STANDARD OPERATING PROCEDURE (SOP)
For
INSTITUTIONAL ETHICS COMMITTEE

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
DEHRADUN-248007

ENERGY ACRES: Bidholi, Via. Prem Nagar, Dehradun-248007 (Uttarakhand), India T: +91 135 2770137, 2776053/54/91, 2776201; F: +91 135 2776090/95
KNOWLEDGE ACRES: Kandoli Via Prem Nagar, Dehradun-248007 (Uttarakhand), India T: +918171979021/2/3, 7060111775

Standard Operating Procedures (SOP)
for
Institutional Ethics Committee (IEC)

University of Petroleum and Energy Studies (UPES) Dehradun-248007

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SOP prepared by: Faculties of SOHST, UPES Dehradun

Approved by: Dean SOHST, UPES Dehradun

Prof. Latika Mohan, Chairperson, UPES-IEC, AIIMS Rishikesh

Contents: **Page No.**

1. Introduction

Biomedical research involves a number of ethical issues that need to be addressed. The Institutional Human Ethics Committee (IHEC)/IEC plays an important role in guiding researchers in the ethical aspects associated with the biomedical research. Apart from ethical issues, IEC will also review the research proposals for the scientific relevance and risk involved in research. IEC functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2017 (ICMR National Ethical Guidelines).

2. Objective

The objective of this Standard Operating Procedures of the Institutional ethics committee (IEC) of UPES, Dehradun is to maintain effective functioning of the UPES- IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects and New Drugs and Clinical Trials Rules 2019.

3. Authority under which UPES-IEC is constituted

UPES-IEC is an Institutional standing ethics committee that functions independently. The Dean, School of Health Sciences and Technology, UPES is authorized to nominate members in consultation with the Chairperson of the IEC among those who possess the qualifications, competence and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure/period of IEC members will be for 3 years or till further orders. An IEC sub-committee is also constituted to scrutinize submitted projects for expedited review, recommendation of which will be presented before IEC. The committee will function Independently in the decision-making process and will function according to the New Drugs and Clinical trials rule 2019 and ICMR National Ethical Guidelines. The institute will provide infrastructure, administrative and financial support for the functioning of the Ethics Committee.

4. Composition

UPES-IEC			
Sr. No.	Designation	From	Number
i.	Chairperson	Nominated by the Dean SOHST, UPES, an expert from outside the institute	1
ii.	Member secretary	Institutional	1
iii.	Medical scientists	From the Institute or from outside	05 members
iv.	Medical scientists	From outside the Institute	01 members
v.	Clinician	From outside the Institute	01 member
vi.	Non-Medical	Social Scientist/ philosopher/ ethicist/ theologian	01 member
vii.	Legal expert	From the Institute	01 member
viii.	Layperson		01 member

IEC-Sub-committee Committee

Sr. No.	Designation	From	Number
i.	Member secretary	Institutional	01 member
ii.	Medical scientists	From the Institute or from outside	01 member
iii.	Clinician/Pharmaceutical	From the Institute or from outside	01 member
iv.	Non-Medical /Legal expert/Layperson	Social Scientist/ philosopher/ ethicist/ theologian / From the institute	01 member

#Presence of at least one woman on the committee is compulsory.

5. Role & Responsibilities of UPES-IEC

The main responsibility of UPES-IEC is to review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well-being of research participants before approving the research proposals**.**

It should ascertain that all the ethical principles of research such as Autonomy, Beneficence, non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research. IEC will review each study proposal for its both scientific and ethical review.

Members of IEC are expected to attend all IEC meetings and prior information should be provided if a member is unable to attend a meeting.

The composition, affiliations, qualifications, member specific roles and responsibilities are given below:

Sl No.	**Members of UPES-IEC**	**Affiliation and qualification**	**Member specific roles and responsibilities**
01	Chairperson	Non-affiliated A well-respected person from any background with prior experience of having served/serving in an EC	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of both Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an

			Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
02	Member Secretary	Affiliated • Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills • Should be able to devote adequate time to this activity which should be protected by the institution	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
03	Basic Medical Scientist(s)	Affiliated/ non-affiliated	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design,

		• Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
04	Clinician(s)	Affiliated/ non-affiliated Should be individual/s with recognized medical qualification, expertise and training	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
05	Legal expert/s	Affiliated/ non-affiliated • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • To review whether provision for reporting of incidence of SAE included or not, and arrangement for compensation as per NDCTR 2019. • Interpret and inform EC members about new regulations if any

06	Social scientist/ philosopher/ ethicist/theologian	Affiliated/ non-affiliated Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal/community representative and bring in ethical and societal concerns.
07	Lay person(s)	Non-affiliated • Literate person from the public or community • Has not pursued a 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 • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities	• Ethical review of the proposal, ICD along with translation(s). • 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.

Additionally, the following member should be held responsible for specific activities:

Coordinating staff (Affiliated):

- To support the Member Secretary in executing functions of the IEC.
- Correspondence with the IEC members and investigators. Arranging IEC meetings
- Receiving all research proposals
- Assisting in preparing agenda and minutes of the meetings
- Maintaining and archiving study documents
- To perform any other functions as instructed by Member Secretary/ Chairman

Members are expected to show their full commitment, responsibility, respect for divergent opinions, maintain confidentiality review proposals from bias and without any external influences. All IEC members must be familiarized with guidelines related to research and ethics such as ICMR National Ethical Guidelines2017, New Drugs and Clinical Trials Rules 2019,

ICH-GCP guidelines. When there is any change in the SOP the same will be communicated to the members and necessary training will be imparted. Record will be maintained regarding the training of members and changes in the SOP/guidelines.

Members are expected to declare conflicts of interest, if any, before the commencement of the meeting. IEC members should not take part in discussion or decision-making on research proposals in which they are PI or Co-investigators or if there are any other conflicts of interest.

The IEC has the right to revoke its approval accorded to scientific study/clinical study protocol, and further, it has to record the reasons for doing so and communicate the same to the Investigator as well as to the Licensing Authority/ other relevant stakeholders. IEC may review the progress of the approved studies periodically till the completion of the study through periodic study progress reports/internal audit reports.

The investigator is responsible for reporting all SAEs. Reporting of SAE may be done through email or fax communication. A report on how the SAE was related to the research must also be submitted within 14 days. SAEs must be reported for all trials and if applicable timelines as specified by regulators to be followed (within 24 hours to the sponsor, IEC and regulator, if applicable, followed by a due analysis report in 14 days). The IEC shall forward the report on any SAE (including, death), after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, to the Chairman of the Expert Committee constituted by the Licensing Authority. A copy of the report has to be submitted to the Licensing Authority within twenty-one calendar days of the occurrence of the SAE.

6. Policy for updating/training of IEC members

6.1. All relevant information on ethics will be brought to the attention of the members of UPES-IEC by the Member Secretary.

6.2. All IEC members shall be required to undergo refresher course in Good clinical practice (GCP) once in two years or earlier in case of indication for the same.

6.3. The Chairman, Member Secretary and members will be encouraged by the appointing authority to attend national and international training programs/ conferences/ workshops/ seminars/ courses at least once in two years in the field of research ethics (over and above his own discipline) to help in improving the quality of review of research protocols/ethics committee submissions and other related activities.

7. Membership requirements and procedure for appointment of IEC Members

The Dean SOHST after appointing the chairperson shall, in consultation with the Chairperson, nominate the members of IEC, who have the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.

i. The normal term for an IEC member will be for 36 months.
ii. Dean SOHST can renew the appointment of the member on the basis of Contribution.

iii. During the term, Dean SOHST in consultation with the chairperson can disqualify any member if the contribution is not adequate and, or there is a long period of (member) non-availability.

iv. Member can discontinue from membership of IEC after giving at least 1-month advance notice.

v. Dean SOHST can replace the member of IEC or add a new member as and when required.

vi. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.

vii. Members shall be appointed to the UPES-IEC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

viii. Requirements for an appointment:

Every IEC member must:

- Provide an updated CV with signature
- Consent letter
- Submit training certificates on human research participant protection and good clinical practice (GCP) guidelines. If not trained 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
- Declare Conflict of Interest (COI) in accordance with the policy of the IEC, if applicable, at the appropriate time
- Sign 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

8. The terms of reference of the committee

i. The Dean SOHST after appointing the chairperson shall, in consultation with the Chairperson, nominate the members of IEC, who have the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.

ii. The appointment letter issued to all members shall specify the terms of reference. The letter issued by the Dean SOHST should include, at the minimum, the following:

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

iii. The normal term for an IEC member will be for 36 months after which they may be either replaced or reappointed with a fresh appointment letter prior to the end of tenure of members by the IEC secretariat.

iv. Dean SOHST can renew the appointment of the member on the basis of Contribution.

v. During the term, Dean SOHST in consultation with the Chairperson can disqualify any member if the contribution is not adequate and, or there is a long period of (member) non-availability.

vi. Member can discontinue from membership of IEC after giving at least 1-month advance notice.

vii. Dean SOHST can replace the member of IEC or add a new member as and when required in consultation with the Chairperson.

viii. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.

ix. Members to be part of UPES-IEC must fulfil the following requirements:

- Provide an updated CV with signature
- Consent letter
- Submit training certificates on human research participant protection and good clinical practice (GCP) guidelines. If not trained 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
- Declare Conflict of Interest (COI) in accordance with the policy of the IEC, if applicable, at the appropriate time
- Sign 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
- Be committed and understanding to the need for research and for imparting protection to research participants in research.

x. Resignation:

 A member can resign by submitting a letter of resignation addressed to the Chairman and delivered to the Member Secretary the same will be informed by the Secretary to the appointing authority for formal acceptance and to initiate necessary replacement/recruitment procedure for filling up the vacancy.

