BHARATI VIDYAPEETH DEEMED UNIVERSITY

PUNE

INSTITUTIONAL ETHICS COMMITTEE MANUAL

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Institutional Ethics Committee Manual

BVDU/IECM/05

Reference - Guide Book Standards for Accreditation of Ethics Committee
National Accreditation Board for Hospitals and Healthcare providers (NABH)
1st Edition, December 2016

LIST OF Amended SOPs

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SR.NO.	ABBREVIATION	EXPANSION
01	BVDU	Bharati Vidyapeeth DeemedUniversity
02	AE	Adverse Event
03	Amd.	Amendment
04	BA/BE	Bioavailability / Bioequivalence
05	CDSCO	Central Drugs Standard Control Organization
06	COI	Conflict of Interest
07	DCGI	Drug Controller General of India
08	DSMB	Data and safety Monitoring Board
09	IEC	Institutional Ethics Committee
10	ICMR	Indian Council of Medical Research
11	GCP	Good Clinical Practice
12	IP	Investigational product
13	IT	Information Technology
14	LAR	Legally Acceptable Representative
15	PI	Principal Investigator
16	SAE	Serious Adverse Event
17	SOP	Standard Operating Procedure
18	TOR	Terms of Reference
19	AI	Artificial Intelligence

Sr. No.	Pg No.	Amd Date	Section/Clause/ Para/Line	Amendment details	Reasons of Amd	Made by	Authorized signatory

Amendments made in IEC manual from time to time will be traced through the Amendment Record sheet maintained in the IEC Secretariat office. Amendment Record sheet will show the current amendment No. and date. The arrangement of the Amendment details would be such that the latest amendment (decided by Date) will be mentioned first followed by the other amendments arranged in reverse chronological order and the first amendment will be shown as the last item. Whenever the issue changes for any of the reasons mention above, the amendment record sheet will start afresh, not indicating the amendments made in the previous issue. The previous issued document will be stamped as defunct and retained under the custody of Secretariat.

The following are the authorized controlled copy holders of the IEC Manual:

Sr. No.	DESIGNATION OF THE CONTROLLED COPY HOLDER
01	INSTITUTIONAL ETHICS COMMITTEE - SECRETARIAT (HARD & SOFT COPY)
02	IEC MEMBERS - (HARD/ SOFT COPY)
03	QUALITY ASSURANCE DEPT (SOFT COPY)
04	PRINCIPAL INVESTIGATOR (HARD/ SOFT COPY)

FORMS

SR. NO.	RECORD NO.	TITLE
01	BVDU/IECM/F/01	Agenda of Meeting
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01	BVDU/IECM/FL/01	Committee meeting file
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03	BVDU/IECM/FL/03	DCGI Correspondence file
04	BVDU/IECM/FL/04	Project wise file
05	BVDU/IECM/FL/05	IEC Members CV and Training record
06	BVDU/IECM/FL/06	IEC Finance file
07	BVDU/IECM/FL/07	Inward file
08	BVDU/IECM/FL/08	Outward file
09	BVDU/IECM/FL/09	Standard Operating Procedure (SOP) file
10	BVDU/IECM/FL/10	NABH Correspondence file

REGISTERS

SR. NO.	RECORD NO.	TITLE
01	BVDU/IECM/R/01	Inward Register
02	BVDU/IECM/R/02	Outward Register
03	BVDU/IECM/R/03	Archival Register
04	BVDU/IECM/R/04	IEC record destruction

Research in human subjects is now guided by principles laid down by guidelines/ policies at National and International levels. It is essential to follow Good Clinical Practices (GCP) and New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E). The Indian Council of Medical Research (ICMR) has also issued National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, National Ethical Guidelines for Biomedical Research Involving Children 2017 and National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic. All these principles are put into practice through formulation of an Institutional Ethics Committee (IEC).

IEC BVDU has been formed so that an independent, competent and consistent ethical review mechanism is put in place.

- IEC will review the research proposals involving human participants to be conducted at the various Health and Allied Institutes of Bharati Vidyapeeth Deemed University and their collaborators, to evaluate the possible risks to the subjects and expected benefits.
- IEC shall assess the adequacy of documentation for ensuring privacy, confidentiality of the subjects and ensure justice to the subjects.
- IEC will ensure the protection of subject's rights, safety and wellbeing.
- IEC provides a multidisciplinary forum for the analysis and discussion of guidelines, regulatory laws and cardinal principles of research ethics viz. autonomy, beneficence, non-malfeasance and justice and ensures that these are adhered to in planning, conducting and reporting of proposed research through the Committee's advisory, educational, policy development, and service functions.
- To ensure that the research projects carried out are sound in design, have statistical validity and are conducted according to the Indian Council of Medical Research and International Conference on Harmonization/Good Clinical Practice guidelines.

SOP	NAME OF SOPs
01	SOP FOR PREPATION, REVISION AND AMENDMENT OF SOP
02	SOP FOR AUTHORITY ON FORMATION AND APPOINTMENT OF IEC MEMBERS
03	SOP FOR COMPOSITION AND TERMS OF REFERENCE
04	SOP FOR CONFLICT OF INTEREST ANDCONFIDENTIALITY AGREEMENT
05	SOP FOR RESPONSIBILITY OF IEC, MEMBERSANDPRINCIPAL INVESTIGATOR
06	SOP FOR MANAGEMENT OF RESEARCH PROPOSAL SUBMISSION
07	SOP FOR REVIEW OF NEW STUDY PROPOSAL
07 (A)	SOP FOR REVIEW OF INFORMED CONSENT
08	SOP FOR REVIEW OF RESUBMITTED AND AMENDED STUDY DOCUMENTS
09	SOP FOR DECISION MAKINGAND POST MEETING ACTIVITIES
10	SOP FOR ONGOING REVIEW OF STUDIES
11	SOP FOR SAE ANALYSIS, SAFETY REPORTS AND COMPENSATION
12	SOP FOR HANDLING PROTOCOL DEVIATION/VIOLATION
13	SOP FOR VULNERABLE SUBJECTS
14	SOP FOR MONITORING THE CLINICAL TRIALS
15	SOP FOR PROTECTION OF SUBJECT RIGHTS, SAFETY AND WELLBEING
16	SOP FOR DEALING WITH PARTICIPANTS' REQUESTS AND/OR COMPLAINTS TO INSTITUTIONAL ETHICS COMMITTEE
17	SOP FOR SELF ASSESSMENT AND INTERNAL ASSESSMENT
18	SOP FOR TRAINING OF IEC MEMBERS
19	SOP FOR COMMUNICATION WITH ALL STAKEHOLDERS
20	SOP FOR ADMINISTRATIVE SUPPORT ANDFINANCIAL DECLARATIONS
21	SOP FOR ARCHIVAL, RETRIEVAL AND DESTRUCTION OF THE DOCUMENTS
22	SOP FOR REVIEW OF BIOMEDICAL & HEALTH RESEARCH DURING COVID-19 PANDEMIC

PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the Institutional Ethics Committees (IEC BVDU). The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian regulations, relevant national (ICMR & CDSCO guidelines) and international ethical guidelines.

SCOPE:

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the IEC.

RESPONSIBILITY:

It is the responsibility of the Chairperson of the IEC to appoint SOP team to formulate a new SOP or to revise/ amend the existing SOP. The SOP team shall do this by following the standard procedures while drafting or editing any SOP of the IEC.

PROCEDURE:

The current SOP is valid for a period of three years from the effective date, and it will be reviewed, discussed and revised every three yearly or earlier as and when required for effective functioning of the IEC. The Previous version of the SOP will be valid till the effective date of next version. The SOP version will be updated every three yearly and amendment will be done for any interim revision/s.

SOP will be revised within reasonable period of time when there are changes in regulation and / or guidelines that impact functions of Ethics Committee for the defined scope. Any member of the IEC or an Investigator can make a request for revision or amendment to make any important changes or to remove inconsistency / discrepancy in the existing SOPs. If majority of the IEC members agree to the request, the Chairperson will appoint SOP team. This team will revise / formulate the SOP. If IEC members do not agree to the request, no further action will be taken.

The Chairperson of the IEC will appoint a SOP team to formulate the SOP, which will consist of Member Secretary and 1-2 IEC members. The SOP team shall draft the SOP which will be reviewed by all the IEC members including Chairperson.

There should be documented SOPs for these mandatory procedures and these are as follow:

a) Terms of reference for Ethics Committees

i) Composition (names and qualification of the members), new induction, resignation, replacement or removal of members.
ii) Declaration of Conflict of Interest and ConfidentialityAgreement.
iii) Frequency of Ethics Committee meetings.
iv) Financial Declaration of payments received and disbursed.
v) Policy regarding training for new and existing members.
vi) Any other or to do all such other lawful acts, deeds and things as are incidental and conductive to attainment of objects of any of them.
vii) IEC Secretariat - IEC Secretariat shall be set up which will assist in executing functions of the IEC.

b) Protocol submission

i) Procedure for receipt of applications- original, revised, amended with supporting annexures.

c) Ethical review

i) Review and decision making of proposals.
ii) Procedure to be followed for vulnerable population.
iii) Procedure for risk-benefit analysis.
iv) Procedure for review of Informed Consent Document (Subject/Participant Information Sheet and Informed Consent Form) and Informed Consent Process.

d) Decision making, minutes recording, post meeting activities including monitoring

i) Procedure for deliberations and maintaining minutes
ii) Procedure for reporting, analysis of SAEs and making opinion on compensation.
iii) Procedure for handling issues related to noncompliance, protocol violation, negligence, complaints by the participants and other stake holders.
iv) Procedure for review of protocol amendments.

e) Documentation and archiving

i) Procedure for control and archiving of records with confidentiality

ii) There should be documented SOPs for these mandatory procedures.

iii) SOPs should have a scope, detailed process and applicable nameplate/ checklists/ flowcharts and be as per applicable rules and regulations.

iv) SOPs should have authorized signature of individuals who has /have prepared, reviewed and approved the SOP. In emergency situations like pandemics, disease outbreaks or disasters, lock-down etc. when signatures of individual members for revised SOP are not feasible, approval of may be obtained via mail from the IEC members.SOPs should include issue date and validity date.

v) SOPs should be accessible to all stake holders for reference.

Suggestions/ addition/ subtractions in the draft SOP requested by all the IEC member/s may be incorporated as applicable and the final version will be forwarded to the Chairperson for review and approval.

Once approved, revised version of SOP will be distributed to all the IEC members. The IEC members will be given training of amended/ revised SOP by Member Secretary or will be asked to do self training of the SOP.

Both hard and soft copies of the latest version of SOPs shall be available in the Secretariat office. The copy of the old version of SOP will be archived.

Approved SOPs will be implemented from the effective date.

PURPOSE:
To provide guidelines for formation of IEC and appointment of IEC members.

SCOPE:
IEC and Institution

RESPONSIBILITY:
University Authorities or their designee has responsibility of IEC formation and appointment of IEC members. It is the responsibility of all the IEC members and the Secretariat staff/ IEC Co-ordinator to read, understand, follow and respect this SOP.

PROCEDURE:
Introduction:
Research in human subjects is guided by principles laid down by guidelines/policies at National and International levels. It is essential to follow Good Clinical Practice (GCP) adopted internationally. In India, clinical research activities should follow New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E), CDSCO guidelines, Indian Council of Medical Research (ICMR) guidelines for Biomedical Research on Human participants. The Institutional Ethics Committee (IEC) shall adhere to applicable rules & regulations.

Authority under which IEC is constituted:
University Authorities, Bharati Vidyapeeth (Deemed to be University) constituted the Institutional Ethics Committee in year 2005, in order to ensure that Health and Allied Institutes of the University conduct research on human subjects, using research methodology that meets international and local regulations, ethical standards and is consistent with principles of GCP, ICMR, New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E), & Medical Devices Rules 2017 and its amendments

'Institutional Ethics Committee, Bharati Vidyapeeth Deemed University (IECBVDU)' is established so that an independent, competent and consistent ethical review mechanism, in an objective manner, is put in place for all clinical trials and health and biomedical research proposals dealt with by the committee in accordance with National rules and regulations, & Good Clinical Practices.
The IEC BVDU is registered with DCGI.

Ethics Committee current Registration No. ECR/313/Inst/MH/2013/RR-19, issued under Rule 122DD of the Drugs & Cosmetics Rules1945.
IEC shall be re registered every 5 yearly/ as per the prevalent regulations.
IEC NABH (National Accreditation Board for Hospital and Healthcare Providers) Accreditation number is EC-CT-2018-0016.
The final registration number of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR) is - EC/NEW/INST/2023/MH/0217

Appointments:
University authorities had appointed the IEC members at the inception of the IEC from varied backgrounds as per the regulatory guidelines.

The IEC shall not have any institutional official with any commercial interests as its member. If a member completes his or her tenure or does not wish to continue and opts to leave before the completion of his/ her tenure or dies during the tenure, a new member with a similar background will be appointed in his or her place.

The appointment letter issued to all members should specify the TORs. The letter shall include the following:

- Roles and responsibility of the member in the committee
- Duration of appointment
- Conditions of appointment

When there is need to appoint new IEC member/s, it will be notified to the University authorities. University authorities or their designee will appoint the new IEC member/s with similar background in his or her place.

RECORD:
1. Authority letter from Vice Chancellor/ Designee of Bharati Vidyapeeth (Deemed to be University)
2. Letter of appointments of members

NABH Standard for Accreditation of Ethics Committee, 1st edition, December 2016.

PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provides the framework for constitution, selection, roles and responsibilities of the Institutional Ethics Committee (IEC) and procedures for maintaining confidentiality of all activities and documents.

SCOPE:

This SOP applies to the constitution of the IEC, selection, roles and responsibilities of members of the IEC and maintenance of confidentiality of all activities and documents.

RESPONSIBILITY:

The selection and appointments of IEC members will be done by the University Authorities or their designee. It is the responsibility of all the IEC members and the Secretariat staff/IEC Co-ordinator to read, understand, follow and respect this SOP.

PROCEDURE:

Composition of IEC:

The composition of the IEC will be multidisciplinary and multi-sectorial and adequate for its functioning. It shall be compatible with the requirements of New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E), ICH GCP guidelines to ensure its independence and competence. The composition may be as follows:

The Ethics Committee shall have a minimum of seven members from medical, non-medical, scientific and non-scientific areas with at least**,**

(i) one lay person;

(ii) one woman member;

(iii) one legal expert;

(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute. The IEC members from the institution/ college from where the research project

is submitted for review and approval will be considered as internal members. The other IEC members will be considered external (nonaffiliated) members.

Members are appointed to the IEC for a particular role. Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC. Members should not have any known record of misconduct.

They cannot substitute for the role of any other member who is absent for a meeting. The Chairperson/ Member Secretary could have dual roles in the IEC as they could fulfill role based on their qualifications in addition to taking on the role of Member Secretary and the Chairperson.

The Chairperson shall be a well-respected person from any background with prior experience of having served/serving in an EC. He/ she should preferably be from the 'health' field but should not belong to the institution BVDU. He/ She shall be appointed by University Authorities or their designee. The previous Chairperson will continue till the new Chairperson joins.

The Member Secretary shall be from Bharati Vidyapeeth (Deemed to be University) Medical College/Institution for administrative convenience. He/She should have knowledge and experience in clinical research and ethics, be motivated, have good communication skills and should be able to devote adequate time.

The committee shall include at least one member whose primary area of interest or specialization is non-scientific and should have balance of medical & non-medical members.

The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

For review of each protocol, the quorum of Ethics Committee should be of at least 5 members with the following representations as per the regulatory requirement:

i. Medical Scientist (preferably a pharmacologist);
ii. Clinician;
iii. Legal expert;
iv. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
v. Lay person

Minimum one non-affiliated member should be part of the quorum. The quorum should include both medical, non-medical or technical or/ and non-technical members. No decision is valid without fulfillment of quorum.

All the IEC members shall be committed to the designated roles & responsibility.

Subject experts / representatives of specific patient groups (based on requirement of protocol e.g. HIV, genetic disorders, Ayurvedic/ Homeopathy drugs, representatives of vulnerable subjects, etc.) can be invited to offer their views. As they are not IEC members, they will not be part of decision making.

The members of the Ethics Committee shall follow the Good Clinical Practice Guidelines and other regulatory requirements to safeguard the rights, safety and well-being of trial subjects.

Every member of the Ethics Committee shall be required to undergo such training and development programs as may be specified by the Central Licensing Authority from time to time.

Provided that any member, who has not successfully completed such training and developmental programs, shall be disqualified to hold the post of member of the Ethics Committee and shall cease to be a member of such committee.

No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no Conflict Of Interest.

The member list as per the Annexure I, will be updated as and when required. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licensing Authority within thirty working days.

TERMS OF REFERENCE:

Membership Requirements:

- A member of the IEC will have tenure of three years.
- Each member can have a membership of a maximum of two consecutive tenures. The member may be continued till the new member in his/her place is appointed.
- Thereafter a member may be re-appointed for the new tenure, after a gap of minimum 3 years.
- All members shall have to sign the ‘Confidentiality Agreement’ and the ‘Agreement for Declaration of Conflict of Interest (COI)’.

Replacement, Resignation and Removal Procedure:

- If a member completes his or her tenure or does not wish to continue and opts to leave before the completion of his/her tenure or dies during the tenure, a new member with a similar background will be appointed in his or her place.
- The member shall communicate his or her resignation preferably in writing/via mail to the IEC.
- If a member is found to be unable to discharge his or her responsibilities, he or she will cease to be a member.

Honorarium/Consultancy to the Members/ Invited Experts etc.:

- An honorarium of Rs. 3000/- (Rupees Three Thousand only) will be paid to each of the IEC members or the experts who attend the meeting.
- If there is any change in the honorarium then it will be recorded in the minutes of the meeting in which it is changed.
- Transport may be provided to the IEC members for attending the meetings if required.
- Honorarium will be paid to the IEC member/s for site monitoring visit/s and SAE review committee members.

