevant elements listed in NDCT Rules 2019 were covered during the discussion with the participant?

    - Yes / No
    - Remarks:

4. Were introductions of each person involved in the informed consent process and the audio-visual recording process made in front of the camera? Were the names, age, designation, his/ her role in the research study, current date and time, enquiry of the language the participant understands best, and showing the consent form in the camera which is going to be used for the study, included in the consent and recording process? Was the participant explained the need for recording the consent process? Were the following - person conducting the informed consent discussion, the potential participant/legally acceptable representative (LAR), and where relevant the impartial witness – included in the consent and recording process?

    - Yes / No
    - Remarks:

5. The following minimum elements should feature in the recording of the informed consent process: the study's purpose, treatment allotment, randomization, study procedures, follow-up, benefits and risks, compensation for participation, compensation for study related injuries, nominee name and details, voluntariness, right to withdraw from the study, and the contact details of designated persons for further information including the investigator's name and the IEC Chairperson or Member Secretary's name.

- Yes / No
- Remarks:

6. Was the informed consent administered by a designated person who is not medically qualified?

   - Yes / No
   - Remarks:

7. Has evidence been recorded that the participant's medical queries have been answered during the informed consent process or assurance has been given to clarify the same later?

   - Yes / No
   - Remarks:

8. Was the consent taken in the language the participant/legally acceptable representative (LAR) understands best and is literate in?

   - Yes / No
   - Remarks:

9. Was it conveyed to the participant/LAR and/or the impartial witness (where applicable), that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules? And was this process recorded as well?

   - Yes / No
   - Remarks:

10. Was it conveyed (and recorded) to the participant/LAR/impartial witness (where applicable) that the confidentiality of information and privacy of participants is assured?

    - Yes / No
    - Remarks:

11. Was it conveyed (and recorded) to the participant/LAR/impartial witness (where applicable) that the recording may be shown to government agencies, authorized auditors, and/or IEC members as and when required?

    - Yes / No
    - Remarks:

12. Was a thorough explanation/narration of the study details and participant's rights given by the person conducting the informed consent process?

    - Yes / No
    - Remarks:

13. Was the audio-visual recording performed for all study subjects, independently?

    - Yes / No
    - Remarks:

14. Were the questions regarding participation asked by the potential participant/LAR satisfactorily answered?

    - Yes / No
    - Remarks:

15. Was ample time given to the participant/LAR/impartial witness to read and understand the consent and patient information documents?

    - Yes / No
    - Remarks:

16. Was the participant/LAR/impartial witness given the opportunity to discuss his/her participation with his/her family members?

    - Yes / No
    - Remarks:

17. Were the statements mentioned in the informed consent document read out by the participant/LAR/impartial witness?

    - Yes / No
    - Remarks:

18. Did the participant clearly state whether he/she agrees or not with each statement listed in the informed consent document?

    - Yes / No
    - Remarks:

19. Was it checked and confirmed if the participant was able to fully understand the study details, patient information documents, consent documents and the informed consent process?

    - Yes / No
    - Remarks:

20. Were the signatures of all those involved in the informed consent process documented?

    - Yes / No
    - Remarks:

21. Was the audio-visual recording clear and complete?

    - Yes / No
    - Remarks:

22. Check if re-consenting is required and has been recorded for changes in the informed consent documents and the legally acceptable representative of the participant?

    - Yes / No
    - Remarks:

23. Check if the re-consenting process has been undertaken by the same investigator as the original consent?

    - Yes / No
    - Remarks:

24. Confirm if the re-consenting process has been carried out in the same language as original and if this language is the best that the participant/LAR/impartial witness understand?

    - Yes / No
    - Remarks:

25. How much timing was taken for the re-consenting process?

    - Yes / No
    - Remarks:

26. Have the audio-visual recordings been stored in a password protected laptop/desktop computer and/or a secure, password protected hard drive or labelled CD?

- Yes / No
- Remarks:

27. Is the access to the audio-visual recordings of participant consent only permitted to the principal investigator and designated members of the study team?

- Yes / No
- Remarks:

Principal investigator / Co-investigator
(Signature, name, designation, date)

Annexure 2: AIIMS-BLS/IEC-H/SOP20/V1/ANX02
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

20.6 Workflow

	Activity	Responsibility
1.	Identifying the need for audio-visual recording of informed consent process	Principal investigator, IEC members
2.	Making arrangements for audio-visual recording of informed consent process	Principal investigator, research team
3.	Carrying out the informed consent process and making an audio-visual recording of the process	Principal investigator, research team
4.	Review of the audio-visual recording of the informed consent process	IEC, authorized auditors, authorized government officials
5.	Storage and archival of the audio-visual recordings of the informed consent process	Principal investigator, research team

21 Site monitoring visits and post-monitoring activities of the Institutional Ethics Committee for biomedical and health research

21.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the scenarios and procedures relevant for carrying out trial site visits and monitoring by the institutional ethics committee (IEC) for biomedical and health research, AIIMS, Bilaspur, for the approval of interventional study protocols.

21.2 Scope

This SOP applies to any visit or monitoring of a study site approved by the institutional ethics committee, AIIMS, Bilaspur, for an interventional study. A trial site visit may be required for regular study monitoring or may be carried out for "For-cause site monitoring".

21.3 Responsibility

It is the responsibility of the IEC Chairperson, Member Secretary, or the full IEC board to decide to conduct on-site monitoring of an interventional study. An on-site inspection of study may be carried out for a specific cause or for routine monitoring. It is further the responsibility of designated IEC members to perform the on-site inspection of the approved research study.

21.4 Detailed instructions

21.4.1 Selection of study sites

1. Routine monitoring:
    - Routine monitoring for a site may be decided at the time of project approval by the full IEC board.
    - The above should be recorded in the IEC decision form and in IEC minutes.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

- The Chairperson will identify and designate one or more IEC members or an independent site monitor to carry out the routine monitoring of the study site.

2. "For-cause monitoring":

- "For-cause monitoring" will be performed at a study site for reasons identified by any member of the IEC, after approval of the Chairperson.
- The reasons for identifying a particular site for "for-cause monitoring" could include any one or more of the following:
    - Large number of protocol deviations
    - High number of protocol violations
    - Large number of studies carried out at the study site or by the investigator
    - Large number of serious adverse event (SAE) reports
    - High recruitment rate
    - Complaints received from participants or any other person
    - Frequent failure to submit the required documents
    - Any other reason deemed important by the IEC

21.4.2 Before the site monitoring visit

Irrespective of the reason for carrying out site monitoring the following procedure will be followed:

- The Chairperson will identify and select one or more IEC members or an independent site monitor to evaluate the study site.

- The selected members will be issued an appointment letter for carrying out the site monitoring.

- The agenda of site monitoring will be decided by the site monitors in consultation with the Member Secretary and the Chairperson.

- The IEC Secretariat will decide the date of site monitoring in consultation with the site monitors and the scheduled date will be communicated to the principal investigator and the site monitors.

- The Secretariat will provide the site monitors relevant reference material and documents related to the project.

- The site monitors will receive from the Secretariat relevant reference material and documents to review and make appropriate notes.

- The site monitors will carry with them a site monitoring visit form and a form for audio-visual recording of AV consent process (if applicable), provided by the Secretariat.

- The independent monitor will sign a confidentiality and conflict of interest agreement prior to reviewing the study related documents and visiting the study site.

21.4.3 During the site monitoring visit

The site monitors will follow the following checklist:

- Check the log of delegation of responsibilities of the study team

- Check if the study site is using current versions of the IEC approved protocols, informed consent documents, case record forms, diaries, advertisements, etc.

- Observe the informed consent process, if possible.

- Randomly review participant files to ensure that participants are signing the correct informed consent.

- Check whether investigational product accountability is adequately controlled and documented throughout the product flow at the study site. This includes arrival, dispensing, use, return from the subject, and return/destruction after the study.

- Check that storage times, storage conditions and expiry dates should be acceptable and sufficient supplies should be available as and when needed.

- Verify that the investigators follow the IEC approved protocols and approved amendments, if any.

- Ensure that the principal investigator and study trial staff are adequately informed about the trial.

- Verify that the principal investigator and the trial staff are performing their specified study functions, in accordance with the IEC approved protocols, and any other written agreement between the sponsor and the investigator/institution. The investigators and the study staff should not have delegated these functions to unauthorised individuals.

- Verify that the investigator is enrolling only eligible subjects.

- Determine whether all SAE have been properly reported within the recommended time and as per the applicable regulatory requirements. Case record forms should be checked

to review patient safety data including, adverse events and SAE for their frequency and severity.

- Review the project files to ensure that documentation is filed appropriately.
- Review the source documents for their completeness.
- Collect the views of the study participants, if possible.
- The site monitors will fill the site monitoring visit form and a form for monitoring and recording the audio-visual consent process (if applicable), with signatures and date.

21.4.4 After the visit

- The site monitors will submit the completed site monitoring visit form, and a form for monitoring and recording the audio-visual consent process (if applicable), to the IEC Secretariat within 7 working days of conducting a site monitoring visit, or at the time of the next full board meeting, whichever being earlier.
- The report should describe the findings of the site monitoring visit.
- The Member Secretary will present the monitoring report at the next full board IEC meeting and the concerned site monitors will provide additional details and clarifications to the members, as required.
- The IEC will discuss the findings of the monitoring process and take appropriate action by voting or a combination of actions, some of which are listed below:
    - Continuation of project with or without changes
    - Restrictions on enrolment
    - Recommendation for additional training
    - Recruiting additional study team members
    - Revising or providing appropriate qualifications and experience criteria for members of the study team
    - Suspension of the study
    - Termination of the study
- If the site monitor has encountered findings that impact the safety of the participants, the site monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson, and an appropriate action from the above list may be taken.

- The final decision taken at the full board meeting by the Chairperson will be recorded in the site monitoring visit form.

- The Secretariat will convey the decision to the principal investigator in writing within 14 working days of the meeting.

- The Secretariat will place a copy of the report in the study file.

21.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP21/V1/ANX01 – Site monitoring visit form
Annexure 2: AIIMS-BLS/IEC-H/SOP21/V1/ANX01 – Monitoring of audio-visual recording of AV consent process
Annexure 3: AIIMS-BLS/IEC-H/SOP21/V1/ANX03 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP21/V1/ANX01
Site monitoring visit form

IEC project number:	Date of visit:
Study title:	
Principal investigator and department:	
Study sponsor:	
Date of IEC approval:	Date of study initiation:
Duration of study:	
Reason for monitoring:	Routine: For-cause (state reason):
Last monitoring done (if any):	
Project status:	• Ongoing • Completed • Recruitment completed • Follow-up/extension study • Suspended • Terminated
If response to the above question is options 5 or 6, kindly specify reasons:	
Are the present study team members as per the list approved by the IEC?	• Yes • No • Comment:
Are the site facilities appropriate?	• Yes • No • Comment:
Is the recent version of IEC approved informed consent document (ICD), being used?	• Yes • No • Comment:
Whether appropriate vernacular consent has been taken from all patients?	• Yes • No • Comment:

Have other findings been noted about the informed consent documents?	• Yes • No • Comment:
Are the recent, IEC approved version of the research protocols being used?	• Yes • No • Comment:
Are the eligibility, inclusion, and exclusion criteria being adhered to?	• Yes • No • Comment:
Have any adverse events been noted?	• Yes • No • Comment:
Have any SAE been noted?	• Yes • No • Comment:
Were the SAE informed to the IEC within stipulated timelines specified by the CDSCO?	• Yes • No • Comment:
Number of deaths reported?	• Yes • No • Comment:
Any other study related injury (besides death)?	• Yes • No • Comment:
Compensation paid for study related injury/death?	• Yes • No • Comment:
Are there any protocol non-compliance, deviations, or violations?	• Yes • No • Comment:
Have the protocol non-compliance, deviations or violations been informed to the IEC?	• Yes • No • Comment:
Are all case record forms up to date?	• Yes • No

	• Comment:
Is the storage of study data and investigational products secure?	• Yes • No • Comment:
How well are the participants protected?	• Good • Fair • Not-fair • Comment:
Any other remarks:	
Duration of visit …… hours	Started at: Finished at:
Name of the study team members present (with signature and date):	
Name of IEC members, representatives who attended the site monitoring visit (with signature and date):	

Annexure 2: AIIMS-BLS/IEC-H/SOP21/V1/ANX01
Monitoring of audio-visual recording of AV consent process

1. Facility where the audio-visual informed consent process should be carried. The location should be well lit, free from noise, and with adequate privacy.