 The members if opts to step down due to any genuine cause may do so with prior notice and proper information to the appointing authority.

xi. Disqualification:

 If Dean SOHST, UPES Dehradun, Chairman or Member Secretary receives a communication in writing alleging misconduct by a member.

 A member may be disqualified if fails to attend more than 3 regular consecutive IEC meetings without prior intimation.

xii. A list of members of the IEC, UPES Dehradun, their appointment letters, bio-data and consent forms would be maintained by Member Secretary of the IEC, UPES Dehradun. This list and the copy of the working procedures would be made available to any investigator, for the purpose of filing of research projects, upon written request for the same to the Chairman.

xiii. Hierarchy:

 The Chairman will be head of the committee.
 All the other IEC members will be regular committee members with equal ranking.
 The Member Secretary will be the guardian of all documents, record and funds in the possession of the committee.

xiv. Responsibilities of UPES-IEC

The UPES-IEC is to ensure that the research projects carried out are sound in scientific design, have statistical validity and are carried according to the standard guidelines as prescribed by Good Clinical Practice (GCP), Indian council of Medical Research (ICMR) guidelines and New Drugs and Clinical Trials Rules, 2019. The responsibilities of UPES-IEC Dehradun are:

- To protect the safety, dignity, rights and wellbeing of the potential research participants.
- To include solely those patients who have given informed consent for participation in the research. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To ensure equitable recruitment of subjects in the study.
- To ensure that the research is conducted under the supervision of the medical persons or scientists with required experience and expertise.
- To assist in the development and the education of a research community responsive to local health care requirements.

The UPES-IEC Dehradun would review all new research projects and if approval is given it would be for a duration as mentioned in the study protocol. After completion of the duration, the progress of the project would be reviewed, and further extension may be provided if requested. Status of any project can be retrieved by tracking the record document. The UPES-IEC would maintain a list of all projects submitted, approved, disapproved and outcome of each project with confidentiality.

The UPES-IEC should ensure that patients' rights are not compromised regarding any payments proposed to be made in the study to the patients towards reimbursement of incidental expenses.

xv. Administration and management of UPES-IEC

UPES Dehradun should have an office for the IEC which have adequate space, infrastructure and staff to the IEC for maintaining a full-time secretariat, safe archival of records and conduct of the meeting. A fee for review [Rs. 10,000/- for project from industry, Rs. 5,000/- for projects from Academic institutes (Outside UPES)] may be charged by the IEC to cover the expenses related to optimal functioning in accordance with Institutional policies for industry-sponsored projects/funded projects. These fees are applicable for up to 3 reviews, beyond which an additional charge of Rs. 5,000/- will be applicable for each additional

review. There should be a provision for allocating a reasonable amount of funds for the smooth functioning of the IEC. An honorarium of INR 10,000/-per sitting to the Honourable Chairperson and Rs. 5,000/- per sitting will be paid by the institute to the UPES non-affiliated members attending the meeting. Additionally, TA will be paid to all UPES non-affiliated members for attending the meeting in offline mode.

9. Quorum requirements

i) A minimum of five members must be present (including online and offline mode) in the meeting room.
ii) The requisite quorum of five members consisting at least one Medical scientist (preferably a pharmacologist), Clinician, Legal expert, Social scientist or representative of a nongovernmental voluntary agency or a philosopher or an ethicist or a theologian or a similar person and one Layperson from the community besides the Chairman and member Secretary are must for discussion on any research proposal.
iii) Minimum one non-affiliated member should be part of the quorum.
iv) Preferably the layperson should be part of the quorum.
v) For clinical trial, the five members of quorum must be from Medical scientist (preferably a pharmacologist), Clinician, Legal expert, Social scientist or representative of a nongovernmental voluntary agency or a philosopher or an ethicist or a theologian or a similar person and one Layperson from the community as per New Drugs and Clinical Trials Rules, 2019.
vi) No decision is valid without fulfillment of the quorum.

10. Convention and Conduct of IEC meetings

The Chairperson will conduct all meetings of the UPES-IEC. In the absence of the Chairperson, an alternate Chairperson will be elected from the other members on the day of the meeting (or Chairperson should nominate a committee member as Acting Chairperson for that meeting) by the members present, who will conduct the meeting. The alternate or acting chairperson should have the powers of the chairperson and should be a non-affiliated person. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. Member Secretary will prepare the minutes of the meetings and get them approved by the Chairperson and all the members. In the absence of the Member Secretary, alternate Member Secretary among the members will organize the IEC meeting.

All proposals will be received at least 3 weeks before the meeting and after initial scrutiny by Member Secretary, the proposals will be circulated to the IEC members. The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of student's proposals. If required additional review meetings can also be conducted with a short notice period.

11. Selection and responsibilities of subject

11.1. Purpose:

For Obtaining the expertise of a professional as a subject expert either affiliated or non-affiliated, to the Institutional Ethics Committee.

11.2. Responsibility:

Upon the advice or recommendation of the secretariat or any IEC member, it is the responsibility of the IEC to nominate the name of one or more special subject experts and be endorsed by the Chairman for the given project.

11.3. Recommendation:

The IEC will designate subject experts from the different specialties and the Chairman / Member Secretary on behalf of the IEC will invite subject expert selected by the IEC in writing to assist in the review of the project and provide his/ her independent opinion. Depending upon the complexity of the issue(s) are not within the collective expertise of all members, the Chairman/ Member Secretary on behalf of the IEC will invite one or more experts.

11.4. Selection:

The final approval from the IEC Chairman to refer the project to the specified subject expert will be taken by the Secretariat.

11.5. Co-ordination with subject expert:

Subjects experts will participate after they agree to the confidentiality clause and abide by the rules and regulations of IEC whose opinion would be valuable, but they would not be involved in the decision-making process of the Ethics committee. The expert would be requested to provide an opinion in writing within 30 working days, depending upon the gravity and seriousness of the matter. The following would be designated as Subject expert during the meetings of the IEC, UPES Dehradun.

- Investigator or Co-investigator/ Study coordinator of the project under review.

- Any expert in the field of study as and when invited by the IEC, UPES Dehradun.

The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the subject experts if any doubts or questions are raised. The Chairman / Legal expert / IEC members can provide any further explanations. If deemed necessary, subject expert may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet, incidental expenses, etc.

12. Application procedures

All proposals should be submitted to IEC on any working day ***3 weeks in advance*** of the scheduled meeting in the prescribed application form along with relevant documents.

Eight (8) hard copies along with soft copy of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / should be submitted to IEC

Principal Investigators shall be forwarded their application to the Chairperson IEC, through Member Secretary and the receipt of the application will be acknowledged by the IEC office. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of the IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and clarify the points raised by the members. IEC can suggest online meetings and virtual presentations of the investigators in special situations such as the COVID-19 pandemic, etc.

If a revision is to be made, the revised proposal in the required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5% of their sanctioned budget. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like CRM, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non-Profitable Organizations etc.

13. Details of documents to be submitted for EC review

a) Cover letter to the Member Secretary
b) Type of review requested
c) Application form for initial review
d) Permission of using copyrighted proforma/ questionnaire
e) A complete protocol
f) Approval of the project for Institute Scientific Committee
g) The correct version of the informed consent document (ICD) in English and the local language(s).
h) Case record form/questionnaire
i) Recruitment procedures: advertisement, notices (if applicable)
j) Patient instruction card, diary, etc. (if applicable)
k) Investigator's brochure (as applicable for drug/biologicals/device trials)
l) Details of funding agency/sponsor and fund allocation (if applicable)
m) Brief curriculum vitae of all the study researchers
n) A statement on COI, if any
o) GCP training certificate (preferably within 5 years) of investigators (Sponsored clinical trials)
p) Any other research ethics/other training evidence, if applicable as per EC SOP
q) List of ongoing research studies undertaken by the principal investigator (if applicable)
r) Undertaking with signatures of investigators
s) Regulatory permissions (as applicable)
t) Relevant administrative approvals (such as HMSC approval for international trials)
u) Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)

v) MoU in case of studies involving collaboration with other institutions (if applicable)
w) Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)
x) Insurance policy (if applicable)

14. Details of documents to be included in the protocol

The protocol should include the following:

A. The first page carrying the title of the proposal with signatures of the investigators;
B. Brief summary/ lay summary of the protocol;
C. Background with a rationale of why a human study is needed to answer the research question;
D. Justification of inclusion/exclusion of vulnerable populations;
E. Clear research objectives and endpoints/ outcome;
F. Eligibility criteria and participant recruitment procedures;
G. Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;
H. Duration of the study;
I. Justification for use of placebo, benefit-risk assessment, plans to withdraw and rescue medication. If standard therapies are to be withheld,
J. Procedure for seeking and obtaining written informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. Informed consent for the storage of samples; assent; re-consent
K. Plan for statistical analysis of the study;
L. Plan to maintain the privacy and confidentiality of the study participants;
M. For research involving more than minimal risk, an account of the management of risk or injury; Proposed compensation, reimbursement of incidental expenses and management of research-related injury/illness during and after research period and insurance policy
N. Provision of ancillary care for unrelated illness during the duration of research;
O. An account of storage and maintenance of all data collected during the trial; and
P. Plans for publication of results – positive or negative – while maintaining the confidentiality of personal information/ identity.
Q. Ethical considerations and safeguards for protection of participants

15. Review procedures

I. The meeting of the IEC will be held periodically unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the workload.
II. The proposals should be sent to the IEC at least 3 weeks in advance of a scheduled meeting.
III. The Member-Secretary with the support of the secretarial staff shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, *exemption from review, expedited review and full committee review.*
IV. Decisions will be taken by consensus after discussion, and whenever needed voting will be done.