Role of Expert Advisors:

- The IEC will maintain a list of Expert Advisors in various specialties, who may be invited to attend the meeting and advise the Committee on a subject related to their specialty and thus help the Committee in making the decision.
- Their opinion or advice will be recorded, but they will not take part in the decision making process.

  IEC shall keep Curriculum Vitae (CV) of the respective subject expert invited for the meeting. He/ She will have to sign 'Confidentiality Agreement' and the 'Agreement for Declaration of Conflict of Interest'. The documents of the protocol will be shared with the subject expert only after signing the 'Confidentiality Agreement'. The soft copies of the documents will be shared via mail. In emergency situations like pandemics, disease outbreaks or disasters, lock-down etc. when EC meeting in person is not possible, online/ web meeting may be held to review the projects. In this case Confidentiality Agreement and COI would be taken by mail from the respective subject expert.

RECORD:

1. Terms of Reference of Ethics Committee
2. Current list of IEC members

PURPOSE:

The purpose of this SOP is to describe the process to identify and manage Conflict Of Interest (COI) & Confidentiality Agreement among Institutional Ethics Committee (IEC) members.

SCOPE:

This SOP covers taking Confidentiality Agreement & the policy related to identification, declaration and management of Conflict Of Interest and is applicable to all IEC members.

RESPONSIBILITY:

All IEC members are responsible for understanding definition of Conflict Of Interest (COI) and for self-identifying and disclosing these. The Chairperson would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies. All members shall have to sign the 'Confidentiality Agreement'.

PROCEDURE:

Definition:
Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain.

- No IEC member shall participate in the review, comment or approval of the projects in which he/she has a conflict of interest.
- All the IEC members shall sign the agreement of 'Declaration of the Conflict of Interest' (Annexure III) at the time of joining the committee.
- The member who has a conflict of interest shall declare the same in the beginning of meeting in writing to the Chairman of the IEC.
  In case of online meeting, COI will be confirmed by each member attending the IEC meeting, prior to starting the meeting, and this will be documented in the Minutes of Meeting (MOM).

- The member who discloses a conflict of interest may attend the presentation done by the investigator team, but shall not participate in the deliberative discussion or the decision making of the protocol.
- The Chairperson shall reassess the quorum when any member withdraws from the decision making due to conflict of interest.
- This shall be documented in the minutes of the meeting.
- This policy applies to all research proposals reviewed by the Committee, including initial and continuing reviews where approvals for the study or other study related documents are accorded.
- All members shall have to sign the 'Confidentiality Agreement' and the 'Agreement for Declaration of Conflict of Interest' (As per annexure II & III).

RECORD:

The **'**Declaration of the Conflict of Interest' and 'Confidentiality Agreement' signed by the IEC members will be maintained and filed in the IEC office.

PURPOSE:

This SOP describes the scope & responsibility of IEC, its members and Principal Investigator (PI).

SCOPE:

All types of biomedical and health research (clinical, basic science, policy, implementation, epidemiological, behavioral, public health research, etc.) shall be reviewed by an IEC. The IEC is responsible for scientific & ethical review of research proposals. Academic & most of the Investigator initiated studies shall be reviewed by another EC constituted by Bharati Vidyapeeth (Deemed to be University) Medical College, Pune.

IEC provides a multidisciplinary forum for the analysis and discussion of proposals, its amendments, SAEs, etc. IEC follows guidelines, regulatory laws and cardinal principles of research ethics viz. autonomy, beneficence, non-maleficence and justice and ensures that these are adhered to in planning, conducting and reporting of proposed research through the Committee's advisory, educational, policy development, and service functions.

RESPONSIBILITY:

The SOP describes some important responsibilities of the IEC, its members and PI.

PROCEDURE:

<u>Responsibilities of IEC</u>:

1. To safeguard the dignity, rights, safety and well-being of all actual and potential research participants.
2. To ensure that the research projects carried out are sound in design, have statistical validity and are conducted according to the New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E) and its amendments, International Conference on Harmonization/ Good Clinical Practice guidelines and ICMR guidelines 2017.
3. To ensure ethical conduct of research by the investigator team. So that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
4. To assist in the development and the education of a research community responsive to local health care requirements and to allot appropriate funds for the same.

5. IEC would conduct Periodic self assessments & corrective and preventive actions (as required) would be implemented.
6. The IEC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
7. The IEC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
8. The SOPs should be given to IEC members at the time of their appointment.
9. The Secretariat staff/IEC coordinator should support the Member Secretary in all the IEC functions and should be trained in documentation and filing procedures under confidentiality agreement.
10. The IEC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
11. The IEC reviews progress reports, final reports and AESI/ SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
12. The IEC should recommend appropriate compensation for research related injury, wherever required and send its opinion on causality assessment and compensation to the regulatory authorities.
13. The EC should carry out monitoring visits at study sites as and when needed.
14. The EC should participate in continuing educational activities in research ethics and get updated on relevant guidelines and regulations.
15. The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. ‘Me too’ research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.
16. To maintain records of the activities such as agenda, minutes of the meeting etc.

IEC shall follow all the applicable Regulations and Guidelines:

- New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E) and its amendments
- National Ethical Guidelines for BioMedical and Health Research Involving Human participants 2017 and National Ethical Guidelines for BioMedical Research Involving Children-2017

- International Conference/ Council on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practices
- Good Clinical Practices Guidelines issued by the Central Drug Standard Control Organization (CDSCO), Directorate General of Health Services, Government of India ICMR Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research
- DCGI order for Audio- Visual recording of ICF process dated 19 Nov 2013 and GSR 611(E) dated 31 July 2015.
- The Gazettes of India dated 30 Jan 2013 and 01 Feb 2013.
- National Guidelines for Ethics committee reviewing Biomedical and Health Research - During Covid-19 Pandemic – ICMR April 2020
- Medical Devices Rules 2017 and its amendments
- Ethical guidelines for application of Artificial Intelligence (AI) in Biomedical Research and Healthcare
- Newer rules & regulations/ GSR as applicable

Responsibilities of the Chairperson:

- The Chairperson will head the Committee, preside over its meetings and conduct the meetings according to the GCP guidelines. He/she shall be accountable for independent and efficient functioning of the committee.
- He/ She shall ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations.
- He/ She shall ratify minutes of the previous meetings
- If he/she is unable to attend the meeting, he will nominate an IEC member to preside over the meeting and conduct it. In case of long absence of the chairperson (for more than 3 months) the Chairperson in consultation with member secretary will nominate another member for performing his functions during his absence. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- If he/she has conflict of interest as a Principal/Co-Investigator, in any of the research projects, he/she shall nominate another non-affiliated member as Acting Chairperson for that particular project discussion.
- Chairperson is the concluding authority in IEC final decisions on the proposals, he/she will sign the minutes.

- If Member Secretary has a conflict of interest as a Principal/Co-Investigator, in any research project or on leave, then documents communicating IEC decisions like approval letter shall be signed by the Chairperson.
- He/ She shall seek COI declaration from members and ensures quorum and fair decision making.
- Shall handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data etc.
- Any other

Responsibilities of the Member Secretary:

Member Secretary is responsible for all the administrative work of the committee.

- Receive all correspondence related to research proposals.
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for IEC review.
- Check the new proposal documents for its completeness.
- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review.
- Schedule IEC meetings, prepare the agenda and minutes.
- Forward the proposals/ matters for review to the IEC members.
- Invite the Principal Investigator for the scheduled meeting.
- Prepare minutes of the meeting and place the minutes of the previous meeting for the confirmation by the IEC members in the current meeting.
- Assess the need for expedited review/exemption from review or full review.
- Invite independent consultant, subject experts, patient or community representatives as & when needed. Ensure quorum during the meeting and record discussion sand decisions.
- Organize IEC documentation, communication and archiving.
- Training of Secretariat staff/IEC coordinator and members.
- To update SOPs as and when required.
- Ensure adherence of IEC functioning to the SOPs.
- Prepare for and respond to audits and inspections.
- Communicate Serious Adverse Event (SAE) occurring at the site to which IEC accorded the approval, to all IEC members via email. Discuss any action to be taken on the SAE report

with the Chairperson and communicate the same to the Investigator or other members as applicable.

- To send the SAE Review report including the causality assessment and opinion on compensation to the DCGI as per the regulatory guidelines.
- To renew registration of IEC with DCGI in timely manner.
- Notify to DCGI in case of change in membership in IEC.
- Respond to the queries or clarifications to the observations submitted to the IEC by the Investigators.
- Take 'Confidentiality agreement' (Annexure II) and 'Agreement for the Declaration of the Conflict of Interest' (Annexure III) from the IEC members.
- Train the IEC members on the Standard Operating Procedures of the Ethics Committee.
- To ensure that complaints and concerns of study subjects are addressed and managed appropriately.
- Member Secretary shall be custodian of all the documents pertaining to the IEC.

If the Member Secretary is unavailable for more than a week, the chairperson will designate one of the affiliated IEC members to carry out the duties in his/her absence.

Responsibilities of the IEC Members:

- Attending meetings on a regular basis
- Maintaining strict confidentiality regarding protocol information, reviews and decisions and all matters discussed at committee meetings
- Disclosing conflict of interests, respecting each other's views and the deliberative process
- Deciding independently whether the design and conduct of proposed studies will protect participants' safety, rights and welfare
- Evaluate the possible risks to the study participants with proper justifications, expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice
- Remaining impartial and objective when reviewing protocols
- Serving as main reviewers for research in their areas of expertise
- Keeping up-to-date with national and international research ethics and regulatory guidelines.
- Attend trainings on regular basis
- Trained in the SOPs
- Taking part in research ethics-related continuing education programs.

- Protection of vulnerable subjects
- To carry out work delegated by Chairperson and Member Secretary
- Provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable
- Either be trained in human research protection and / or GCP at the time of induction into the IEC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy)
- Be willing to undergo training or update their skills/ knowledge during their tenure as an EC member
- Be aware of relevant guidelines and regulations
- Read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time
- Sign a confidentiality and conflict of interest agreement/s
- Be willing to place her/ his full name, profession and affiliation to the EC in the public domain and
- Be committed and understanding to the need for research and for imparting protection to research participants in research
- Any other points as per the need

A. <u>Responsibilities of Clinicians</u>:

Clinician should be individual/s with recognized medical qualification, expertise and training. The clinicians are responsible for in depth review of Protocol and ICF for:

- Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge
- Participant recruitment procedures
- Inclusion and exclusion criteria for entry of participants
- Appropriateness of type of study design (observational, experimental, pilot, randomized, blinded etc.) in relation to the objectives of the study
- Review of intended intervention, dosages of drugs, route of administration, duration of treatment & details of invasive procedures. Thus Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics

- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents including CV of Principal Investigator
- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation
- Plan to withdraw or withhold standard therapies in the course of research
- Procedure for seeking & obtaining informed consent (with sample of patient information sheet and informed consent forms in English and local language.)
- Ongoing review of the protocol, study progress and completion report
- Review of SAE, protocol deviation/ violation
- Plans for publication of results- positive or negative –while maintaining the privacy and confidentiality of the study participants

B. <u>Responsibilities of Medical Scientist</u>:

He/she may be non-medical or medical person with qualifications in basic medical sciences. In the IEC reviewing clinical trials with drugs, the Medical Scientist should preferably be a pharmacologist.

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report for clinical trials, pharmacologist to review the drug safety and pharmacodynamics
- The medical scientist reviews the Investigator Brochure with an in depth review of the known and expected adverse events
- He/ she reviews of ICF to ensure that all the information about the IP and trial procedure is being conveyed to the participant
- He/she reviews the Protocol to confirm that the scientific rationale of the study is in consonance with the preclinical findings and prior clinical research if any

C. <u>Responsibilities of Legal expert</u>:

Legal expert should have a basic degree in Law from a recognized university, with experience; Training in medical law is desirable, following are his/her responsibilities:

- Ethical review of the proposal, ICD along with translations, MOU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, and researcher's undertaking
- He/she is responsible for the in depth review of the CTA with special emphasis on Confidentiality, Indemnification, Insurance, Dispute Resolution & Arbitration
- He/she must carry out in depth review of ICF with special emphasis on:
  a. Policy on Compensation
  b. Availability of medical treatment for such injuries or risk management
  c. Steps taken for ensuring confidentiality
  d. No loss of benefit on withdrawal
  e. Benefits sharing in the event of commercialization
- Check for protocol specific other permissions, such as HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform IEC members about new regulations if any

D. <u>Responsibilities of Social Scientist</u>:

He/she should be an individual with social/ behavioral science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values or can be from an NGO involved in health-related activities.
He/she shall do ethical review of the proposal, ICD along with the translations for:

- Discomfort to the patient if any
- Frequency and type of invasive procedures
- Reimbursement/inconvenience payment being offered to the participants if any
- Maintenance of privacy and confidentiality of the participants
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
  He/she shall serve as a patient/participant/ societal/community representative and bring in ethical and societal concerns

E. <u>Lay Person</u>:

- He/she may be the Literate person from the public or community who has not pursued medical science/health related career in the last 5 years, may be a representative of the community from which the participants are to be drawn and is aware of the local

language, cultural and moral values of the community. Desirable if involved in social and community welfare activities.

Responsibilities of Lay Person:

- Ethical review of the proposal, ICD along with translation(s) for analysing convenience of the participant with respect to the study procedures involved
- To check aspects like the comprehensibility of the ICF and other study documents to be used for participants, the study schedule and related activities and caregiver involvement
- To evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks
- Serve as a patient/ participant/ community representative and bring in ethical and societal concerns
- Assess on societal aspects if any

Responsibilities of Principal Investigator (PI):

The Principal Investigator of a new research project is invited to attend the IEC meeting wherein his/her project is being reviewed, to give study presentation and to answer any queries pertaining to the project.

The committee expects the following from the PI after his/ her research proposal is approved:

- The PI should enroll subjects in the clinical trial, only after written approval from IEC, regulatory authorities and the clinical trial is registered in www.ctri.nic.in.
- To inform IEC on enrollment of first subject in the said clinical trial
- The PI should submit the study status report as per the IEC recommendation.
- A written report of 'on site SAE' should be reported within 24 hours to the IEC, Sponsor or its representative and Licensing Authority.
- The report of SAE including death after due analysis shall be submitted within stipulated timelines to the IEC, Sponsor or its representative, Licensing Authority and the head of the Institution where the trial has been conducted, as per the regulatory guidelines.
- Adequate medical care to be provided to study participants as and when required.
- Safety reports such as CIOMS/SUSARs etc. should be submitted within 10 calendar days of receipt.

- To inform the IEC of study completion or discontinuation with reasons
- To submit justification for approval to restart studies discontinued earlier by the IEC and not to restart it before such approval has been accorded
- To submit the final study report, on its completion/closure or termination
- To inform about any changes in the protocol and /or patient information informed consent
- To comply with the IEC during monitoring visits, audits and inspections etc.

RECORD:

Appointment letters

PURPOSE:

This SOP describes the receipt & submission of research proposal for the IEC meeting.

SCOPE:

Submission of Research proposals

RESPONSIBILITY:

It is responsibility of the IEC secretariat staff/Co-ordinator & the Member secretary to prepare the meeting agenda, to receive & circulate the research proposals.

PROCEDURE:

The study documents for review and approval should be submitted to IEC office well in advance, so as to circulate the study documents at least two weeks prior to the proposed IEC meeting. In case of expedited review of the proposals, the documents of the meeting shall be circulated via mail to all IEC members, minimum 5 days prior to the proposed IEC meeting. Study proposal submitted to the IEC shall be reviewed within three months of receipt.

PI is informed of the List of documents to be submitted for IEC review and approval as mentioned in Annexure IV.

The research proposals for approval by the committee shall be submitted to the **Secretariat Office** at the following address.

Institutional Ethics Committee Office:

4th floor, Bharati Hospital & Research Centre
Pune - Satara Road, Dhankawadi
Pune - 411043
Phone No - 020 40555555, Ext.2265
Email ID - iec.bvdu@bharatividyapeeth.edu

The Member Secretary/ IEC secretariat staff/Co-ordinator shall assign a unique number to each proposal and check it for its completeness. If any critical item is missing, the Member Secretary shall inform the PI and request for it in writing. If it is done on phone, fax or e-mail, the same shall be documented.

The Member Secretary/ IEC secretariat staff/Co-ordinator shall circulate the meeting agenda along with the study documents to the members. IEC secretariat staff/Co-ordinator will make copies of the relevant documents and make it available at the meeting.
All the documents submitted to the IEC shall be acknowledged by the Member Secretary. If the Member Secretary is an investigator for any project, then any other IEC member including the Chairperson shall acknowledge the receipt of documents submitted to IEC for that project. If the Member Secretary is unavailable for more than a week, the chairperson will designate one of the IEC members to carry out the duties in his/her absence.

Preparation of the IEC meeting agenda:
Member secretary prepares the meeting agenda prior to circulation of documents to the IEC

- New study Projects
- Amendments to the study documents if any
- Renewal of approval of the ongoing studies
- All documents notified to IEC since last meeting
- SAE and compensation

If the IEC secretariat receives new proposal submission after meeting documents are circulated to the members, then the Member secretary in the consultation with the Chairperson shall decide whether the proposal can be taken up for discussion and if so then the study documents shall be sent to the members.

Frequency of Meetings:

Member Secretary in consultation with the Chairperson shall convene the meeting in the following conditions:

- IEC has at least two projects for discussion
- Once in two to three months if there is at least one project or any important issues/ review of documents for a study to which IEC has accorded the approval
- The frequency of meetings can be increased if required.

Institutional Ethics Committee Fee:

The IEC fee should be paid by Cheque/ Demand Draft in favour of **'Bharati Vidyapeeth University Institutional Ethics Committee'**.

I. Fees for review of Clinical trials:

S. N.	Details of the study	Fees in INR
1.	Phase I, II and III studies	Rs. 45,000/- (Rupees Forty Five Thousand only)
2.	Phase IV studies	Rs.35,000/- (Rupees Thirty Five Thousand only)
3.	Expedited / Urgent review	Rs. 60,000/- (Rupees Sixty Thousand only)
4.	Amendment	Rs. 5,000/- (Rupees Five Thousand only)

GST will be applicable as per the regulations.

