Institutional Ethics Committee
Institute of Human Behaviour & Allied Sciences, Delhi
Version 2; 31 May, 2022

Standard Operating Procedures
Institutional Ethics Committee (IEC-IHBAS)

2022

INSTITUTE OF HUMAN BEHAVIOUR & ALLIED SCIENCES

DELHI-110095

Standard Operating Procedures

Institutional Ethics Committee
Institute of Human Behaviour & Allied Sciences,
Delhi- 110095.

Approved by Director, Institute of Human Behaviour & Allied Sciences, Delhi-110095 and Institutional Ethics Committee, Institute of Human Behaviour & Allied Sciences, Delhi-110095.

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GLOSSARY

CDSCO	Central Drugs Standard Control Organization
CTRI	Clinical Trial Registry of India
DCGI	Drugs Controller General of India
FCRA	Foreign Contribution (Regulation) Amendment Act, 2020
HMSC	Health Ministry's Screening Committee
ICD	Informed Consent Document
ICJME	International Committee of Medical Journals Editors
ICMR	Indian Council of Medical Research
IEC-IHBAS	Institutional Ethics Committee-Institute of Human Behaviour & Allied Sciences
MoU	Memorandum of Understanding
PI	Principal Investigator
PIS	Patient Information Sheet
RPAC	Registered Physician Assistant – Certified or Residency Program Advisory Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedures

1. Objective

The objective of this SOP is to contribute to the effective functioning of the Institutional Ethics Committee (IEC-IHBAS) for human research so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee as prescribed by the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, Indian Council of Medical Research 2017 and National Ethical Guidelines for Biomedical Research Involving Children 2017 (henceforth jointly referred to as ICMR Ethical Guidelines, 2017), Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945 (including the amendments), and New Drugs and Clinical Trials Act and Rules 2019.

The Institutional Ethics Committee, Institute of Human Behaviour & Allied Sciences, Delhi-110095, is registered by the DCGI and by Department of Health Research and will be referred as IEC-IHBAS in this document.

IEC-IHBAS follows all the provisions in ICMR Ethical Guidelines 2017 as not everything œnbe included in these SOPs. These ICMR guidelines will be followed for anything not included in these SOPs. This has also been mandated by the New Drug and Clinical Trials Rules, 2019.

2. Roles and Responsibilities of IEC-IHBAS

a. IEC-IHBAS conducts scientific, administrative, and ethical review of the research proposals, and approves all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety, and wellbeing of all actual and potential research participants. Human samples/material likely to affect human health also comes under the purview of the IEC-IHBAS. Internal audit and prescription audit, however, requires only intimation to the IEC-IHBAS. However, this does not preclude any administrative permission wherever needed. The goals of research, however, important, are never be permitted to override the health and wellbeing of the research participants.

b. The IEC-IHBAS takes care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-beneficence, and Justice in planning, conduct and reporting of the proposed research. For this purpose, it investigates the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required to the patient. It reviews the proposals before start of the study as well as monitors the research

throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports, and site visits for assessment of quality of conduct of research, documentation, reporting of SAEs, and data safety & storage, etc. The committee also examines compliance with all regulatory requirements, applicable guidelines, administrative & financial rules, and the relevant laws.

c. The mandate of the IEC-IHBAS is to review all research projects involving human subjects (including any biological samples and behavioral issues) to be conducted at the Institute, irrespective of the funding agency or when no external funding agency is supporting the research.

d. The IEC-IHBAS members are responsible for declaration of Conflict of Interest to the Chairperson / Member Secretary at each meeting and it will be ensured that the same is recorded in the minutes.

3. Composition of IEC-IHBAS

a. The ICMR Ethical Guidelines, 2017 and the New Drugs and Clinical Trial Act & Rules, 2019 has been followed while constituting the IEC-IHBAS.

b. Present IEC-IHBAS has 15 members, a minimum of FIVE persons are required to compose a quorum. The quorum should include both medical, non-medical members. Legal experts' presence is a must for review of clinical trial proposal. Minimum one non-affiliated member should be part of quorum. Preferably lay person should be part of quorum. Preferably Chairperson and Member Secretary should be present in all meetings. The Member Secretary belongs to the same Institution and conducts the business of the Committee. The affiliations, qualifications, member specific roles and responsibilities of IEC-IHBAS are as per ICMR Ethical Guidelines, 2017. If required, subject experts are invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included.

c. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. However, such member(s) do not take part in decision making on the project.

d. A prior approval of the Director for concordance of administrative as well as financial aspects of 'funded and intramural research projects' is required before consideration by the IEC-IHBAS.

4. Authority under which IEC-IHBAS is constituted

The Director, IHBAS, has constituted the IEC, of which the Chairperson is from outside the institute vide order No. F.1(12)/Dir/IHBAS/2022/98 dated 14th March 2022. The following are the members of the IEC-IHBAS, IHBAS for the period between 2022-2026.

1	Dr. R.C. Jiloha	Former Professor & Head, Department of Psychiatry, GB Pant Hospital, Delhi	Clinician	Chairperson
2	Dr. Sangeeta Sharma	Professor & Head, Department of Neuropsychopharmacology, IHBAS	Pharmacology	Member Secretary/Convenor
3	Ms. Varuna Bhandari	Advocate, Supreme Court of India	Legal Expert	External Member
4	Dr. N.C. Jain	ICMR Emeritus Scientist, Division of HRD, ICMR Hqrs. Delhi	Social Scientist	External Member
5	Shri K.K. Srivastava	Retd. Additional Deputy CAG, Delhi	Literate person from the public or Community	External Member
6	Dr. K.S. Anand	Professor of Neurology, RML Hospital, New Delhi	Clinician	External Member
7	Prof (Dr.) Achal Srivastava	Department of Neurology, AIIMS, New Delhi	Clinician	External Member
8	Prof (Dr.) Dinesh Kataria	Department of Psychiatry, LHMC, New Delhi	Clinician	External Member
9	Prof. (Dr.) Nand Kumar	Professor of Psychiatry, AIIMS, New Delhi	Clinician	External Member
10	Dr. Om Prakash	Professor of Psychiatry, IHBAS	Clinician	Internal Member
11	Dr. Suman Kushwaha/Dr. Siddharth Maheshwari	Professor & HOD (neurology)/Assistant Professor (Neurology), IHBAS	Clinician	Internal Member
1	Dr. Anshu	Associate Professor	Basic	Internal Member