   Yes …….. No ……..
   Remarks: ……

2. The informed consent is taken in the language that the participant or the legally acceptable representative of the participant understands best and is literate in.

   Yes …….. No ……..
   Remarks: ……

3. Introduction of each person involved including, the person conducting the informed consent discussion, research participant, legally acceptable representative and an impartial witness. Information about the necessity of the audio-visual recording.

   Yes …….. No ……..
   Remarks: ……

4. Information provided to the research participant or to the legally acceptable representative of the research participant, and the impartial witness, that the informed consent process if being recorded for the purpose of documentation as required by government rules.

   Yes …….. No ……..
   Remarks: ……

5. Information provided to the research participant or to the legally acceptable representative of the research participant, and the impartial witness, that the confidentiality of the information being recorded and the privacy of the participant will be maintained at all times during and after the study.

   Yes …….. No ……..
   Remarks: ……

6. Information provided to the research participant or the legally acceptable representative of the research participant, and the impartial witness, that the recording may be shown to government agencies or members of the IEC.

   Yes …….. No ……..
   Remarks: ……

7. Explanation or narration by the person conducting the informed consent discussion.

   Yes …….. No ……..
   Remarks: ……

8. Whether the questions asked by the research participant or the legally acceptable representative of the research participant were answered satisfactorily.

   Yes …….. No ……..
   Remarks: ……

9. Were ample time and opportunity provided to the research participant or the legally acceptable representative of the research participant, to read and understand the information provided in the informed consent documents, and discuss the details with the participant's family members?

   Yes …….. No ……..
   Remarks: ……

10. Were the statements mentioned in the informed consent read out by the research participant or by the legally acceptable representative of the research participant, or by the impartial witness, and did the participant state whether he/she agrees with the statements in the informed consent?

    Yes …….. No ……..
    Remarks: ……

11. Documentation of signatures of all those involved in the audio-visual informed consent process.

    Yes …….. No ……..
    Remarks: ……

12. Clarity and completeness of the audio-visual recording of the informed consent process.

    Yes …….. No ……..
    Remarks: ……

13. Storage of the recording in a secure, password-protected computer, hard drive or labelled compact disc, with access to these to only those authorised including, the principal investigator and designated members of the study team.

Yes …….. No ……..

Remarks: ……

Annexure 3: AIIMS-BLS/IEC-H/SOP21/V1/ANX03
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Sushruti Kaushal; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

21.6 Workflow

	Activity	**Responsibility**
1.	Selection of study sites	Chairperson, Member Secretary
2.	Delegation of site monitoring responsibility to selected IEC members	Chairperson
	Inform principal investigator in writing	IEC Secretariat
	Review of IEC research project file	Delegated IEC members
3.	Site monitoring visit	Delegated IEC members, IEC Secretariat
4.	Complete site monitoring report and present in full board IEC meeting	Delegated IEC members, IEC Secretariat
5.	Communication of the IEC decision to the principal investigator	IEC Secretariat

22 Dealing with participant requests and complaints by the Institutional Ethics Committee for biomedical and health research

22.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for dealing with requests for information by research participants regarding their rights as a participant or to resolve their complaints that are related to their participation in research approved by the institutional ethics committee (IEC) for biomedical and health research, at AIIMS Bilaspur.

22.2 Scope

This SOP applies to handling of requests for information/complaints made by the participants concerning their rights and well-being while participating in research studies approved by IEC, AIIMS Bilaspur.

22.3 Responsibility

It is the responsibility of the IEC Member Secretary to provide the required information to the research participants, patients or their representatives, in response to the queries received. It is also the responsibility of the IEC Chairperson / Member Secretary to initiate the process of furnishing sought information to the participants, and identify and address any injustice that has occurred.

22.4 Detailed Instructions:

A request, complaint or query, received from a research participant will be accepted by the IEC Secretariat and forwarded to the IEC Member Secretary, after entering it into the request record form (AIIMS-BLS/IEC-H/SOP22/V1/ANX01). The Member Secretary may receive a request, complaint or query directly from the participant and will record it in the request record form and notify the Secretariat.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

The Member Secretary will ascertain the details of the request, query or complaint by examining any relevant documents and interviewing the participant if needed. If required, Member Secretary will call for additional relevant information and documents from the principal investigator.

The Secretariat will inform the Chairperson about the request, query or complaint received from the research participant. In case of request for additional information or clarification, the Member Secretary in consultation with the Chairperson will provide the information or will designate one or more IEC members to furnish the information.

22.4.1 In case of a complaint received from a research participant

The Member Secretary, in consultation with the Chairperson will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairperson will direct the Member Secretary to:

- Appoint a sub-committee of two or more IEC members for an inquiry and resolution of the matter

- Call for an emergency meeting with two or more IEC members for consideration if the matter should be tabled for discussion at the next full board meeting

The Chairperson, Member Secretary or designated IEC members will assess the situation and mediate a dialogue between the research participant and the principal investigator in an attempt to resolve the matter. The IEC will insist on factual details to ascertain if there are any gaps between the truth and individual perceptions. The final decision will be taken by the Member Secretary in consultation with the Chairperson based on the recommendations of any of the above and it will be informed to the research participant and the principal investigator by the IEC Secretariat. The information, including any action taken or follow-up, and the final decision will be recorded in the request record form and the form will be signed and dated. In cases where the requests and complaints were not discussed in a full board meeting, the IEC members will be informed about the action taken and the outcome in the forthcoming IEC meeting. The Secretariat will place the documents in the relevant study file.

22.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP22/V1/ANX01 – Request / complaint record form
Annexure 2: AIIMS-BLS/IEC-H/SOP22/V1/ANX02 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP22/V1/ANX01
Request / complaint record form

Date received:

Received by (Name of staff):

Request / complaint received:

Telephone no: ……. Fax No: ……
Letter date: ……. Email date: ……...
Walk-in date and time: …….…….
Other, specify:

Participant's name: ……
/ (anonymous)
Contact address:

Phone no:

IEC project number:
Title of the study:

Starting date of participation:

Information requested/ complaint/ query (please give details):

Action taken:

Reviewed by:

Final decision:

Outcome:

Chairperson / Member Secretary
(Name and signature)

Date:

Annexure 2: AIIMS-BLS/IEC-H/SOP22/V1/ANX02
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Sushruti Kaushal; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

22.6 Workflow

	Activity	**Responsibility**
1.	Receive the query, complaint or request from the research participant	IEC Secretariat, Member Secretary
2.	Providing relevant information to the research participant	IEC Secretariat, Member Secretary, Chairperson
3.	Initiate the process to identify the problem	IEC Secretariat, Member Secretary, Chairperson
4.	Deliberations to arrive at a solution	Member Secretary, Chairperson, IEC Members
5.	Communicate the conclusions and final action taken to the research participant	Chairperson, Member Secretary
6.	File the documents pertaining to the query, complaint or request	IEC Secretariat

23 The review of biomedical and health research during emergency situations by the Institutional Ethics Committee for biomedical and health research

23.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe how the institutional ethics committee for biomedical and health research at AIIMS, Bilaspur will function and conduct ethics review of research studies in emergency situations. Emergency situations include humanitarian emergencies and disasters that pose a critical threat to the health, safety and well-being of a community or a large number of people, usually spread across a large geographical area.

23.2 Scope

This SOP covers the procedures required for reviewing research proposals by the IEC during the emergency situations such as an infectious disease outbreak, social strife, displacement of large populations due to draught, earthquake, war or war-like situations accompanied by the disruption of transport and basic amenities.

23.3 Responsibility

All basic ethics principles will remain the same as mentioned in relevant IEC SOPs. Depending on the nature of the emergency, commensurate procedures will need to be implemented. The IEC Member Secretary and Chairperson are responsible for formulating, amending, communicating and implementing the correct IEC procedures based on the emergency situation. These changes should also be communicated to the Institute's faculty and research community.

23.4 Detailed instructions

23.4.1 Research and ethical challenges during humanitarian emergencies

Humanitarian emergencies can be natural or man-made. Emergencies, such as earthquakes, floods, mass migration, conflicts, and disease outbreaks lead to substantial material and

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Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

human loss creating an imbalance between the available resources and the needs of the survivors or the people whose lives are threatened during the emergency.

- Research is necessary in emergency circumstances to enable efficient and appropriate health and humanitarian response and to plan for future emergency situations.

- While there may be a need to undertake research quickly, this should not compromise scientific quality, validity and ethics of research. Close attention should be paid to the effect of the emergency on perceptions of ethical questions, altered or increased vulnerabilities, provider–patient and researcher–participant relationships, issues related to integrity of studies and ethical review processes.

- Designing or adopting innovative and relevant research, based on rapidly evolving scientific and ethical uncertainties will pose significant challenges. Researchers may be left with inadequate time, resources and infrastructure, along with a fractured socio-economic environment to design relevant studies.

- The role of the IEC in such circumstances is very important in reviewing research protocols prepared for such emergency situations. The IEC needs to provide clear, unambiguous instructions for carrying out all IEC activities in accordance with the National Ethical Guidelines for Biomedical Research involving Human Participants (ICMR-2017), National Guidelines for Ethics Committees reviewing Biomedical and health Research during COVID -19 Pandemic (ICMR-2020) and the Guidance for managing Ethical Issues in Infectious Disease outbreaks (WHO-2016).

- Any other situation identified by the Ministry of Health and Family Welfare and National Disaster Management Authority.

23.4.2 Guidance on ethical issues during emergency situations

23.4.2.1 Community engagement

- Engaging with the community in a culturally sensitive manner can improve public trust, help improve design, conduct and responsiveness to health needs. Various measures should be taken to educate the public or communities about humanitarian emergencies, disasters, and pandemics such as the COVID-19 outbreak, within the context of the proposed research, its risks and benefits, the persons to be contacted etc.

- Efforts should be made to prevent the spread of false and/or sensationalized information. Wherever possible, community representatives should be engaged in the conceptualization, review, research, and dissemination of results in such settings.

23.4.2.2 Storage of biological material and data

- Biological samples collected during an infectious disease outbreak can include, but may not be limited to, sputum, endotracheal aspirate, bronchoalveolar lavage, blood, plasma, dried blood, cerebrospinal fluid, urine, stool, tissue and organs. Handling and storage of infectious samples requires appropriate safeguards which should be incorporated into the research proposals.