II. For review of other research studies:

The research proposals submitted to government or non-government agencies for funding can be reviewed prior to receipt of fees. PI should submit IEC fees on receipt of funds, as applicable.

Fees for review of other research studies:

S. N.	Details of the study	Fees in INR
1.	Projects having budget of <5 Lac Rupees	Rs.10,000/- (Rupees Ten Thousand only)
2.	Projects having budget >5 Lac Rupees	Rs.20,000/- (Rupees Twenty Thousand only)

GST will be applicable as per the regulations.

III. Fee waiver may be considered for certain projects, decided on case to case basis e.g. if there is no direct funding for the institute, fee waiver may be granted.

RECORD:

1. IEC submission letters
2. Communication with PI and circulation of documents

PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) members will perform an initial review of a new research study protocol especially for clinical trials.

SCOPE:

This SOP applies to the initial review and assessment of all research study protocols submitted for review and approval from the IEC.

RESPONSIBILITY:

Review of new study proposal is responsibility of all the members present for the meeting.

PROCEDURE:

The primary task of the IEC is review of research proposals and their supporting documents with special attention given to the Informed Consent process, documentation, the suitability, feasibility of the protocol and competence of the individual investigators. IEC will take into account prior review by the Scientific Review Committee, and the requirements of applicable rules and regulations.

The ethical review of the new research study should be done in the formal IEC meetings (in person/online).

Institutional Ethics committee should ensure that scientific evaluation and ethical review of the research proposal is done prior to approval to ensure that subjects are exposed to minimal risk. The Ethics Committee should assess the risk-benefit ratio for the population especially in placebo controlled trials.

The Member Secretary shall convene the meeting of the Committee in consultation with the Chairperson.

a. If a proposal/ documents require urgent/expedited review, a special meeting may be convened in consultation with the Chairperson.

b. The meeting shall be scheduled after ascertaining the availability of the members for the proper quorum.

c. The quorum shall consist of at least 5 members as follows:

For approval of a drug trial, the IEC quorum should satisfy the recommendation of New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E), According to this, the quorum should have the following representations:

1. Medical scientist (preferably one pharmacologist)
2. Clinician
3. Legal expert
4. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or similar person
5. Lay person

d. A member can play more than one role in the Ethics Committee depending upon his expertise, but during the meeting he/ she can play only one role at a time.

e. The Member Secretary/Secretariat staff/IEC Co-ordinator shall maintain the attendance log of each meeting.

f. The Member Secretary may decide and invite the experts for the meeting whenever required.

g. The Member Secretary/secretariat staff/IEC Co-ordinator shall inform the PIs, whose proposal is being discussed, of the date, time and the venue of the meeting and request them to be available for project presentation and for clarification, if any.

h. The Chairperson shall preside over the meeting and conduct the proceedings. If he/she is unable to attend, he/she shall nominate any other member to act on his behalf.

i. Only those members, who attend the meeting and take part in the deliberations, shall participate in decision making of the proposal.

j. If a member is not able to attend the meeting for some genuine reason and remains absent for the meeting with the prior consent of the Chairperson, the written comments/ observations communicated by him/ her may be considered for discussion.

k. PI or his / her representative shall make a presentation of the study to the IEC.

l. IEC shall review all the study documents submitted for the review and approval. In the initial review of proposed clinical trial IEC shall evaluate the scientific validity of the protocol, risk to subjects, expected benefit and ethical standards as per applicable rules and regulations. IEC shall discuss the study in detail in the meeting.

m. Informed Consent Document, assent form (as applicable), its translations and back translations shall be reviewed for appropriateness of language, accuracy and completeness

of information. IEC will also review it for implications of its contents, safety, compensation of research participant and other ethical considerations.

- IEC shall ensure that Informed consent document has all the essential elements as per applicable rules and regulations.
- IEC shall check for certificates for translation and back translations of the ICFs.

n. Ethics committee shall review the informed consent process proposed to be followed at the site for a particular trial. Recruitment strategies shall be reviewed by the Ethics Committee and ensure that the principal investigator shall have a recruitment policy to ensure unbiased selection of adequate number of suitable subjects according to the protocol. The Ethics Committee should ensure that the advertisements do not induce the participants.

o. Selection of subjects should be such that the benefit and burden is equally distributed.

p. Proposal involving special group and vulnerable population shall be evaluated as per rules and regulations. Appropriate experts should assess the proposal as required. e.g. a proposal of pediatric population should be assessed by a Pediatrician.

q. Contract/ MOU and budget shall be evaluated, for indemnity, compensation, roles and responsibilities as per applicable rules and regulations. The legal member of the Ethics Committee shall evaluate the contract/ MOU to ensure protection of the research participant, indemnification and arbitration.

r. The Ethics Committee shall review the CV of Principal Investigator (PI), Co-Investigator and other team to ensure the qualification and expertise is appropriate for the proposal.

s. IEC shall check for the site feasibility, adequacy of the site, the supporting staff, available facilities, and emergency care.

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

Thus the IEC shall review the project in detail for (This is mainly applicable for clinical trials), as per the Checklist (Annexure VIII A)**:**

The checklist will be circulated to IEC members via mail before IEC meeting. The IEC members shall check the documents for the adequacy as per their roles. In case of online IEC meeting, the Member Secretary shall confirm this at the time of meeting and it will be mentioned in the Minutes of Meeting. The checklists will be signed by the Member Secretary in case of online IEC meeting.

- Suitability of the investigators' qualifications and experience for the proposed study

- Rights and responsibility of subject are documented. Subject's confidentiality and privacy is protected.
- The appropriateness of the study design in relation to the objectives of the study
- Recruitment strategies
- The statistical methodology (including sample size calculation)
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
- Subject's participation and withdrawal from the trial is voluntary.
- The justification for the use of control arms, criteria for prematurely withdrawing research participants
- Criteria for suspending or terminating the research as a whole
- The adequacy of provisions made for monitoring and auditing the conduct of the research
- The manner in which the results of the research will be reported and published.
- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.
- Medical care to be provided to research participants during and after the course of the research.
- Contract and budget for indemnity, compensation etc.
- Insurance policy

EXPEDITED APPROVAL:

The Chairperson or another member nominated by him/her may approve a proposal without holding a formal meeting only under following conditions:

1.The proposal involves little or no risk to the participants. Minimal risk would be defined as one 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.

2. If there are minor modifications in the study documents or to a proposal already reviewed within proceedings, and concerns either an administrative matter, or a change that does not affect the safety of the participant.

3. The protocol reviewed in an earlier meeting has been considered approvable with suggested amendments, and has now been amended accordingly.

4. Research involving clinical materials i.e. data, documents, records, or specimens in emergency situations like serious outbreaks or disasters. When a full review of the research proposal is not possible, prior written permission of IEC may be taken before use of the test intervention.

5. IEC meeting may be called for review of clinical trial proposal which requires expedited approval by the IEC. In such cases the documents may be circulated to members of Scientific Review Committee and IEC simultaneously. The proposal shall be discussed in formal (in person/online) meeting. The review may be obtained from IEC members by mail which shall be decided by chairperson on case to case basis.

ONLINE/ WEB MEETING:

The details of online/ web meeting are mentioned in SOP no. 22 also.

The online meeting may be planned if 'in person' meeting is not feasible/ convenient for the Chairperson and majority of the IEC members.

In emergency situations like pandemics, disease outbreaks or disasters, lock-down etc. when EC meeting in person is not possible, online/ web meeting may be held to review the projects for expedited approval. The documents of the meeting will be circulated via mail to all IEC members, minimum 5 days prior to the meeting. The decision regarding the projects discussed during the meeting shall be communicated to respective PI within 7 days.

Records of the online meeting shall be maintained. The minutes of meeting will be prepared on this basis.

Exempt from full quorum review is permitted in cases of Registry studies and studies in which no risk is involved to participants. A subcommittee may be appointed by the Chairperson for such exempted studies. This subcommittee shall submit its report to the Chairperson who would take the final decision.

All proposals considered for exemption and expedited approval shall be presented in subsequent full IEC meeting for ratifying the decision.

Whenever a physical meeting is planned, a member essential to complete the quorum will be allowed to join virtually with permission of Chairperson.

Any communication sent through IEC office should be considered confidential and any study related documents, relevant files/ communication should be deleted after the study completion.

RECORD:
Minutes of Meeting

PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to describe informed consent process.

SCOPE:

This SOP applies to review and assessment of Informed Consent Documents and its process.

RESPONSIBILITY:

Review of Informed Consent Documents and its process is responsibility of all the members present for the meeting.

PROCEDURE:

The primary task of the IEC is to review the research proposals and their supporting documents with special attention given to the Informed Consent Documents and its process.

In the Initial review of proposed clinical trial, IEC shall evaluate the Informed Consent Documents thoroughly as per the Checklist (Annexure VIII B):
The checklist will be circulated to IEC members via mail before IEC meeting. The IEC members shall check the documents for the adequacy as per their roles. In case of online IEC meeting, the Member Secretary shall confirm this at the time of meeting and it will be mentioned in the Minutes of Meeting. The checklists will be signed by the Member Secretary in case of online IEC meeting.

- Informed Consent Document, Assent Form (as applicable), its translations and back translations shall be reviewed for appropriateness of language, accuracy and completeness of information. IEC shall also review for implications of its contents, safety, compensation of research participant and other ethical considerations.
- IEC shall check for certificates of translation and back translations of the ICFs.
- IEC shall ensure that Informed Consent Form and the Assent Form have all the essential elements as per applicable rules and regulations.

  IEC shall ensure that the essential elements of Informed Consent Form to be explained to subjects / parents of the subjects should be as follows:
  - ❖ Study involves research and purpose of the research
  - ❖ Expected duration of the Subject's participation in the Study
  - ❖ Procedures to be followed (including invasive procedures)

- ❖ Reasonable foreseeable risks or discomforts to the subject
- ❖ Any benefits may or may not result to the subject from participating in the study
- ❖ Specific appropriate alternative procedures or therapies available to the Subject
- ❖ Confidentiality of records identifying the subject will be maintained and who will have access to subject's medical records
- ❖ Trial treatment schedule(s) and the probability for random assignment
- ❖ Compensation and / or medical management in the event of trial related injury
- ❖ Whom to contact for trial related queries, rights of subjects and in the event of any injury
- ❖ The anticipated prorated payment, if any, to the subject for participating in the trial
- ❖ Subject's responsibilities on participation in the trial
- ❖ Participation is voluntary
- ❖ Statement that there is a possibility of failure of Investigational Product to provide intended therapeutic effect
- ❖ Statement that in case of placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect
- ❖ Any other pertinent information

- Assent Form is applicable in pediatric trials where the child is capable of making decisions and voluntarily confirms his/her willingness to participate in the clinical trial after being informed of all the aspects of the trial that is relevant to his/her decision making.
- Ethics committee shall review the informed consent processes proposed to be followed at the site for a particular trial to ensure that the Subject/ LAR/ Parents/ Impartial Witness are provided appropriate information, adequate time is given for comprehension of the information, impartial witness used as applicable. The role of Impartial Witness and LAR should be clear.
- In some cases, fresh or re-consent may need to be taken, such as when:

  - ➢ New information becomes available which would necessitate amendment/deviation of protocol (excluding 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 is planned at a later stage.
  - ➢ There is change in treatment modality, procedures, site visits.

- Attains 18 years of age, or the legally acceptable representative has changed.
- There is possibility of disclosure of identity through data presentation or photographs (which should be camouflaged adequately) in an upcoming publication.
- Future research may be carried out on stored biological samples if not anonymized.

Electronic consent may be obtained as per requirement of Sponsor & Protocol.

IEC shall ensure that:

- There should be evidence that Subject's/ Parents/ LAR's queries and concerns are addressed and he/ she signs the Informed Consent Form only after understanding of all the information in the informed consent document.
- Adequate time is given for reading and understanding the ICF.
- There should be provision for Subject/ Parents/ LAR to take opinion from family members, family physician if they wish to.
- Audio Visual (AV) recording is carried out as per rules and regulations. Time & date is recorded on the AV consent recording.
- The Subject/ Parents/ LAR should be provided with an Informed Consent Document in the language he/ she knows and understands.
- Subject/ Parent/ LAR should sign first in front of the Investigator/ designee and thereafter the Investigator/ designee should sign the Informed Consent Form.
- A copy of signed Informed Consent Document should be given to the Subject/ Parents/ LAR.

RECORD:

1) Minutes of meeting
2) Documents submitted by Principal Investigator

PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) manages resubmitted and amended study documents.

SCOPE:

This SOP applies to the review of:

A. Study protocols and related documents that have been resubmitted to the IEC by the Principal Investigator (PI) with clarifications and modifications sought by the IEC in the initial review.
B. Amendments to study protocols and related documents that have been approved earlier.

RESPONSIBILITY:

Member Secretary and Chairperson have responsibility to review the resubmitted Study protocols and related documents and to review the amended study documents for deciding whether it needs full quorum approval.
It is responsibility of all the IEC members to review the amendments to the study documents, to be discussed in the meeting, as per the Checklist (Annexure VIII C).The checklist will be circulated to IEC members via mail before IEC meeting. The IEC members shall check the documents for the adequacy as per their roles. In case of online IEC meeting, the Member Secretary shall confirm this at the time of meeting and it will be mentioned in the Minutes of Meeting. The checklists will be signed by the Member Secretary in case of online IEC meeting.

PROCEDURE:

A. Study protocols and related documents that have been resubmitted to the IEC by the Principal Investigator (PI) with clarifications and modifications sought by the IEC in initial review, will be reviewed by the Member Secretary and Chairperson.
   The decision taken shall be communicated to the respective PI in writing.

B. Sometimes the study documents which are approved by the IEC are amended by the Sponsor/ Investigator. The amended study documents are submitted by the PI to the IEC office. If the amendment is only for the minor or administrative changes, then the documents may be

circulated via mail to the IEC members for approval or the documents may be notified to the IEC. Any significant amendment/s to the originally approved study documents i.e. Protocol, Consent Forms, Investigator Brochure etc. shall be discussed in the full quorum meeting to evaluate the risk to the trial subjects.

RECORD:

1. Communication from PI regarding amendments
2. Minutes of Meeting

PURPOSE:

This SOP describes the process of decision making of the IEC, its communication and post meeting activities.

SCOPE:

IEC

RESPONSIBILITY:

1. Decision making is the responsibility of the Chairperson and the members present in the meeting to discuss the research proposal.
2. Post meeting activities are carried out by the Member Secretary with help of the IEC Secretariat staff/IEC Co-ordinator.

PROCEDURE:

Decision making process (approval, recommendations, and conditional approval/ disapproval) shall be independent and as per the applicable rules and regulations, ensuring quorum and consensus requirements are fulfilled.

Decisions regarding a project submitted to the IEC shall be taken by consensus. Consensus offered by more than 50% of members is required for approval of the project. In case of equal number of consensus, Chairperson's opinion will be the deciding factor.

The project proposal shall be rejected, when the consensus is not reached and PI shall be advised to re-submit the project with recommended modifications.

If an IEC member is the Principal Investigator/ study team member for a particular research project, he/ she will not participate in decision making for that project.

Member shall declare Conflict Of Interest (COI), if any, prior to the review and voluntary withdrawal during decision making process, which will be documented in the minutes.

Decisions shall be based on risk benefit assessment, scientific validity and adherence to ethical principles, as per the applicable checklists (Annexure VIII).

The checklist will be circulated to IEC members via mail before IEC meeting. The IEC members shall check the documents for the adequacy as per their roles. In case of online IEC meeting, the Member Secretary shall confirm this at the time of meeting and it will be mentioned in the

Minutes of Meeting. The checklists will be signed by the Member Secretary in case of online IEC meeting.
The decision on each proposal shall be minuted, including all the dissents regarding rejection of proposal.

The Member Secretary with the help of Secretariat staff/IEC Co-ordinator shall prepare the minutes of the meeting and letters to the PIs whose proposals were discussed in the meeting. The format for according approval to clinical trial protocol by Ethics Committee shall be as per Table 1 (B) – Third Schedule of New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E).

Deliberations and decisions made during the meeting shall be documented, approved, signed by the Chairperson or designee and maintained as minutes of meeting.

a. The Chairperson shall approve the minutes of the meeting. Letters to the respective principal investigators shall be issued by the Member Secretary. In case the Member Secretary is part of the study team, the letters shall be signed by the Chairperson. A copy of this communication is maintained in the IEC file.

b. Decisions regarding the research proposal shall be communicated to the PI in writing within 10 working days after the meeting and within 7 working days after expedited review of proposal.

c. For proposals where DCGI approval is pending, 'Conditional approval' shall be given. Final approval for the study proposal shall be granted only after submission of DCGI approval.

d. PI shall recruit subjects only after receipt of written final approval from IEC, regulatory authority and the clinical trial is registered in www.ctri.nic.in.

e. Approval for the research projects will be renewed every yearly (if required) after reviewing annual study progress report. Approval for long term studies will be given for the entire study period, though continuation of approval will be issued every yearly after reviewing annual study status report.

Documentation of Minutes:

Minutes shall be documented with enough detail to reconstruct its decisions at a later date, additionally; comprehensive minutes show concern for participants' rights, safety and well-being. The minutes may include the following:

- Meeting logistics: date, time of start and venue.
- Review and approval of minutes of previous meeting.

- The minutes will identify all members attending the meeting
- It will be documented if any subject expert was called for the meeting.
- The minutes will document when a member voluntarily withdraws from discussion and decision making due to a Conflict Of Interest (COI).
- The minutes will reflect the agenda of the meeting
- The minutes will include a summary of the discussion of the projects, amendments mentioned in the agenda and the resolutions.
- It will include discussion and due analysis of the SAEs and assessment of compensation to be paid, if any.
- Issues like protocol deviations/ non compliance discussed shall be included.
- The minutes will also include the discussion on the other relevant points which were not included in the agenda.
- The minutes will include a summary of expedited approvals given by the IEC since last IEC meeting.
- The minutes shall include all the important discussions done in the meeting.
- Minutes will be made available to the NABH assessors/ regulatory personnel during inspection of IEC or the site, as & when required.