2	Gupta	(Pathology), IHBAS	Scientist	
13	Dr. Rachna Agarwal	Associate Professor & HOD (Neurochemistry), IHBAS	Basic Scientist	Internal Member & Co-Convener
14	Dr. Sarbjeet Khurana	Associate Professor & HOD (Epidemiology), IHBAS	Public Health	Internal Member
15	Dr. Naveen Grover	Assistant Professor (Clinical Psychology), IHBAS	Clinical Psychology	Internal Member

5. Terms of reference

1. To review and approve all research involving human participants conducted at IHBAS and SAKSHAM:

a. To ensure that ethical and scientific standards are maintained to protect participants from harm by weighing up the risks of harm against the likelihood of benefit. This is done by minimizing risks of harm to the greatest extent possible and by balancing the risk of harm relative to the likelihood of benefit. The IEC's deliberations are concerned not only with current research participants, but also with societal interests and future hypothetical beneficiaries. The IEC is mandated to review and approve a study based on documents submitted to it, other sources of information, and its understanding of the context and interests of the various stakeholders and role-players.
b. To consider in its review of a study the rights and interests of all stakeholders and role-players in a particular study. These include but are not limited to research participants, researchers, institutions, communities, and society. In particular, protecting the rights, dignity, safety, and well-being of all human participants in health-related research.
c. The IEC is mandated to make its approval subject to conditions, to require remedial action, and to withdraw its approval.
d. To monitor the execution of studies and to suspend a study when a reasonable ethical concern arises.
e. To set standards, propose and review policy, procedures, and practice on the ethical conduct of research in the Institute.

2. Genome-wide association study (GWAS). Genetic epidemiology, also known as whole genome-wide association study, involves an examination of many common genetic variants in different individuals to see if any variant is associated with a trait. A GWAS typically focuses on associations between single-nucleotide polymorphisms

(SNPs) and traits like major diseases, particularly multifactorial disorders with a possibility of getting variations of known or unknown significance and to apprise the participants of these facts. All gene therapies are considered as research and all protections for human research participants should be in place.

3. Stem cell proposals do not come under the purview of this committee and such proposals should be reviewed and approved by the institutional committee for stem cell research (IC-SCR) before being submitted to the EC for consideration, in accordance with the National Guidelines for Stem Cell Research (2017).

6. Membership requirements

a. The duration of appointment initially shall be for a period of 3 years.

b. At the end of 3 years, the committee will be reconstituted, and one-third of the members will be replaced by a defined procedure (those who have had the longest standing in the IEC-IHBAS shall be phased out and new members taken in against the vacant posts). A member can continue maximum for two terms.

c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

d. A member can tender resignation from the committee with proper reasons to do so.

e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.

f. Conflict of interest should be declared by members of the IEC-IHBAS, if any is there, at any time for any project or decision (Annexure 1)

7. Quorum requirements

A minimum of 05 members including Chairperson and Member Secretary are required to compose a quorum. All decisions are taken in the physical meetings or online meeting or hybrid mode. Proposals are not approved by circulation of project proposals only. Quorum for a clinical trial will include at least one representative from the following:

a. Basic medical scientist (preferably one pharmacologist)

b. Clinician

c. Legal expert

d. Lay person

8. Conduct of meeting

a. The Chairperson conducts all meetings of the IEC-IHBAS. If for reasons beyond control, the Chairperson is not available; Vice-chairperson conducts the meeting.

b. The Member Secretary is responsible for organizing the meetings, maintaining the records, and communicating with all concerned. He/she prepares the minutes of the meetings and gets it approved by the Chairman before communicating to the researchers. If for reasons beyond control, the Member-Secretary is not available; co-convener conducts the meeting.

c. The records are archived for a period of 5 years from the end of the project.

d. E-archiving is being done in view of the space and cost constraints. Where indicated, archiving may be done for a longer time.

e. The meetings can be held on virtual platform also.

9. Independent consultants

IEC-IHBAS may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases, or methodologies, or represent specific communities; patient groups or special interest groups e.g., Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision-making process which will be made by the members of the IEC-IHBAS. Member Secretary can take comments of experts (preferably prior to the meeting) if it is likely to assist the IEC-IHBAS in the review of the project.

10. Application Procedures

a. All research proposals are submitted in the prescribed application form on email address “iec@ihbas.org”, the details of which are given (Annexure 2) and under Documentation; along with

i. **a pdf copy by e-mail** to the Member-Secretary, IEC-IHBAS at the email address (iec@ihbas.org), and

ii. **Two printed copies** of all the relevant documents with signatures in ink as needed.

b. Cover letter to the Member Secretary mentions the type of review requested along with all enclosures complete for review in the prescribed format and required documents. In case the researcher asks for the expedited or exemption from review or expedited review the justification should be mentioned in the cover letter along with duly filled Annexures 3 & 4.

c. The details of the documents to be included in the protocol (Check list Proposal related at point 12-17 of Annexure 5).

d. One 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 forwarded by the Head of the Department of the PI and Head of the Institution to the IEC-IHBAS.

e. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications. Presentation or virtual presentation should be kept handy.

f. Primary reviewers would be internally decided within the Ethics committee members who would go through the protocol in detail and present comments and observations, if any, before the Committee.

g. The decision is communicated in writing or by email. In case of Research Proposal where the Principal Investigator (PI) happens to be the Member-Secretary of IEC-IHBAS, the approval letters and routine correspondence shall be signed/counter-signed by the Chairperson of IEC/Co-convener.

h. If revision is to be made, the revised document (1 printed copy) and the softcopy (pdf copy) along with pointwise reply to the comments/observations of the IEC should be submitted within a stipulated period as specified in the communication or 4 weeks before the next meeting. The revised document should clearly mention the IEC project number along with the date and version of the document in the footer for reference.

i. IEC-IHBAS charges a fee from funded projects by pharmaceutical companies, Rs 25,000 (twenty-five thousand) for initial review and Rs 10,000 (ten thousand) for subsequent reviews. The fees are deposited in the IHBAS account. EC may allow waiver of this fee from the funded projects supported by government agencies and

in other circumstances as deemed fit by IEC-IHBAS.

j. The funded projects are levied institutional overhead charges 5 and 10% of the total budget of the research projects/clinical regulatory trials respectively (as the case may be) when the project begins in the IHBAS, Delhi. The PI shall give the reasons if this provision is not there in a project.