- Data emerging from the research studies should be well organised, and maintained and stored in secure physical and/or electronic forms, while safeguarding the confidentiality and privacy of the participants. The study should provide clear details on sample and data custodianship.

- The biological samples and data may be anonymized as per the requirements of the emergency situation and the research protocol.

- The samples and data can also be made available via a secure repository for future forecasting of disease trends and hotspots.

23.4.2.3 Public health and socio-behavioural aspects

- The isolation, separation, quarantine, and/or segregation of individuals from their families during an emergency, like that seen during the COVID-19 pandemic, raises ethical issues pertaining to individual dignity, psychological and emotional harm, social harm and informational risk.

- Emergency circumstances can render individuals vulnerable to be coercion for participation. The individuals may not have access to formal or informal support during emergency times e.g. families, counselling centres, rehabilitation centres, police protection, etc.

- The social distancing norms may not allow conventional methods of data collection. Alternative study designs may be required e.g. online or remote methods for conducting interviews, focus groups, surveys or questionnaires. Social media research using data in public domain may still be evaluated for potential privacy threats.

- For obtaining quality data, verification of identity of research participant is required. However, exchanging confidential information electronically is prone to security threats. The privacy and security features of the virtual tool used must be assessed to a reasonable extent.

23.4.2.4 Role of funding agencies, sponsors and research governance

- In case of an infectious disease outbreak, monitored emergency use of unregistered and experimental interventions (MEURI) may be approved with the following precautions.
- Thorough scientific review followed by an ethics review either locally or by a national level ethics committee
- Tackle public concerns and ensure oversight by the IEC. Use good manufacturing practices, make rescue medicines/supportive treatment accessible. Meticulous documentation of therapeutic processes including adverse events
- Fast track research and possible sharing of data on safety and efficacy for further research
- Consent process is important and must be carried out with care.
- Community engagement and ensuring fair distribution of scarce supply of resources
- Facilitate post-trial access of the successful investigational drug/ vaccine free of cost to the trial participants till the same is available in the market.

23.4.2.5 Biosafety in laboratories and hospitals

- The handling of suspected infectious samples during infectious disease outbreaks like Ebola, influenza, and SARS-CoV-2, should only be done in an appropriate biosafety level laboratory (BSL-2 to BSL-4) with specific controls for containment of microbes and biological agents.
- Majority clinical tasks including handling of clinical specimens which do not involve non-propagative work like viral culture, isolation, and neutralization can be carried out in BSL-2 facilities as per NITI Aayog Guidelines for sharing of Biospecimen and Data for Research related to COVID-19 No15(8)/2020-H&FW, dated 21st April 2020 (https://niti.gov .in/ node/1127).
- The lab must ensure proper labelling and handling of specimens (suspected/confirmed for infection) and relevant biosafety precautions and relevant regulatory standards to protect individuals and the environment/testing in National Accreditation Board for Testing and Calibration Laboratories (NABL) certified labs.
- Regulatory requirements for biosafety labs should be strictly followed as prescribed by Department of Biotechnology (DBT) and Ministry of Environment and Forests, Government of India.

- Personnel must be trained about additional precautions, decontamination with appropriate disinfectants, hand hygiene, use of personal protective equipment (PPE) or other physical barriers, biomedical waste handling to reduce the risk of exposure.

- Every effort should be made to limit contact with patients at triage, cohort of patients with infection, limit the numbers of staff providing care.

- Telemedicine can be used for research when possible. Patient consent is necessary for any telemedicine consultation for research.

23.4.3 Informed Consent

23.4.3.1 Informed consent process

- Obtaining valid informed consent during humanitarian emergencies like the COVID-19 pandemic is a challenge due to practical difficulties in reaching out to a patient, who may be in a COVID-19 ward, isolation or quarantine facility. In addition, the decision making capacity of the hospitalized patient with moderate or critical disease would be very low and it may not be possible for the patient to differentiate between the medical care being offered and associated research components.

- Appropriate standard operating procedures are to be followed for informing participants about the research study and for subsequently taking their consent.

- The informed consent documents should be preferably employed electronically for obtaining consent. Alternatively written consent should be obtained while maintaining adequate social distancing and taking all safety precautions.

23.4.3.2 Electronic consent

- During infectious disease outbreaks alternative procedures should be adopted for interacting with the patients/participants, especially if they are under quarantine or isolation, to avoid direct contact.

- Digital technology should be leveraged to prepare interactive forms and platforms to include relevant text, graphics, audio, video, podcasts, and interactive websites.

- The patient consent can also be electronically documented. If digital signatures are to be employed they should be reviewed and approved by the IEC before commencing patient recruitment.

- If required, the informed consent procedure can also be documented using audio-visual recording.

23.4.3.3 Waiver of consent

- If appropriate, the investigators can also apply to the IEC for a waiver of consent. Correct procedures are to be followed for preparing and submitting the application, as stipulated in the SOP for consent waiver.

23.4.4 Vulnerability

- All relevant procedures for identifying and safeguarding vulnerable participants need to be followed during emergency situations too.

- Participants and patients who have been directly or indirectly affected by the humanitarian emergency may also be vulnerable of being additionally stigmatized e.g. risk of being stigmatized during contagious outbreaks like the COVID-19 pandemic.

- During emergencies and outbreaks, health care workers in hospitals and the field, including doctors, nurses, ward staff, sanitation workers, security personnel, food suppliers, etc. are also at risk of being rendered vulnerable.

- Socio-economically or politically disadvantaged individuals such as the stranded migrant workers are also at high risk of being exploited.

- Such vulnerable groups of individuals may not be capable of taking voluntary informed decisions and their autonomy may be compromised temporarily or permanently.

- Vulnerable individuals may be able to give consent, but their voluntariness and understanding may be compromised due to their situation during the calamity.

- Vulnerable individuals may get unduly influenced either by the expectation of benefits or by the fear of retaliation in case they refuse to participate, which may lead them to give consent.

- Terminally ill or critically injured patients may readily agree to provide consent in hope of receiving novel treatments or interventions.

23.4.4.1 Additional safeguards for vulnerable individuals

Additional safeguards should be put in place for participants and patients during an emergency because they may be under duress or may be traumatized:

- Research on vulnerable patients to clearly address the needs of such participants and justify their inclusion.

- Benefits and risks of the research should be carefully determined and risks involved should be minimized by employing appropriate strategies.

- Safeguards should be in place in the research protocols to prevent any coercion, force, undue influence, threat, misrepresentation or incentives.

- The informed consent process should be carried out in a respectful and sensitive manner.

- All efforts should be made to set up support systems to deal with associated medical and social problems.

- Protection of the privacy, confidentiality and rights of the participants should be of paramount importance at all times.

- Whenever possible, ancillary care may be provided.

23.4.4.2 Safety of health care workers involved in research

- During an emergency and pandemics like the COVID-19 outbreak, the safety of researchers and health care workers involved in the study should also be of utmost importance to prevent transmission of infection.

- The research team may be subjected to trauma, humiliation and threats of violence while conducting the research, and ensuring their safety and well-being is the responsibility of the institution, sponsors and local authorities.

- Additional precautions should include prioritizing relevant research studies and their timelines to prevent overcrowding, provide adequate training, ensure appropriate biosafety precautions, expose minimum number of researchers, communications using electronic platforms, use of protection gear/PPE, safety against any assault from public or others, insurance cover etc.

23.4.4.3 Psychological safeguards and mental health

- Persons affected by a humanitarian emergency, natural disaster, or tested positive during an infectious disease outbreak, require psychosocial support not only for themselves but also for their family members.

- Affected individuals should be dealt with respect, empathy and compassion and should not be subjected to any form of stigma or discrimination.

- Individuals in isolation or quarantine may face enormous stress and anxiety. Managing their mental and psychosocial health is important.

- The research proposal and participating institutions must ensure measures to provide psychosocial and emotional support, good communication protocols, flexible working plans, and ways to ensure physical and psychological well-being of the participants.

23.4.5 Ethics review procedures

The IEC must prioritize the review of research proposals based on their urgency and utility. The IEC should facilitate the initiation of new research that can be beneficial for managing the emergency situation. Ongoing research studies should also be reviewed as required to implement amendments as per the need of the situation e.g. implementing social distancing protocols during the COVID-19 pandemic.

23.4.5.1 Responsibilities of the ethics committee

- The IEC should continue to provide thorough scientific and ethical review of research proposals as per national guidelines and regulations to safeguard the dignity, rights, safety and well-being of research participants.

- The IEC should ensure interventional studies continue to follow procedures for registration with the Clinical Trial Registry of India (CTRI) and for seeking approvals as per relevant guidelines and applicable regulations.

- The Member Secretary should continue to categorize proposals submitted to the IEC for full board review, expedited review or review exemption.

- Relevant research proposals during emergencies can be reviewed through an expedited review or unscheduled full committee meetings on a case-to-case basis depending on the urgency and need. If an expedited review is done, full ethical review can follow whenever next possible.

- Quorum for decision making should have a minimum of five members, including medical, non-medical, technical, and non-technical members, with at least one non-affiliated member.

- Measures such as virtual or tele-/web-conferences should be employed and face-to-face meetings should be avoided to observe social distancing norms.

- In exceptional emergency situations, preliminary research procedures including but not restricted to data and biological sample collection that are likely to rapidly deteriorate or perish may be allowed while the ethics review process is still underway.

- Available research protocol templates can be reviewed to expedite the process and interim review or re-review can be done if the emergency situation changes.

23.4.5.2 Ethics review

- Researchers should continue to submit their research proposals as per the stipulated IEC formats and procedures. However, print copy submissions may be optional depending on the emergency situation.

- Electronic copies of the research proposals submitted to the IEC will be screened by the IEC Secretariat for their completeness. The proposals will be categorization under the exempt, expedited, emergency full committee review, standard full board review categories depending on the urgency and need of the research.

- Electronic documents may be accepted for all review procedures and communication, and the review timelines may be shortened to accelerate procedures wherever feasible.

- Virtual or tele-/video-conferences should be employed to ensure social distancing where face-to face meetings are not be suitable. Suitable virtual platforms and software for video conferencing should be employed to enable virtual face-to-face discussions. Teleconferencing should be employed as an alternative when connectivity is an issue.

- The agenda of virtual meetings should be kept short, however, the IEC may meet more frequently for fast track review.

- The IEC may invite subject experts for reviewing research proposals when needed. The subject expert can participate as a special invitee during the web-meeting and will leave the meeting before any decision making procedures commence.

- During the review process, the IEC should consider the following:

    - If written consent is not possible (e.g., physical isolation/severe COVID-19 patients), consent could be given orally or employ electronic methods to document and record.

    - If oral consent is allowed, then recording of the oral consent and documenting it should be considered and there should be an independent witness for the procedure, whether done in-person or electronically.

- Due to the inability of the participant to attend the study site (for e.g. due to social distancing), the contact/communication can be made via phone or video-conferencing, to enquire and identify adverse events, serious adverse events and ensure medical care and oversight with documentation.

- In an ongoing study, if the designated principal investigator is indisposed for a period, she/he may need delegate parts of her/his duties temporarily to others/ co-investigator and the same should be documented and reported to EC at the earliest.

- Withholding information in public health emergencies may be a threat to national security, and therefore the right balance must be maintained to protect individual privacy and confidentiality, and relevant disclosure to public health authorities.

- Suggest steps to protect participants and researchers from possible stigma or discrimination.

- EC members present during a virtual meeting should decide through consensus or cast an online vote to reach decisions. Any disagreement should be recorded along with cited reasons.