V. The PI / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will be allowed to present the proposal. Researchers will be invited to offer clarifications on a case-to-case basis if needed
VI. The review discussions/ decisions will be charted down, and the final minutes will be approved by the Chairperson.
VII. After the IEC meeting, the decision of the IEC members regarding the discussed proposals is to be obtained on the same day of the meeting.
VIII. The proceedings of the meeting will be video recorded with prior permission from all the members attending the meeting.
IX. The type of EC review based on the risk involved in the research, is categorized as follows

Type of risk	Definition/description
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. Research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where the occurrence of serious harm or an adverse event (AE) is unlikely. Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. • Routine research on children and adolescents; Research on persons incapable of giving consent • Delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; • Use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; • Trying a new diagnostic technique in pregnant and breastfeeding women etc. • Research should have a social value. Use of personally identifiable data in research also imposes indirect risks. • Social risks, psychological harm and discomfort may also fall in this category
More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or

	liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures

15.1 Exemption from review

Proposals that present "less than minimal risk" fall under this category. Following situations may come under this "less than minimal risk" category:

Research on educational practices such as instructional strategies or effectiveness, or the comparison among instructional techniques, curricula, or classroom management methods. Exceptions:

1. When research on the use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

2. When interviews involve a direct approach or access to private papers

15.2 Expedited Review

The proposals presenting "no more than minimal risk" to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do an expedited review only if the protocols involve

1. Minor deviations from originally approved research protocol during the period of approval.
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories

- Clinical studies of drugs and medical devices only when -

A. Research is on already approved drugs except when studying drug interaction or conducting trials on vulnerable population or Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
B. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
C. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

a. Research on interventions in an emergency situation

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new interventions as an investigational drug (IND)/ devices/ vaccines to provide emergency medical care to their patients in life-threatening conditions. Research in such instances of medical care could be allowed in patients –

i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention is given to the relative/ legal guardian when available later.
ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor have obtained prior approval of DCGI;
iii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.
iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data.

b. Research on disaster management

It may also be unethical sometimes not to do research during a disaster. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned to be conducted after a disaster should be essential, culturally sensitive and specific in nature with possible application in future disaster situations.
ii. Disaster-affected community participation before and during the research is essential and its representatives or advocates must be identified.
iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.
iv. Protection must be ensured so that only minimal additional risk is imposed.
v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster-affected population and *a priori* agreement should be reached on this, whenever possible, between the community and the researcher.
vi. All international collaborative research in the disaster-affected area should be done with a local partner on an equal partnership basis.
vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

D. Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

15.3 Full Review

All research presenting with "more than minimal risk", proposals/ protocols which do not qualify for exempted or expedited review and projects shall be subjected to full review by all the members.

a) Research involving vulnerable populations, even if the risk is minimal.
b) Research with a minor increase over minimal risk
c) Studies involving the deception of participants.

d) Research proposals that have received an exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee.
e) Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, case record forms, etc.) involving an altered risk.
f) Major deviations and violations in the protocol.
g) Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit-risk assessment.
h) Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need.
i) Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

16. Review of research proposals involving vulnerable population

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. Include economically and socially disadvantaged; children (up to 18 years); women in special situations; tribal and marginalized communities; refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations; afflicted with mental illness and cognitively impaired individuals, differently-abled –mentally and physically disabled; terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or have diminished autonomy due to dependency or being under a hierarchical system and 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.

IECs should carefully determine the benefits and risks of the study and examine the justification provided and risk minimization strategies. Additional safety measures should be strictly reviewed and approved by the IECs. IEC must ensure that the informed consent process should be well documented and recording of assent in case of research studies involving children aged 7 to 18 years and re-consent, when applicable. Informed consent from vulnerable populations may be obtained from LAR (Legally authorized representative) in presence of impartial witnesses after thorough explanation of risks and benefits.

IEC members are responsible for receiving, verifying, and reviewing the research protocols pertaining to vulnerable populations using the Risk benefit assessment tool. Such protocols should be reviewed keeping in mind the following points when it concerns research that involves groups that could be potentially vulnerable to coercion:

 Measure to protect autonomy,

 Risk/benefit determinations with respect to the vulnerability

 Bearing unequal burden in research.

Member of the IEC who would be reviewing such protocols should be well versed with the potential harm or risk of such population participating in the study. For example, children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Committee will review the safety and the rights of justice issues involving vulnerable population if applicable for any particular study involving such populace. Vulnerable Subjects will be defined as per the standard guidelines by ICMR (http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf] A vulnerable category of subjects are those who are relatively (or absolutely) incapable of protecting their own interests which includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence. When a trial is to be carried out in the vulnerable populations like the pediatrics, geriatric population, pregnant women, etc., the consent of the trial subject and subject's Legally Acceptable Representative (LAR) is to be mandatorily taken and the IEC will determine that the proposed protocol and/or other document(s) adequately address the relevant ethical concerns and meet applicable regulatory requirements for such trials. Where required assent of the participant will also be taken and this will be ensured during review and approval of the ICF.

16.1. Responsibility. It is the responsibility of the Secretariat of IEC to maintain up-to-date tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.

16.2. IEC Chairperson/ Member Secretary is responsible for ensuring that IEC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

16.3. IEC member is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP

16.4 Secretariat of the Institute Ethics Committee will

o IEC Secretariat will provide a suitable checklist according to the participant to be recruited in study to the investigator. Inform the investigator to download the appropriate application form and informed consent document/assent form. If the checklists are not available (for e.g. critically/terminally ill or socially/economically disadvantaged/HIV/Leprosy patients/marginalized population) the investigators want to include the above-mentioned population in the study. They have to mention in the protocol details regarding justification of including the vulnerable population for the study, risk and benefits to the study participants along with mechanism of minimizing risks, measures to protect their autonomy, measures for recruitment of such participants along with measures taken for protection of privacy and confidentiality.

o IEC can recommend for written / verbal Informed consent /audio–visual consent /audio consent (leprosy patients) in the vulnerable population. All the protocol dealing with vulnerable population will be considered for full board review.

o IEC Secretariat will provide appropriate reference material or help reviewer to locate such material related to vulnerable populations when specifically requested for, by a reviewing member.

16.5. Protocol Review:

o IEC Members will review the protocol and the informed consent document or assent form.

o The Member Secretary will confirm that the IEC recommendations have been incorporated in the revised protocol and in the final draft of informed consent document or assent form.

16.6. Approval:

o The protocol will be approved by the IEC with the appropriate checklist as given in (Annexure: XXI to XXVII).

o Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants changes for e.g.; unconscious patient gaining consciousness, then the protocol should be amended and resubmitted to the IEC for reconsideration and approval following which the participant should be re-consented and reconsidered for the same.

16.7. Obligation and duties of stakeholders:

All stakeholders will have different responsibilities to protect vulnerable participants as described below:

Stakeholders Obligations / duties	**Stakeholders Obligations / duties**
Researchers	• Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • Ensure that prospective participants are competent to give informed consent.

	• Take consent of the LAR when a prospective participant lacks the capacity to consent. • Respect dissent from the participant. • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations.
Ethics Committees	During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • UPES-IECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • UPES-IECs should have SOPs for handling proposals involving vulnerable populations.
Sponsors	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC).

	• The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

17. Review of multicentric research

Multicenter research is conducted at more than one center by different researchers usually following a common protocol.

- All sites are required to obtain approval from their respective ECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants.
- The ECs/Secretariats of all participating sites should establish communication with one another
- If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon.
- The EC can suggest site-specific protocols and informed consent modifications as per local needs.
- A separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention
- Common review for all participating sites in multicentric research - In order to save time, prevent duplication of effort and streamline the review process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.
- Common review process may be applied to research involving low or minimal risk, survey or multicentric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.
- The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, the local participating sites would be required to obtain local ethical approval.

18. Independent consultant/Invited subject experts

Subject experts will be called to provide special reviews for selected research proposals, if required. They can give their opinion/specialized views, but they do not take part during decision-making by IEC members.