11. Documentation

a. The PI submits a complete research proposal to the IEC-IHBAS for review. Contents of the research proposal as per Annexure 1

b. For a thorough and complete review, all research proposals should be submitted with the following documents:

i. Cover letter* to the Member Secretary mentioning the type of review requested [Exempt from review/Expedited review/Full committee review].

ii. In case expedited or exempt from review is requested, the same is submitted as per Annexure 3 and 4.

iii. Application Form for initial review (Annexure 5)* duly forwarded by Head of the Department and other relevant documents depending on the nature of the research proposal (Annexure 6-8).

iv. Research protocol (contents as per Annexure 1)*

v. The correct version of the informed consent document (ICD) in English and the local language(s)*. Translation and back translation certificates (if applicable)

vi. Case record form/questionnaire*

vii. Brief presentation (upto-5-6 slides) including the details of research protocol, patient information sheet, informed consent form and case record form, and any other information likely to support the decision making by IEC-IHBAS.

viii. Details of funding agency/sponsor and fund allocation (if applicable) including those related to insurance.

ix. Brief curriculum vitae (1-2 pages maximum) of all the study researchers/PIs-Co-

PIs (as per Annexure 9)

x. In case of clinical trial, undertaking with signatures of investigators [including undertaking to report any serious adverse events (SAE) to IEC-IHBAS within 24 hours; undertaking to comply with the relevant national and applicable international guidelines (Annexure 10)*.

xi. Recruitment procedures for the research participants: advertisement, notices (if applicable).

xii. Patient instruction card, diary, etc. (if applicable)

xiii. A statement on Conflict of Interest*

xiv. Good Clinical Practices training certificate (preferably within 5 years) of investigators, preferable in non-regulatory research but mandatory for regulatory research and clinical trials*.

xv. List and the status of the on-going research studies earlier approved by IEC-IHBAS including all studies (investigator-initiated studies, regulatory studies, etc. except those under post-graduate thesis) where the investigator of the current proposal is Principal Investigator or Co- Principal Investigator or Co-investigator*. If the current proposal is the first proposal of the investigator, then the same may be mentioned in this document.

xvi. Any other information or training evidence or document which is likely to supplement the review of the current proposal including permission of the competent authority to conduct research in schools/colleges/universities or other institutions.

xvii. Regulatory permissions (as applicable)

xviii. Relevant administrative approvals (such as HMSC approval for international trials)

xix. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)

xx. Clinical trial agreement between the sponsors, investigator, and the head of the institution(s) (if applicable)

xxi. Documentation (or plan) of clinical trial registration

xxii. In respect of clinical trials, site specific Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable) as per the New Drug and Clinical Trial Act and Rules, 2019 or any other act or rules applicable.

xxiii. In respect of clinical trials, site specific Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable).

xxiv. In case the research is proposed in collaboration with an institution or department or center or any other entity from a foreign country, the PI should state the plan for obtaining the approval of Health Ministry Screening Committee, Department of Health Research, Ministry of Health and Family Welfare, Govt. of India (Indian Council of Medical research), New Delhi. The PI should submit to the IEC-IHBAS a written statement clarifying whether this collaboration qualifies for prior HMSC approval or not, if not then sufficient justification should be provided.

xxv. In case the research is proposed in collaboration with an institution or department or center or any other entity from a foreign country and funds are proposed to be received from foreign collaborator, the appropriate sections (and latest amendments) of Foreign Contributions (Regulation) Act, 2010, where applicable, state the applicability of the provision(s) of FCRA,2010.

xxvi. Any additional document(s), as required by IEC-IHBAS (such as other EC clearances for multi-centric studies, proposed budget in case of funded research including any payment of honorarium or fee to the investigators). In case the PI is a government functionary and is to receive any fee, prior approval of the competent authority should be obtained.

xxvii. For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/countries, if available. If it is a new drug or device (or unlicensed drug or device) then the permission of DCGI/CDSCO for conduct of the research study.

xxviii. Investigator's brochure (as applicable for drug/biologicals/device trials)

xxix. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.

xxx. Any other information relevant to the study.

c. MoU in case of studies involving collaboration with other institutions/agencies/ organizations/ companies etc. (if applicable) is necessary.

d. In case the research is planned in collaboration with an institute/department/center outside the Institute of Human Behaviour & Allied Sciences, Delhi, then the MoU should be between the 2 institutions or between the department (of IHBAS) and the other participating institution/department/center. The signatory on the behalf of IHBAS or its department may be the Director IHBAS (when 2 or more departments are involved), or the Head of the Department where research idea emanated or the Principal Investigator (PI) or Co-PI of the research project belongs to (when several Co-PIs or Units or wider interests are involved) or the PI (where the MoU is related to the current research proposal only).

e. The MoU and the approval include duly signed (a) assent and approval for the proposed research project, (b) the name of the Co-PI from the department, and (c) publication plan for dissemination and authorship, and (d) any other terms and conditions. Material Transfer Agreement (as in collaborative research) where any biological samples are to be transferred from the Institute to other institute or laboratories or other agencies for testing or storage or for any future use.

*The documents listed above at serial numbers above from I to xi, are mandatory requirements for submission of all the research proposal for review. In addition, documents at xii to xvi for all research proposals; document at xvi- xxviii for clinical trials are required; document at xxiii to xxv for collaborative and/or multi-disciplinary research; documents at point 'e' above required when biological samples are to be transferred to other institute or laboratory or agency; xxiii -xxiv documents in case of funded research; and the information mentioned in case of foreign collaboration are mandatory with initial submission of any research protocol. Without the above documents the proposals are not likely to be reviewed by IEC-IHBAS or the PI shall provide reasons for not providing the required documents.

12. Review procedures

a. All the research proposals or other communications with IEC-IHBAS are reviewed following the provisions given in ICMR Guidelines, 2017 and the New Drugs and Clinical Trials Rules, 2019. The administrative and financial aspects are also be reviewed, wherever applicable, with the help of administrative and financial officials. The following procedure is followed for review of the research proposals or report or

any other communication (physical or electronic) with IEC-IHBAS. The process may vary depending on the needs of the review.

b. The Member Secretary/Secretariat 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.

c. A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the IEC. The decision on the type of review required rests with the IEC and will be decided on a case-to-case basis. Researchers can approach the IEC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.

d. The meeting of the IEC-IHBAS is held whenever enough projects/proposals are there for review and about usually once in 4 months meetings are held.

e. More meetings are organized, if needed. Additional meetings may be called upon by the Member-Secretary after approval of the Chairperson.

f. The proposals (as soft copy) will be sent to members 2 weeks in advance by e-mail. For every proposal, minimum one primary and one secondary reviewer are identified from amongst the IEC-IHBAS members. These reviewers' first study the submitted documents and enclosures as defined above and lead the discussion during IEC-IHBAS meeting.

g. A decision is taken by consensus after discussions in the meeting, and whenever needed voting is done.

h. Researchers are invited to make presentation and to offer clarifications if need be.

i. Independent consultants/Experts are invited to offer their opinion on specific research proposals if needed. Opinion of independent expert may be taken by mail/email, if needed.

j. IEC-IHBAS carries out various types of reviews including (1) Exemption from review, (2) Expedited review, and (3) Full committee review.

k. IEC-IHBAS may ask the PI for obtaining permissions from regulatory agencies, HMSC, or the administration.

l. The decisions are minuted and Chairperson's approval taken in writing by email/mail.