Appeal on Rejection:

1.If the proposal is rejected by the IEC, the PI may resubmit the proposal for reconsideration after providing the justification of such reconsideration.

2.If major modifications are required in the study documents, the PI may submit a fresh proposal to IEC.

RECORD:

1. Minutes Of Meeting
2. Letters to PI about informing the decisions

PURPOSE:

The purpose of the continuing review is to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants.

SCOPE:

This SOP applies to conduct any continuing review of already approved study protocols at pre-specified intervals. All the long term projects approved by the IEC will be reviewed at least once a year, for renewal of approval. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

RESPONSIBILITY:

It is the responsibility of the IEC Secretariat staff/IEC Co-ordinator to remind the PIs and Member Secretary regarding continued review of protocols at the correct interval.

PROCEDURE:

Periodic review of research studies to whom IEC has accorded approval shall be done for continuation, risk evaluation and adverse event monitoring.

The approval to the research proposal granted by the IEC is subject to annual review and renewal of approval shall be done in the full quorum meeting. Study Progress report needs to be submitted annually for approval for continuation of the study. The project may be submitted for annual review within 3 months of the renewal due date. For the studies, pending renewal of approval, Member Secretary may issue permission for continuation of clinical trial activities for enrolled subjects till the time renewal is granted by the IEC in full quorum IEC meeting. The new subjects not to be enrolled till that time.

For all the studies approved by the IEC, six monthly report on the progress of the study should be submitted to the IEC. The report shall have details of the study i.e. no. of subjects recruited, Serious Adverse Events, protocol deviations/ violations and non-compliance, summary of amendments etc.

RECORD:

1. Minutes Of Meeting
2. Study status report

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) reported to the IEC for any study under the oversight of the Institutional Ethics Committee (IEC).

SCOPE:

This SOP applies to the review of SAE reports (Safety reports/ onsite SAE as well as SAEs of the multicenter studies occurring at other sites offsite) submitted to the IEC.

RESPONSIBILITY:

It is the responsibility of the IEC to review all onsite SAEs reported to the IEC in a timely manner as per the applicable regulatory guidelines.

PROCEDURE:

Review of SAE and Safety Reports:

a. The Investigator / Sponsor is responsible to submit ongoing safety updates, onsite SAEs and outside CIOMS, SUSARs, PSURs to the IEC.
b. In case of onsite Serious Adverse Event (SAE), the initial SAE report should be submitted within 24 hours to the IEC as per the applicable regulatory guidelines.
c. IEC must get the 2nd report after due analysis, from Investigator and sponsor within 14 days/ as per the applicable regulatory guidelines at that time.
d. IEC will discuss the Serious Adverse Event (SAE) to check whether adequate medical care was provided to the subject for that SAE as per rules & regulations.
e. Follow up reports of the SAE, should be forwarded to the IEC within specified timelines as per the regulatory guidelines.
f. Safety reports such as CIOMS/SUSARs etc. should be submitted within 10 calendar days of receipt.
g. On receipt of the onsite SAEs by the Secretariat, it shall be communicated to all IEC members through email.

h. All the onsite SAEs i.e. SAEs in the studies which have received IEC approval, shall be reviewed as per regulations either in the full quorum IEC meeting or by SAE review committee.
i. The SAE review committee shall comprise of the Chairperson, Member Secretary, Clinician/s and Pharmacologist.
j. The committee may additionally have a legal expert member when opinion on compensation needs to be given.
k. IEC/ SAE review committee will assess and analyse the SAE for causal relationship, risk benefit ratio etc. and decide about the compensation to be paid, if any. Causality assessment review shall be done using the causality assessment tools like WHO-UMC scale, Naranjo algorithm causality assessment scale as mentioned in Annexure- IX.
l. SAE review shall be done via mail/ Virtual/ Physical meeting. The documents related to SAE shall be sent via mail to the Committee members. The opinion of these members regarding causality assessment will be obtained via mail. In case of difference of opinions, the Member Secretary in consultation with Chairperson shall arrange the Virtual/ Physical meeting and final decision will be taken regarding causality assessment.
m. The IEC shall send its due analysis report on SAE along with its opinion on causality and financial compensation, if any, within stipulated timelines to the Licensing authority, and it shall also be forwarded to the PI of that study. The IEC shall ensure that due compensation (if any) is paid to the subject as per applicable regulatory guidelines.
n. The SAEs reviewed by the SAE review committee will be presented in subsequent IEC meeting.
o. An honorarium will be paid to the SAE review Committee members for SAEs which will be reviewed in SAE review Committee.

All the documents shall be filed in respective files in the IEC office.

RECORD:

1. Minutes of meeting
2. Ethics Committee correspondence

PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to describe action(s) to be taken by the IEC when investigator(s)/ trial site(s) submits protocol deviations/ violations.

SCOPE:

This SOP applies to all IEC approved research protocols involving human research participants.

RESPONSIBILITY:

The IEC secretariat staff is responsible for receiving protocol deviation/ violation reports submitted by the Principal Investigator (PI) /others, informing Member Secretary and placing it on the agenda of the meeting.

The IEC members should review and take action on such reports.

PROCEDURE:

Definitions of Protocol Deviation and Protocol Violation:

Protocol violation/deviation - Any change, divergence or departure from the study design or research procedures that has not been approved by the IRB. Most protocol violations/deviations are considered noncompliance.

Major protocol deviation - Any change that affects the rights and welfare of subjects and others, increases risks to subjects and others, decreases potential benefits, compromises the integrity or validity of the research, or represents willful or knowing misconduct.

Minor protocol deviation - Any change that did not increase the risk or decrease the benefit or significantly affect the subject's rights, safety or welfare and/or the integrity of research data (for example, a routine lab missed at a visit and redrawn, shortening the duration between a planned study visit etc.)

Protocol Violation- A protocol violation is a deviation from the IEC approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data.

The PI will report the major protocol deviation/violation to the IEC within 7 working days of its occurrence.

PI should also report the minor Protocol deviations, benchmarking will be more than 5 minor protocol deviations in a month, in the said study.
All other minor protocol deviations shall be reported in the six monthly study status report.

All the major protocol deviation/ violation shall be discussed in the next full quorum meeting. IEC members will review the information available and deliberate on it. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded.
IEC shall evaluate the protocol deviations for root cause analysis, corrective & preventive actions (CAPA) to be taken which shall be informed to PI in writing.

Actions taken by the IEC:
The action of the IEC will be based on:

- The nature and seriousness of the deviation/ violation.
- Frequency of deviation/ non-compliance in the study in the past.
- Frequency of deviation/ non-compliance in previous studies conducted by the same PI

The decision taken by IEC may include one or more of the following.

- Determine that no further action is required, or take other actions as appropriate.
- Inform the PI that the IEC has noted the violation/ deviation, and instruct the PI to ensure that deviations/ violations do not occur in future and to follow IEC recommendations.
- Enlist measures & corrective and preventive actions (CAPA) that the PI would undertake to ensure that such deviations/ violations do not occur in future.
- Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC.
- Inform DCGI/ other relevant regulatory authorities if deemed necessary.
- The letter of decision shall be sent to the PI and Department Head(s) (if required on case to case basis) and Institutional Officials (if required on case to case basis).

The copy of the notification letter shall be kept in the respective project file in the Secretariat.

RECORD:

1. Protocol deviations records
2. Minutes of Meeting

PURPOSE:

This Standard Operating Procedure (SOP) describes the process to safeguard the rights, safety and wellbeing of the vulnerable population participating in the Clinical Trials.

SCOPE:

This Standard Operating Procedure describes the steps to be followed to provide additional protection to the vulnerable population and prevent their exploitation.

RESPONSIBILITY:

Although advisable, sometimes participation of the vulnerable population in a clinical trial can not be avoided. All IEC members shall take utmost care while reviewing the projects which involve vulnerable population to safeguard their rights, safety, dignity and well being.

INTRODUCTION:

Vulnerable Population:

Vulnerable Persons are individuals/ belonging to certain groups of persons who are relatively or absolutely incapable of protecting their own interests. Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate (ICH GCP 1.61).

This includes

- Individuals who are minors, prisoners, pregnant, physically handicapped, mentally challenged, old, economically disadvantaged, educationally disadvantaged or subordinates in hierarchical groups (e.g. soldiers, students, jail inmates). (45 CFR 46, Subparts A-D).
- COVID-19 patients may be additionally vulnerable of being stigmatized due to the contagious nature of the disease. Also at risk are health care workers in COVID-19 hospitals including doctors, nurses, ward staff, sanitation workers, security personnel, food suppliers, or others.
- Socially, economically or politically disadvantaged individuals such as the stranded migrant workers who are susceptible to being exploited;
- Incapable of making a voluntary informed decision or whose autonomy is compromised temporarily or permanently;
- Able to give consent, but voluntariness/ understanding compromised due to their situation

- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent
- Terminally ill patients ready to consent in search of new interventions.

Additional Safeguards:

Participants may be under duress and traumatized, therefore, additional safeguards are required for participants and it should be ensured that,

- Research to address the needs of participants and justify inclusion of vulnerable persons.
- Benefits and risks carefully determined and the risk minimization strategies are examined.
- There is no coercion, force, undue influence, threat or misrepresentation or incentives.
- Informed consent process is conducted in a respectful manner.
- Efforts 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.
- Whenever possible, ancillary care may be provided.

PROCEDURE:

IEC shall follow the following procedures while reviewing a proposal involving vulnerable population to protect them.

1. **Procedures for Study on Pregnant or Nursing Women:**

   - As a general rule, pregnant or nursing women should not be participants of any clinical trials except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

   - Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. The same should be mentioned in the Informed Consent Form.

   - For new drugs intended for use during pregnancy, follow up data on the pregnancy, fetus and child should be collected.

2. **Procedures for Study on Pediatric Population:**
   a. IEC shall review the following for studies in pediatric population:

- Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society.
- Interventions that are intended to provide therapeutic benefit should be likely to be at least as advantageous to the individual child participant as any available alternative interventions.
- The risk presented by interventions not intended to benefit the individual child participant should be low when compared to the importance of the knowledge that is to be gained.

b. IEC should have member/s, with pediatric expertise when providing opinion on a study involving children:

- The expert/s may be member of the IEC, or invited to provide advice and consultation.
- Name and expertise of invited experts should be documented and recorded.
- Pediatric experts should be independent of the sponsor, the Investigator and the research proposed. Experts should be available during the review of the initial protocol as well as any subsequent significant changes.

c. The basic framework for review of research proposals by IEC remains the same as for research in adults.

d. As the signature from a subject less than 18 years is not legally valid, for all practical purposes the Informed Consent Form must be signed and dated by the parent.

e. If the child does not have living/ known parents, consent shall be taken from the Legally Acceptable Representative (LAR). In this case special permission from the IEC shall be obtained for this, as IEC allows only parents to sign the ICF.

Age and method of obtaining assent:

Assent is defined as a child's affirmative agreement to participate in research.

In children between 7 to 12 years of age, verbal/ written assent (as applicable) must be obtained in presence of parent/ Legally Acceptable Representative. In children between 13 to 18 years of age, written assent must be obtained. In case of assent of the child, the parent's counter-signature must be obtained.

When a child who was enrolled in research with parental or guardian's permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the subject's participation in the research should be continued after obtaining an Informed Consent from the participant who has become major now, unless the IEC waves off the requirement for obtaining Informed Consent.

3. Procedures for Study on Mentally Challenged and Mentally differently able Persons:

- IEC shall take care that rights and welfare of mentally challenged or mentally differently able persons who are incapable of giving Informed Consent/ Assent or those with behavioral disorders are protected.
- Appropriate proxy consent from the legal guardians should be taken.

4. Other Vulnerable Population:

IEC shall look for the adequate justification for the involvement of participants such as students, subordinates and employees etc. who have reduced autonomy as research participants**.**

For reviewing studies involving vulnerable groups like pregnant women, children, geriatric population, mentally challenged group etc, there should be at least one member from the respective field who may be an IEC member or an invited expert or a member from Scientific Advisory Committee who has given approval for the study. The Scientific Advisory Committee member should be independent of the study team.

RECORD:

1. Assent Form
2. Minutes of Meeting

PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for site monitoring of Institutional Ethics Committees (IEC) approved clinical trials.

SCOPE:

This SOP applies to all IEC approved studies for which a routine or for-cause on-site monitoring may be undertaken by the IEC.

RESPONSIBILITY:

It is the responsibility of all the members and/or Chairperson and Member Secretary to decide to conduct on-site monitoring. It is further the responsibility of the designated IEC member(s) to perform on-site monitoring of selected study site(s).

PROCEDURE:

It is responsibility of the IEC to monitor the sites to which they have accorded approvals for the conduct of the study. Subject's rights, safety and wellbeing shall be monitored. The monitoring committee members may interact with study participants during visits.

- The committee members shall conduct the site monitoring as deemed necessary. The Chairperson shall appoint 1-2 members in the monitoring committee, for conducting the site monitoring visits and it shall be communicated to them in person or via mail.
- The IEC can randomly select studies approved by the IEC, for routine monitoring.
  IEC may conduct 'for-cause' monitoring of the studies in following situations:
  - High number of protocol violations/ deviations
  - Large number of proposals carried out at the study site or by the same researcher
  - Large number of SAE reports
  - High recruitment rate
  - Complaints received from participants
  - Any adverse media report
  - Adverse information received from any other source
  - Non compliance with EC directions
  - Scientific and ethical misconduct
  - Any other cause as decided by the IEC

- Principal Investigator shall be informed about the date and time of the monitoring visit in writing and acknowledgement from PI/ site obtained prior to the monitoring visit.
- During the monitoring, the committee shall look for following (as per the Checklist in Annexure VIII E):
  - It shall ensure equitable selection of subjects, with special attention to vulnerable and high risk subjects.
  - The adequacy of the site, including the supporting staff, available facilities, and emergency procedures.
  - To ensure that subject is recruited in the trial only after written approval from the IEC and the regulatory authority.
  - The recruitment process, Informed consent process for accuracy and appropriateness.
  - Completeness and validity of the documents including Informed Consent Documents/ Forms (ICF) & Audio Visual recording (if applicable).
  - Compliance with the Protocol and GCP guidelines.
  - Adherence with the current rules and regulations.
  - Other activities shall be conducted as felt relevant.
  - Protocol deviations, violations and non compliance are evaluated and appropriate actions taken by PI.
  - To review the measures taken for care, rights, safety, wellbeing and protection of the research participants.

- Review of SAE and compensation to be provided as applicable.
- To review the complaints and concerns of study subjects and the action taken by the investigators to address them.

At the end of the monitoring visit, the committee shall discuss the observations with the PI and the team. The PI will be given opportunity to provide clarifications to the observations. The committee shall prepare and submit the monitoring report to the secretariat and PI within 14 working days. The monitoring report shall include:

- What was reviewed?
- Outcome of the review
- Clarifications already provided by the PI for the observations
- Pending clarifications to be sought from PI
- Overall impression about compliance to regulations, guidelines and protocol etc.
- Areas of improvement and appropriate actions required, if any

- In the next IEC meeting, the findings of the monitoring report shall be discussed in detail.
- The PI may be called for the meeting to seek clarification when the monitoring report is to be discussed.
- Appropriate action shall be decided by the committee, which may include:
  - Continuation of the project with or without changes
  - Recommendation for additional training
  - Recommendation for recruiting additional members in the study team
  - Suspension of the study
  - Opportunities for improvement are identified and appropriate actions are initiated
  - Any other

- The secretariat staff/IEC Co-ordinator will convey the decision to the Principal Investigator (PI) within 14 days of the IEC meeting.
- An honorarium will be paid to the IEC members who will perform the monitoring visit.

RECORD:

1. IEC Correspondence
2. Monitoring visit report
3. Minutes of Meeting

PURPOSE:

To provide guidelines for protection of rights, safety and well-being of study participants especially in clinical trials

SCOPE:

Study participants

RESPONSIBILITY:

- Subject
- Principal Investigator
- IEC

PROCEDURE:

1. **SUBJECT'S RIGHTS**

To be ensured by Investigator:

- To have enough time to decide whether or not to be in the research study, and to make that decision without any undue influence.
- To refuse to be in the study or to stop participating at any time after being in the study. If decided to stop participating in the study, have a right to continued, necessary medical treatment as per existing standard of care.
- To be told what the study is trying to find out, what will happen to participant, what drug/ device will be used in the study, and what will be asked to do if participated in the study.
- To be informed and comprehension (initial and ongoing) of associated foreseeable risks of being in the study.
- To be told about the possible benefits of being in the study.
- To be told whether there are any costs associated with being in the study and whether participant will be compensated for participating in the study.
- To protect confidentiality and privacy of subjects.
- To be told who will have access to information collected and how confidentiality will be protected.
- To be told whom to contact with questions about the research, about research-related injury, and about the rights as a research subject.
- If the study involves treatment or therapy:
  - To be told about the other non-research treatment choices available.

- To be told where treatment is available should you have a research-related injury, and who will pay for treatment of research-related injury

- To receive a copy of the signed consent form.
- Liberty to ask any questions.
- Participation and withdrawal from the study shall be voluntary.
- Risk and benefits or consent draft should be in the local language of patients.
- Compensation provided to subjects for participation in the trial shall be appropriate and as per the rules and regulation and is reflected in contracts.
- Serious adverse events are addressed, adequate medical care provided and an appropriate reporting mechanism is followed.
- Right to voice complaints.

2. RESPONSIBILITIES OF SUBJECT (To be explained to the potential participant/parents):

- Completely read the consent form and ask the Principal Investigator (PI)/ study team member any questions you may have. You should understand what will happen to you during the study before you agree to participate.
- Know the duration of study participation.
- Carefully weigh the possible benefits (if any) and risks of being in the study.
- Talk to the Principal Investigator/ Study Team member, if you want to stop being part of the research study.
- Contact the PI or designee with complaints or concerns about your participation in the study.
- Report to the PI or designee immediately any and all problems you may be having with the study drug/procedure/device.
- Fulfill the responsibilities of participation as described on the consent forms unless you are stopping your participation in the study.
- Ask for the results of the study, if you want them.
- Keep a copy of the consent form for your records.
- Withdrawal from the trial shall be with prior intimation.