- The IEC Chairperson and Member Secretary can take a final call in case of minor discrepancies arising after the committee approves the project.

- IEC meeting can be digitally recorded (audio/video) with permission of the members. The IEC Secretariat will be responsible for noting the attendance and participation in online meetings.

- Once a research proposal is approved, the IEC should be updated about the progress of the approved studies, especially if they have been ratified in an emergency. The IEC may decide the frequency of the continuing review reports of such projects, and these can be more than once in a year.

23.4.5.3 Review of multicentre research

- Common review is generally carried out for research involving low or minimal risk, survey or multi-centric studies using anonymized samples or data, or those that are public health research studies determined to carry low or minimal risk.

- The IEC is free to accept the decision of the designated ethics committee, or to perform an expedited or full committee review expeditiously. Local site specific issues or concerns,

informed consent translations, local study implementation and monitoring may be reviewed.

- However, in an emergency situation like the COVID-19 pandemic, all types of research including high risk studies, or those involving vulnerable populations, can be taken up for fast track common review while ensuring strict monitoring and oversight by registered local ethics committees.

23.4.5.4 Continuing review and monitoring

- Research protocols approved during emergency should be monitored more frequently. The principal investigators may be requested to give their continuing review reports every 6 months.

- If virtual monitoring can be done, through scans and documents, it may be implemented that way. Otherwise physical monitoring in a safe environment should be conducted.

- The IEC should continually evaluate the progress of ongoing research studies, monitor the approved study sites for compliance, review SAE reports, protocol deviations, violations, non-compliance, DSMB reports, new information that emerges, and assess final study reports.

- For protocol deviations and violations the IEC should examine the corrective actions taken. If the violations are serious the IEC may halt the study.

- Compensation must be given for research-related injuries if applicable, as determined by the IEC and as per regulatory requirements (if applicable).

23.4.5.5 Decisions regarding ongoing studies

- Emergencies like the COVID-19 pandemic also tend to impact various aspects of ongoing studies especially the ongoing recruitment and continued monitoring and involvement with participants for their safety and well-being.

- During the COVID-19 pandemic, it is the responsibility of the IEC in consultation with the Chairperson to carefully evaluate the need and relevance of ongoing non-COVID-19 research studies, their near term status, direct benefits, and what risks and disadvantages would be incurred if they are temporarily halted mid-course. The IEC has to review mechanisms to keep such studies active where necessary.

- The following measures can be considered depending on the nature of the research project:

- The study duration can be extended where necessary
- The study may be temporarily halted at some or all study sites
- The commencement of the study can be suspended or postponed at sites where it has not been initiated yet in the interest of safeguarding the wellbeing of the participants and research team
- A study may be allowed to continue with limited study parameters being active
- Physical visits in a given study may be converted into telephonic or video visits
- Follow-up visits may also be postponed or cancelled keeping only the most essential visits active
- Certain ongoing studies may need to re-consent their enrolled participants to incorporate urgent changes in light of the emergency circumstances
- Re-consenting can be done via telephone or video-calls as well, and the oral consent obtained by such means can be supplemented with email confirmation, where possible
- Existing travel restrictions, confinement rules for study participants and research staff should also be accounted for while implementing patient/participant follow-up visits.

23.4.5.6 Review of new non-emergency research

- If priority for ethics review in a defined timeframe is given to emergency related research, other subject research must not suffer. Studies evaluating treatments for chronic conditions or other communicable diseases or injuries or others may also be considered for review by the IEC as these may also be important.
- The IEC should review and assess if a planned study may have a negative impact on the participants' safety or increase the risk to participants as a result of the ongoing emergency situation like the COVID-19 outbreak, and make a sound decision with relevant suggestions for additional safeguards for conducting research in such emergency.
- Depending on the situation and the quantum of projects to be reviewed by EC during an emergency period, the IEC could take a decision on whether it will be able to review non-emergency proposals, or till what time it will not be able to review such proposals.
- The review of non-emergency studies may be done through virtual IEC meetings ensuring appropriate scientific and ethical review and fulfilling the quorum requirements.

23.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP23/V1/ANX01 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP23/V1/ANX01
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

23.6 Workflow

	Activity	**Responsibility**
1.	Submit research proposal electronically	Principal investigator
2.	Receive and verify if the submitted proposal is complete; allot IEC project number	IEC Secretariat
3.	Categorize proposal into expedited, full board review, or exempted review; identify need for independent consultants	Member Secretary, Chairperson
4.	For expedited review designate two IEC members, one legal expert, and one social science member	Member Secretary, IEC members
5.	Initial review of proposal	Designated IEC reviewers
6.	Virtual agenda preparation and full board IEC meeting	IEC Secretariat, Chairperson, Member Secretary, IEC members
7.	Communication of review decision to principal investigator and maintenance of records	IEC Secretariat, Member Secretary
8.	Managing ongoing projects and related issues like follow-up, monitoring, SAE review, non-compliance, violations, complaints etc.	Member Secretary, Chairperson, IEC members

24 The maintenance of active project files and administrative records, archival of closed files and retrieval of documents by the Institutional Ethics Committee for biomedical and health research

24.1 Purpose

The purpose of this standard operating procedure (SOP) is to provide instructions for the organization and maintenance of active research project files and other related documents approved by the institutional ethics committee (IEC) for biomedical and health research, AIIMS, Bilaspur.

24.2 Scope

This SOP applies to the maintenance, archival and retrieval of various documents and files associated with the research projects submitted to the IEC for review and approval, and IEC administrative documents related to the functioning of the IEC. This SOP delineates the various processes required to be followed by the IEC for the organization, maintenance, archival and retrieval of these documents.

24.3 Responsibility

It is the responsibility of Member Secretary with the assistance of the IEC Secretariat to ensure that all active study files and records are prepared and maintained during the study period, and stored securely for a period of five years after the closure or termination of the project.

24.4 Detailed instructions

24.4.1 Maintenance of active study files

- A study master file is to be created and maintained by the Secretariat for every research proposal submitted to the IEC for review. The study master file will comprise of all the documents and correspondence related to a research proposal.

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On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
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- All documents pertaining to the approval of a study will also be gathered, classified and stored in the study master file. These documents include (but may not be limited to):
    - A print and electronic copy of the research proposal and its associated documents
    - Documents pertaining to the review of research proposals
    - Study approval letter
    - Reviewed and approved informed consent documents
    - Protocols amendments and all related correspondence
    - Study progress reports including, interim, annual and completion reports
    - Serious adverse event reports
    - Any other documents or reports pertaining to the research proposals
    - All IEC correspondence related to a study
    - All correspondence between the IEC members and the research investigators regarding the application process, decisions and follow-up
    - Copies of all decisions communicated to the investigators
    - Recommendations given by the IEC for ascertaining compensations for IEC activities/consultations for a research proposal

- Strict confidentiality should be maintained for all the files. All active and archived files should be kept in a secure file cabinet with regulated access. A log book for accessing the files by authorised staff and members should be maintained.

- A register for documenting all communications including, phone conversations, queries, complaints, etc. should be maintained. Correspondence with IEC members, researchers and other regulatory bodies should also be recorded and maintained. Email printouts should be archived after certification by the Member Secretary.

- The IEC shall maintain the above documents and records for a minimum period of five years after the decision on the submitted proposals and completion of the studies.

24.4.2 Maintenance of the IEC administrative records

The IEC records will include the following:

A. IEC member records
- Appointment and acceptance letters of each member
- Signed and dated confidentiality agreements
- Updated curriculum vitae in print or electronic version
- Training records for each IEC member (e.g. GCP, SOP)
- Documentation of resignations /terminations

B. IEC membership list
   - Names of IEC members
   - Age
   - Gender
   - Qualifications (with copies for record)
   - Role in the IEC
   - Status of affiliation with AIIMS, Bilaspur (e.g. affiliated or unaffiliated)
   - Regular or alternate member of the IEC (if applicable)

C. IEC mandate
D. Correspondence related to changes in IEC membership with DCGI
E. IEC attendance list
F. Agenda and minutes of IEC meetings
G. Standard operating procedures (SOP)
H. Annual reports
I. Documents related to workshops and conference organized by the IEC (Continuing education for members & staff)
J. SOP training and distribution logs
K. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments

24.4.3 Maintenance of closed study files

- Once the study file is closed, after study completion or premature termination of the project, the related study files should be shifted to the IEC archives.

- All closed study files should be archived in the IEC archival room for a period of five years from the date of closure of the study.

- A log book for the archival of study documents should be maintained.

24.4.4 Maintenance of records for clinical trials

- The IEC will maintain the data, records, registers and all other documents related to the functioning and review of clinical trials, bioavailability studies, and bioequivalence studies for a period of five years after the completion of such studies.

- In particular, the IEC will maintain the following records for a period of five years after the completion of every clinical trial, bioavailability study and bioequivalence study:

    - The constitution and composition of the ethics committee
    - The curriculum vitae of all members of the ethics committee

- The national and international guidelines followed by the ethics committee
- Copies of the research protocol, data collection formats, case report forms, investigation brochures, and all other study related documents
- All correspondence with committee members and investigators regarding the application, decisions and follow-up of the study
- Agenda of all ethics committee meetings and minutes of the meetings bearing the signature of the Chairperson
- Copies of all decisions communicated to the study applicants
- All records relating to any order issued for premature termination of a study with a summary of the reasons thereof
- The final report of the study including microfilms, compact discs, hard drives, and/or audio-visual recordings
- Recommendations given by the ethics committee for determining compensation
- All records relating to the serious adverse events, medical management of the trial subjects and the compensation paid.

- The IEC should be able to furnish the above data and information to the licensing authority or any other authorised officer on its behalf, as and when sought by the authority.

24.4.5 Accessibility and retrieval of documents

- Study files and administrative records will be made available for audit, for making photocopies (when requested by an investigator), or for any other purpose (e.g. for research on SAE) or request, if authorised by the Member Secretary and/or Chairperson.

- The representatives of regulatory authorities may be granted access at all times.

- A log book recording the retrieval of documents should be maintained.

24.4.6 Disposal of closed files and copies of protocols and documents submitted to the IEC for review

- At the end of archival period, the closed files, will be shredded and disposed of by authorised IEC personnel.

- Extra copies of research protocols and related documents submitted to the IEC for review will be shredded by authorised IEC personnel after ratification in an IEC meeting and without any notification to the principal investigator.

- A formal disposal log will be maintained, providing details of all documents that are disposed.

24.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP24/V1/ANX01 – Document request form
Annexure 2: AIIMS-BLS/IEC-H/SOP24/V1/ANX02 – Log for disposal of study documents
Annexure 3: AIIMS-BLS/IEC-H/SOP24/V1/ANX03 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP24/V1/ANX01
Document request form

IEC project no:
Project title:

Principal investigator:

Documents requested:

Documents requested by:

Purpose of the request:

Signature of the person requesting:

Principal investigator:
(Signature with date)

Member Secretary / Chairperson:
(Signature with date)

Annexure 2: AIIMS-BLS/IEC-H/SOP24/V1/ANX02
Log for disposal of study documents

Project No.	Project title	Principal investigator	No. of files	Date of IEC approval	Date of study initiation	Date of study closure	Disposed by (Name and signature of authorized person)

Annexure 3: AIIMS-BLS/IEC-H/SOP24/V1/ANX03
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Yangshen Lhamo; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

24.6 Workflow

	Activity	**Responsibility**
1.	Organise the contents of the active study file	IEC Secretariat
2.	Maintain the active study files and administrative documents	IEC Secretariat
3.	Archival of study files	IEC Secretariat
4.	Authorising retrieval of archived documents	Chairperson / Member Secretary
5.	Disposing closed study files and maintaining the document disposal log	IEC Secretariat

25 Maintaining confidentiality of ethics committee documents by the Institutional Ethics Committee for biomedical and health research

25.1 Purpose

The usual sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. The purpose of this standard operating procedure (SOP) is to describe the procedures that the institutional ethics committee (IEC) for biomedical and health research, at AIIMS, Bilaspur, needs to follow for maintaining the confidentiality of the various types of original documents and their copies that the IEC manages.