13. Elements of review

a. The type of EC review based on risk involved in the research, is categorized as given by ICMR Ethical Guidelines 2017 (Table 1 and 2). The IEC-IHBAS evaluates the possible risks to the subjects, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality, and justice issues.

b. The following types of research are considered to involve more than minimal risk and require ethical approval:

i. All research involving those who lack normal physical or mental capacity, or those who during the research project has become lacking in capacity.
ii. Research involving sensitive topics – for example participants' sexual behavior, their illegal or political behavior, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status.
iii. Research involving groups where permission of a guardian is normally required for initial access to members. This includes research involving guardians such as adult professionals (e.g., those working with children or the elderly), or research in where access to research participants is not possible without the permission of another adult, such as another family member (e.g., the parent or husband of the participant) or a community.
iv. Research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals.
v. Research which could induce psychological stress, anxiety or humiliation or cause more than minimal pain. Research involving intrusive interventions or data collection methods – for example, the administration of substances, vigorous physical exercise, or techniques such as hypnotism. In particular, where participants are persuaded to reveal information which they would not otherwise disclose during everyday life.

c. IEC-IHBAS considers the following ethical and scientific issues related to reviewing a protocol:

i. Social values
ii. Scientific design and conduct of the study
iii. Benefit-risk assessment
iv. Selection of study population and recruitment of research participants
v. Payment for participation
vi. Protection of research participants privacy and confidentiality

vii. Community considerations including permission to conduct research in schools, or another vulnerable group of populations.

viii. Qualification of researchers, number and status of the on-going research projects, and adequacy assessment of study sites; One researcher is allowed to conduct not more than 2-3 regulatory/funded and 2-3 academic research projects with a maximum of 5 research projects as PI (except post-graduate thesis) at a time. Any PI/researcher who already has 5 research studies running and wants to do more research may request IEC-IHBAS for approval while justifying the same. IEC-IHBAS may approve more projects for individual researcher on a case-to-case basis considering as in ICMR Guidelines, 2017.

ix. Disclosure or declaration of potential conflict-of-interest(s)

x. Plan for medical management and compensation for study related injury

xi. Review of the informed consent process.

d. The informed consent document (ICD), including patient/participant information sheet (PIS) and informed consent form (ICF) is complete having all the required elements as per ICMR Guidelines 2017.

   i. For all biomedical and health research involving human participants, it is the primary responsibility of the researcher to obtain the written, informed consent of the prospective participant or legally acceptable/authorized representative (LAR) or the nominated representative as defined in Mental Healthcare Act 2017 (typically parents/guardians or state-appointed persons) in all aspects of decision making for mental health care of minors. In case of an individual who is not capable of giving informed consent, the consent of the LAR should be obtained. If a participant or LAR is illiterate, a literate impartial witness should also be present during the informed consent process.

   ii. Circumstances where audio/audio-visual recording of the informed consent process may be required, in certain clinical trials as notified by CDSCO.

e. Disclosure of data of individual participants/community in certain circumstances requiring permission of the IEC such as specific orders of a court of law, threat to a person's or community's life, public health risk that would supersede personal rights to privacy, serious adverse events (SAEs) that are required to be communicated to an appropriate regulatory authority etc.

f. Verbal/oral consent/waiver of consent/re-consent as required under certain

conditions after due consideration and approval by the IEC.

g. Ensure proper storage, transport and control access to biological samples or medical records/data, coding or anonymization of personal information while conducting research by the PI.

h. Justification for placebo in control arm, if any

i. Availability of products after the study, if applicable

j. Adherence to all regulatory requirements, applicable guidelines, General Financial Rules, and other relevant service rules

k. Competence of investigators, research and supporting staff

l. Facilities, infrastructure of study sites, and availability of the proposed clinical material/patients or laboratory tests; and

m. Criteria for withdrawal of patients, suspending or terminating the study.

14. Obligations/duties of ethics committee regarding proposals for research on vulnerable population

a. Special considerations would be taken while reviewing projects involving research on vulnerable population like pregnant women, children (up to 18 years), economically disadvantaged, sexual minorities, terminally ill, suffering from mental, stigmatizing, or rare diseases, tribals and marginalized communities, differently abled-mentally and physically disabled, have diminished autonomy due to dependency etc.

b. The IEC-IHBAS examines whether inclusion/exclusion of the vulnerable population is justified.

c. Only the full Committee does initial and continuing review of such proposals. If possible, empowered representatives from the specific populations are included during deliberations.

d. Efforts are made to ensure that individuals or communities who are economically or socially disadvantaged and are invited for research are selected in such a way to ensure a balanced benefit-risk and advise risk minimization strategies wherever

possible.

e. Additional safeguards, such as more frequent review and monitoring, including site visits are done.

f. When research is conducted on participants who are suffering from mental illness and/or cognitive impairment the IEC-IHBAS-IHBAS exercises caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. IEC-IHBAS ensures that these exceptions are as minimal as possible and are clearly spelt out in the ICD.

g. The rights and welfare of mentally challenged and differently abled persons who are incapable of giving informed consent or those with behavioral disorders are protected. It is ensured that appropriate proxy consent from legal guardian is taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures undertaken. It is ensured that the entire consent process is adequately documented.

h. Adequate care is taken while reviewing proposals involving patients such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research participants since the consent provided could be under duress or due to other compulsions.