3. PROCEDURE TO PROTECT SUBJECT RIGHTS & RESPONSIBILITIES BY ETHICS COMMITTEE:

- Ethics committee members shall understand rights and responsibilities of the trial subjects.

- By verifying the subject.
- By witnessing a consenting process.
- Review the consent process in the written record and the Audio- visual consent.
- To ensure the subjects/ LAR participates and withdraws in the trial without any coercion or influence.
- Shall have process to ensure that subjects are well informed of all the risks and benefits in the clinical trial initially and ongoing basis throughout the trial period.
- IEC shall ensure ICF should include the risks and benefits in local language of subjects only.
- Shall have process to address the breach in confidentiality and privacy.
- Shall not reveal the subject's details to anybody not authorized by the study.
- Safe storage space of all the documents is available and access is restricted to ensure confidentiality and privacy.
- To ensure unique coding number to study subject file for clinical trial.
- To ensure equitable selection of subjects on age, sex, socio economic condition, literate illiterate subjects etc. (unbiased selection of subjects).
- To review periodically subject's selection details.
- Shall have mechanism to ensure that compensation is paid to the subject as per the Informed Consent Document (ICD), contract and applicable rules and regulations.
- Amount paid to subjects needs to be approved by IEC.
- To be aware of the applicable rules and regulations and ensure that investigator is also aware and follow the requirements.
- Should have mechanism to ensure that compensation is paid to the subject as per applicable rules and regulations.
- Should follow mechanism to track for injury to the subjects due to non compliance of protocol.

RECORD:

1. Subject rights and responsibilities charter
2. Informed Consent Form and its process

PURPOSE:

To provide guidelines for dealing with study participants' requests and/or complaints to Institutional Ethics Committee.

SCOPE:

Study Participants
IEC

RESPONSIBILITY

- Secretariat
- Member Secretary
- IEC Chairperson

PROCEDURE:

Detailed instructions

1. Availability of **REQUEST/ COMPLAINT FORMs** shall be displayed prominently at the study site and IEC office. This will be informed to the study participants/ subject's parents.
2. If study participants/ subject's parents have any concern or request they shall be requested to fill the request/complaint form and give it to the site personnel or IEC office. If a site personnel receives the request/ complaint form, it shall be submitted to IEC Secretariat.
3. The Secretariat staff/IEC Co-ordinator will inform the Member secretary/ Chairperson about the request, query or complaint received from the research participant.
4. A request, complaint or query, from a research participant received by the Secretariat staff /IEC Co-ordinator shall be forwarded to the IEC Member Secretary after entering into the request record form.
5. The Member Secretary/ Chairperson may receive a request, complaint or query directly from the participant. It will be recorded in the request record form and notified to the Secretariat.
6. The Member Secretary will additionally ascertain details of the request/ complaint by examining any relevant documents and by interviewing the participant if necessary. If

required, the Member Secretary will call for additional relevant information and documents from the Principal Investigator (PI).

7. In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairperson will provide the information himself / herself or will designate one or more IEC member(s) to provide such information.

8. In case of a complaint received from a research participant:

a. 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 subcommittee of two or more IEC members for enquiry in order to resolve the matter.
- Call an emergency meeting of two or more IEC members for discussion or
- Consider the matter for discussion at the next full quorum meeting

b. The Chairperson/ Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.

c. The IEC shall insist on factual details to determine gap, if any, between truth and individual perception.

9. The final decision will be taken by the Member Secretary in consultation with the Chairperson based on the recommendation of any one of the above and it will be informed to the research participant and the PI by the Secretariat.

10. The information including any action taken or follow-up and final decision will be recorded in the form and the form is signed and dated.

11. The IEC members will be informed about the action taken and the outcomes, in the forthcoming IEC meeting (in case of requests/ complaints not discussed in full board meeting) and documented in minutes of meeting.

12. The Secretariat staff/ IEC Co-ordinator will place all documents in the relevant study file.

Roles and Responsibility for handling study participants' requests / complaints

Sr. No.	Activity	Responsibility
1.	Receiving the request/ query/complaint from research participant	IEC Member Secretary/ Secretariat staff/ IEC Co-ordinator
2.	Initiating process to identify the problem	IEC Chairperson/ Member Secretary
3.	Deliberations to arrive at solution	IEC Chairperson/ Member Secretary/ Members
4.	Communication with the research participant	IEC Secretariat staff/ IEC Co-ordinator
5.	File the request document	IEC Secretariat staff/ IEC Co-ordinator

REQUEST/COMPLAINT FORM

Request / Complaint Form	
Received by :	**Date:**
Request/ Complaint received through:	1. Telephone No: 2. Letter date: 3. Email date: 4. Walk in /Date/Time: 5. Other specify:
Participant's Name:	
Contact details **Address & Phone:**	
IEC Project no.	
Title of Project:	
Starting date of participation:	
Information requested/complaints/query:	
Action Taken:	
Reviewed by:	
Final Decision:	
Date of IEC meeting (if applicable):	
Name and Sign of Member Secretary: **Date:**	

RECORD:

1. Request/ Complaint form

PURPOSE:
To decide strategies for self assessment

SCOPE:
The SOP applies to all the IEC members and the secretariat.

RESPONSIBILITY:
It is the responsibility of the Member Secretary, Chairperson, IEC Members and the IEC secretariat staff/IEC Co-ordinator to keep IEC documents ready for Assessment and to be available to answer questions during Assessment or inspection by administrative and regulatory authorities.

PROCEDURE:

OBJECTIVES OF SELF ASSESMENT (INTERNAL ASSESMENT) –

1. To evaluate the appropriateness of its composition.
2. Attendance of members is reviewed.
3. Review whether there are adequate resources for Ethics Committee functioning
4. No. of protocols reviewed

TOOL USED: NABH Self Assessment Tool kit of IEC accreditation, Checklist for Self-Assessment of IEC (Annexure VIII D), Checklist for Self-Assessment of IEC members, [Separate checklist for Chairperson (Annexure VIII F), Member Secretary (Annexure VIII G) and IEC members (Annexure VIII H)]

FREQUENCY OF SELF ASSESSMENT – Bi annually

PROCEDURE:

1. Member Secretary and Chairperson shall be responsible for planning and organizing Internal Assessments.
2. Those who have attended Programme of Implementation on IEC NABH Accreditation can assist in Self Assessment.
3. The Assessments shall be scheduled based on Annual Assessment Plan.

4. Assessments shall be scheduled and executed as per a plan with built in flexibility for rescheduling in case of exigencies.
5. The internal Assessments shall be done by identified staff and multidisciplinary committee who is trained internally/externally in IEC policies and SOPs. OR who has attended Programme of Implementation, of NABH i.e. Internal Assessors training programme.
6. Assessor will assess IEC records independently.
7. Internal Assessment check lists shall be prepared based on applicable standard and particular objective elements as per self assessment tool kit.
8. Assessors brief the Assessed on the area being Assessed.
9. Assessor studies the recommendation made in the past and assess the current operations to ensure the elimination of non-conformity brought out by the previous Assessment.
10. During the Assessment, Assessor seeks the following:
    a. Determine whether procedures, manual and instructions meet the requirements of the Standard.
    b. Verify whether procedures and instructions are being implemented.
    c. Examine the data and records to ensure for compliance with specified procedure.
    d. To ensure the understanding of procedures and instructions and follow-up.
    e. IEC members training shall be checked.
    f. The Assessors shall ensure all points are covered as per internal Assessment checklist and details of all observations are recorded in check list.
11. All the instances of compliance and non compliance shall be recorded in the Assessment report.
12. The report shall contain the summary of findings and observations and overall conclusion on the effectiveness of the quality system.
13. At the end of Assessments, formal meeting shall be conducted to summarize the findings and corrective action and preventive action measures to be taken are documented.
14. On completion of the Assessment, the findings shall be reviewed and clarifications are obtained.
15. IEC Committee should do root cause analysis to identify if there is a process failure or a system failure.
16. Evidence of Non-Conformity and concurrence of the Assessment is recorded in the NC Report, CAPA (Corrective & Preventive actions) for closing the observed non conformity

and also the corrections, corrective actions recommended are recorded by the Assessment in the non conformity report along with the target date and sent to IEC secretariat.

17. Internal Assessment Summary Report shall be prepared. The summary highlights the reasons for recurrence of non compliance, frequent non conforming areas, activities and recommended corrective action.

18. Internal Assessment Summary Reports will be reviewed in the next IEC meeting.

19. The effectiveness of CAPA is verified and discussed in the Meeting.

20. Indicators for Performance of IEC: % of Research activities approved by IEC

21. Attendance by the IEC members

22. Average duration from submission to approval of the project

23. Number of projects discussed and reviewed since last assessment

RECORD:

1. The Member Secretary/ designated IEC member/ secretariat staff /IEC Co-ordinator must keep record of the assessment/inspection visit reports and action plans in a separate Assessment/inspection file.

2. The completed checklist and findings from the internal follow-up Assessment (if applicable) must also be maintained in the internal Assessment file.

3. Self-Assessment forms of IEC members (Chairperson, Member Secretary and IEC members)

PURPOSE:

The purpose of this SOP is to describe requirements and methodology for training and performance assessment of the Institutional Ethics Committee (IEC) members and the secretariat staff.

SCOPE:

The SOP applies to all the IEC members and the secretariat staff.

RESPONSIBILITY:

It is the responsibility of the IEC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the IEC members and the secretariat staff.

PROCEDURE:

The IEC members shall be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted or professional body (ies), so that they become aware of their role and responsibilities.

All new IEC members shall be trained on the Standard Operating Procedures of the Ethics Committee.

These members will be given training by Member Secretary or a copy of SOP will be given for self training.

A copy of New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E), ICMR Guidelines on Biomedical Research on Human Participants, ICH - Good Clinical Practices (GCP), Indian GCP, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, Medical Devices Rules 2017 and its amendments, and Ethical guidelines for application of Artificial Intelligence in Biomedical Research and Healthcare will be given for self training.

Record of the SOP training will be maintained in the secretariat office of the IEC.

For drug trial review, it is preferable that all the IEC members are trained in Good Clinical Practice, every yearly. Any change in the regulatory requirements shall be brought to their attention.

They should be aware of local, social and cultural norms, as this is the most important social control mechanism.

IEC may organize Clinical Research and Ethics related training programs for the IEC members or for the faculty or students of the constituent units of Bharati Vidyapeeth Deemed University or may provide financial assistance for conduct of such programs.

IEC may provide financial assistance to the IEC members or other faculty of the constituent units of BVDU who would take such training from a professional body (ies).

IEC members should have knowledge of the following:

1. Relevant research ethics and regulatory guidelines
2. Roles and Responsibilities of IEC members
3. Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy
4. Recent Developments in relevant health science specialties
5. SOPs of the IEC

Secretariat staff/IEC Co-ordinator should have knowledge and relevant skills for conducting the following activities:

1. Competency in working on Microsoft word, Excel, IEC office software
2. Maintenance of IEC Database
3. Communication skills- written and verbal
4. Knowledge about the SOPs

Training of new IEC Members

1. Member Secretary will provide training on IEC SOPs to the new member. The new IEC members would be encouraged to undergo online EC training programme and GCP training.

2. The IEC Member Secretary, members, Chairperson will be encouraged to receive continued training by participating in workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc.

3. The IEC may conduct workshops on ethics in clinical research and Good Clinical Practice from time to time to impart training to the IEC Members and to the Institutional faculty members.

4. The IEC may sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program (if applicable).

Training of the Secretariat staff/IEC Co-ordinator

The IEC Member Secretary along with other members will train the secretariat staff/IEC Co-ordinator on 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.

RECORD:

Maintenance of training records of the IEC Members and the Administrative Staff

The secretariat staff/IEC Co-ordinator shall maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual IEC members.

Training attendance sheet shall be maintained as a record.

PURPOSE:

To provide guidelines for communication process with all stake holders.

SCOPE:

- Principal Investigator
- Ethics Committee
- Institution head
- Regulatory authority
- IEC Secretariat
- Study participants

RESPONSIBILITY:

- Ethics Committee Secretariat staff/IEC Co-ordinator and Member Secretary/Chairperson

PPROCEDURE:

1. IEC shall have a process for communication with the Principal Investigator, the Institution, and the Regulatory Authority.
2. Communication with PI is important for resolving issues or bringing to notice any non compliance.
3. If there is any change in the PI, it should be approved by the IEC and notified to the DCGI.
4. All such communications needs to be done in writing/via email.
5. Correspondence of communication and supportive documents needs to be maintained by the secretariat staff/EC coordinator.

Member secretary/Chairperson shall sign all the written IEC communications/correspondence and it shall be sent to the respective stakeholders and to all concerned members of committee.

a. Correspondences between the IEC and the PI /study team and other relevant records will be retained for a minimum period of five years after completion / termination of the study or last communication from the PI about study status.

b. Correspondences between the IEC and the regulatory bodies will be retained for a minimum period of five years after completion / termination of the study or the last communication from the PI about study status.

Ethics Committee procedures for communication with Stakeholders:-

I. To & from the Principal Investigator:

1. Investigator submits study protocol and other applicable documents for review and approval which is reviewed for its completeness and if any critical item is missing, the Member Secretary shall inform the PI and request for it in writing. If it is done on phone, fax or e-mail, the same shall be documented.

2. Invitation letters to the PI for attending the IEC meeting are sent by mail
   The following documents submitted by PI shall be reviewed and discussed in the full quorum meeting:
   a. New study proposal
   b. Amendment in protocol and relevant documents for approval [Investigator Brochure, Protocol, Participant Information Sheet with Informed Consent Form (PIS with ICF) etc.]
   c. Any protocol deviation/violation, SAE reports, adverse events, safety reports etc.
   d. Periodic study status reports and final study report at end of study

3. PI shall also inform regarding:
   - Change in PI
   - Renewal of the Insurance Policy
   - Clinical Trial Agreement and its addendum
   - Any other

4. Decisions regarding the research proposal shall be communicated to the PI in writing within 10 working days after the meeting. PI shall recruit subjects only after receipt of written approval from IEC, Regulatory Authority and the clinical trial is registered in www.ctri.nic.in.

5. PI shall be informed of the date and time for site monitoring visits. The committee shall submit the monitoring report to the secretariat and PI within 14 working days. In the next IEC meeting, the findings of the monitoring will be discussed in detail. The secretariat

staff/IEC Co-ordinator will convey the decision to the Principal Investigator (PI) within 14 days of the meeting.

II. Communication with the study participants:

a. In case of any complaint received from a research participant, it shall be thoroughly assessed and the final decision will be taken by the Member Secretary in consultation with the Chairperson and it will be informed to the research participant and the PI by the Secretariat staff/EC coordinator.
b. During site monitoring visit, the committee members may interact with the study participants for assessment of subject safety and wellbeing.

III. Communication with Regulatory authorities:

a. Member list shall be sent as and when updated along with the new member's CV and other relevant documents, as per the current guidelines
b. Communication for Registration and re-registration with DCGI
c. SAE/Related AEs review, opinion on causality assessment and compensation shall be sent within timelines stated in prevalent regulatory guidelines
d. For any other issues
e. Copy of DCGI communication shall be sent to PI as applicable to the respective study and shall be maintained in the respective study file.

IV. Communication with the Institution/University Authorities shall be done for:

a. IEC office facilities, personnel as and when required
b. Appointment of new members
c. For IEC finance audits
d. Any other

RECORD:

1. Written communications/correspondence with stakeholders
2. Site monitoring report

PURPOSE:

To provide guidelines for administrative support to IEC and maintenance of financial records

SCOPE:

Institutional Ethics Committee - IEC

RESPONSIBILITY:

- Institutional management
- Member Secretary

PROCEDURE:

1. IEC Secretariat shall be set up which will assist in executing functions of the IEC.
2. Adequate financial support, material resource allocation and manpower i.e. secretariat staff/ IEC Co-ordinator for administrative work and record keeping shall be ensured, with due care and confidentiality.
3. Dedicated Member Secretary should be appointed for smooth functioning of committee.
4. The administrative staff will be provided by the Institution and shall work under guidance of Member secretary /Chairperson.
5. IEC Co-ordinator shall be appointed for the administrative activities of the IEC secretariat.
6. Additional staff may be appointed and duties assigned; as and when deemed necessary by the IEC.
7. Details of compensation/expenses done for IEC needs to be kept separately for record.
8. There shall be financial transparency of Ethics Committee activities and functioning.

Following financial Declarations record needs to be kept:

- Details of Ethics committee fees for their services
- Honorarium payment to each of the members
- Other expenses incurred
- Annual financial audit reports

Duties of IEC Secretariat staff/ IEC Co-ordinator:

- Correspondence with IEC members and external experts
- Correspondence with the investigators
- Preparing agenda and minutes of the IEC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving, maintaining, retrieval and destruction the study files, SOPs, all correspondences
- Maintaining electronic database of the IEC records
- Any other

RECORD:

- Financial record including Annual financial audit reports
- Secretariat office files

PURPOSE:

To provide instructions for archival, maintenance, retrieval and destruction of study files and other related documents approved by the Institutional Ethics Committee (IEC), IEC administrative documents.

SCOPE:

This SOP applies to maintenance, archival, retrieval, destruction of all study files, study related documents, IEC correspondence and administrative documents by the IEC secretariat.

RESPONSIBILITY:

It is the responsibility of Member Secretary with assistance of secretariat staff /IEC Co-ordinator to ensure that all study files, other related documents approved by the Institutional Ethics Committee (IEC), IEC correspondence, administrative documents are kept securely for a period, as per the applicable rules and regulations after the closure/ termination of the project.

PROCEDURE:

All the study documents and communications of IEC shall be labeled, filed and archived in a secure place. Security, confidentiality, integrity of all the proposals and associated documents archived shall be maintained and reviewed from time to time. Only persons, who are authorized by the IEC Chairperson/ Member Secretary, will have access to these documents. Register for archival, retrieval & destruction of the documents shall be maintained at the secretariat office.