25.2 Scope

This SOP applies to maintaining confidentiality while handling, distribution and storage of submitted study protocols, IEC documents, and correspondence with experts, auditors and the general public.

25.3 Responsibility

The confidentiality of study protocols, IEC documents, and correspondence with experts and auditors is mandatory. All IEC members and staff are required to sign confidentiality agreements with the Institute that enforces the confidentiality. If individuals who are not a member of the IEC, need copies of IEC documents, it is the responsibility of the IEC members and staff to maintain the confidentiality of the concerned documents.

25.4 Detailed instructions

25.4.1 Access to IEC documents

- The IEC members and the Secretariat staff must read, understand and agree to the following:

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

A. Member Secretary and IEC members

- Sign a confidentiality agreement with the IEC for biomedical and health research, AIIMS, Bilaspur, before beginning work for the IEC.
- Shall have access to all IEC documents
- Are free to request and use original documents and their copies.

B. IEC Secretariat

- The secretarial assistant of the IEC will be a staff member of AIIMS, Bilaspur
- The Secretariat staff will also sign a confidentiality agreement with the IEC for biomedical and health research, AIIMS, Bilaspur. The staff will be given access to the documents issued or received by the IEC.

25.4.2 Classification of confidential documents

The types of documents reviewed by the IEC members include:

- Study proposals and their related documents like case report forms, informed consent documents, diary forms, scientific documents, expert opinions, and reviews.

- IEC documents including, SOPs, meeting minutes, advice, and decisions.

- Correspondence with experts, auditors, study participants, investigators, etc. All forms of communication are included including, written or printed correspondence, emails, fax, audio, visual, etc.

Copies of all versions of documents, including drafts and sequential definitive versions, are to be kept private and confidential except those listed in the following sections.

25.4.3 Copies of confidential documents

Copies of documents, including drafts and sequential versions, are considered to be confidential and are not permitted to be brought out except when a document is needed for day-to-day operations.

25.4.3.1 Copy Authorization

- Only members of the IEC are allowed to ask for copies.

- Only staff members of the IEC Secretariat are allowed to make such copies.

- The Member Secretary of the IEC may seek help for making copies, but remains responsible for maintaining the confidentiality of all documents.

25.4.3.2 Log of copies

- A log of copies must be maintained by the IEC Secretariat.
- The log should include: the name and signature of the individual receiving the copy; the signature of the IEC secretary who made the copy; the number of copies made; and the date on which the copies were made.

25.4.3.3 The Log of copies file

- The "Log of copies" of original documents must be maintained and stored with the original documents.
- The "Log of copies" of original documents is not a confidential document and can be reviewed upon request.

25.4.3.4 Copies requested by non-members of the IEC

- Copies of IEC documents requested by non-members of the IEC should only be issued after the permission from the Chairperson or Member Secretary. The person requesting the documents should also sign a confidentiality agreement.
- Copies made for non-members of the IEC must be recorded in both the "Log of requests" for copies of IEC documents and the "Log of copies" made out of the original documents.

25.5 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP25/V1/ANX01 – Log of requests for copies of IEC documents
Annexure 2: AIIMS-BLS/IEC-H/SOP25/V1/ANX02 – Log of copies of original documents
Annexure 3: AIIMS-BLS/IEC-H/SOP25/V1/ANX03 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP25/V1/ANX01
Log of requests for copies of IEC documents

SN.	**Date**	**Documents requested**	**Number of copies**	**Name of recipient**	**Signature of recipient**	**IEC Secretariat initials**

Annexure 2: AIIMS-BLS/IEC-H/SOP25/V1/ANX02
Log of copies of original documents

Title of the document: ……..
……..

SN.	**Date**	**Name of recipient**	**Number of copies**	**Reason for request**	**Signature of recipient**	**IEC Secretariat initials**

Annexure 3: AIIMS-BLS/IEC-H/SOP25/V1/ANX03
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Yangshen Lhamo; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

25.6 Workflow

	Activity	**Responsibility**
1.	Access IEC documents	IEC members and Secretariat
2.	Classify confidential documents	IEC members and Secretariat
3.	Copy confidential documents	IEC Secretariat
4.	File log of copies made	IEC Secretariat

26 Review of research proposals involving vulnerable populations by the Institutional Ethics Committee for biomedical and health research

26.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures that are required for reviewing research proposals involving vulnerable populations. The SOP delineates various procedures for the Institutional Ethics Committee (IEC) for biomedical and health research, at AIIMS, Bilaspur, for conducting the review of such proposals in accordance with Indian laws and relevant national and international guidelines.

26.2 Scope

This SOP covers the policies and procedures that apply to different types of research dealing with vulnerable populations. The emphasis of this SOP is on participant groups that can be vulnerable to coercion, whose autonomy can be at risk, who can be exposed to conditions that may expose them to risks, and research protocols that can result in unequal representation. Such participant groups need additional protection and consideration.

26.3 Responsibility

- Since the regulations and guidelines for vulnerable groups are constantly evolving and getting updated, it is the responsibility of the Member Secretary with the IEC Secretariat to maintain up-to-date tools and check-lists for reviewing research proposals involving vulnerable groups.

- The IEC Chairperson and Member Secretary are responsible for ensuring that all IEC members are well-versed in the new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training programs.

- The Chairperson and Member Secretary are responsible for selecting primary reviewers with appropriate expertise to review such research proposals. They are also responsible for securing appropriate consultation with experts as and when required for specific studies.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

- The IEC members are responsible for reviewing research studies proposing enrollment of vulnerable populations, especially for assessing potential risk for coercion.

26.4 Definitions and mandate

26.4.1 Vulnerability

Individuals, groups and populations are considered vulnerable if they are relatively or absolutely incapable of protecting their own interests because of personal disability, environmental burden, social injustice, lack of power of understanding, inability to communicate, or other reasons. Individuals are considered to be vulnerable if:

- They are socially, economically or politically disadvantaged and therefore susceptible to exploitation
- They are incapable of making a voluntary informed decision for themselves
- Their autonomy is compromised temporarily or permanently:
    - Unconscious patients
    - Differently abled individuals
    - Able to consent but their voluntariness or understanding is compromised due to their circumstances and/or conditions
    - Unduly influenced either by the expectation of benefits or fear of retaliation if they refuse to participate

26.4.2 The following are some examples of vulnerable individuals, groups and populations:

1. Economically and socially disadvantaged – unemployed, impoverished, orphaned, abandoned, homeless individuals; ethnic minorities; sexual minorities (lesbian, gay, bisexual, transgender individuals)

2. Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate - medical, dental and nursing students; subordinate hospital staff; and laboratory personnel; patients with incurable diseases, emergency patients

3. Children (up to 18 years of age)

4. Women in special situations - pregnant or lactating women, those who have poor decision-making powers, women with poor access to healthcare

5. Tribal and marginalized communities

6. Refugees, migrants, homeless individuals; populations in conflict zones, riot areas or disaster zones

7. Individuals afflicted with mental illness, cognitively impaired individuals, differently abled – mentally and physically disabled

8. Terminally ill individuals, patients in search of new interventions after exhausting approved therapeutic options

9. Individuals suffering from stigmatizing or rare diseases

10. Individuals with limited autonomy due to dependency on another; individuals under a hierarchical system e.g. students, employees, subordinates, defense services personnel, healthcare workers

11. Institutionalized individuals, under trials and prisoners

26.4.3 Mandate

The gazette notification dated 31st July 2015 [GSR 611(E)] has mandated audio-visual recording of informed consent process for vulnerable participants being enrolled in clinical trials of new chemical or molecular entities.

26.5 Detailed instructions

26.5.1 Guidelines for review of research involving vulnerable populations

Effort should be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

- Research on genetics should not lead to racial inequalities.

- Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them.

- Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented.

- Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, and service personnel etc., who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

26.5.2 Principles of research among vulnerable populations

- Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well. If any vulnerable group is to be solely recruited, then the research should answer the health needs of the group. Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.

- In vulnerable populations, when potential participants lack the ability to consent, a legally authorized representative (LAR) should be involved in decision making. Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.

- If vulnerable populations are to be included in research, all stakeholders must ensure that additional safeguards/protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

26.5.3 Safeguards and protection mechanisms

- When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation, retaliation, rewards, or credits, as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them. In the first case, they may be subjected to undue pressure, while in the second, they may be easily exploited. If they perceive that their caregivers want them to participate in research, or if the caregiver stands to benefit from the dependent's participation, the feeling of being pressed to participate may be irresistible which will undermine the potential voluntariness of the consent to participate.

- Researchers must justify the inclusion of a vulnerable population in the research. IEC must satisfy itself with the justification provided and record the same in the proceedings of the IEC meeting. Additional safety measures should be strictly reviewed and approved by the IEC. The informed consent process should be well documented. Additional measures such as recording of assent and re-consent, when applicable, should be ensured. IEC should carefully determine the benefits and the risks of the study and examine the risk minimization strategies. As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for

participation during the entire research period. Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.

- Research on sensitive issues such as mental health, sexual practices/preferences, HIV/AIDS, substance abuse, etc. may present special risks to research participants. Researchers should be cognizant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful. Participants may be prone to stigma or discrimination, specifically when the participant is enrolled as a normal control or is recruited from the general population in certain types of research. Efforts should be made to set up support systems to deal with associated medical and social problems. Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion. Whenever possible, ancillary care may be provided such as setting up of a facility, school for unattended children of the participants or a hospital, or counselling center.

26.5.4 Stakeholders' obligations and duties

26.5.4.1 Researchers

- Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection.
- Justify inclusion/exclusion of vulnerable populations in the study
- Conflicts of interest must be addressed
- Have well defined SOPs to ensure a balanced benefit-risk ratio.
- Ensure that prospective participants are competent to give informed consent.
- Take consent of the LAR when a prospective participant lacks the capacity to consent.
- Respect dissent from the participant.
- Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities etc.
- Research should be conducted within the purview of existing relevant guidelines/ regulations.

26.5.4.2 Ethics committee

- During review, determine whether the prospective participants for a particular research are vulnerable.
- Examine whether inclusion/exclusion of the vulnerable population is justified.
- Ensure that conflict of interest do not increase harm or lessen benefits to the participants.
- Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.
- Suggest additional safeguards, such as more frequent review and monitoring, including the visits.

- Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.

- IEC has special responsibility when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentially of departure from the guidelines governing research. IEC should ensure that these exceptions are as minimal as possible and are clearly spelt out in the informed consent document (ICD)

- IEC should have SOPs for handling proposals involving vulnerable populations.

26.5.4.3 Sponsors

- The sponsor, whether a government, an institution, or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their rights/safety.

- The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC)

- The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

26.5.5 Requirements to be met when enrolling children

- As per the National Commission for Protection of Child Rights, a child is defined as a person from 0 to 18 years of age.

- Research proposals should be scientifically sound.