19. Decision-making & Communication of decision

a. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by a voting procedure.
b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and the same should be conveyed to the Chairperson prior to the review of the application and recorded in the minutes.
c. Decision will be made only in meetings where a quorum is complete.
d. Only the members can make the decisions. The expert consultants (subject experts) will only offer their opinions.
e. Decision may be to approve, reject, or revise the proposals. Specific suggestions for

modifications and reasons for modifications and reasons for rejection will be given.

f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
g. Modified proposals will be reviewed by an expedited review through identified members.
h. Decision taken on the proposals will be communicated by the Member Secretary/secretariat in writing to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified format
i. IEC approval will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after one year, where required.
j. The communication of the decision will include:
   I. Name and address of IEC.
   II. The date, place and time of decision.
   III. The name and designation of the applicant.
   IV. Title of the research proposal reviewed.
   V. The clear identification of protocol no., version no., date, amendment no., date.
   VI. Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.
   VII. List of EC members who attended the meeting- clear description of their role, affiliation
   VIII. and gender.
   IX. A clear statement of the decision reached.
   X. Any advice by the IEC to the applicant including the schedule/plan of an ongoing review by the UPES-IEC
   XI. In case of a conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
   XII. In case of rejection of the proposal, the reason(s) for the rejection will be clearly stated.

k. Signature of the member secretary with date

20. Policy for resolution of conflict

The IEC, UPES Dehradun would refer to the GCP guidelines, ICMR guidelines and New Drugs and Clinical Trials Rules, 2019 and their modifications in case of any conflict as mentioned below for which the following format will be used to take undertaking from the concerned member of IEC. No members having a conflict of interest will be involved in the oversight of the clinical trial or bioavailability or bioequivalence or biomedical or any health research study being reviewed by his/her and it is responsibility of each member to withdraw voluntarily, by expressing to the Chairman in writing that there is no conflict of interest with a sign. The details in respect of the conflict of interest of the members will be recorded in the minutes of the meetings.

21. Record keeping and archiving of documents

✓ All Research proposals (8 hard copies along with soft copy) along with the information and documents submitted will be dated and filed.

- ✓ The documents will be archived for a minimum period of 3 years and for sponsored clinical trials for 5 years after completion/termination of the study.
- ✓ IEC members should not retain any documents with them after the meeting is over.

List of documents to be filed and archived

1. Constitution of IEC
2. SOP
3. CV & consent of IEC members
4. IEC Registration
5. Honorarium details, Income and expenses
6. Agenda & minutes of the meetings
7. One copy of the proposal
8. Copy of recommendations/decision communicated to the applicant
9. Review reports, documents received during the follow-up period and final reports of the study

22. Terms of reference

Terms of reference will be maintained in the office of IEC. This includes:

A. Membership Requirements
B. Terms of Appointment with reference to the duration of the term,
C. The policy for removal, replacement, resignation procedure**,**
D. Frequency of meetings, and
E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts etc.

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage (35 to 50%) of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons familiar with ethical guidelines and laws of the country.

23. Administration and management

UPES Dehradun should have an office for the IEC which have adequate space, infrastructure and staff to the IEC for maintaining a full-time secretariat, safe archival of records and conduct of the meeting. A fee for review [Rs. 10,000/- for project from industry, Rs. 5,000/- for projects from Academic institutes (Outside UPES)] may be charged by the IEC to cover the expenses related to optimal functioning in accordance with Institutional policies for industry-sponsored projects/funded projects. These fees are applicable for up to 3 reviews, beyond which an additional charge of Rs. 5,000/- will be applicable for each additional review. There should be a provision for allocating a reasonable amount of funds for the smooth functioning of the IEC. An honorarium of INR 10,000/-per sitting to the Honourable Chairperson and Rs. 5,000/- per sitting will be paid by the institute to the UPES non-affiliated members attending the meeting. Additionally, TA will be paid to all UPES non-affiliated members for attending the meeting in offline mode.

24. Web page for IEC:

A dedicated webpage will be created and maintained for IEC. Details of composition, SOP, registration details, circulars/notifications related to IEC meetings and status of submitted proposals and ongoing projects, submission forms, guidelines and contact details will be displayed on this page

25. Contact details:

Dr. Sandip K Nandi
Member Secretary, IEC, UPES, Dehradun Uttarakhand-248007
Contact number: 9971025944
Email ID: UPES-IEC@ddn.upes.ac.in
Whatapp: 9971025944

26. Annexures

Annexure-I

Letter Ref. No:

From Date: DD/MM/YYYY

Dean, School of Health Sciences & Technology
University of Petroleum and Energy Studies, Dehradun

To

Dr. XX,
XXXXXX

Sub: Invitation letter to a member for constitution of Institute Ethics Committee

Dear Dr. XX

I am pleased to inform you that your name has been nominated as a Member of the Institutional Ethics Committee of UPES. Kindly send your written acceptance in the enclosed format. On receipt of your acceptance, I shall send you the formal appointment letter.

Also, kindly attach a one-page CV and training certificates in Ethics and Good clinical practice, if you have already undergone a training, else let us know convenient dates for attending the training.

Yours sincerely

Annexure-II

To
Dean, School of Health Sciences & Technology
University of Petroleum and Energy Studies, Dehradun

Date: DD.MM.YYYY

Sub: Consent to be a member of Institute Ethics Committee

Reg. Ref: You're Letter No:

Dear Sir,

In response to your letter stated above, I give my consent to become a Member of the University of Petroleum and Energy Studies, Dehradun. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study-related documents with me after the discussion and final review. I shall maintain all the research project-related information confidential and shall not reveal the same to anybody other than project-related personnel.
Thanking you

Yours Sincerely

Signature

Annexure-III

APPOINTMENT ORDER

Ref No: Date: DD/MM/YYYY

Dr/ Mr. / Mrs.,

I am pleased to appoint you as the_____of the Institutional Ethics Committee (IEC) at the University of Petroleum and Energy Studies Dehradun (UPES Dehradun) following the receipt of your acceptance letter. The appointment shall be effective from_____ for a period of_____year/_____months or till further notice provided the following conditions are satisfied.

1. You should be willing to publicize your full name, profession & affiliation.
2. You are willing to record all reimbursement for work & expenses, if any, within or related to an IEC & make it available to the public upon request.
3. You consent to sign a confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.

Further, the renewal of your appointment will be by consensus & one-month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC, UPES Dehradun.

You will be paid a sum of INR/……../- per sitting as Honorarium for your services rendered towards attending the IEC meetings at UPES Dehradun as per the institutional norms.

We sincerely hope your association with IEC, UPES Dehradun will be scientifically productive and beneficial to the Institute & the community at large.

Signature with date

Annexure-IV

Application for Initial Review

Section A - Basic information

a. Title of the study:
   Acronym/Short title (If any):

b. Name of PI:
c. Department:
d. Date of submission:
e. Designation:
f. Email ID:
g. Type of review requested:
   Exemption from review ☐ Expedited review ☐ Full committee review ☐
h. Protocol number (If any):
   Version number:
i. Details of Investigators:

	Designation and Qualification	Department and Institution	Address for communication
Investigator/Guide			
Co-investigator/student/fellow			

j. Number of studies where the applicant is a:

   i. Principal Investigator at time of submission
   ii. Co-Investigator at time of submission:

k. Duration of the study:

l. Funding details and budget

   a. Total estimated budget for site:
   b. Self-funding☐ Institutional funding☐ Funding agency *(Specify)*☐

Section B - Research related information

1. Overview of research

a) Lay summary (within 300 words):

b) Objective of the study:

c) Type of study:

Basic Sciences	☐	Clinical	☐	Cross-Sectional	☐
Retrospective	☐	Epidemiological/ Public Health	☐	Case-Control	☐
Prospective	☐	Cohort	☐	Qualitative	☐
Socio-behavioral	☐	Biological samples/ Data	☐	Quantitative	☐
Systematic Review	☐	Mixed-Method	☐	Any others (Specify)	☐

d) Justification for the conduct of this study:

1. Methodology

i. Sample size/ number of participants
At site: total sample size
Control group / Study group

Justification for the sample size chosen (100 words); In case of qualitative study, mention

the criteria used for saturation

ii. Inclusion criteria:
iii. Exclusion criteria:
iv. Study design:
v. Investigations specifically related to projects:
vi. Is there an external laboratory/outsourcing involved for investigations? Yes/ No/ NA
vii. How was the scientific quality of the study assessed?
Independent external review/ Review by sponsor or Funder/ Review within PI's institution/ Review within multi-center research group/ No review
viii. Date of the Review:
ix. Research Comments of scientific committee/IRC, if any (100 words)

Section C - Participant related information

1. Recruitment and research participants

a) Type of participants in the study:

Healthy volunteers	☐	Vulnerable persons/ Special groups	☐
Patients	☐	Others (Specify)	☐

Who will do the recruitment?

b) Participant recruitment methods used:

Posters/leaflets/Letters	☐	TV/Radio ads	☐
Patient/ family/ friends	☐	Telephone	☐
Others *(Specify)*	☐		

c)

i. Will there be vulnerable persons / special groups involved? Yes ☐ No ☐ NA ☐
ii. If yes, type of vulnerable persons / special groups

Children under18yrs	☐	Pregnant or lactating women	☐
Employees/Students/Nurses/Staff	☐	Elderly	☐
Differently abled (Mental/Physical)	☐	Institutionalized	☐
Economically and socially disadvantaged	☐	Terminally ill (stigmatized or rare diseases)	☐
Refugees/Migrants/Homeless	☐	Any other *(Specify)*:	☐

iii. Provide justification for inclusion/exclusion

iv. Are there any additional safeguards to protect research participants?

d) Is there any reimbursement to the participants? Yes ☐ No ☐
If yes, Monetary ☐ Non-monetary ☐ *Provide details*

e) Are there any incentives to the participants? Yes ☐ No ☐
If yes, Monetary ☐ Non-monetary ☐ *Provide details*

f) Are there any participant recruitment fees/incentives for the study provided to the PI/Institution? Yes ☐ No ☐
If yes, Monetary ☐ Non-monetary ☐ *Provide details*

2. Benefits and risks

a)

i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐
If yes, categorize the level of risk:

Less than Minimal risk	☐
Minimal risk	☐
Minor increase over minimal risk or low risk	☐
More than minimal risk or high risk	☐

ii. Describe the risk management strategy:

iii. What are the potential benefits from the study?