The Member Secretary/Secretariat staff/IEC Co-ordinator will supervise the day-to-day activities and will maintain the correspondence pertaining to the IEC. All the documentation shall be dated, filed and archived. The office will maintain all the records pertaining to the functioning of the IEC such as:

a. The current list of the IEC members, their CVs, consent documents, Confidentiality Agreement, Declaration of the Conflict of Interest, GCP and other relevant training certificates etc.

b. The current version of the SOP.

c. The agenda and minutes of the IEC meetings.

d. Reference documents which are regularly required by the IEC for its deliberations- Declarations of Helsinki, New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E), ICMR Bioethical Guidelines on Human Participants, GCP guidelines etc.

e. Correspondence between the IEC and the PI /study team and other relevant records will be retained for a minimum period of five years after completion / termination of the study or no communication from the PI for three consecutive years about study status.

f. Correspondence between the IEC and the regulatory authorities will be retained for a minimum period as per the applicable rules and regulations or no communication from the PI for three consecutive years about study status.

The study-specific identified essential documents after completion of the study will be archived after completion / termination of the study for minimum period as per regulatory guidelines.

The documents shall be filed study wise, labeled and shall be archived in the cupboards in the archival room, which shall be provided with Lock and Key security. The keys shall be under the custody of IEC office. The records and documents shall be stored in such a way that they can be retrieved easily.

The cupboards and area for storing essential documents shall be maintained properly. Precautions shall be taken, so that the documents are not damaged by pest/ insects/ rodents or any other means, as per the hospital policy.
The retrieval of documents shall be done as and when required, e.g. for Audit and Inspection, with prior permission in writing and it shall be documented.

The copies of the study documents returned by the IEC members will be destroyed by shredding periodically.
After retention period of archived documents is over, the pages shall be torn (so as to maintain confidentiality of the documents) and then shredded in the hospital shredding machine. This shall be documented in the log book and the 'Destruction Certificate' shall be generated. The 'Destruction Certificate' shall be kept in the file maintained at the IEC Office. The torn pages may be given to an external agency for shredding and the same will be documented.
If the archived documents are given to third party for destruction then signed confidentiality agreement would be obtained.
A formal 'log for disposal' shall be maintained, providing details of documents that are disposed.

RECORD:
Corresponding files

PURPOSE:

To describe how the IEC will function and conduct review in an emergency situation with restrictions as imposed by social distancing requirements during the COVID-19 outbreak or similar situations.

SCOPE:

This SOP applies to the initial review and assessment of all research study protocols submitted for IEC review and approval, in emergency situations like pandemics, disease outbreaks or disasters, lock-down etc.

RESPONSIBILITY:

It is the responsibility of Member Secretary with assistance of secretariat staff to categorize research into full review, expedited review or exemption from review. Member Secretary in consultation with Chairperson will identify need for review by subject experts, special invitees, patient representatives, others for prior review or to present views during the meeting.
Review of new study proposal is responsibility of all the members present for the meeting.

GENERAL ETHICAL ISSUES:

Public health and socio behavioral research:

- Health system preparedness is critical to control spread of COVID-19 and focused research and public health interventions are needed to prevent, delay, or contain the spread.
- Isolation, quarantine, segregation from families during the COVID-19 disaster has given a new dimension to risk to individual dignity, psychological/ emotional harm, social harm, informational risk.
- Emergency circumstances have rendered participants vulnerable to be coerced to participate. They may not have access to formal or informal support during these times e.g. families, counselling centers, rehabilitation centers, police protection, etc.
  The social distancing norms may not facilitate conventional methods of data collection and alternative study designs may be required such as online or remote methods to conduct interviews, focus groups, surveys or questionnaires. Social media research using data in public domain may still be evaluated for potential privacy threats.
- Stakeholders are to consider the fact that technological requirements of the study design may exclude participants without access to the technology.

- 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.
- Collection of identifying information, GPS location, IP address tracking, etc. should be reviewed by EC on case-case basis.

PROCEDURE:

- IEC to ensure a thorough scientific and ethical review of research as per national guidelines and regulations to safeguard the dignity, rights, safety and well-being of research participants.
- Research during emergencies can be reviewed through expedited review/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.
- The Research Proposal should be submitted as hard copy or e-copy according to IEC requirement. Once received, the secretariat staff/IEC Co-ordinator will verify protocol for completeness (if not ask PI) and number.
- Member Secretary to categorise research into full review, expedited review or exemption from review.
- Member Secretary (in consultation with Chairperson) will identify need for review by subject experts, independent consultants, special invitees, patient representatives, others for prior review or to present views during the meeting.
- The documents of the meeting will be circulated via mail to all IEC members, minimum 5 days prior to the proposed meeting date.
- In rare situations, the projects of extreme importance or need to be taken up at the earliest can be reviewed after 48 hrs.
- In exceptional and emergency situations, preliminary research procedures including but not restricted to data/ biological sample collection that are likely to rapidly deteriorate or perish may be allowed while the ethics review process is still underway.
- A subcommittee may be appointed by the Chairperson for expedited and exempted studies. This subcommittee shall submit its report to the Chairperson who would take the final decision.
- All proposals considered for exemption and expedited approval shall be presented in subsequent full IEC meeting for ratifying the decision

- The project for full review will be included in agenda of virtual full-committee meeting to be scheduled by the Member Secretary in consultation with the Chairperson.
- Measures such as virtual or tele/web conferences should preferably be attempted and face-to-face meetings can be avoided to observe social distancing norms. A suitable virtual software platform, preferably a video conference to enable face to face discussion or teleconference if connectivity is an issue shall be used.
- The members will be briefed about the technological requirements and virtual platform used for the conduct of the meeting.
- Quorum requirements for review will be applicable as per Section 4.8.4 ICMR National Ethical Guidelines, 2017
- Review procedures as per ICMR National Ethical Guidelines will also hold good for the virtual web ethics meeting.
- Available protocol templates could be reviewed to expedite the process and interim review/ re-review can be done if the emergency situation changes.

- During the review process, the Ethics Committees shall consider the following:
  - ❖ If written consent is not possible (e.g., physical isolation/severe COVID-19 patients), consent could be given orally/ use electronic methods to document and record.
  - ❖ Due to inability of the participant to attend the site (for e.g., social distancing), the contact/communication can be made via phone, 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 (PI) 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.

- Decisions regarding a project discussed shall be taken by consensus of the EC members present during the meeting. Any disagreement to be recorded with reasons.
- The project proposal shall be rejected, when the consensus is not reached and PI shall be advised to re-submit the project with recommended modifications.
- Quorum for decision-making should have a minimum of five members, including both medical/ non-medical or technical/non-technical members with one non-affiliated member.
- Meeting could be digitally recorded (audio/video) with permission of members and secretariat staff/EC coordinator is responsible to note the attendance/ participation in the online meeting.

- The decision regarding the projects discussed during the meeting shall be communicated to respective PI within 7 days.

Decisions Regarding Ongoing Studies:

- The impact of COVID-19 on ongoing and existing studies, ongoing recruitment and continued involvement of participants needs to be considered.
- Secretariat in consultation with Chairperson, must carefully evaluate need for other non COVID-19 research studies that are ongoing/ near term/ have direct benefit(s) and if stopped, may pose risk to participants. These may be continued/suggest mechanisms for continuation.
- Following measures can be taken in consideration such as, extension of study duration; temporary halt of study at some/all sites; Suspension/ Postponement of study or activation of sites that have not yet been initiated without compromising safety and well-being of patients; Continuation of study with limited parameters; conversion of physical visits into phone or video visits, postponement or complete cancellation of visits to ensure that only strictly necessary visits are performed at sites; ongoing study may need to take re-consent of already enrolled participants to implement urgent changes; it can be done via phone or video-calls and obtaining oral consents supplemented with email confirmation.
- Further, travel restrictions, confinement of study participants and staff to perform visits should be taken into account.

Electronic Consent:

- In light of COVID-19 infection control measures, the alternative procedures to avoid direct interaction with the patient in isolation must be explored.
- Technology should be utilized to prepare interactive formats and using electronic tools such as text, graphics, audio, video, podcasts, interactive website, platforms to explain information related to a study and to electronically document informed assent/consent the same.
- Electronic methods (e.g. digital signature) must be reviewed and approved by the EC a priori.
- Process can be documented through audio or video recording (if required).

Waiver of Consent:

For seeking waiver of consent, the researchers should give the rationale justifying the waiver which EC can approve a waiver after careful discussion in the following situations:

- Research cannot practically be carried out without the waiver and the waiver is scientifically justified like, cluster randomization trials.
- Retrospective studies, where the participants are de-identified or cannot be contacted
- Research on anonymized biological samples/data
- Certain types of public health studies/ surveillance programs/ program evaluation studies
- Research on data available in the public domain; or
- Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent.
- When consent of the participant/ LAR/ assent is not possible due to the emergency situation, informed consent can be administered at a later stage, when the situation allows for it, and if it is so envisaged, prior permission must be obtained from the EC.

Safety of Health Care Workers (HCW) involved in research:

- In wake of the pandemic, safety of researchers must get due attention as transmission of infection to one member in a lab or clinical setting could jeopardize the entire program.
- Ensuring safety is the responsibility of the institution, sponsors and local authorities, since research team may be subjected to disturbing instances (trauma, humiliation and threats of violence) while conducting research.
- IEC shall recommend research team to follow COVID appropriate behavior. Additional precautions such as; Prioritize research and schedules to prevent overcrowding, adequate training, appropriate biosafety precautions, expose minimum number of researchers, communication using electronic platforms, due protection gear/PPE and facilities to undertake research, safety against any assault from public or others, insurance cover etc.
- 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.

EC shall encourage the researchers and sponsors regarding post-research access of the community to successful interventions and benefit sharing if relevant.

RECORD:

- Minutes of Meeting
- Recording of minutes of meeting

SR. NO.	TITLE
I	Format For Institutional Ethics Committee Member List
II	Confidentiality Agreement
III	Agreement for declaration of Conflict of Interest
IV	List of documents to be submitted for IEC review and approval
V	Undertaking by the Investigator
VI	Format for according approval to clinical trial protocol by the Ethics Committee
VII	Serious Adverse Event reporting
VIII	Checklists A. Proposal Evaluation Form for Initial Review (Esp. For Clinical Trials, Checklist) A.1. Checklist For Risk Benefit Analysis A.2. Checklist For Legal Expert (Clinical Trial Agreement) A.3. Checklist For Vulnerable Population B. Checklist for Review of Informed Consent Document/ Assent Form C. Checklist for Review of Amended Study Documents D. Self-Assessment of IEC E. Site Monitoring by IEC F. Self-Assessment of Chairperson G. Self-Assessment of Member Secretary H. Self-Assessment of IEC Member I. Feedback Form - English
IX	Causality Assessment Tool (Table 1, 2 & 3)

Annexure I

Format for Institutional Ethics Committee Member list:

Sr. No.	Name	Qualification	Affiliation	Role in the IEC	External/Internal

Annexure II

Date:

To,

The Member
Institutional Ethics Committee
Bharati Vidyapeeth Deemed University

CONFIDENTIALITY AGREEMENT

The Institutional Ethics Committee (IEC), Bharati Vidyapeeth Deemed University is honoured to have you as a member of the Committee.

The IEC receives from investigators, clinical research documents for review and approval. As an esteemed member of the IEC, these documents will be shared with you. The documents and the discussions that occur during the meetings are highly confidential. You are requested to comply with this code of confidence of the IEC.

If you agree to the foregoing, kindly indicate your acceptance thereof by signing this document.

Yours sincerely,

Member Secretary/Chairperson
Institutional Ethics Committee, BVDU

Agreed and accepted

Name: _____

Signature: _____

Date: _____

Annexure III

Date:

To,
The Member
Institutional Ethics Committee
Bharati Vidyapeeth Deemed University

Agreement for declaration of Conflict of Interest

The Institutional Ethics Committee (IEC), Bharati Vidyapeeth Deemed University is honoured to have you as a member of the Committee.
The IEC receives from investigators, clinical research documents for review and approval. The professional judgement concerning a primary interest like participant's welfare or the validity of 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 (COI).
You are requested to declare the conflict of interest if any in the projects submitted to you for review. This conflict of interest shall be declared in writing to the chairman of the IEC before the review of the project. You are requested to comply with this code of Conflict of Interest of the IEC.
If you agree to the foregoing, kindly indicate your acceptance thereof by signing this document. A copy of the same will be given to you for your records.

Yours sincerely,

Member Secretary/Chairperson
Institutional Ethics Committee, BVDU

Agreed and accepted

Name: _____

Signature: _____

Date: _____

Annexure IV

CRPU No.:

The list of documents to be submitted for IEC review and approval is as follows:

Checklist for initial submission of IEC documents:

Sr. No.	Documents	Yes	No	Remark
1	Approval letter from the Scientific Review Committee, BVDUMC			
2	A covering letter addressed to the Chairperson			
3	Protocol or Study Plan a) Synopsis b) Full version			
4	Case Report Form (CRF)			
5	Patient Information Sheet and Informed consent form in English and vernacular language. • including updates, if any • back translations, if any • translation certificates, if applicable			
6	Investigators Brochure (IB), if applicable			
7	Proposed methods for patient accrual including copies advertisement (s) etc. proposed to be used for the purpose.			
8	Permission from competent Regulatory Authority, if applicable. • Drug Controller General of India (DCGI) submission/ approval for new drug (Rule 122E of Drugs and Cosmetics Rule) • National Bioethics Committee under Department of Biotechnology (DBT) clearance for genetic studies • Concerned competent authorities for medical devices • If it is not considered a new drug / the drug already			

	existing in the market, then the PI should give a written statement saying the same to the IEC with some proof.			
9	CV of the Principal Investigator (PI)			
10	Details of the research grant to support the project/ Investigator's Agreement with the Sponsor (Clinical Trials Agreement - Draft/Executive)			
11	Insurance Policy for the clinical trials			
12	Investigator's undertaking			
13	Strategy for enrollment of Clinical Trial Participant			
14	CTRI no.			
15	Funds to be received in INR or other currency			

Documents should be submitted both in hard and soft copy.

Signature of IEC Secretariat staff/ Member Secretary:

Annexure V

Undertaking by the Investigator

1. Full name, address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications).

3.Name and address of all clinical laboratory facilities to be used in the study.

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

7.Commitments:

i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.

ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

iii. I agree to personally conduct or supervise the clinical trial at my site.

iv. I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, Ethics Committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

x. I agree to inform all serious adverse events to the Central Licensing Authority, Sponsor as well as the Ethics Committee within 24 hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event.

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the Ethics Committee and the Head of the institution where the trial has been conducted within 14 days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of Investigator with Date:

Annexure VI

Format for according approval to clinical trial protocol by the Ethics Committee

To,

Dr.

Dear Dr._____

The Institutional Ethics Committee / Independent Ethics Committee (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled "..." on..... (Date).

The following documents were reviewed:

a. Trial Protocol (including protocol amendments), dated_____ Version no. (s) _____
b. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/ or vernacular language.
c. Investigator's Brochure, dated _____ Version No. _____
d. Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.
e. Principal Investigator's current Curriculum Vitae.
f. Insurance Policy or Compensation for participation and for serious adverse events occurring during the study participation.
g. Investigator's Agreement with the Sponsor.
h. Investigator's Undertaking (Table 4 of Third Schedule).

The following members of the Ethics Committee were present at the meeting held on (date, time, and place)

_____ Chairperson of the Ethics Committee
_____ Member Secretary of the Ethics Committee
_____ Name of each member with designation

We approve the trial to be conducted in its presented form.

The IEC to be informed about enrollment of the first study participant in the said clinical trial.

IEC expects to be informed about the progress of the study, any Serious Adverse Event (SAE) occurring in the course of the study, any changes in the protocol and patient information / informed consent, deviations, any new information that may affect adversely the safety of subjects or conduct of the study and asks to provide a copy of the final report.

Kindly submit a report on the progress of the study every six months. Annual study status report needs to be submitted for approval for continuation of the study.

Yours sincerely,

Member Secretary/ Chairperson
Institutional Ethics Committee

Annexure VII

Serious Adverse Event Reporting

AS PER CURRENT REGULATORY GUIDELINES.