- Risk or harm is a very important consideration in research involving children. Risk refers to a potential harm that can occur to the child as a direct or indirect consequence of the research procedure. The risks entailed in research procedures need to be considered when they are over and above the routine care of the participant.

- Research may include any procedure the participant undergoes for research including questionnaires, investigations such as blood sampling, bone marrow aspiration, liver biopsy etc., or therapeutic interventions such as medication or surgery, over and above the routine standard of care for the patient. Harm occurring from participating in research may be physical (such as pain from needle prick for blood sampling), psychological (such as fear

of separation from parents) or social (such as missing school and friends etc.). Risks must be assessed in relation to benefits.

- A benefit is a good outcome. The benefit is usually potential, which means positive but uncertain outcome. The benefit may be direct, as in a direct benefit to the participant; or indirect.

- Examples of direct benefits include the possibility of recovery, reduction in pain, improvement in disease severity, etc. payments for participation should not be considered in the benefit- risk ratio. Also, patients and participants may consider other benefits such as better access to doctors, assess to investigations which are not otherwise freely available, being special patients as part of research etc. These indirect benefits may be more misunderstood by patients from poor socio-economic strata.

- The equation between the potential benefit and the risk or potential harm should be at least as favorable for the proposed research procedure as for the alternatives available to the children.

- There should be benefit to the children in general and, in most cases, to the individual child subject. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participants must be justified in relation to potential risks involved in the study and benefits to the society.

- The need for the study must be justified by a thorough review of literature.

- The research must be conducted by a team of investigators who have the requisite expertise. One or more members of the team should be a pediatrician and/or have prior experience of research involving children.

- Research involving children should take into consideration the unique physiology, anatomy, psychology, pharmacology, social situation and special needs of children and their families.

- Research involving children should be conducted in a child-friendly environment, as far as possible. The settings of the research should provide the child and parent adequate medical and psychological support. Both pain and emotional discomfort should be prevented as much as possible. When unavoidable, it should be adequately managed and reduced. To do this non-invasive procedures should be preferred.

- In most cases, pediatric testing of a new drug should be started only after adult testing has reached phase III and beyond. Exception will be needed only for drugs of therapeutic value

for a primary disease of children. E.g. surfactant use in premature babies with respiratory distress syndrome.

- Research involving children should only be conducted if the intervention being studied is likely to be at least as advantageous to the individual participant as any available alternative intervention.

- Children should not be involved in research which can be carried out equally well in adults.

26.5.6 Consent and assent for enrolling children

- Consent is parental or LAR's permission for the child's participation in the research study. Assent on the other hand is the child's agreement to participate in a study.

- The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors or adolescents, unless there is no medically acceptable alternative to the therapy provided or tested, and consent has been obtained from at least one parent or guardian.

- Investigators must seek to involve children in discussions about research and obtain their assent to participation in accordance with their developmental level and decision making capacity.

- A child should be enrolled in study only after the child's assent and with consent of at least one parent or guardian (decision to participate in a research study must be a joint decision between the child and the parent or LAR).

26.5.6.1 Assent

- Assent is defined as a child's affirmative agreement to participate in research. A mere failure of the child to decline his/her participation should not be interpreted as assent.

- Since assent is a part of the informed consent process, CDSCO guidelines for regulatory clinical trials apply for assent as well.

- The method of obtaining assent varies by the age of the child:

    - For a child < 7 years of age, parental consent is sufficient
    - For children between 7-11 years of age, oral assent in the presence of a parent or LAR
    - For children aged between 12-18 years a written assent should be obtained

- If a child turns 13 years old during the course of a study, a written assent must be obtained.

- In cases of verbal assent, a parent or LAR should counter-sign to confirm that the child's verbal assent has been taken.

- The type and amount of information given in an assent form needs to be simplified as per the child's cognitive and developmental level. The information should be age-appropriate.

- Dissent or refusal of a child to participate must always be respected. Explanation must be given to ensure that the child understands that he/she may withdraw his/her assent at any time during the study.

26.5.6.2 Waiver of assent

A waiver of assent may be provided by the IEC in following situations:

- The research has the potential of directly benefitting the child and this benefit is available only in the research context. In such cases, child's dissent may be overruled.

- Waiver of assent may also be considered if the research involves children with mental retardation and other developmental disabilities, where the children may not have the developmental level and intellectual capability of giving assent.

- Assent may also be waived under the same conditions in which adult's informed consent maybe waived.

26.5.6.3 Consent for illiterate parents/ LARs

- When a participant is willing to participate but not willing to sign or give thumb impression or cannot do so, then verbal/oral consent may be taken with approval of the IEC, in the presence of an impartial witness who should sign and date the document. This can be documented through audio or video recording of the participant, the principal investigator and the impartial witness, all of whom should be captured in the frame. However, verbal consent should be an exception for specific reasons carried out with the approval of the IEC and not to be followed routinely.

- In non-regulatory, observational studies, sometimes literate or illiterate, parents/LARs may verbally agree to participate but refuse to give their thumb impression. In such cases, again, the documentation of the consent process needs to be done by a literate impartial witness.

26.5.6.4 Circumstances for re-consent

- New information becomes available which would necessitate amendment or deviation from the approved research protocol; except any new safety related information which can harm the participant if not immediately implemented by the investigator.
- A research participant regains consciousness from an unconscious state or becomes mentally competent to understand the study. Procedures to address such a possibility should be spelt out in the informed consent form.
- Long-term follow-up or study extension planned at a later stage.
- There is change in treatment modality, procedures, and/or site visits.
- Attains 18 years of age, or legally acceptable representative has changed.
- There is a possibility of disclosure of identity through data presentation or photographs (which should be camouflaged adequately) in an upcoming publication.
- Future research when required be carried out on stored biological samples but the samples and data are not anonymized.

26.5.6.5 Ethical approval based on degree of risk

Determinants of risk

- *Age and developmental status:* risk assessment in children must take into account their age, developmental status and maturity e.g., taking 10 ml blood sample may be low risk for a 10 year old but high risk for a preterm neonate.
- *Underlying medical condition:* children with underlying medical conditions that place them at risk due to research procedures should be excluded from the study.
- *Cumulative characteristics of risk during research:* determinants about risk should consider the cumulative characteristics of research interventions or procedures and the time period for which they are done e.g., a single X-ray is a low-risk procedure vs. multiple X-rays over time.

26.5.6.6 Guidelines for ethical approval based on degree of risk

For research procedures intended to provide potential direct diagnostic, therapeutic or preventive benefit for the individual child participant, a risk category higher than minimal risk

may be justified. For studies having interventions not intended to directly benefit the individual child participant, the risk levels should be minimal risk or low risk.

26.5.6.7 Data and Safety Monitoring Board (DSMB)

- The need for a data and safety monitoring board may be determined as an additional safeguard by the IEC depending on the anticipated risks to the children involved in the research. The DSMB should have members with appropriate expertise in reviewing clinical studies in children.

- Factors to consider while establishing DSMB for a study:

    - The study endpoints are such that a highly favorable or unfavorable result, or even a finding of futility during an interim review, might make the continuation of the study unethical.

    - Indicators concerning participant safety e.g. an invasive procedure or a potentially toxic drug

    - The study is being performed in a potentially vulnerable population such as neonates.

    - The study involves a population at heightened risk of death or other serious adverse health outcomes.

    - The study includes a large number of individuals, is of a long duration, or is multi-centric.

26.5.7 Research in neonates

- While reviewing research studies proposing the enrollment of neonates, the IEC should keep in mind that:

- Neonates are the most vulnerable pediatric population

- Neonates stand to suffer the potential long-term effects of interventions subjected on them

- The IEC should have an advisory member with expertise in neonatal research and care.

- Risk-benefit analysis of the proposal should be thoroughly assessed

- The proposed research is to be allowed only if expected outcomes of the study are likely to have implications for neonatal healthcare.
- When possible, older children should be studied before neonates.
- Studies on critically ill neonates should be considered even more carefully.
- Strategies such as continuous consent should be considered
- Consent of one parent is required for studies which:
    - Expose neonates to none or minimal risk
    - Offer the prospect of direct benefit
- Consent of both parents is required for studies which (except when only one parent has legal responsibility for the care and custody of the child, one parent is deceased, unknown, incompetent, or not reasonably available):
    - Expose neonates to high risk
    - Do not offer the prospect of direct benefit.

26.5.8 Considerations for research in pregnant women

Pregnant and lactating women should be part of clinical trials only if:

- Research carries none or minimal risk to fetus or nursing infant
- Research aims to obtain new knowledge about fetus, pregnancy or lactation
- The justification for participation of these women in clinical trials is that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that provide therapeutic or preventive benefits.
- Research related to termination of pregnancy (as per MTP act 1971)
- Research related to pre-natal diagnostic techniques. Such studies should be limited to detecting fetal abnormalities or genetic disorders and not for fetal sex determination (as per PC-PNDT act 1994)

26.5.9 Categorization and review of proposals involving vulnerable populations

- Research involving vulnerable population should be subjected to full board initial review and is not eligible for expedited review or exemption from review.

- The IEC evaluates whether additional safeguards have been included in the study to protect the rights and welfare of vulnerable populations.

- The IEC requires at least one or more individuals who are knowledgeable about or have experience in working with vulnerable participants, and are part of the review process.

- New study submissions, amendments and continuing review applications involving vulnerable populations should be reviewed by the full IEC board.

- If research includes a vulnerable population that is not covered in the above list or there are no national or international guidelines for ensuring protection, the IEC will evaluate the research proposal to ensure that all precautions are taken to protect the participants.

- The protocol should be reviewed keeping in mind the following points:

    - Measures to protect autonomy
    - Risk/benefit determination with respect to vulnerability
    - Whether vulnerable populations are bearing unequal burden in research

- IEC members reviewing research proposals involving vulnerable populations should be well-versed with the potential harm or risk to such populations participating in the study.

- The check-list provided in annexures for different vulnerable populations should be used.

- Special justification is required for inviting vulnerable individuals to serve as research participants.

- Means of protecting their rights and welfare must be strictly adhered to.

- The extent of protection offered should depend on the risk of harm and the likelihood of benefit.

- The judgement that individuals lacking autonomy should be periodically reviewed, will vary in different situations.

- The IEC should make sure that the subject's ability to exercise free choice is not limited in any way.

- The IEC should evaluate the following about the consent/assent process planned by the study:

    - The proposed plan for assessment of the capacity to consent is adequate.

- Before requesting assent/ surrogate consent to participate in clinical trials, the investigator must provide the LAR and/or impartial witness with the following information in a language that is non-technical and understandable by the LAR and/or impartial witness and the same shall be recorded through audio-visual means.

- Assent/surrogate consent of the participants is a requirement wherever possible, and, if so, whether the plan for assent/ surrogate consent is adequate.

- There is adequate room for ensuring the involvement of the LAR and/or impartial witness in the consent process.

- Details of such questions, if any, asked by the LAR or impartial witness and his/her understanding of the consent are also to be recorded through audio-video means. The process of signing/putting thumb impression by the LAR/impartial witness should also be video-recorded.

- When a research participant regains consciousness from unconscious state or is mentally competent to understand the study. If such an event is expected, procedure to address it should be spelt out in the informed consent form.