	Yes	No	If yes, Direct	If yes, Indirect
For the participant	☐	☐	☐	☐
For the society/community	☐	☐	☐	☐
For improvement in science	☐	☐	☐	☐

iv. Please describe how the benefits justify the risks

v. Are adverse events expected in the study? Yes ☐ No ☐ NA ☐

vi. Are reporting procedures and management strategies described in the study?

Yes ☐ No ☐

If Yes, Specify

3. Informed consent

a) Are you seeking waiver of consent? If yes, please specify reasons and skip to item no.4
Yes ☐ No ☐

b) Version number and date of Participant Information Sheet (PIS):

c) Version number and date of Informed Consent Form(ICF):

d) Type of consent planned for:

Signed consent ☐	Verbal/ Oral consent ☐	Witnessed consent ☐	Audio-Video (AV) consent ☐
Consent from LAR (If so, specify from whom) ☐	For children <7 yrs parental/LAR consent ☐	Verbal consent from minor (7-12 yrs) along with parental consent ☐	Written consent from minor (13-18 yrs) along with parental consent ☐
Other (specify) ☐			

e) Who will obtain the informed consent?

PI/Co-I ☐	Nurse/Counselor ☐	Research Staff ☐	
Other (Specify) ☐	Any tools to be used		

f) Participant Information Sheet (PIS) and Informed Consent Form (ICF)
List the languages in which translations were done
English ☐ Local language ☐
Other (Specify) ☐
If translation has not been done in local language, please justify

g) Provide details of consent requirements for previously stored samples if used in the study

h) Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

Simple language ☐	Data/ Sample sharing ☐	Compensation for study related injury ☐
Risks and discomforts ☐	Need to recontact ☐	Statement that consent is voluntary ☐
Alternatives to participation ☐	Confidentiality ☐	Commercialization/ Benefit sharing ☐
Right to withdraw ☐	Storage of samples ☐	Statement that study involves research ☐
Benefits ☐	Return of research results ☐	Use of photographs/ Identifying data ☐
Purpose and procedure ☐	Payment for participation ☐	Contact information of PI and Member Secretary of EC ☐
Others (Specify) ☐		

4. Payment/ compensation

a) Who will bear the costs related to participation and procedures?
PI ☐ Institution ☐ Sponsor ☐
Other agencies (specify) ☐

b) Is there a provision for free treatment of research related injuries? Yes ☐ No☐ N/A ☐
If yes, then who will provide the treatment?

c) Is there a provision for compensation of research related SAE? Yes ☐ No ☐ N/A ☐
If yes, specify
Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐
Insurance ☐

d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? Yes ☐ No ☐ N/A ☐
If yes, specify

e) Is there a provision for ancillary care for unrelated illness during the study period?
Yes ☐ No ☐ N/A ☐
If yes, specify

5. Storage and confidentiality

a. Identifying Information: Study Involves samples/data. Yes ☐ No ☐ NA ☐
If yes, specify

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐
Irreversibly coded ☐ Identifiable ☐
If identifiers must be retained, what additional precautions will be taken to ensure that access is limited/ data is safeguarded? (e.g., data stored in a cabinet, password-protected computer, etc.)

b. Who will be maintaining the data pertaining to the study?

c. Where will the data be analyzed and by whom?

d. For how long will the data be stored?

e. Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe☐
If yes, explain how you might use stored material/data in the future?

Section D: Other issues

1. Publication, benefit sharing and IPR issues

   a. Will the results of the study be reported and disseminated? Yes □ No □ NA □
   If yes, specify

   b. Will you inform participants about the results of the study? Yes □ No □ NA □
   c. Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? Yes □ No □ NA □
   If yes, describe in brief (Max50words)

   d. Is there any plan for post research benefits haring with participants? Yes □ No □ NA □
   If yes, specify

   e. Is there any commercial value or a plan to patent/IPR issues? Yes □ No □ NA □
   If yes, please provide details

   f. Do you have any additional information to add in support of the application, which is not included elsewhere in the form? Yes □ No □ NA □
   If yes, please provide details

Section E: Declaration and checklist

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guidelines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, New drugs and Clinical Trial Rules 2019 GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/ collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IIEC-approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of the study.
☐	I/We have the following conflict of interest (PI/Co-I): 1. 2.
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI:

Signature with date:

Name of Co-PI:

Signature with date:

Name of Guide:

Signature with date

Name of HOD:

Signature with date

Administrative requirements

S. No	Items	Yes	No	Enclosure No	IEC remarks
1	Cover letter	☐	☐		
2	Brief CV of all Investigators	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐		
4	Approval of scientific committee	☐	☐		
5	IEC clearance of other centers	☐	☐		
6	Agreement between collaborating partners	☐	☐		
7	MTA between collaborating partners	☐	☐		
8	Insurance policy/certificate	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐		
Proposal related					
12	Copy of the detailed protocol	☐	☐		
13	Investigators Brochure (If applicable for drug/ biologicals/ device trials)	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF) (English and translated)	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐		
16	Proforma/ Questionnaire/ Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters, etc)	☐	☐		

Permission from governing authorities					
	Other permissions	**Required**	**Not required**	**Received**	**Applied (dd/mm/yy)**
18	CTRI	☐	☐	☐	
19	DCGI	☐	☐	☐	
20	HMSC	☐	☐	☐	
21	NAC-SCRT	☐	☐	☐	
22	ICSCR	☐	☐	☐	
23	RCGM	☐	☐	☐	
24	BARC	☐	☐	☐	
25	Others (specify)				

Annexure-V

Continuing Review / Annual report format

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of IEC approval
2. Validity of approval
3. Date of start of the study
4. Proposed date of the study completion
5. Period of a continuing report from to
6. Does the study involve the recruitment of participants? Yes □ No □
   a) If yes,
      Total number expected: Number Screened:
      Number Enrolled: Number Completed:
      Number on follow up
   b) Enrolment status – ongoing/ completed/ stopped
   c) Report of DSMB Yes □ No □ NA □
   d) Anyother remark

   e) Have any participants withdrawn from this study since the last approval?
      Yes □ No□ NA□
      If yes, total number withdrawn and reasons:

7. Is the study likely to extend beyond the stated period? Yes □ No □
   If yes, please provide reasons for the extension.

8. Have there been any amendments in the research protocol/ Informed Consent Document

(ICD) during the past approval period? Yes ☐ No ☐
If No, skip to item no.9
If yes, date of approval for protocol and ICD:
In case of amendments in the research protocol/ ICD, was re-consent sought from participants? Yes ☐ No ☐
If yes, when/ how:

9. Is any new information available that changes the benefit-risk analysis of human participants involved in this study? Yes ☐ No ☐
If yes, discuss in detail:

10. Have any ethical concerns occurred during this period? Yes ☐ No ☐
If yes, give details

11. Have any adverse events been noted since the last review? Yes ☐ No ☐
Describe in brief:

12. (a) Have any SAE's occurred since the last review? Yes ☐ No ☐
If yes, number of SAE's
Type of SAE's:
(b) Is the SAE related to the study? Yes ☐ No ☐
(c) Have you reported the SAE to EC? Yes ☐ No ☐
If no, state reasons

13. Has there been any protocol deviations/ violations that occurred during this period? Yes ☐ No ☐
a) If yes, number of deviations
b) Have you reported the deviations to EC? Yes ☐ No ☐
c) If no, state reasons

14. In case of multi centric trials, have reports of off-site SAEs been submitted to the EC? Yes ☐ No ☐ NA☐

15. Are there any publications or presentations during this period? Yes ☐ No ☐
If yes, give details.

Any other comments:

Signature of PI:

Annexure-VI

Application/ Notification form for Amendments

1. Title of study:

2. IEC ref no:
3. Principal Investigator (Name, Designation and Affiliation):

4. Date of EC approval
5. Date of Start of study
6. Details of Amendments

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ ICD

7. Impact on Benefit and risk analysis – Yes/No If yes describe in brief
8. Is any re-consent necessary? Yes/No
   If yes, have necessary changes been made in the informed consent? Yes/No
9. Type of review requested for amendment:
   Expedited review (No alteration in risk to participants) ☐
   Full review by EC (There is an increased alteration in the risk to participants) ☐
10. Version number of amended Protocol/ Investigator's brochure/ ICD:

Signature of PI:

Annexure-VII

Protocol Violation/Deviation Reporting Form (Reporting by case)

1. Title of Study:

2. IEC ref no:
3. Principal Investigator (Name, Designation and Affiliation):

4. Date of EC approval:
5. Date of Start of study:
6. Participant ID:
7. Total number of deviations /violations reported till date in the study:
8. Deviation/Violation identified by:
   Principal Investigator/ study team/ Sponsor/ Monitor/ SAE Sub Committee/ EC
9. Is the deviation related to (Tick the appropriate box)?