Annexure VIII (Checklists)

A. PROPOSAL EVALUATION FORM FOR INITIAL REVIEW (ESP. FOR CLINICAL TRIALS, CHECKLIST)

IEC meeting details: **Date:**

Study Title: **Version & Date :**	**PI Name :**

Declaration of Conflict Of Interest (COI)	
Name of Member	**Reason**

Sr. No.	**Points to be Checked**	**Acceptable Yes/No**	**Remark**
A	**All the following essential documents submitted by PI are reviewed**		
1	Approval letter from the Scientific Review Committee, BVDUMC		
2	A covering letter addressed to the Chairperson		
3	Protocol or Study Plan – • Synopsis • Full version		
4	Case Report Form (CRF)		
5	Patient Information Sheet and Informed consent form in English and vernacular language. • including updates, if any • back translations, if any • translation certificates, if applicable		

6	Investigator's Brochure (IB), if applicable		
7	Proposed methods for patient accrual including copies advertisement (s) etc. proposed to be used for the purpose		
8	Permission from competent Regulatory Authority, if applicable. • Drug Controller General of India (DCGI) approval for new drug (Rule 122E of Drugs and Cosmetics Rule) • National Bioethics Committee under Department of Biotechnology (DBT) clearance for genetic studies • Concerned competent authorities for medical devices		
9	CV of the Principal Investigator (PI)		
10	Details of the research grant to support the project/ Investigator's Agreement with the Sponsor (Clinical Trials Agreement - Draft/Executive) (Separate Checklist)		
11	Insurance Policy for the clinical trials		
12	Investigator's undertaking		
B	**Scientific validity of protocol is checked**		
1	Study title		
2	Objectives & end points		
3	Study Rationale		
4	Study design & methodology		
5	Recruitment strategies		
6	IP management		
7	Statistical analysis		
C	**Subject diary card in English& its translations**		
D	**Risk & Benefits of the proposed study** (Separate Checklist)		
E	**Site feasibility**		

F	**Compensation & reimbursement to study participants**		
G	**Funds to be received in INR or other currency**		

Role in IEC	**Points specifically checked as per checklist**
Chairperson	
Member Secretary	
Clinician	
Medical Scientist	
Legal Expert	
Social Scientist	
Lay Person	

The list of IEC members:

S.N.	**Name**	**Role in the IEC**	**Signature & Date**

A. 1. CHECKLIST FOR RISK BENEFIT ANALYSIS

IEC meeting details: **Date:**

Study Title: **Version & Date :**	**PI Name :** **Sponsor/CRO**

Declaration of Conflict Of Interest (COI)	
Name of Member	**Reason**

Potential therapeutic risks				
	Minimal	Acceptable	Unacceptable	NA/Comment
What may be the risks to the participants Physical/ Social/ Psychological/ Discomfort				
Harm due to study product/ device/ procedure				
Risks related to the usage of Investigational products as compared to standard treatment/ Placebo				
Expected adverse reactions				
Risk and consequences of dose miscalculation				
Risk and consequences of missed dose				
Risk and consequences of overdose				

Risk and consequences of drug allergy				
Risk from study procedure (drug administration, diagnostic and other procedures)				
Risks associated with use of placebo				
Risks associated with non use of prohibited medications				
Incidence of safety incidents (SUSAR/CIOMS reports)				
Risk of non-compliance by participant				
Risk to privacy and confidentiality of the participant				
Risk of financial loss				
Risk associated with personal restriction				

Potential Benefits				
	Yes	No	NA	
Individual				
Societal				
Contributes to further knowledge				
Any other				
Availability of insurance in case of injury during participation				
Category of Risk Benefit Assessment: A /B /C /D				

Comments/Queries/ Opinions:

The benefits resulting from the usage of the investigational product outweigh the risk posed.

Yes ☐ No ☐

The name and signature of Clinician and Medical Scientist of IEC BVDU:

S.N.	Name	Signature & Date

GUIDELINE FOR RISK BENEFIT ASSESSMENT CATEGORY

Class A – High Risk/ Low Benefit	
Risks: • Completely new drug/ formulation • Highly Toxic substances • Safety/Effectiveness not established through earlier studies • High incidence of SAEs/ side effects in Prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large number of participants • Violation legal/ statutory regulations • Inadequate project documentation • Inadequate PI/ Staff expertise • New/ untried procedures	**Benefits: C** • Cost of treatment/ Drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No port-trial alternatives
Class B – High Risk/ High Benefit	

Risks: • Completely new drug/ formulation • Highly Toxic substances • Safety/Effectiveness not established through earlier studies • High incidence of SAEs/ side effects in Prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large number of participants • Violation legal/ statutory regulations • Inadequate project documentation • Inadequate PI/ Staff expertise • New/ untried procedures	**Benefits:** • Completely new cure • Preventive for life i.e. Vaccinations • Significant improvement over Existing cures/ treatment • Minimal side effects vis-à-vis existing treatments • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs/ mode (ex. Pill vs surgery) • Extension of benefits/ availability treatment post trial • Benefits large no. of participants
Class C – Low Risk/ High Benefit	
Risks: • Proven/ Acceptable toxicity • Proven safety and efficacy • Drug/ formulation a variation of approved drug/ class of drugs • SAEs indicate min or/ acceptable reactions, side effects • No drug but only data analysis • Minimal data disclosure/ leakage possibilities • Minimal risk to legal/ statutory regulations	**Benefits:** • Completely new cure • Preventive for life i.e. Vaccinations • Significant improvement over Existing cures/ treatment • Minimal side effects vis-à-vis existing treatments • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs/ mode (ex. Pill vs surgery) • Extension of benefits/ availability treatment post trial

	• Benefits large no. of participants
Class D – Low Risk/ Low Benefit	
Risks: • Proven/ Acceptable toxicity • Proven safety and efficacy • Drug/ formulation a variation of approved drug/ class of drugs • SAEs indicate min or/ acceptable reactions, side effects • No drug but only data analysis • Minimal data disclosure/ leakage possibilities • Minimal risk to legal/ statutory regulations • Standard operating/ surgical procedures	**Benefits:** • Cost of treatment/ Drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No port-trial alternatives

A.2. CHECKLIST FOR LEGAL EXPERT (CLINICAL TRIAL AGREEMENT)

IEC meeting details: **Date:**

Study Title: **Version & Date :**	**PI Name :**

Declaration of Conflict Of Interest (COI)	
Name of Member	**Reason**

Sr. No.	Points to be Checked	Acceptable Yes/No	Remark
	Details of the research grant to support the project/ Investigator's Agreement with the Sponsor (Clinical Trials Agreement -)		
1.	Draft [ ] / Executive [ ]		
2.	Tri-partite [ ] / Quadri-partite [ ]		
3.	Parties mentioned		
4.	Clear mention of Protocol title		
5.	Roles and responsibilities of the various stakeholders involved		
6.	Confidentiality (Terms of confidentiality and non-disclosure)		
7.	Indemnification		
8.	Insurance		
9.	Dispute resolution clause		
10.	Grounds for termination of contract		
11.	Budget		
12.	Institute as Payee		
13.	Documents retention period at site		

14	Intellectual property		
a	Ownership of data		
b	Publication rights		
c	Permission for monitoring, audit and inspection of the trial site		

The name and signature of Legal expert of IEC BVDU:

S.N.	Name	Signature& Date

A.3. CHECKLIST FOR VULNERABLE POPULATION

IEC meeting details: **Date:**

Study Title: **Version & Date :**	**PI Name :**

Declaration of Conflict Of Interest (COI)	
Name of Member	**Reason**

Sr. No.	For vulnerable population	Yes/No/Not applicable	Remark
1.	Is inclusion of vulnerable population justified?		
2.	Does the investigator have the requisite expertise to deal with vulnerable population?		
3.	Care taken to minimize the risk involved to the participants?		
4.	Any expert member opinion required for review?		
5.	Is the investigational product safe to use for the said vulnerable category? Is safety data available in protocol/ IB?		
	For children		
1.	Consent to be signed by parents		
2.	Are provisions made to obtain the assent of children over 7 years and where appropriate, honoring their dissent?		
3.	Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?		

Sr. No.	For vulnerable population	Yes/No/Not applicable	Remark
	For pregnant and lactating women		
1.	Scientific appropriateness for including pregnant or lactating women in the study and available safety data like preclinical studies including studies on pregnant animals, and/or clinical studies including studies on non-pregnant women. Data made available for assessing potential risks to pregnant or nursing women, nursing infant and fetuses		
2.	The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child		
3.	If the research involves minors who are pregnant, assent and permission will be obtained in accordance with the National Guidelines		
4.	Does the study involve discontinuation of nursing for the sake of participation in research?		
5.	If yes, is the cessation of breast-feeding to the nursing child justified?		
6.	If yes, does the research has provisions for compensation in terms of supplying supplementary food such as milk formula?		
7.	Is this research related to termination of pregnancy?		
8.	If yes, is it as per the Medical Termination of Pregnancy Act, GOI, 1971.		
9.	Does this research violate any provisions of the Medical Termination of Pregnancy Act, GOI, 1971?		
10.	Is this research related to pre-natal diagnostic techniques in pregnant women?		

Sr. No.	For vulnerable population	Yes/No/Not applicable	Remark
11.	If yes, does it follow research limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus?		
12.	Does this research violate any provisions of the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994?		

The name and signature of Clinician of IEC BVDU:

S.N.	Name	Signature & Date

B. CHECKLIST FOR REVIEW OF INFORMED CONSENT DOCUMENT/ ASSENT FORM

IEC meeting details: **Date:**

Study Title:	**Review date:**
Version / Date :	

Declaration of Conflict Of Interest (COI)	
Name of Member	**Reason**

Sr. No.	Points to be Checked	Acceptable Yes/ No	Remark
	ICF should have all the following essential elements		
A	**List of essential elements**		
1	Study involves research and purpose of the research		
2	Expected duration of the Subject's participation in the Study		
3	Approximate number of subjects enrolled in the study		
4	Procedures to be followed (including invasive procedures)		
5	Reasonable foreseeable risks or discomforts to the subject		
6	Any benefits may or may not result to the subject from participating in the study		
7	Specific appropriate alternative procedures or therapies available to the Subject		
8	Confidentiality of records identifying the subject will be maintained and who will have access to subject's medical records		

9	Trial treatment schedule(s) and the probability for random assignment		
10	Compensation and / or medical management in the event of trial related injury		
11	Whom to contact for trial related queries, rights of subjects and in the event of any injury		
12	The anticipated prorated payment, if any, to the subject for participating in the trial		
13	Subject's responsibilities on participation in the trial		
14	Participation is voluntary & right to withdraw from the study at any time		
15	Statement that there is a possibility of failure of Investigational Product to provide intended therapeutic effect		
16	Statement that in case of placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect		
17	Any other pertinent information		
B	**Appropriateness of language**		
C	**Completeness of information**		
Additional elements, which may be required			
a.	Additional costs to the subject that may result from participation in the study.		
b.	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject		
c.	Statement that the subject or subject's representative will be notified in a timely manner if significant new finding develop during the course of the research which may affect the subject's willingness to continue participation will be provided		

d.	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable		

Role in IEC	**Points specifically checked as per checklist**
Chairperson	
Member Secretary	
Clinician	
Medical Scientist	
Legal Expert	
Social Scientist	
Lay Person	

The list of IEC members:

S. N.	**Name**	**Role in the IEC**	**Signature & Date**

C. CHECKLIST FOR REVIEW OF AMENDED STUDY DOCUMENTS

IEC meeting details: **Date:**

Study Title :	**PI Name :**
Following amended study documents of the above referred study are reviewed _____ _____	

Declaration of Conflict Of Interest (COI)	
Name of Member	**Reason**

Sr. No.	Points to be Checked	Yes	No	Remark
A	Justification for amendment - Appropriate			
B	Amended documents' contents Appropriateness			
C	Alteration in Risk- benefit if any			
D	Alteration in safety &well being of participant			

The list of IEC members:

S. N.	Name	Role in the IEC	Signature & Date

D. CHECKLIST FOR SELF ASSESSMENT OF IEC

Date of Assessment:

Name of Internal Assessor:

A. Is there change in IEC composition since last assessment?
YES NO

If YES:
Details of the changes:
a. Names & Qualification of new members
b. Names of members who have resigned
c. Replacement/ removal of member
d. Does the new composition fulfill regulatory requirement of quorum?
e. Is new updated member list notified to DCGI?
YES / NO

If No – reason & action taken
If Yes-Document review: YES / NO
Comments:

Are subject experts and representatives of vulnerable subjects invited and consulted?
Whether membership, appointment, reconstitution and resignation in Ethics Committee are defined as per terms of reference?

B. Declaration of conflict of interest:
a. Is it signed by all new members?
Yes / NO
If No – reason & action taken
If Yes- Document review: YES / NO

b. Is COI declared prior to each meeting?
Yes / NO
If No – reason & action taken
If Yes- Document review: YES / NO
Comments:

C. Declaration of confidentiality agreement
Is it signed by all new members?
Yes / NO
If No – reason & action taken
If Yes- Document review: YES / NO
Comments:

D. Training for new and existing committee members:
Details of training:
Certificates/evaluation sheets checked: YES / NO
Comments:

E. IEC meeting attendance by members:

F. Review Process: The Ethics Committee follows documented procedures for initial review of the trial related documents, review of amendments and periodic review.

S. N.	Point	Yes	No
1.	Review is done by the Ethics Committee in a formal meeting within a reasonable time following appropriate submission of documents by investigator as per rules and regulation.		
2.	Initial review of proposed clinical trial evaluates the scientific validity of the protocol, risk to subjects, expected benefit and ethical standards as per applicable rules and regulations. Minimal risk is defined.		

3.	Informed consent document, assent form (as applicable) and translations are reviewed for appropriateness of language, accuracy and completeness of information.		
4.	Ethics Committee reviews the informed consent processes to ensure that subject/ their LAR are provided appropriate information, adequate time is given and impartial witness used as applicable.		
5.	Recruitment strategies are evaluated.		
6.	Proposals involving Special group (pregnant mother and children) and vulnerable population are evaluated as per regulations.		
7.	Contract and budget is evaluated, for indemnity, compensation, roles and responsibility as per applicable rules and regulations.		
8.	Review of amendments except minor ones of the originally approved protocol, consent forms, investigators brochure is done in formal meetings to evaluate the risk to trial subjects.		
9.	Periodic review of study is done for continuation, risk evaluation and adverse event monitoring.		
10.	Checklist are filled & attached to Minutes of meeting		
11.	Average duration from submission to approval of the project		
12.	Number of projects discussed & reviewed since last assessment		

Comments:

G. Review of SAEs:

a. No. of SAEs reviewed

b. Details

c. Were they reviewed in formal meeting? YES / NO

d. Serious adverse events are analysed and compensation amount assessed and reported to regulatory authority as per rules and regulations.

e. Letter regarding compensation issued: YES / NO

H. Review of Protocol deviation/violation:

a. No. of Protocol deviation/violation

b. Details of Protocol deviations, violations and noncompliance are evaluated and appropriate actions are taken.

I. Decision making and post meeting activities:

The Ethics Committee follows documented procedures for decision making process and post meeting activities.

S.N.	Check-List	Yes	No
1.	Decision making process (approval/disapproval/pending) is as per applicable rules and regulations, ensuring quorum and consensus/voting requirements are fulfilled.		
2.	Ensure that subject is recruited into the trial only after written favorable opinion from Ethics committee and approval by regulatory authority.		
3.	Conflict of interest is declared prior to the review and voluntary withdrawal during decision making process is documented.		
4.	Decisions are based on risk assessment, scientific validity and adherence to ethical principles for the initial and periodic approvals.		
5.	Deliberations and decisions made during the meetings are documented, approved, signed and maintained as minutes of Meeting		
6.	All decisions/opinions are notified to the investigator in writing.		

J. Monitoring: The Ethics Committee follows documented procedures for monitoring and for-cause assessment.

Details of site Monitoring reports & action taken since last assessment:

S. N.	Check-List	Yes	No
1.	Subject's rights, safety and wellbeing are monitored.		
2.	Adequacy and continuity of consent process is ensured.		
3.	For-cause assessments are conducted following non-compliance and/or complaints for the trials approved by the Ethics Committee.		
4.	Opportunities for improvement are identified and appropriate actions are initiated		

K. Protection of subject rights, safety and wellbeing:

S. N.	Check-List	Yes	No
	Whether Ethics Committees follows documented procedures for subject protection-		
1.	Rights and responsibility of the subject		
2.	Subject's participation and withdrawal from the trial is voluntarily.		
3.	Subjects are informed and comprehend (initial and ongoing) of the associated risks and benefits of the trial.		
4.	Confidentiality and privacy of subjects is protected.		
5.	Monitoring of trials is done to ensure equitable selection of subjects, with special attention to vulnerable and high risk subjects.		
6.	Compensation provided to subjects for participation in the trial is appropriate and as per the contract.		
7.	Serious adverse events are addressed, adequate medical care provided and an appropriate reporting mechanism is followed as per applicable regulations.		

8.	Compensation for injury to the subject is appropriate as per the regulations and monitored for noncompliance.		
9.	Complaints and concerns of subjects are addressed and managed appropriately.		

L. Administrative support:

S. N.	Check-List	Yes	No
1.	Whether Ethics Committee has Adequate financial, human resource allocation and secretariat for administrative work and record keeping?		
2.	Is there financial transparency of Ethics Committee activities and functioning?		
3.	Is there communication between Ethics Committee, Regulatory authorities, Investigator/relevant site staff and institution?		