26.6 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP26/V1/ANX01 – Checklist: Requirements for research involving children
Annexure 2: AIIMS-BLS/IEC-H/SOP26/V1/ANX02 – Checklist: Requirements for research involving pregnant or nursing women, fetuses and nursing infants
Annexure 3: AIIMS-BLS/IEC-H/SOP26/V1/ANX03 – Checklist: Requirements for research involving cognitively impaired adults
Annexure 4: AIIMS-BLS/IEC-H/SOP26/V1/ANX04 – Checklist: Requirements for research involving students, employees, or residents
Annexure 5: AIIMS-BLS/IEC-H/SOP26/V1/ANX05 – Checklist: Considerations for genetic research
Annexure 6: AIIMS-BLS/IEC-H/SOP26/V1/ANX06 – Checklist: Requirements for research involving terminally ill patients
Annexure 7: AIIMS-BLS/IEC-H/SOP26/V1/ANX06 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP26/V1/ANX01
Checklist: Requirements for research involving children

IEC project number:
Study title:
Principal investigator:

For the principal investigator (please tick)		For IEC office
Risk determination	**Benefit assessment**	**IEC action**
Minimal risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
	• Potential benefit to the child ( )	• Approved ( ) • Not approved ( )
	• No direct benefit to the child but offers general knowledge about the child's condition or disorder and may benefit the society or future generations ( )	• Approved ( ) • Case by case with special safeguards ( ) • Not approved ( )
Less than minimal risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
	• Potential benefit to the child ( )	• Approved ( ) • Not approved ( )
	• No direct benefit to the child but offers general knowledge about the child's condition or disorder and may benefit the society or future generations ( )	• Approved ( ) • Case by case with special safeguards ( ) • Not approved ( )
Minor increase over minimal risk or low risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
	• Potential benefit to the child ( )	• Approved ( ) • Not approved ( )
	• No direct benefit to the child but offers general knowledge about the child's condition or disorder and may benefit the society or future generations ( )	• Approved ( ) • Case by case with special safeguards ( ) • Not approved ( )
More than minimal risk or high risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )

	• Potential benefit to the child ( )	• Approved ( ) • Not approved ( )
	• No direct benefit to the child but offers general knowledge about the child's condition or disorder and may benefit the society or future generations ( )	• Approved ( ) • Case by case with special safeguards ( ) • Not approved ( )

- Minimal risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examination or tests where occurrence of serious harm or an adverse event is unlikely.

- When risk may not be more than a minor increase over minimal risk, consent of both parents will be required under normal circumstances.

	Yes	**No**	**NA**
Does the research pose greater than minimal risk to children?			
If yes, are convincing scientific and ethical justifications given?			
If yes, are adequate safeguards in place to minimize these risks?			
Does the study involve normal volunteers?			
If yes, is the inclusion of normal volunteers justified?			
Are studies conducted on animals and adults appropriate and justified?			
If no, is the lack of studies conducted on animals and adults justified?			
Will older children be enrolled before younger ages?			
Is permission of both parents necessary?			
If yes, are conditions under which one of the parents may be considered: 'not reasonably available' justified?			
If yes, are the conditions acceptable?			
Will efforts be made to ensure that the parents' permission to involve children in research studies is free from coercion, exploitation and/or unrealistic promises?			

	Yes	No	NA
Are provisions in place to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
Are provisions in place to protect the subject's privacy and the confidentiality of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of adolescents such as counselling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve implications for other family members? (e.g. genetic risk, HIV infection, Hepatitis C)			
If yes, are there adequate mechanisms in place to deal with other members of the family?			
Are parents required to be present during the conduct of research? (Are proposed participants going to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?)			

Approval to proceed with this category of research must be made by the administrator of the IEC, with input from selected experts.

Principal investigator
(Signature and date)

For IEC office use only
Comments:
Primary reviewer's signature and date:

Annexure 2: AIIMS-BLS/IEC-H/SOP26/V1/ANX02

Checklist: Requirements for research involving pregnant or nursing women, fetuses and nursing infants

IEC project number:
Study title:
Principal investigator:

For the principal investigator (please tick)		For IEC office
Risk determination	**Benefit assessment**	**IEC action**
Less than minimal risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
Minimal risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
Minor increase over minimal risk low risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
More than minimal risk or high risk ( )	• Potential benefit ( )	• Approved ( ) • Not approved ( )
More than minimal risk or high risk ( )	• No direct benefit to the participant but increases the knowledge of the disorder/condition and may benefit the society or future generations.	• Approved ( ) • Approvable on a case to case basis, with special safeguards ( ) • Not approved ( )

Section 1

Research involving pregnant women, fetuses before delivery and nursing women

	Yes	**No**	**NA**
Have scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses?			
The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.			
Any risk involved, is the least possible, for achieving the objectives of the research.			
The woman's consent or the consent of the legally authorized representative is obtained in accordance with the informed consent provisions, unless altered or waived by the IEC.			
The woman or her legally authorized representative, is fully informed regarding the reasonable foreseeable impact of the research on the fetus or the resultant child.			

	Yes	No	NA
If the research involves minors who are pregnant, assent and permission will be obtained in accordance with the NDCT Rules 2019 and ICMR guidelines.			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy.			
Women's participation in the research will not have an effect on the decisions by the investigator with respect to the timing, method or procedures used to terminate a pregnancy.			
The decision of the investigator determining the viability of a fetus will not have an effect if the woman participates in the research.			
Does this research promise therapeutic or preventive benefits e.g. to test the efficacy and safety or a drug for reducing prenatal transmission of HIV infection from mother to child; trials for detecting fetal abnormalities; and for conditions associated with or aggravated by pregnancy.			
Does the study involve the discontinuation of nursing for the sake or participation in the research?			
Is the cessation of breast feeding to the nursing child justified?			
Is breast feeding harmful to the infant?			
Does the research have provisions for compensation in terms of supplying supplementary food such as formula milk?			
Can this research be conducted in women who are not pregnant or nursing?			
Does this research protect or advance the health of pregnant or nursing women, fetus, or nursing infants.			
Is this research related to termination of pregnancy and is as per the Medical Termination of Pregnancy Act, Government of India, 1971?			
Does this research violate any provisions of the Medical Termination of Pregnancy Act, Government of India, 1971?			
Is this research related to prenatal diagnostic techniques in pregnant women?			
Is this research limited to detect the fetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, Government of India, 1994, and not for sex determination of the fetus?			
Does this research violate any provision of the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, Government of India, 1994?			

Section 2

Research involving fetuses after delivery

	Yes	No	NA
Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses?			
Individuals providing consent are fully informed regarding the reasonable foreseeable impact of the research on the fetus or the resultant child?			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy			
Women's participation in the research will not have an effect on the decisions by the investigator with respect to the timing, method or procedures used to terminate a pregnancy?			
The decision of investigator determining the viability of a fetus will not have any effect if the women participate in the research?			

AND

A) Fetuses of uncertain viability	**Yes**	**No**	**NA**
Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible risk for achieving the objectives of the research?			
OR			
The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research.			
The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.			

AND/OR

B) Non-viable fetuses	**Yes**	**No**	**NA**
Vital functions of the fetus will not be artificially maintained			
There will be no risk to the fetus resulting from the research			
The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means			
Legally effective informed consent of both parents of the fetus will be obtained except that the waiver and alteration of provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence or temporary incapacity, the informed consent of one parent of a non-viable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a non-viable fetus will not suffice to meet the requirements of this paragraph.			

If the response to any of the above is 'No', the research is not approvable by the IEC at this time.

Section 3
Research studies that can be conducted only after:

- The IEC finds that the research presents a reasonable opportunity to further the understanding, prevention and/or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses.

  AND

- The Chairperson and Member Secretary, after consultation with a panel of experts in pertinent disciplines (for example, science, medicine, ethics, and law) determine either:

  - That the research in fact satisfies the conditions of NDCT Rules 2019, as applicable **OR**
  - The research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses

  - The research will be conducted in accordance with sound ethical principles

  - Informed consent will be obtained in accordance with informed consent provisions of NDCT Rules 2019 and other applicable subparts, unless altered or waived in accordance with IEC rules.

Principal investigator
(Signature and date)

For IEC office use only
Comments:

Annexure 3: AIIMS-BLS/IEC-H/SOP26/V1/ANX03
Checklist: Requirements for research involving cognitively impaired adults

- The purpose of this checklist is to provide guidance to IEC members or the designated reviewer when reviewing research proposals involving cognitively impaired adults as subjects.

- For review, this checklist is to be completed by the designated reviewer to document the determinations required by the regulations and protocol specific findings justifying these determinations.

1) Research involving cognitively impaired adults in which there is anticipated direct benefit to the subjects		
	Yes	**No**
One of the following is true (check the box that is true): • The risk to the participants is presented by an intervention or procedure that holds out prospect of direct benefit to the individual [ ] • More than minimal risk to participants is presented by monitoring procedure that is likely to contribute to the participants' well being [ ]		
The risk is justified by the anticipated benefit to the participants		
The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches		
The proposed plan for the assessment of the capacity to consent is adequate		
Assent is required from (check the box that is true): • All participants [ ] • All participants capable of being consulted [ ] • None of the participants [ ]		
The consent document included a signature line for a legally authorized representative		

2) Research involving cognitively impaired adults in which there is no anticipated direct benefit to the subject		
	Yes	**No**
The proposed plan for the assessment of the capacity to consent is adequate		
The objectives of the trial cannot be met by means of study of participants who can give consent personally		
The foreseeable risks to the participants are low		
The negative impact on the subjects' well-being is minimized and low		
The trial is not prohibited by law		

Participants have a disease or condition for which the procedures in the research are intended		
Participants will be closely monitored		
Participants will be withdrawn if they appear to be unduly distressed		
Assent is required from (check the box that is true): • All participants [ ] • All participants capable of being consulted [ ] • None of the participants [ ]		
The consent document includes a signature line for a legally authorized representative		

Comments:

Lead discussant / Reviewer:
(Name and signature)

Date:

Annexure 4: AIIMS-BLS/IEC-H/SOP26/V1/ANX04
Checklist: Requirements for research involving students, employees, or residents

Study participants who are students, employees or residents require special considerations.

IEC project number:
Study title:
Principal investigator:

	Yes	No
The proposed plan for the assessment of the capacity to consent is adequate		
Have the participants been assured that their status (education, employment, and/or promotion) will not be affected by their decision to participate or not?		
Have the risks to participants been minimized?		
Have participants been assured that participation is voluntary (no signs of coercion)?		
Have participants been assured that their confidentiality will be maintained and protected?		

Comments:

Lead discussant / Reviewer
(Name and signature)

Date:

Annexure 5: AIIMS-BLS/IEC-H/SOP26/V1/ANX05
Checklist: Considerations for genetic research

IEC project number:
Study title:
Principal investigator:

	Yes	No
Will the samples be made anonymous to maintain confidentiality? If yes, stop here.		
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research results?		
Has the appropriateness of the various strategies for recruiting participants and their family members been considered?		
Does the proposed study population comprise family members?		
Will family members be implicated in the study without consent?		
Will the samples be destroyed in the future?		
Is genetic counselling being offered?		