Consenting	☐	Source documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Safety Reporting	☐
Others(specify)	☐		

10. Provide details of Deviation/Violation:

11. Corrective action taken by PI/Co-I:

12. Impact on (if any): Study participant/ Quality of data/
13. Are any changes to the study/ protocol required? Yes/No
    If yes, give details

Signature of PI with date:

Annexure-VIII

Serious Adverse Event Reporting Format (Biomedical Health Research)

1. Title of the study

2. IEC ref no:
3. PI – Name, Designation and Affiliation

4. Date of EC approval:
5. Date of Start of study:
6. Participant details:
   Initials/ID:
   Age at the time of event:
   Gender: Male/Female
   Weight (Kgs):
   Height (cms):
7. Suspected SAE diagnosis:
8. Date of onset of SAE:
9. Describe the event:

10. Date of reporting SAE:
11. Details of suspected intervention causing SAE

12. Report type: Initial/ Follow-up/ Final
13. If Follow-up report, state date initial report
14. Have any similar SAE occurred previously in this study? Yes/No
    If yes, please provide details.
15. In the case of a multi-centric study, have any of the other study sites reported similar SAEs? (Please list number of cases with details if available)

16. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention

being evaluated and not disease process)

a. Expected event/ Unexpected event
b.

Hospitalization	☐	Increased Hospital Stay	☐
Death	☐	Congenital anomaly/ birth defects	☐
Event which poses threat to life	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐
Persistent or significant disability/ incapacity	☐	Others	☐

17. In case of death, state probable cause of death:

No permanent/ significant functional/ cosmetic impairment	☐
Permanent/ significant functional/ cosmetic impairment	☐
Not Applicable	☐

18. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

19. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom

20. Outcome of SAE

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other(specify)	☐

21. Provide any other relevant information that can facilitate assessment of the case such as medical history

22. Provide details about PI's final assessment of SAE relatedness to research.

Signature of PI with date

Annexure-IX

Premature Termination/ Suspension/ Discontinuation Report Format

1. Title of the study:

2. IEC ref no:
3. PI – Name, Designation and Affiliation

4. Date of EC approval:
5. Date of Start of study:
6. Date of last progress report submitted to EC:
7. Date of termination/suspension/discontinuation:
8. Reason for Termination/ Suspension/ Discontinuation:

9. Action taken post Termination/Suspension/Discontinuation (if any):

10. Plans for post study follow up/withdrawal (if any):

11. Details of study participants

Total number of participants to be recruited:
Screened:
Screen failures:
Consent withdrawn:
Reason (Details):
Withdrawn by PI- reason:
Reason (Details):
Active on treatment:
Completed treatment:
Participants on follow-up:
Participants lost to follow up:
Number of dropouts :
Reasons for each drop-out:

Any other:

12. Total number of SAEs reported till date in the study:
13. Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes/No
14. Have there been participant complaints or feedback about the study? Yes/No
    If yes, provide details

15. Have there been any suggestions from the SAE Sub Committee? Yes/No
    If yes, have you implemented that suggestion?

16. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare?
    (e.g., making arrangements for medical care of research participants) Yes/ No
    If yes, provide details Summary of results:

Signature of PI with date

Annexure-X

Application Form for Clinical Trials

1. Title of the study:

2. PI details:

3. CTRI registration number:
4. NABH accreditation number:
5. EC registration number:
6. Type of Clinical trial – Regulatory trial/ Academic trial
   If regulatory trial, provide status of CDSCO permission letter

Approved and letter attached/ Applied, under process/ Not applied (State reason)

7. Tick all categories that apply to your trial

Phase-I	☐	Phase-II	☐
Phase-III	☐	Phase-IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	Drug/ device combination	☐
New innovative procedure	☐	Bioavailability/ Bioequivalence studies	☐
Non-drug intervention	☐	Repurposing an existing intervention	☐
Indian system of (AYUSH) medicine Phytopharmaceutical drug	☐	Approved drug for any new indication or new route of administration	☐
Stem cells	☐	Others (specify)	☐

8. Trial design of the study

Randomized	☐	Factorial	☐
Non-randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched-pair	☐	Non-inferiority trial	☐
Equivalence trial	☐	Others (specify)	☐

a. If there is randomization, how will the participants be allocated to the control and study

group(s)?

b. Describe the method of allocation concealment (blinding/ masking), if applicable.

9. List the primary/ secondary outcomes of the trial.
10. Is there a Contract Research Organization (CRO)/ Site Management Organization (SMO)/ Any other agency such as public relation/human resource? Yes □ No □
If yes, Name and Contact details:

11. State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	□	Clinical and medical monitoring	□
Regulatory affairs	□	Data management	□
Statistical support	□	Medical writing	□
Site management	□		

12. Please provide the following details about the intervention being used in the protocol
Drug/s, device/s and/or biologics; Yes □ No □ NA□
If yes, provide regulatory approval details.

Already approved drugs or a combination of two or more drugs with new indications/ change in dosage form/ route of administration. Yes □ No □ NA □
If yes, provide details.

Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.

Provide details of patent of the drug/s, device/s and biologics.

13. Describe in brief any preparatory work or site preparedness for the protocol?
If yes, provide details Yes □ No □ NA□

14. Is there an initial screening/use of existing database for participant selection?
If yes, provide details Yes□ No□ NA□

15. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention? Yes □ No □ NA □
If yes, provide details of arrangements made to address them.

16. Does the study use a placebo? Yes □ No □ NA □
If yes, justify the use of the placebo and risks entailed to participants.

17. Will current standard of care be provided to the control arm in the study? Yes □ No □ NA□
If no, please justify.

18. Are there any plans to withdraw standard therapy during the study? Yes □ No □ NA □
If yes, please justify

19. Are there any rules to stop the protocol in case of any adverse events? Yes □ No □ NA□
If yes, please specify

20. Does the study have a Data and Safety Monitoring Plan? Yes □ No □ NA□
If no, please justify.

16. Participant Information Sheet (PIS) and Informed Consent Form (ICF)
English □ Local language □ Other(Specify) □

(certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

17. Involvement/consultation of a statistician in the study design Yes □ No □ NA □
18. Is there any insurance coverage of the trial? If yes, provide details. Yes □ No □

19. Is the PI registered with the Medical Council of India (MCI) or the State Medical Council registration? Please provide details. Yes □ No □

20. Is the PI trained in GCP in the last 3 years? Yes □ No □
If yes, please enclose the certificate.

Signature of PI with date

Annexure-XI

Serious Adverse Event Reporting Format (Clinical trials)

1. Title of the study

2. PI details:

3. Participant details
   Initials and Case No:
   Subject ID:
   Age at the time of the event:
   Gender: Male/Female
   Weight (Kgs):
   Height (cms):
4. Report type: Initial ☐ Follow-up ☐ Final ☐
   If Follow-up report, state date of Initial report:

5. What was the assessment of relatedness to the trial in the initial report?

By PI – Related	☐	By Sponsor – Related	☐
By EC – Related	☐	Unrelated	☐
Unrelated	☐	Unrelated	☐

6. Describe the event and specify suspected SAE diagnosis

7. Date of onset of SAE:
8. Date of reporting:
9. Onset lag time after administration of intervention:
10. Location of SAE (Clinic/Ward/Home/Other)
11. Details of suspected study drug/device/investigational procedure causing SAE:
    a. Suspect study drug (include generic name) device/intervention:
    b. Indication(s) for which suspect study drug was prescribed or tested:
12. Route(s) of administration, daily dose and regimen, dosage form and strength

13. Therapy start date: Stop date:
14. Was study intervention discontinued due to the event? Yes ☐ No ☐

15. Do the reaction decline after stopping or reducing the dosage of the study drug/ procedure? If yes, provide details about the reduced dose Yes ☐ No ☐

16. Did the reaction reappear after reintroducing the study drug/ procedure? Yes☐ No☐ NA☐ If yes, provide details about the dose

17. Concomitant drugs history and lab investigations:
    a. Concomitant drug (s) and date of administration:
    b. Relevant test/laboratory data with dates:
    c. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

18. Have any similar SAE occurred previously in this study? Yes ☐ No ☐
    If yes, please provide details

19. Seriousness of the SAE:

Death	☐	Congenital anomaly	☐
Life-threatening	☐	Required intervention to prevent	☐
Hospitalization-initial or prolonged	☐	Permanent impairment/ damage	☐
Disability	☐	Others (specify)	☐

20. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

21. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other (specify)	☐

22. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐
23. Provide details about PI's final assessment of SAE relatedness to trial.

24. Has this information been communicated to sponsor/CRO/regulatory agencies?
Yes □ No □

25. Provide details if communicated (including date)
26. Does this report require any alteration in trial protocol? Yes □ No □
27. Provide details of compensation provided/ to be provided to the participants (Include information on who pays, how much, and to whom)

Signature of PI with date

Annexure-XII

Study completion/Final report format

1. Title of study:

2. PI (Name, Designation and Affiliation):

3. Date of EC Approval:
4. Date of Start of Study:
5. Date of study completion:
6. Provide details of
   a) Total no. of study participants approved by the EC for recruitment:
   b) b) Total no. of study participants recruited:
   c) Total number of participants withdrawn from the study (if any):
7. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) –

8. Describe the main Ethical issues encountered in the study (if any):

9. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

10. Describe in brief Plans for archival of records / Record Retention:

11. Is there a plan for post-study follow-up –

12. Do you have plans for ensuring that the data from the study can be shared/ accessed

easily?