15. Expedited review

n. All revised proposals, unless specifically required to go to the main committee, are examined by the sub-committee convened with permission of the Chairman in a meeting or by email or by the Member Secretary to expedite decision making.

o. Expedited review is also be taken up in cases of nationally relevant proposals requiring urgent review. The natures of the applications, amendments, and other considerations that will be eligible for expedited review are specified at the time of the consideration of the original proposal.

p. An expedited review, when designated for a particular proposal during its original discussion, requires the Chairperson/Member-Secretary, 1-2 internal member(s) and preferably one External member. However, the Chairman can authorize a group of members for conducting expedited review. Approvals granted through expedited

review must be ratified in next full review committee meeting. Verification of furnished documents and regulatory clearances is done at the level of the Member-Secretary.

16. Decision-making

a. Members discuss the various issues before arriving at a consensus decision.

b. A member is required to withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises (e.g., member is PI or Co-PI) and this is indicated to the chairperson prior to the review of the application and is recorded in the minutes.

c. Administrative and financial aspects are reviewed prior to submission of the proposal to the committee. This administrative/financial approval should be specifically documented in the cover letter along with supporting documents. In case the same has not been obtained the same should be obtained before issuing IEC-IHBAS approval. However, ethical approval will be solely by IEC-IHBAS and will not require prior approval of the Director.

d. Decisions are made only in meetings where quorum is complete.

e. Only members make the decision. The expert consultants only offer their opinions.

f. Decisions by IEC-IHBAS may be:

   i. Approved –with or without suggestions or comments,

   ii. Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be

   iii. Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval; or

   iv. Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission.

g. Specific suggestions for modifications and reasons for 'non approval' should be given.

h. Modified proposals may be reviewed by an expedited review through identified members or by the Member Secretary as above.

i. Depending on the risk involved approval may be granted for the entire duration of the proposed research or can be subject to review annually or at shorter intervals (quarterly, half yearly) as per Annexure 8. The EC should review the annual report (counted from the day of approval or date of actual start of the study) for continuation as per SOP.

j. Procedures for appeal by the researchers include representation within four weeks of the decision communicated to the researcher. The appeal should be directed to the Member-Secretary and will need to be taken up in the next IEC-IHBAS meeting.

k. In case where the issues remain unresolved, PI can appeal to the Director as the Director is the appellate authority.

17. Provisional permission

Provisional permission will not be issued to any researcher under any circumstances.

18. Permission in back date

No ex-post facto ethical approval is provided to any researcher under any circumstances.

19. Payment of research investigations

Patients should not be made to pay for any investigations that are a part of the research. If any investigation is needed as part of the research proposal, the researcher should ensure that this is not paid by the participant.

20. Policy for training of members of the IEC-IHBAS

a. The IEC-IHBAS members are encouraged to keep abreast of all national and international developments in ethics through orientation course on related topics so that they become aware of their role and responsibilities. For drug trial reviews, it is mandatory that the members are trained in Good Clinical Practice. They should be aware of the local social and cultural norms as this would be the most important social control mechanism.

b. Relevant new guidelines are discussed during the meetings of IEC-IHBAS and adopted with modifications, if found suitable and appropriate.

c. Members are encouraged to attend national and international training programs in

research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

21. Resolving conflicts of interest

It is recognized that the potential for conflict of interest will always exist but has faith in the Institutional Ethics Committee, IHBAS (IEC-IHBAS) and its chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the IEC-IHBAS that no member participates in the review, comment, or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC-IHBAS for Clinical Studies/research. The Member immediately discloses to the Chairperson of the IEC-IHBAS any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

Examples of conflict-of-interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment

a. Every IEC-IHBAS member signs a COI agreement and give declaration to maintain confidentiality (Annexure 1) before ethical review tasks of the EC commence.

b. IEC-IHBAS members disclose in writing to the member secretary/designee all real, potential, or perceived COI interest for themselves and their family members– spouse, children, friends, or their professional associates when submitting a proposal.

c. Such disclosure is sufficiently detailed and timely to allow the IEC-IHBAS administration to transfer the project to another EC member or allow time for an alternate member to attend the EC meeting to meet quorum.

d. If an investigator is a member of the IEC-IHBAS, he/she cannot participate in the review and approval process for any project in which he/she is involved as principal investigator, co-investigator, or has any other potential COI.

e. At the beginning of each convened IEC-IHBAS meeting, the chairperson/member-secretary asks the EC members if anyone has a financial or nonfinancial COI regarding any of the research projects on the agenda for review at the meeting.

f. The chairperson/member-secretary reviews disclosures, to determine whether a COI exists and to determine appropriate management of the COI.

g. Any EC member, who has COI in a research project, abstains from deliberations and the decision-making process, except to provide information as requested by the IEC-IHBAS. Such abstentions are documented in the minutes.

h. If any unanticipated COI affects quorum, that project proposal is not discussed and is deferred to the next scheduled meeting.

i. In case the member-secretary of the EC is the principal investigator or a co-investigator for project under discussion, he/she declares COI and leave the meeting room. Another EC member nominated as Acting Member Secretary will perform the function of the Secretary for this proposal.

j. Care is taken that all queries (e.g., from patients, others) on the project during its life are managed by the acting member secretary.

k. In case of several projects being discussed in the meeting, the minutes should clearly delineate the projects where the Member Secretary had a COI and hence was not part of the decision-making process.

l. The IEC does not approve a research study where a COI is not eliminated.

22. Obligations/duties of ethics committee regarding new research directly related to COVID-19/any other pandemic

The global pandemic of COVID-19 and the ensuring lockdowns have created a challenge for routine functioning of the IEC-IHBAS, in accordance with the existing Standard Operating Procedures of the Committee.

a. To ensure that there no barriers to research even during emergencies like the ongoing COVID-19 pandemic, the IEC-IHBAS has drafted additional points to ensure its smooth functioning in line with the ICMR guidelines for Ethics Committee during COVID-19 PANDEMIC. These are applicable in such emergency situations.

b. Electronic documents will be accepted for review and timelines shortened for

accelerated procedures.

c. Member Secretary in consultation with Chairman of the Committee will prioritize the urgency of review of the research protocols and will categorize proposals into exempt/expedited/or full review category as per National Ethical Guidelines and plan next steps for fast-track review.

d. In case of any funded research project being undertaken by a faculty member, prior administrative approval is mandatory. However, in case of non-funded research, prior administrative clearance may be waived off during the pandemic times.

e. IEC-IHBAS ensures that all COVID-19 related research (all clinical trials as well as biomedical and health research) are registered as Clinical Trial Registry of India (CTRI) and seek approvals as per relevant guidelines and applicable regulations.

f. Research during emergencies can be reviewed through expedited review/unscheduled full committee meetings on a case-to-case basis depending on the urgency and need. If an expedited review is done, full ethical review can follow whenever next possible.