M. Archival:

a. Any new document archived since last assessment?
YES / NO
b. Has it been done as per the SOP?
YES / NO
c. Is archival log updated?
YES / NO

N. Compliance with SOPs:

YES / NO
If No: Give details & reason
SOP amendment needed?
YES / NO

O. Quality Indicator as per NABH:

Self Assessment Report:

Sign & Date of Chairperson/Member Secretary:

E. CHECKLIST FOR SITE MONITORING BY IEC

Sr. No	Name of the document reviewed	Objective Evidence	Findings	Comments
1	Adequacy of the site facilities including emergency procedures			
2	Source documents for Compliance with the Protocol & GCP Guidelines			
3	Informed Consent documentation & ICF narrative			
4	AV consent declaration form			
5	Audio Visual Consent			
6	Protocol deviations, violations and non compliance if any			
7	Management of AE & SAE			
8	Patient's registration			
9	Study team (CV, Interview)			
10	Logs			
11	IEC correspondence			
12	Duty Delegation log			
13	Subject travel Reimbursement sheet			
14	Approvals			
15	Any Other for e.g. study details			

F. SELF ASSESSMENT OF CHAIRPERSON

Name:

Period of Self assessment: First Half of the year (Jan to Jun)/ Second Half of the year (Jul to Dec)

S. N.	Self-assessment item	Response
1.	Current tenure	First/ Second
2.	GCP training in the current period	
3.	Any other trainings (CDSCO guidelines, SOP training etc.)	
4.	Number of IEC meeting held	
5.	Number of IEC meeting attended	
6.	Declaration of Conflict Of Interest (COI)	Yes/No
7.	Active participation in the IEC meeting	
8.	Participation in Serious Adverse Event (SAE) report review process	Yes/No
9.	Participation in site monitoring	Yes/No/ NA
10.	Review of Protocol deviation/ Violation	Yes/No
11.	Whether quorum requirement fulfillment ensured as per regulatory guidelines	
12.	Whether considerations related to COI considered	
13.	Decision making on proposal review	
14.	Minutes of Meeting (MOM) reviewed and signed after meeting	

Signature of Chairperson & Date:

G. SELF ASSESSMENT OF MEMBER SECRETARY

Name:

Period of Self assessment: First Half of the year (Jan to Jun)/ Second Half of the year (Jul to Dec)

S. N.	Self-assessment item	Response
1.	Current tenure	First/ Second
2.	GCP training in the current period	
3.	Any other trainings (CDSCO guidelines, SOP training etc.)	
4.	Number of IEC meeting held	
5.	Number of IEC meeting attended	
6.	Declaration of Conflict Of Interest (COI)	Yes/No
7.	Active participation in the IEC meeting	
8.	Participation in Serious Adverse Event (SAE) report review process	Yes/No
9.	Participation in site monitoring	Yes/No/ NA
10.	Review of Protocol deviation/ Violation	Yes/No
11.	Proposals to be discussed in the IEC meeting, received and sent within timelines	Yes/No
12.	Training workshops conducted	Yes/No
13.	Preparation/ amendment of SOP	Yes/No if Yes details:
14.	Minutes of Meeting (MOM) reviewed after meeting	
15.	Letter to Principal Investigators issued within timelines	Yes/No

Signature of Member Secretary & Date:

Remark of Chairperson:

Signature of Chairperson & Date:

H. SELF ASSESSMENT OF IEC MEMBER

Name:
Designation:

Period of Self assessment: First Half of the year (Jan to Jun)/ Second Half of the year (Jul to Dec)

S. N.	Self-assessment item	Response
1.	Current tenure	First/ Second
2.	GCP training in the current period	
3.	Any other trainings (CDSCO guidelines, SOP training etc.)	
4.	Number of IEC meeting held	
5.	Number of IEC meeting attended	
6.	Declaration of Conflict Of Interest (COI)	Yes/No
7.	Active participation in the IEC meeting	
8.	Participation in Serious Adverse Event (SAE) report review process	Yes/No
9.	Participation in site monitoring	Yes/No/ NA
10.	Review of Protocol deviation/ Violation	Yes/No

Remark by IEC member:

Signature of IEC member & Date:

Remark of Chairperson:

Signature of Chairperson & Date:

I. FEEDBACK FORM - ENGLISH

Name of the Study/Drug/Vaccine you are enrolled in:

_____

Name of study Participant/Parent:

_____

DOB/Age of participant:

_____

Address:

_____

_____

_____

Mobile Number of study participant/parent:

_____

Email Id of study participant/parent:

_____

Feedback regarding clinical trial participation:

1. Did you know that you have participated in a research study? Yes No

   Comment:

2. Do you remember signing a consent form to take part in a research study? Yes No

   Comment:

3. Are you satisfied with the information provided to make a decision about whether to take part in the research study? Yes No

If not; Please give reasons:

4. Which one of the statements listed below best describes your options if you chose to quit the research study? Choose the correct answer.

a. You could drop out at any time and for any reason.
b. You could drop out of the research study only if Dr. (*Investigator name*) let you drop out.
c. I'm not sure what the policy was for dropping out of the research study.
d. Other:

5. Did anyone from the research staff put pressure on you to sign the consent form?
Yes No
Comment:

6. Did the consent form or the research staff tell you about possible risks, discomforts, or inconveniences expected from being in the study? Yes No
Comment:

7. Did the research staff inform you about possible alternatives for treatment and care if you did not participate in the study? Yes No
Comment:

8. Did you have enough time to read and ask questions about the Subject Information Sheet and Informed Consent Form of the research study?
Yes No
Comment:

9. Were all of your questions/ queries answered by the research staff? Yes No
Comment:

10. Did the research staff give you a copy of the Information Sheet and Informed Consent Form after you signed it? Yes No
Comment:

11. Did you know that participating in the research study was voluntary and that you didn't have to take part in the study if you didn't want to? Yes No
Comment:

12. Do you think the study staff would have treated you differently if you had stopped the study early? Yes No
Comment:

13. Did you know whom to call on the research staff if you had questions or concerns during the study? Yes No
Comment:

14. Did you know you could call the Ethics Committee contact person if you had questions or concerns about your rights as a research participant? Yes No
Comment:

15. Did you receive travel payment/ reimbursement? Yes No
Comment:

16. Are you willing to participate in future research studies? Yes No
Comment:

17. Would you tell others to participate in the research studies? Yes No
Comment:

How was your experience of research team?

Please tick those apply	**Very good**	**Good**	**Satisfactory**	**Average**	**Poor**
Giving you prompt attention					
Being polite					
Listening to you					
Assessing your medical condition					
Explaining you the study and treatment					
Involving you in decisions about your treatment					
Providing or arranging treatment for you					

If you have any additional comments, complaints or questions, list them below:

Name of the person filling Feedback form:

_____

Relationship with participant:

_____

Sign & Date:

_____

Annexure IX

Causality Assessment Tool

Table 1: Types of causality as per WHO-UMC scale

Causality term	Causality term Assessment criteria
Certain	'Event or abnormal laboratory tests, with a temporal relationship to drug intake' 'Cannot be explained by disease or other drugs' 'Positive De-challenge required' 'Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or recognized pharmacological phenomenon)' 'Re-challenge Positive'
Probable/ Likely	'Event or abnormal laboratory tests, with a temporal relationship to drug intake' 'Unlikely to be attributed to disease or other drugs' 'Response to withdrawal clinically reasonable' 'Re-challenge not required"
Possible	'Event or abnormal laboratory tests, with a temporal relationship to drug intake' 'Could also be explained by disease or other drugs' ' Information on drug withdrawal may be lacking or unclear'
Unlikely	'Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)' 'Disease or other drugs provide plausible explanations'
Conditional/Unclassified	'Event or abnormal laboratory tests' 'More data for proper assessment needed', or 'Additional data under examination and waiting for data'

Unassessable/ Unclassifiable	'Report suggesting an adverse reaction' 'Cannot be judged because the information is insufficient or contradictory data' 'Data cannot be supplemented or verified'

Table 2: The WHO-UMC causality assessment method includes the following 4 criteria

Causality type	Time relationship	Other drugs/ disease ruled out	Dechallenge	Rechallenge
Certain	Yes	Yes	Yes	Yes
Probable	Yes	Yes	Yes	No
Possible	Yes	No	No	No
Unlikely	No	No	No	No

Table 3: Naranjo algorithm causality assessment scale

Naranjo Adverse Drug Reaction Probability Scale				
Question	**Yes**	**No**	**Do Not Know**	**Score**
Are there previous conclusive reports on this reaction?	**+1**	**0**	**0**	
Did the adverse event appear after the suspected drug was administered?	**+2**	**-1**	**0**	
Did the adverse reaction improve when the drug was discontinued or a specific antagonist drug was administered?	**+1**	**0**	**0**	
Did the adverse event reappear when the drug was re-administered?	**+2**	**-1**	**0**	
Are there alternative causes (other than the drug) that could on their own have caused the reaction?	**-1**	**+2**	**0**	
Did the reaction reappear when a placebo was given?	**-1**	**+1**	**0**	
Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	**+1**	**0**	**0**	
Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	**+1**	**0**	**0**	
Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	**+1**	**0**	**0**	
Was the adverse event confirmed by any objective evidence?	**+1**	**0**	**0**	
Total score : ≤0= Doubtful, 1-4 Possible, 5-8 Probable, ≥9 Definite				

Sr No.		Amd Date	Section/ Clause/ Para/Line	Amendment details	Reasons for Amd	Made by	Authorized signatory
1	**a.**	30/09/2023	Whole IEC Manual	From version 05 to 06 Annexure VIII from version 02 to 03	Three yearly update as per norms	Dr. Prasad Pore Dr. Shashikala Sangle Dr. Rishi Patel	Dr. Srikanth Prasad Tripathy, IEC Chairperson
	b.	30/09/2023	SOP 02	DHR final registration number added.	IEC received final registration number from DHR in Jan 2023		
	c.	30/09/2023	SOP 03	The member may be continued till the new member in his/her place is appointed.	Requirement of IEC		
	d.	30/09/2023	SOP 05 & 18	• Medical Devices Rules 2017 and its amendments • Ethical guidelines for application of AI in Biomedical Research and Healthcare These guidelines are added.	Updated as new guidelines are introduced.		

	e.	30/09/2023	SOP 06	Gmail ID of IEC deleted. GST related clause is added.	Updated as outlook mail ID of IEC is being used.		
	f.	30/09/2023	SOP 08	The clause regarding the amendment to the originally approved study documents is updated.	Update		
	g.	30/09/2023	SOP 09	The clause regarding the DCGI approval is added.	Revision		
	h.	30/09/2023	Annexure IV	CRPU no. and the point regarding the funds to be received are added.	Update		
	i.	30/09/2023	Annexure VIII A	The point regarding the funds to be received is added.	Update		
2	**a.**	15/10/2022	SOP 01 & SOP 20	The sentence regarding IEC Secretariat is added in TOR	As per the requirement of NABH assessor	Dr. Prasad Pore Dr. Jayshree Dawane Dr. Rishi Patel	Dr. Srikanth Prasad Tripathy, IEC Chairperson
	b.	15/10/2022	SOP 03	The text regarding Ad hoc members deleted. The text in the section	As per the requirement of NABH assessor and DHR		

				'Procedure' is updated.	requirements following ICMR guidelines		
	c.	15/10/2022	SOP 05	The period regarding the long absence of chairperson is specified. SOP is updated.	As per the requirement of NABH assessor and DHR requirements following ICMR guidelines		
	d.	15/10/2022	SOP 09 & 22	The word voting is changed to consensus.	As per the requirement of NABH assessor		
	e.	15/10/2022	SOP 11 & Annexure IX	Causality assessment tools are added.	As per the requirement of NABH assessor		
	f.	15/10/2022	SOP 12	Benchmarking for Protocol deviation and CAPA added.	As per the requirement of NABH assessor		
	g.	15/10/2022	SOP 14	The section 'Procedure' is updated.	As per the requirements DHR, following ICMR guidelines		

	h.	15/10/2022	Annexure VI	The sentence, 'The IEC to be informed about enrollment of the first study participant in the said clinical trial' is added in this annexure.	As per the requirement of NABH assessor		
3	**a.**	02/09/2021	SOP 03	Revision of honorarium of IEC members.	As per advise of University authorities	Dr. Prasad Pore Dr. Rishi Patel	Dr. Subhash Salunke (Chairperson)
	b.	02/09/2021	SOP 06	New mail ID of IEC BVDU is added and extension number is updated.	Addition of new mail ID of IEC BVDU	Dr. Prasad Pore Dr. Rishi Patel	Dr. Subhash Salunke (Chairperson)
4	**a.**	24/06/2021	SOP 22	SOP for Review of Biomedical & Health Research During Covid-19 Pandemic	As per NABH requirement, this SOP is newly formulated.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)

	b.	24/06/2021	SOP 02	Provisional registration number of the Ethics Committee relating to Biomedical and Health Research with the NECRBHR, DHR is added EC/NEW/INST/2020/735	IEC received DHR provisional registration number.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)
	c.	24/06/2021	SOP 03	The clause regarding wash out period of previous IEC member and previous chairperson continuation added. Revision of honorarium of IEC members	Clarification regarding wash out period.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)

	d.	24/06/2021	SOP 05, SOP 18	National Guidelines for Ethics committee reviewing Biomedical and Health Research - During Covid-19 Pandemic – ICMR April 2020 - Added in the applicable Regulations and Guidelines section.	Updated as per ICMR SOP Apr 2020 (during Covid-19 pandemic)	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)
	e.	24/06/2021	SOP 06	It is added that the frequency of meetings can be increased if required.	Clarification regarding frequency of IEC meetings.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)
	f.	24/06/2021	SOP 07	The clause regarding quorum completion & confidentiality of documents/ communication sent through IEC office is added.	Clarification regarding quorum completion & confidentiality of IEC documents/ communication	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)
	g.	24/06/2021	SOP 07A	The clause regarding fresh or re-consent is added.	Clarification regarding fresh or re-consent	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)

	h.	24/06/2021	SOP 09	It is added that in case of expedited review of proposal the decision shall be communicated to PI within 7 working days after review.	Clarification regarding period of decision making procedure of IEC in case of expedited proposal review.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)
	i.	24/06/2021	SOP 11	The procedure for review of site SAE by SAE review committee is updated.	Clarification regarding review of site SAE by SAE review committee	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)
	j.	24/06/2021	SOP 13	The definition of Vulnerable Population is updated.	Updated as per ICMR SOP Apr 2020 (during Covid-19 pandemic)	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)
	k.	24/06/2021	SOP 14	Updated regarding monitoring procedure	Updated as per NABH requirement	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)
	l.	24/06/2021	SOP 17	The point ‘Checklist for Self Assessment of IEC members’ is added.	Updated as per NABH requirement	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)

	m.	24/06/2021	Annexure VIII	Checklists are updated & new checklists are added.	Updated as per NABH requirement	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Subhash Salunke (Chairperson)
5	**a.**	28/08/2020	Whole IEC Manual	From version 04 to 05 Annexure VIII from version 01 to 02	Three yearly update as per norms	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)
	b.	28/08/2020	SOP 01	Approval of revised SOPs in case of emergency/lock-down will be obtained via mail by IEC Members	Due to COVID – 19 pandemic this SOP is updated.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)
	c.	28/08/2020	SOP 03	Update in the role and documentation related to subject expert in IEC meeting.	Due to COVID – 19 pandemic this SOP is updated.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)
	d.	28/08/2020	SOP 04	The procedure for declaration of COI is updated.	Due to COVID – 19 pandemic this SOP is updated.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)
	e.	28/08/2020	SOP 07 A, 07, 08, 09	The process to review documents related to the new study/ projects is revised. In case of online IEC meeting, the	Due to COVID – 19 pandemic these SOPs are updated.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)

				checklist will be sent prior to meeting and will be signed only by Member Secretary.			
6	**a.**	23.04.2020	SOP 02	IEC registration number is updated in this SOP.	IEC received renewed DCGI registration number.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)
	b.	23.04.2020	SOP 06	IEC fees are revised.	Revision of IEC fees	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)
	c.	23.04.2020	SOP 07	The details regarding online/web meeting to be conducted during emergency situations are added.	Due to COVID – 19 pandemic this SOP is updated.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)
	d.	23.04.2020	SOP 08	It is added that the amended study documents, only for the minor or administrative changes, may be circulated via mail to the IEC members for approval.	To clarify regarding the approval of amended study documents.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)

	e.	23.04.2020	Annexure VIII - A	Sub-point 8 of Point B is deleted.	Separate checklist for ICF (Annexure VIII B) is available.	Dr. Prasad Pore Dr. Jayshree Dawane	Dr. Abhijeet Tilak (Acting Chairperson)
7	**a.**	28.06.2019	SOPs 02,03,05,07, 09, 18, 21 & Introduction	The word Schedule Y is replaced with New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E) and SOP 03 is updated as per new CDSCO guidelines.	As per new CDSCO guidelines [New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E)]	Dr. Prasad Pore, Mrs. Vaishali Deshpande, Dr. Jayshree Dawane	Dr. Ramesh Paranjape
	b.	28.06.2019	SOP 10	The point added in renewal of approval of projects.	To clarify about the continuation of study related activities till renewal of approval is granted in full quorum. meeting.	Dr. Prasad Pore, Mrs. Vaishali Deshpande, Dr. Jayshree Dawane	Dr. Ramesh Paranjape
	c.	28.06.2019	Annexure VI & Annexure IV	Ann. VI - The format of IEC approval letter is updated. Ann. IV - The word 'submission' is added in point	As per new CDSCO guidelines	Dr. Prasad Pore, Mrs. Vaishali Deshpande, Dr. Jayshree Dawane	Dr. Ramesh Paranjape

				no. 8 of this Annexure			
8	**a.**	20.03.2019	SOP 05 & SOP 11	The word 'external SAE' is deleted from these SOPs.	The word 'external SAE' refers to SUSARs or CIOMS.	Dr. Prasad Pore, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape
	b.	20.03.2019	Annexures to SOP	1. Annexure VIII (Checklists – A, B, C, D, and E) is added. 2. Annexure V (Undertaking by the Investigator) is updated.	1.As per NABH requirement, for the review and approval of new projects Checklists are necessary. 2. As per G.S.R 227(E)	Dr. Prasad Pore, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape
	c.	20.03.2019	SOPs 07, 07A, 08, 09,14 and 17	The word 'Checklist' is added in these SOPs	As per NABH requirement	Dr. Prasad Pore, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape
	d.	20.03.2019	SOPs 06	The word 'excluding TDS' is added in the section 'Institutional Ethics Committee Fee' of this SOP	To clarify regarding IEC fees.	Dr. Prasad Pore, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape

	e.	20.03.2019	SOP 07	The point regarding 'Expedited meeting' is added in this SOP.	To clarify regarding expedited meeting.	Dr. Prasad Pore, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape
	f.	20.03.2019	SOP 02	IEC NABH Accreditation number is added in this SOP	IEC received NABH Accreditation	Dr. Prasad Pore, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape
	g.	20.03.2019	List of records	Feedback forms (English, Marathi and Hindi) are added	As per NABH requirement	Dr. Prasad Pore, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape
9		03.01.2018	SOP No.16	The details in process describing how the study participant should register complaint or request is added.	As per NABH requirement this SOP is updated.	Dr. Priti Dhande, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape
10	**a.**	03.11.2017	SOP No.05	The specific role & responsibility of individual IEC member is elaborated	As per NABH requirement this SOP is updated.	Dr. Priti Dhande, Dr. Neeta Hanumante and	Dr. Ramesh Paranjape

						Dr. Sushila Kawade	
	b.	03.11.2017	SOP No.07 A	The following clauses are added: 1. Adequate time is given for reading & understanding the ICF. 2. Time & dated is recorded on the AV consent recording.	As per NABH requirement this SOP is updated.	Dr. Priti Dhande, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape
	c.	03.11.2017	SOP No.14	The process is updated.	As per NABH requirement this SOP is updated.	Dr. Priti Dhande, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape
	d.	03.11.2017	SOP No.19	The detail processes for communication are mentioned.	As per NABH requirement this SOP is updated.	Dr. Priti Dhande, Dr. Neeta Hanumante and Dr. Sushila Kawade	Dr. Ramesh Paranjape

GOPALAKRISHNAN JAYAKUMAR
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