Comments:

Lead discussant / Reviewer
(Name and signature)

Date:

Annexure 6: AIIMS-BLS/IEC-H/SOP26/V1/ANX06
Checklist: Requirements for research involving terminally ill patients

IEC project number:
Study title:
Principal investigator:

For the principal investigator (please tick)		For IEC office
Risk determination	**Benefit assessment**	**IEC action**
Minimal risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
	• Potential benefit ( )	• Approved ( ) • Not approved ( )
	• No direct benefit to the participant but offers knowledge about the disorder/condition and may benefit the society or future generations ( )	• Approved ( ) • Case by case with special safeguards ( ) • Not approved ( )
Less than minimal risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
	• Potential benefit ( )	• Approved ( ) • Not approved ( )
	• No direct benefit to the participant but offers knowledge about the disorder/condition and may benefit the society or future generations ( )	• Approved ( ) • Case by case with special safeguards ( ) • Not approved ( )
Minor increase over minimal risk or low risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
	• Potential benefit ( )	• Approved ( ) • Not approved ( )
	• No direct benefit to the participant but offers knowledge about the disorder/condition and may benefit the society or future generations ( )	• Approved ( ) • Case by case with special safeguards ( ) • Not approved ( )
More than minimal risk or high risk ( )	• Direct benefit ( ) • No direct benefit ( )	• Approved ( ) • Not approved ( )
	• Potential benefit ( )	• Approved ( ) • Not approved ( )

	• No direct benefit to the participant but offers knowledge about the disorder/condition and may benefit the society or future generations ( )	• Approved ( ) • Case by case with special safeguards ( ) • Not approved ( )

Minimal risk: probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life of an average healthy individual or general population, or during the performance of routine tests where occurrence of serious harm or an adverse event is unlikely.

	Yes	**No**	**NA**
Does the research pose greater than minimal risk to patients?			
If yes, has convincing scientific and ethical justification been provided?			
If yes, are adequate safeguards in place to minimize these risks?			
Are appropriate studies that have been conducted on animals and adults justified?			
If no, is the lack of appropriate studies conducted on animals and adults justified?			
Do the anticipated benefits justify requiring the subjects to undertake the risks?			
Is inclusion of vulnerable population warranted?			
Can the research question be answered by using a non-vulnerable population?			
Will efforts be made to ensure that the participants are free from coercion, exploitation and/or unrealistic promises?			
Are adequate provisions in place for obtaining consent?			
Are provisions in place to protect participants' privacy and the confidentiality of information regarding procedure?			
Are there special problems that call for the presence of a monitor or IEC member during the consent procedure?			
Are special needs of counselling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in this research?			

Comments:

Lead discussant / Reviewer
(Name and signature)

Date:

Annexure 7: AIIMS-BLS/IEC-H/SOP26/V1/ANX06
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Sushruti Kaushal; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

26.7 Workflow

	Activity	**Responsibility**
1.	Receive, verify (including checklists) and distribute research proposal involving vulnerable populations for review	IEC Secretariat
2.	Review research proposal involving vulnerable populations and provide assessment	IEC members, designated reviewers
3.	Full board IEC meeting to evaluate research proposal	Chairperson, Member Secretary, IEC members
4.	Communicate IEC decision to principal investigator	IEC Secretariat
5.	Storage of original documents	IEC Secretariat

27 Review, audit and inspection of the Institutional Ethics Committee for biomedical and health research

27.1 Purpose

The purpose of this standard operating procedure (SOP) is to provide instructions to the institutional ethics committee (IEC) for biomedical and health research, AIIMS, Bilaspur, for preparing for a review, audit and inspection of the IEC.

27.2 Scope

This SOP applies to the institutional ethics committee for biomedical and health research, at AIIMS, Bilaspur, for the conduct of regulatory inspection of the IEC which can be conducted with or without prior notification by the regulatory agency.

27.3 Responsibility

It is the collective responsibility of the Chairperson, Member Secretary, IEC members, and the IEC Secretariat

It is the responsibility of Member Secretary to ensure that the regulatory inspection is carried out smoothly and furnish the information as and when required by the Central Licencing Authority or any other officer authorised on its behalf.

27.4 Definitions and mandate

27.4.1 Audit

A systematic and independent examination of all activities and documents related to research projects and trials, to ascertain whether the activities were conducted and the data were recorded, analysed and reported as per approved research protocols, study sponsor's SOPs, good clinical practices, and other applicable regulations.

Prepared by:	Reviewed by:	Approved by:	Accepted by:
On behalf of Members IEC-SOP Committee, AIIMS, Bilaspur	Prof. Sanjay Vikrant Dean (Academics), AIIMS, Bilaspur	Prof. VM Katoch IEC Chairperson, AIIMS, Bilaspur	Prof. Vir Singh Negi Executive Director, AIIMS, Bilaspur
Prashant Sood 11/8/21	24.09.2021	7/10/2021	18/10/2021

- Research trial audit: involves the systematic verification of a research trial and is carried out by individuals not involved with the trial in any way. It involves:

    - The scrutiny of study related activities to ascertain consistency with approved protocols

    - Scrutiny of study data to verify that here are no discrepancies between the source documents and the reported data. The data within the source documents are also compared with the results reported in interim and final reports of the study. The audit also investigates if any practices were employed in the management and analysis of the study data, which would impair the validity of the study results.

    - Assessment of study procedures for their compliance with adopted SOPs

27.4.2 Inspection

Inspection is an official review or examination of the documents, records, facilities, and other resources related to various research projects and IEC's activities, and is conducted by regulatory authorities. An inspection may be carried out at the study/trial site, at the sponsor/CRO facility, and/or at the IEC office, to ascertain the adherence of good clinical research practice.

27.4.3 Mandate

The Drug Controller General of India (DCGI), in its gazette notification GSR 72E, dated 8th February 2013, 122DD states that, "The ethics committee shall allow official inspectors authorized by the Central Drugs Standard Control Organization (CDSCO) to enter the IEC premises to inspect any record, data or document related to a clinical trial, and provide adequate answers to an queries raised by the officials/inspectors, as the case may be, in relation to the conduct of a trial."

27.5 Detailed instructions

27.5.1 Receipt of audit or inspection notification

On receipt of a written communication or an email regarding the audit or inspection of the IEC, the Member Secretary will inform the Chairperson, IEC members and the Head of the Institute, about the date and purpose of the audit or inspection.

27.5.2 Preparing for an audit

On being intimated about an upcoming audit or inspection, the IEC Member Secretary and/or IEC members are assigned responsibilities by the Chairperson to prepare for the audit with the assistance of the IEC Secretariat.

The Member Secretary and designated IEC members will make arrangements for the audit/inspection as per the steps provided in this SOP's checklist.
Research studies with incomplete or missing documents will be dealt with separately and all actions take will be documented.
It should be ensured that all documents are arranged and filed in the right order for seamless access and scrutiny.

27.5.3 On the day of the audit or inspection

The Chairperson, Member Secretary, and designated IEC members should welcome and accompany the auditors or inspectors to the reserved meeting room.
All designated IEC members must be present for the meeting.
The auditors / inspectors will inform the purpose of their visit and the type of information they need.
The Chairperson, Member Secretary and IEC members should answer the queries of the auditors or inspectors clearly, politely, truthfully, and precisely.
The information and files requested by the auditors or inspectors should be made available by the IEC Secretariat.
The Member Secretary, designated IEC members and the Secretariat will note the comments and recommendations of the auditors/inspectors.

27.5.4 Correction of deficiencies observed at an audit or inspection

- The Member Secretary, designated IEC members and the IEC Secretariat will review the comments recommendations of the auditors/inspectors.

- On receipt of the audit/inspection report the Chairperson should implement corrective and preventive measures over a defined timeline, in accordance with the recommendations of the auditors/inspectors.

- After seeking approval of the Chairperson, the corrective action plan should be communicated to the auditors or inspectors, by the Member Secretary or designated IEC members.

- If required, a review date for an internal follow-up audit will be scheduled by the Chairperson.

- The Member Secretary and the designated IEC members should report the outcome of the internal audit to the Chairperson.

27.5.5 Recording the audit or inspection

- The Member Secretary, designated IEC members and the IEC Secretariat must keep records of the audit or inspection, and subsequent action taken based on them. These must be held in a separate audit/inspection file.

- The complete checklists and findings from the internal follow-up audit (if applicable) must also be maintained in the audit/inspection file.

27.6 Annexures

Annexure 1: AIIMS-BLS/IEC-H/SOP27/V1/ANX01 – Audit and inspection checklist
Annexure 2: AIIMS-BLS/IEC-H/SOP27/V1/ANX02 – Document history

Annexure 1: AIIMS-BLS/IEC-H/SOP27/V1/ANX01
Audit and inspection checklist

1. Date of communication regarding audit/inspection:
2. Dates on which the audit/inspection has been agreed on:
3. Ensure that the IEC members and staff have been informed about the dates and time of audit/inspection
4. Ensure the availability of the IEC mandate, terms of reference, organization chart, and other IEC related information in the IEC office.
5. Ensure the availability of the latest copies of signed SOPs in print form in the IEC office, and in electronic form in the IEC digital storage.
6. Review the IEC SOPs and note omissions, deviations, and discrepancies, with reasons.
7. Ensure the availability of national and international ethics guidelines and regulations in print and electronic form in the IEC office.
8. Check all the files of ongoing and complete research studies to ensure all the documents are signed and in order. If any documents are missing or incomplete, they should be noted and appropriate measures should be taken to remedy them.
    - Records of research studies, including the research proposals, and their related documents submitted for ethics review
    - Research protocol assessment records, including the comments of IEC members, meeting agendas, and meeting minutes (both documented in individual study files or separately in meeting records file).
    - Records of all correspondence with the research investigators (documented in individual study files).
    - Amendment approvals (documented in individual study files).
    - SAE reports and related correspondence with investigators and regulators
    - Protocol deviations, violations, and exception reports (documented in individual study files).
    - Continuing, completion, and project termination reports (documented in individual study files).
9. Ensure the availability of documents listing all IEC members, their tenure, appointment details, curriculum vitae, and periodic training received by them.
10. Ensure the availability of documents pertaining to the appointment of IEC Secretariat staff, including their curriculum vitae, training details and tenure.
11. Ensure adequate security measures for keeping the IEC office records and electronic databases safe and confidential.
12. Ensure that the maintenance, retrieval, storage, archival, and tracking of the study files are done as per appropriate SOPs laid down by the IEC.
13. Ensure proper labelling and indexing of study files and storage cabinets.
14. Designate which members will communicate with the auditors or inspectors, and ensure that these members are available for audit or inspection, for preparing action plan, and for conducting a follow-up audit, if required.

15. Communicate the findings and report of the audit or inspection to IEC members at the next full board meeting.
16. Arrange the meeting venue for review of documents, along with catering, accommodation and travel of the auditors/inspectors, for their visit to the IEC office.

Annexure 2: AIIMS-BLS/IEC-H/SOP27/V1/ANX02
Document history

No.	Author	Version	Date	Description of changes
1.	Dr. Yangshen Lhamo; Dr. Prashant Sood	Version 1.0	18.10.21	First approved version

27.7 Workflow

	Activity	**Responsibility**
1.	Receipt of audit/inspection notice	IEC Member Secretary
2.	Preparing for the audit/inspection	Member Secretary, designated IEC members, IEC Secretariat
3.	Presenting information and files to the auditor/inspector	Member Secretary, designated IEC members, IEC Secretariat
4.	Review the comments and recommendations of the auditor/inspector	Member Secretary, designated IEC members, IEC Secretariat
5.	Receipt of audit/inspection report	Member Secretary, designated IEC members, IEC Secretariat
6.	Planning corrective and preventive measures and scheduling a timeline for their implementation	Chairperson, Member Secretary, designated IEC members
7.	Conducting internal follow-up audit	Member Secretary, designated IEC members
8.	Recording the audit/inspection	Member Secretary, IEC Secretariat