g. The soft copies of research protocols, including all scanned and signed documents, submitted in the prescribed format of the Institute are circulated on email. Hard copies of the same is kept at secretariat of the IEC-IHBAS. At one time, only a limited number of protocols are emailed to the members. The comments of the members are received within a specified timeframe. The Principal Investigator responds to the comments and the modified protocol with clarifications submitted thereof, is shared with five members, including both medical/non-medical and technical/non-technical members with non-affiliated members.

h. Measures such as virtual or tele/web conferences are attempted. Soft copies of the protocols and comments are obtained prior to the meeting and responses obtained from the PI, are provided to members. The members discuss the proposal during the online meeting and the decision is arrived at by consensus.

i. Finally, minutes of the meeting are made by Member secretary and circulated to all members, after approval by Chairman. The final decision letter is then communicated to the Principal Investigator.

j. The committee reviews the Informed Consent Documents (ICD), taking into consideration the following situations.

   i. If written consent is not possible, consent could be given orally/using electronic methods to documents and records.

   ii. Due to inability or the participant to attend the site, the communication can be made via phone, to enquire & identify adverse events (AE), Serious Adverse Events (SAEs) and ensure medical care & oversight with documentation.

   iii. As per National Guidelines, the ICD will have to parts: PIS and the ICF. Both can be prepared utilizing electronic formats.

   iv. All electronic methods (e.g., digital signature) are reviewed and approved by the EC a priori.

   v. In exceptional and emergency situations, preliminary research procedures including but not restricted to data/biological sample collection that are likely to rapidly deteriorate or perish may be allowed while the ethics review process is still underway.

k. Available protocol templates are reviewed to expedite the process and interim review/re-review is done if the emergency situation changes.

l. Common review of multi-centric research is carried out by one main designated IEC-IHBAS sub-committee for fast-track decision making. IEC-IHBAS may choose to accept the decision of designated committee or to do an expedited or full committee review. The IEC-IHBAS ensures ethics review with reference to site-specific issues.

m. IEC-IHBAS has developed procedures to ensure timely review and monitoring of the approved research. On a case-by-case basis, re-review with time and circumstances if required is done.

23. Review of Ongoing Research Project

a. The researchers should submit a six-monthly progress report including amendments thereof of the project and protocol violations/deviations, serious adverse event (SAEs) reports undertaken to the IEC-IHBAS in a timely manner (As per Annexure 11-15).

b. The timeline for reporting of SAEs should be as per ICMR Guidelines 2017 and Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945 (including the amendments), and New Drugs and Clinical Trials Act and Rules 2019 as amended from time to time.

c. In case a study is prematurely terminated or suspended or discontinued the same should be informed to the IEC as per format (Annexure 16).

d. These reports are reviewed by a member of the IEC-IHBAS designated for this purpose and any discrepancies noted in the work done with reference to the approved protocol is brought to notice of the full committee and merit immediate withdrawal or approval. Failure to submit timely progress reports to the IEC-IHBAS makes the project liable to be considered for withdrawal of approval without further communication.

e. PI to determine and communicate the date of continuing review ongoing research projects and notify the Member-Secretary (Annexure 11).

f. Determining the date of continuing review

   i. The IEC-IHBAS Secretariat reviews the document archives/master chart of projects approved by the IEC-IHBAS for the due date of continuing reviews.

   ii. The Secretariat plans for continuing review of the reports to be reviewed as close as possible to the due date i.e., every 6 months after the approval of the project by IEC-IHBAS.

   a. If the Principal Investigator fails to submit the Continuing review report within one month of the due date, the IEC-IHBAS secretariat will send a reminder within 7 working days of this due date. If there is no response within 15 days after the date of reminder, the IEC-IHBAS secretariat will put up the matter for discussion at the forthcoming full committee meeting for appropriate action which may consist of but not limited to-

      i. A letter reprimanding the Investigator.

      ii. Not reviewing future projects from the PI for a specified period/till the submission of status report of the previous study.

      iii. A letter asking the Investigator to put recruitment of new participants on hold.

   b. Managing completion report upon receipt

i. The Secretariat receives 1 copy (soft and hard) of Study Completion Report filled as per the format (Annexure 17) from the Principal Investigator. The study completion report is expected from the investigator within 1 month of completion of the study at the site. A brief study report containing data analysis from all centers can be submitted by the investigator once available from the sponsor.

ii. In case a study is terminated prematurely or suspended or It is the responsibility of the IEC-IHBAS Secretariat to review the report for completeness. If necessary, the IEC-IHBAS secretariat will retrieve the master file from the archiving with permission of the Member Secretary.

iii. The Secretariat forwards the Study Completion Report along with Study Completion Report Form to the Member Secretary, and the Convener and Chairperson of Ongoing Projects Sub-Committee.

c. Assign reviewers and review the annexure/related documents of continuing review

i. The Convener and Chairperson of Ongoing Projects Sub-Committee will review the Continuing Review Application Form and Study Completion Report. They may designate one/two members of the Sub-committee to review the report and related documents and submit the comments to Convener/Chairperson of Ongoing Projects Sub-Committee.

ii. In case there is a significant finding during the review process by the designated IEC-IHBAS members, this will be communicated to Principal Investigator.

iii. It is the responsibility of Principal Investigator to provide the required information to the IEC-IHBAS.

d. Review of Continuing Review Report and Study Completion Report of Clinical trials

i. After reviewing the Continuing Review Report of the Ongoing clinical trial studies, the Convener/Chairperson of Ongoing Projects Sub-Committee would constitute a Team of 1 affiliated member and 1 non-affiliated member for site visit for review of the progress of the study, the documentation, and other aspects. This Team would conduct the visits department wise or as decided by the team.

ii. The Team will carry out the inspection, and will verify the process of the study, will check the case record forms, and the consent forms. The Team will also obtain the list of the subjects (name, age. Sex, CR No./OPD No./Study Registration Number, and contact number) enrolled in the study. The team will submit its report to the Convener of the Sub-committee within 7 days of the completion of visits (Annexure 18).

iii. The Sub-committee will review the reports submitted by PI and the site visit reports. The Sub-committee could reach one of the following decisions (to be confirmed by the Full Committee Meeting):

   a. ***Noted***: The IEC-IHBAS approves the continuation of the above-mentioned project without any modifications (as per the format *given)*

   b. ***Modifications recommended***: IEC-IHBAS may suggest modifications in the protocol in view of SAEs or any other contingent issue.

   c. ***The project cannot be continued***: The reasons for discontinuation of the project will be mentioned in the letter notifying the decision to the Principal Investigator.

iv. The decision will also include any significant findings that have arisen during review process, and this will be communicated to Principal Investigator. It is the responsibility of Principal Investigator to provide this information to the participants and once done, submit the report to IEC-IHBAS.

v. After reviewing the Study Completion Report, the Member-Secretary/Chairperson of Ongoing Projects Sub-Committee could reach one of the following decisions (to be confirmed by the Full Committee Meeting):

   a. Noted in the IEC-IHBAS records

   b. Request for additional information/clarification

   c. Written communication of the IEC-IHBAS decision to investigator.

   d. The decision is communicated to the PI within 14 days of the approval by the IEC-IHBAS (full board meeting).