13. Is there a plan for post-study benefit sharing with the study participants? Yes □ No □
    If yes, Describe results (summary) with Conclusion:

14. Number of SAEs that occurred in the study:
15. Have all SAEs been intimated to the EC:
16. Is medical management or compensation for SAE provided to the participants?

Annexure-XIII

Participant information sheet

i. Statement that the study involves research and explanation of the purpose of the research. In simple language
ii. Expected duration of the participation of the subject.
iii. Description of the procedures to be followed, including all invasive procedures.
iv. Description of any reasonably foreseeable risks or discomforts to the subject.
v. Description of any benefits to the participant or others reasonably expected from the research. If no benefit is expected participants should be made aware of this.
vi. Disclosure of specific appropriate alternative procedures or therapies available to the participant.
vii. Statement describing the extent to which confidentiality of records identifying the participant will be maintained and who will have access to the participant's medical records.
viii. Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).
ix. Statement describing the financial compensation and the medical management as under:
   a. In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
   b. In the event of a trial-related injury or death, the sponsor or his representative or the investigator or center, as the case may be, in accordance with rule 39, as the case may be, shall provide financial compensation for the injury or death.
x. An explanation about whom to contact for trial-related queries, rights of Subjects and in the event of any injury.
xi. The anticipated prorated payment, if any, to the participant for participating in the trial.
xii. Responsibilities of the subject on participation in the trial.
xiii. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.
xiv. Statement that there is a possibility of failure of the investigational product to provide an intended therapeutic effect.
xv. Statement that in the case of a placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.
xvi. Any other pertinent information.

Additional elements, which may be required:

A. Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.
B. Additional costs to the participant that may result from participation in the study.
C. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
D. Statement that the Participant or participant's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the participant's willingness to continue participation will be provided.
E. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently

unforeseeable.

F. Approximate number of participants enrolled in the study.

Annexure-XIV

Informed consent form

1. Study Title:

2. Study Number:
3. Participant's Initials:
4. Participant's Name:
5. Date of Birth/Age:
6. Address of the Participant:
7. Qualification:
8. Occupation: Student/ Self-Employed/ Service/ Housewife/ Others
9. Annual Income of the subject:
10. Name and address of the nominees and their relation to the subject (for the purpose of compensation in case of trial related death).

11. Place Initial box (Subject)

i. I confirm that I have read and understood the information sheet [ ] dated_____ for the above study and have had the opportunity to ask questions.
ii. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]
iii. I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree with this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]
iv. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes. [ ]
v. I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:
Date:
Signatory's Name:

Signature of the Investigator:
Date: Study Investigator's Name:

Signature of the Witness
Date:
Name of the Witness:

Annexure-XV

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 another facility where the research will be conducted:

3. Education, training & experience that qualifies the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

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

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

6. 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.

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

8. 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. I inform you that no work has been started for this research yet.
   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 favorable 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 Licencing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study-related audit conducted by regulatory officials or authorised 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 Licencing Authority, sponsor as well as the ethics committee within twenty-four 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 Licencing 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 Licencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain the 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.

Signature of Investigator with date.

Annexure XVI

APPLICATION FORM FOR SOCIO-BEHAVIOURAL AND PUBLIC HEALTH RESEARCH

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Data collection method used in the study

Focus group	☐	Questionnaire/survey	☐	Observation	☐
Interviews	☐	Documents and records	☐	Ethnographies/oral history/case studies	☐
Others (Specify)	☐				

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies. Yes ☐ No ☐

2. Type of informed consent is used in the study?

Individual consent	☐	Gate-keeper consent	☐	Community consent	☐
Others (specify)	☐				

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing?
Yes ☐ No ☐

4. Describe strategies to manage if any patterns of behavior of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐

5. Are cultural norms and/or social considerations/sensitivities taken into account while designing the study and participant recruitment?
Yes ☐ No ☐

6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA ☐

7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

8. I. Type of risk related to procedures involved in the study

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

II. Justify reasons if individual harm is overriding societal benefit. Yes ☐ No ☐ NA ☐

III. Describe how do societal benefits outweigh individual harm.

9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception.
Yes ☐ No ☐

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

Signature of PI: Date:

Annexure XVII

APPLICATION FORM FOR EXPEDITED REVIEW

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why expedited review from EC is requested?

- ☐ i. Involve non-identifiable specimen and human tissue from sources like blood banks, tissue banksand left-over clinical samples
- ☐ ii. Involve clinical documentation materials that are non-identifiable (data, documents, records).
- ☐ iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s))
- ☐ iv. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals
- ☐ v. Minor deviations from originally approved research causing no risk or minimal risk
- ☐ vi. Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee.
- ☐ vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modification in the study proposal through full committee meeting/ expedited review depending on the importance of local consent related issues involved specific to the centre.
- ☐ viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017).
- ☐ ix. Any other (please specify)

2. Is waiver of consent being requested ? Yes /No
3. Does the research involve vulnerable person? Yes/ No
   If Yes give details:

Signature of PI: Date:

Comments of EC Secretariat:

Signature of Member Secretary Date

Annexure XVIII

APPLICATION FORM FOR EXEMPTION FROM REVIEW

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why exemption from ethics review is requested?

- ☐ i. Research on data in the public domain/ systematic reviews or meta-analyses;
- ☐ ii. Observation of public behavior/information recorded without linked identifiers and disclosure would not harm the interests of the observed person
- ☐ iii. Quality control and quality assurance audits in the institution
- ☐ iv. Comparison among instructional techniques, curricula, or classroom management methods
- ☐ v. Consumer acceptance studies related to taste and food quality
- ☐ vi. Public health programmes by government agencies
- ☐ vii. Any other (please specify in 100 words):

Signature of PI: Date.

Comments of EC Secretariat:

Signature of Member Secretary

Date

Annexure XIX

UNDERTAKING REGARDING CONFLICT OF INTEREST

To
The Chairperson,
Institutional Ethics Committee,
UPES Dehradun

Date:

I ……., hereby declare that as Principal Investigator/ Co-investigator / Author / Study team (of) / I have financial interest in the study entitled ……
and I realize that there is a possibility of evoking a conflict of interest I will voluntarily withdraw from this meeting after informing the Chairperson in advance and in writing about it.

Sincerely,

Signature

Name:

Role in EC:

Date of meeting

Annexure XX

Application Form for Exemption from Review

Title of study:

Principal Investigator (Name, Designation and Affiliation):

Choose reasons why exemption from ethics review is requested?

i.	Research on data in the public domain/ systematic reviews or meta-analyses	☐
ii.	Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person	☐
iii.	Quality control and quality assurance audits in the institution	☐
iv.	Comparison among instructional techniques, curricula, or classroom management methods	☐
v.	Consumer acceptance studies related to taste and food quality	☐
vi.	Public health programs by government agencies	☐
vii.	Any other (please specify in 100 words):	

Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary with date:

Annexure -XXI

CHECKLIST FOR REVIEWING RESEARCH INVOLVING CHILDREN (VULNERABLE POPULATION)

Investigator: IEC Ref:

Study Title:
……

……..

For the principal investigator		IEC Office
RISK DETERMINATION	**BENEFIT ASSESSMENT**	**IEC ACTION**
Minimal*	Direct benefit No direct benefit	Approvable
Greater than minimal risk	Potential to child	Approvable
Greater than minimal risk	No direct benefit to individual offer general knowledge about the child's condition or disorder.	Approvable case –by-case **

* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.

** Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.

	Yes	No	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			
Does the study involve normal volunteers?			
If yes: Is the inclusion of normal volunteers justified?			
Are the studies conducted on animals and adults, appropriate and justified?			
If No: Is the lack of studies conducted on animals and adults justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
If Yes: Are the conditions acceptable?			
Will efforts be made ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the assent of children over7 and, where appropriate, honoring their dissent?			
Are provisions made to protect subjects' privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor orIEC member during consent procedures?			
Are special needs of adolescents such as counseling andconfidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve implications for other familymember ?(for example, genetic risk , HIV infection , Hepatitis C)			
If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
Are parents required to be present during the conduct of the research? (Are proposed participants to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?)			

- Approval to proceed with this category of research must be made by the IEC Secretariat, withinput from selected experts

Signature of Principal Investigator:_____Date_____

IEC Office use only	
Comments:	
Primary Reviewer(s) Signature & Date	

Annexure -XXII

CHECKLIST FOR RESEARCH INVOLVING PREGNANT WOMEN & FETUSES

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……

SECTION 1

THIS RESEARCH INVOLVES PREGNANT WOMEN OR FETUSES PRIOR TO DELIVERY:

	Yes	No	NA
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non- pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;			
The risk to the fetus is not greater than minimal, or any risk to the fetuswhich is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;			
Any risk is the least possible for achieving the objectives of the research;			
The woman's consent or the consent of her legally authorizedrepresentative is obtained in accord with the informed consent provisions, unless altered or waived.			
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of theresearch on the fetus			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
Women's participation in the research will not have an effect on the decisions by investigator with respect to the timing, method orprocedures used to terminate a pregnancy; and			
The decision of investigator determining the viability of a fetus will nothave an effect if the women participates in the research			

If the response to any of the above is No, the research is not approvable by the IEC at this time.

See section 3

SECTION 2

THIS RESEARCH INVOLVES FETUSES AFTER DELIVERY:

	Yes	No	NA
Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses			
The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the **research** on the fetus			
No inducements, monetary or otherwise, will be offered toterminate a pregnancy;			

Women's participation in the research will not have an effect on the decisions by investigator with respect to the timing, method or procedures used to terminate a pregnancy; and			
The decision of investigator determining the viability of a fetus will not have an effect if the women participates in theresearch			

AND

A. Fetuses of uncertain viability	Yes	No	NA
1. Does the **research** hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability,and any risk is the least possible for achieving the objectives of the **research;**			
OR			
The purpose of the **research** is the development of important biomedical knowledge which cannot be obtained by other meansand there will be no risk to the fetus resulting from the **research**;			
2. The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.			

And/or

B. Nonviable fetuses	Yes	No	NA
1. Vital functions of the fetus will not be artificially maintained;			
2. There will be no risk to the fetus resulting from the research;			
3. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and			
4. The legally effective informed consent of both parents of the fetuswill be obtained except that the waiver and alteration provisions donot apply. However, if either parent is unable to consent because ofunavailability, incompetence, or temporary incapacity, the informedconsent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorizedrepresentative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.			

If the response to any of above is **No,** the research is not approvable by the IEC at this time. See section 3.

SECTION 3

THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:

(a) The IEC finds that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses **and,**

(b) The secretary, after consultation with a panel of experts in pertinent disciplines (for examples:science, medicine, ethics, law) to determine either:

(1) That the research in fact satisfies the conditions set forth in NDCTR, 2019, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetus;

(ii) The research will be conducted in accord in sound ethical principles; and

(iii) Informed consent will be obtained in accord with informed consent provisions of NDCTR,2019 and other applicable subparts, unless altered or waived in accord.

Signature of Principal Investigator:_____Date_____

IEC Office use only	
Comments:	
Primary Reviewer(s) Signature & Date	

Annexure -XXIII

CHECKLIST FOR RESEARCH INVOLVING COGNITIVELY IMPAIRED ADULTS (VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……

- The purpose of this checklist is to provide support for IEC members or the Designated Reviewer when reviewing research involving cognitively impaired adults as subjects.
  1. For review using the expedited procedure this checklist is to be completed by the **Designated Reviewer** to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.
  2. For review using the convened IEC is to document determinations required by the regulations and protocol specific findings justifying these determinations.

1. **Research Involving Cognitively Impaired Adults in which there is Anticipated DirectBenefit to the subject** (All items must be "Yes")		
Yes	No	One of the following is true (Tick - t-hat is true) • The risk to the participants is presented by an intervention or procedure that holds out prospectof direct benefit for the individual subject. • More than minimal risk to participants is presented by monitoring procedure that is likely to contribute to the participants well – being.
Yes	No	The risk is justified by the anticipated benefit tothe participants.
Yes	No	The relation of anticipated benefit to the risk is atleast as favourable to the participants as that presented by available alternative approaches.
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate.
Yes	No	Assent is required of: (One of the following must be "**Yes**") One of the following is true (**Tick - that is true**) • All participants • All participants capable of being consulted. • None of the participants

Yes	No	The consent document includes a signature linefor a legally authorized representative.
2. Research Involving Cognitively Impaired Adults in which there is No AnticipatedDirect Benefit to the subject (All items must be "Yes")		
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate

Yes	No	The objectives of the trial cannot be met by means of study of participants who can giveconsent personally.
Yes	No	The foreseeable risks to the participants are low.
Yes	No	The negative impact on the participants well-being is minimized and low.
Yes	No	The trial is not prohibited by law.
Yes	No	Participants have a disease or condition for which the procedures in the research are intended.
Yes	No	Participants will be particularly closely monitored.
Yes	No	Participants will be withdrawn if they appear to be unduly distressed.
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate.
Yes	No	Assent is required of (One of the following must be **"Yes")** One of the following is true **(Tick - that is true**) • All participants • All participants capable of being consulted. • None of the participants
Yes	No	The consent document includes a signature line for a legally authorized representative.

Signature of Principal Investigator:_____Date

_____

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Comments:	
Primary Reviewer(s) Signature & Date	

Annexure -XXIV

CHECKLIST FOR RESEARCH INVOLVING STUDENTS, EMPLOYEES OR RESIDENTS

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……

Participants who are students, employees or residents require special considerations:

Does the employer or supervisor of the research participant need to be aware of the research project?	No	Yes
Is there a letter of support and/ or internal services checklist?	No	Yes
Have the participants been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	No	Yes
Have the risks to participants been minimized?	No	Yes
Have participants been assured that participation is voluntary (no signs of coercion)?	No	Yes
Have participants been assured that confidentiality will be protected or maintained?	No	Yes

Signature of Principal Investigator:_____Date

_____

IEC Office use only	
Comments:	
Primary Reviewer(s) Signature & Date	

Annexure -XXV

CHECKLIST FOR CONSIDERATION OF GENETIC RESEARCH

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……

	Yes	No
Will the samples be made anonymous to maintain confidentiality? If yes, stop here		
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?		
Has the appropriateness of the various strategies for recruiting participants and their family members been considered?		
Does the proposed study population comprise family members?		
Will family members be implicated in the studies without consent?		
Will the samples be destroyed in the future?		
Is genetic counseling being offered?		

Signature of Principal Investigator:_____Date _____

IEC Office use only	
Comments:	
Primary Reviewer(s) Signature & Date	

Annexure -XXVI

CHECKLIST FOR RESEARCH INVOLVING TERMINALLY ILL PATIENTS

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……

RISK DETERMINATION	BENEFIT ASSEMENT	IEC ACTION
Minimal	With direct benefit: Without direct benefit:	Approved: Not Approved:
	Potential benefit:	Approved: Not Approved:
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit:	Approved case by case safeguards (with special safeguards): Not Approved:
Less than minimal risk	With direct benefit: Without direct benefit:	Approved: Not Approved:
	Potential benefit:	Approved: Not Approved:
	No direct benefit to individual but offergeneral knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit:	Approved case by case safeguards (with special safeguards): Not Approved:
	With direct benefit: Without direct benefit:	Approved: Not Approved:

Minor increase over minimal risk or Low risk	Potential benefit:	Approved: Not Approved:
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit:	Approved case by case safeguards (with special safeguards): Not Approved:
More than minimal risk or High Risk	With direct benefit: Without direct benefit:	Approved: Not Approved:
	Potential benefit:	Approved: Not Approved:
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit:	Approved case by case safeguards (with special safeguards): Not Approved:

Minimal risk- Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely

	Yes	No	NA
Does the research pose greater than minimal risk to patients?			
If yes: Are convincing scientific and ethical justification given?			
If yes: Are adequate safeguard in place to minimize these risks?			
Are appropriate studies that have been conducted on animals andadults justified?			
If No: Is the lack of appropriate studies conducted on animals and adults justified?			
Do the anticipated benefits justify requiring the subjects to undertakethe risks			
Is inclusion of vulnerable population warranted?			
Can the research question be answered by using a non-vulnerable population?			
Will efforts be made ensure that participants are free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the consent?			
Are provisions made to protect participant's privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor orIEC member during consent procedures?			
Are special needs of counseling and confidentiality accounted for inthe research design?			
Are there any special problems such as confidentiality and reportingthat might arise in this research			

Signature of Principal Investigator:_____Date___

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Comments:	
Primary Reviewer(s) Signature & Date	

Annexure -XXVII

CHECKLIST FOR RESEARCH INVOLVING HIV PARTICIPANTS

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……

	Yes	No
Was the consent taken voluntarily?		
During the consent process, is the privacy maintained?		
Is the pre testing counseling provisions are in place?		
Will the samples be made anonymous to maintain confidentiality? If yes, stop here in stored sample study.		
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?		
Where is the test being carried out? Is the laboratory provide high-quality testing services, and quality assurance mechanisms		
The disclosure of the test results will be done only to the study team/sponsors/regulators with the participant consent.		
Has the appropriateness of the various strategies for recruiting participants and their care takers been considered?		
Does the proposed study requires family members/caretakers permission?		
Would the confidentiality will be maintained?		
Will family members / care takers will be disclosed about the test results?		
Will the samples be destroyed in the future?		
Will the samples be stored for future?		
Is post HIV testing counseling being offered and given?		

Would the participant provided with effective referral to appropriate follow- up services as indicated, including long term prevention and treatment support?		

Signature of Principal Investigator:_____Date__

IEC Office use only	
Comments:	
Primary Reviewer(s) Signature & Date	

Annexure -XXVIII

CHECKLIST FOR RESEARCH INVOLVING ECONOMICALLY / SOCIALLYBACKWARD/ILLITERATE PATIENTS

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……

	Yes	No	NA
Does the research pose greater than minimal risk to patients?			
If yes: Are convincing scientific and ethical justification given?			
If yes: Are adequate safeguard in place to minimize these risks?			
Do the anticipated benefits justify requiring the subjects to undertakethe risks			
Is inclusion of vulnerable population warranted?			
Can the research question be answered by using a non-vulnerable population?			
Will efforts be made ensure that participants are free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the consent?			
Are provisions made to protect participants' privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor orIEC member during consent procedures?			
Are special needs of counseling and confidentiality accounted for in theresearch design?			
Are there any special problems such as confidentiality and reportingthat might arise in this research			

Signature of Principal Investigator:_____Date_____

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Comments:	
Primary Reviewer(s) Signature & Date	