24. Completion of project

The researchers submit a completion report of the project undertaken to the IEC-IHBAS

in a timely manner (Annexure 17). The work report is reviewed by a member of the IEC-IHBAS designated for this purpose and any discrepancies noted in the work done with reference to the approved protocol are brought to notice of the full committee and would merit immediate withdrawal of approval. Failure to submit timely completion report to the IEC-IHBAS would make the project liable to be considered for withdrawal of approval without further communication.

25. Publication ethics

a. Researchers should make sure public is accurately informed about results without raising false hopes or expectations. They are advised to not to unnecessarily scare the people and avoid talking to journalists or reporters about preliminary findings as seemingly promising research that subsequently cannot be validated could lead to misconceptions, if reported prematurely. Researchers are advised to avoid premature reports and publicity stunts.

b. If any researchers request to talk to the media, he or she are permitted to do so on condition that the reporter submit a full written version of what will be reported to the researcher, who could be able to make corrections, if needed, prior to publication.

c. The researchers are advised to take consent for publication, in addition, to the consent for participation in cases where it is possible that the identity or the participants may be revealed by the way of publication. This should preferably be done on two different occasions and not as a blanket one-time consent at the time of the commencement of the study. In case a researcher wishes to publish photographs, slides or videos of participants, a prior consent to do so should be obtained. The identification features should be appropriately camouflaged in the picture or in the video.

d. About authorship, the International Committee of Medical Journals Editors (ICJME) guidelines on credit and accountability are followed. Only those who make substantial contribution to the article and take responsibility for the published matter can be co-authors. Plagiarism or falsification of data and ghost/guest authorship are strongly condemned and are deemed as scientific misconduct in research. Misconduct includes fabrication, falsification, plagiarism, selective omission of data and claiming that this was missing, ignoring outliers without declaring them, not reporting data on side effects of adverse reactions, publication of post-hoc analysis without declaring it, gift authorship, not citing others' work and not disclosing conflict of interest etc.

e. The researchers are encouraged to use the latest guidelines for reporting studies such as the CONSORT statement for reporting of Randomized Controlled Trials or PRISMA guidelines for reporting systematic reviews which are available in public domain.

26. Communicating the decision

a. Decisions are communicated by the Member Secretary in writing (by printed letter on paper or by email to the PI).

b. In case of Research where the Principal Investigator (PI) happens to be the Member-Secretary of IEC-IHBAS, the decisions of IEC-IHBAS shall be signed/counter signed by the Chairperson IEC-IHBAS or a co-convener or a member designated for this purpose.

c. Suggestions for modifications, if any, are also communicated by Member Secretary.

d. Reasons for rejection are informed to the researchers.

e. The schedule/plan of ongoing review by the IEC-IHBAS is communicated to the PI.

27. Follow up procedures

The following should be adhered to by PI-

a. Reports of the on-going projects/studies should be submitted at 6 months intervals for review. Status report of the on-going projects [non-thesis projects] should be submitted every 6 months after the beginning of the research study and a completion report when the study is completed.

b. Final report should be submitted at the end of study.

c. These reports are reviewed by IEC-IHBAS or sub-committee as constituted from time-to-time. This sub-committee also supervises and monitors the ongoing research projects approved by IEC-IHBAS.

d. All SAEs and the interventions undertaken should be intimated (Annexure 14/15). Causality assessment of all SAEs should also be submitted as early as possible and within 24 hours of occurrence by PI to IEC-IHBAS, Head of the Institute, and Sponsor. In next 14 days the sponsor must submit an analytic report of causality assessment to the IEC, DCGI and Head of Institution. IEC-IHBAS reviews it over next 30 days and decide on causality of injury, quantum of injury and compensation to research subject (as per the seventh schedule of New Drugs and Clinical Trials

Rules 2019) in cases the cause of SAEs is found to be related to the administration of the interventional product to each of the following criteria mentioned under Rule 41 of New Drugs and Clinical Trials Rules, 2019:

i. Adverse effect of the investigational product

ii. Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator leading to serious adverse event

iii. Failure of investigational product to provide intended therapeutic effect where, the required standard care or rescue medication, though available, was not provided to the subject as per clinical trial protocol

iv. Not providing the required standard care, though available to the subject as per clinical trial protocol in the placebo-controlled trial

v. Adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol

vi. Adverse effect on a child in-utero because of the participation of the parent in the clinical trial

vii. Any clinical trial procedures involved in the study leading to serious adverse event

e. The SAEs are reviewed by SAE Sub-committee. This sub-committee meets as and when necessary to review the SAEs received and further suggests the actions to full board meeting (of IEC-IHBAS). Such emergency meeting may be requested by Member Secretary of IEC-IHBAS. The SAE Sub-committee submits its recommendations and suggestions the actions to IEC-IHBAS based on the provisions in ICMR Guidelines, 2017 and New Drugs and Clinical Trial Act, 2019.

f. Protocol deviation, if any, should be informed with adequate justifications (Annexure 7).

g. Any amendment to the protocol should be resubmitted for renewed approval (Annexure 6).

h. Any new information related to the study should be communicated.

i. Premature termination of study should be notified with reasons along with summary

of the data obtained so far.

j. Change of investigators/sites should be informed.

28. Record keeping and Archiving

The following documents are stored.

a. Curriculum Vitae (CV) of all members of IEC-IHBAS.

b. Copy of all study protocols with enclosed documents, progress reports, and SAEs.

c. Minutes of all meetings duly signed by the Chairperson/Member Secretary.

d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

e. Copy of all correspondence with members, researchers, and other regulatory bodies. Email prints to be archived (certified by the Member-Secretary).

f. Final report of the approved projects.

g. All documents are archived for five-year period unless there is a specific requirement for a longer time.

29. Updating IEC-IHBAS members

a. All relevant new guidelines should be brought to the attention of the members.

b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

30. Procurements and fund disbursal for funded projects

a. The procurements (human resources and materials) for funded projects are to be undertaken at the institutional level as per laid down procedure.

b. The Accounts Functionary supervises and manages funds disbursal and other financial and accounting processes and audit.

31. Validity of the IEC-IHBAS SOPs

The SOPs enlisted above shall remain in force for a period of five years. However, these may be amended/updated from time to time by the IEC-IHBAS and same shall be archived appropriately. These SOPs have been approved by the Director, Institute of Human Behaviour & Allied Sciences Delhi.

(Dr. Sangeeta Sharma)	(Dr. R.C. Jiloha)
Member-Secretary, IEC-IHBAS	***Chairperson, IEC-IHBAS***

Dated: June 9, 2022

Approved by

Dr. Rajinder K Dhamija
Director,
IHBAS

Table 1. Type of risks by IEC

Type of risk	**Definition/description**
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, 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 occurrence of serious harm or an adverse event (AE) is unlikely. Examples include 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. This may present in situations such as 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. Such research should have a social value. Use of personal 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, etc.

(Adopted from National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR Guidelines 2017)

Table 2. Type of review by IEC

Types of review	**Definition/description**
Exemption from review	Proposals with less than minimal risk where there are no linked identifiers, for example: • research conducted on data available in the public domain for systematic reviews or meta-analysis • Case reports or case series provided informed consent from the patients has been obtained and their identity was not disclosed in the study as well as publication • Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; • Quality control and quality assurance audits in the institution • Comparison of instructional techniques, curricula, or classroom management methods • Consumer acceptance studies related to taste and food quality • Public health programmes by govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
Expedited review	Proposals that pose no more than minimal risk may undergo expedited review, for example: • research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples • research involving clinical documentation materials that are non-identifiable (data, documents, records)

	• modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); • revised proposals previously approved through expedited review, full review or continuing review of approved proposals; • minor deviations from originally approved research causing no risk or minimal risk • 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; and • for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. • research during emergencies and disasters
Full committee review	All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are; • Research involving vulnerable populations, even if the risk is minimal • Research with minor increase over minimal risk (see table 1 of sops and table 2.1 of icmr guidelines for further details) • Studies involving deception of participants (see section 5.11 icmr guidelines 2017 for further details) • Research proposals that have received 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 • Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) Involving an altered risk

	• Major deviations and violations in the protocol • Any new information that emerges during the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment • 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 • Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

(Adopted from National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR Guidelines 2017)

Annexure 1. Conflict of Interest Agreement Form for Ethics Committee Members

It is recognized that the potential for conflict of interest will always exist but has faith in the Institutional Ethics Committee, IHBAS (IEC-IHBAS) and its chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the IEC-IHBAS that no member may participate in the review, comment, or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC-IHBAS for Clinical Studies/research. The Undersigned will immediately disclose to the Chairperson of the IEC-IHBAS any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals. While signing the attendance register, the member documents the proposal for which he/she has Conflict-of-Intertest (COI).

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC-IHBAS review or approval except to provide information requested by the Committee.
Examples of conflict-of-interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment

Agreement on Conflict of Interest

Please sign and date this Agreement, if the undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC-IHBAS. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

I, ……., have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals. I shall maintain all the project related documents and information confidential and shall not share or reveal the same to anyone other than the project related personnel.

_____ _____

Undersigned Signature Date

Name

_____ _____

Chairperson's signature Date

Name Dr. RC Jiloha

Declaration of Conflict of Interest

I, ……., have following proposal(s) with the undersigned as Principal Investigator/Co-investigator or real/potential/perceived competing research program under review by the IEC IHBAS. I shall abstain from any participation in discussions or recommendations in respect of the proposal.

I shall maintain all the project related documents and information confidential and shall not share or reveal the same to anyone other than the project related personnel.

Agenda No. Research Proposal No. Research Proposal Title

_____ _____

Signature Date

Name

Annexure 2. Research Proposal Contents

The protocol should include the following:

1. The face page carrying the title of the proposal with signatures of the investigators;
2. Brief summary/ lay summary;
3. Background with rationale of why a human study is needed to answer the research question;
4. Justification of inclusion/exclusion of vulnerable populations;
5. Clear research objectives hypothesis, objectives and end points (outcome variables), if applicable);
6. Type of study, and location of the study.
7. Eligibility criteria and participant recruitment procedures (sampling) procedures (including screening in-person or using various digital modes of communication including but not limited to email, phone calls, message services, social media, etc.).
8. 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 and a flow chart;
9. Duration of the study;
10. Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld justification for the same;
11. Procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. Av recording if applicable; informed consent for stored samples;
12. Audiovisual (AV) recording if applicable; informed consent for future use of stored samples; or a request for waiver of consent.
13. Plan for statistical analysis of the study;
14. Plan to maintain the privacy and confidentiality of the study participants;
15. case record form (or research Performa, screening, or diagnostic tools, etc.), permission to use the licensed or copyrighted material, or plans for payment or commercially available material should also be enclosed wherever required.
16. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period.

17. For research involving more than minimal risk, an account of management of risk or injury;
18. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
19. Provision of ancillary care for unrelated illness during the duration of research;
20. An account of storage and maintenance of all data collected during the trial or research study including physical form and digital form (site, server, country of location of the server, etc. in case of digital storage with duration of storage, the policy for retrieval when required, free or paid.
21. Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity. and authorship criteria incase more than one investigator are there and ethical considerations and safeguards for protection of participants.
22. Ethical considerations and safeguards for protection of participants.

Annexure 3. Application Form for Expedited Review

Title of study:

Principal Investigator (Name, Designation and Affiliation):

Choose reasons why expedited review from EC is requested*?

i. Involve non-identifiable specimen and human tissue from sources like blood banks, tissue banks and 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) ☐

1. Is waiver of consent being requested ? Yes ☐ No ☐
2. Does the research involve vulnerable person*? Yes ☐ No ☐
   If yes, give details:

Signature of PI: Click here to enter a date.

**Refer to Table 2 as above and for more details National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*

Annexure 4. Application Form for Exempted 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: Click here to enter a date.

Comments of EC Secretariat:

Signature of Member Secretary: Click here to enter a date.

**Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to Table 2 of the SOPs and National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

***Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)*

Annexure 5. Application Form for Initial Review

EC Ref. No. (for office use):

Institutional Ethics Committee
Institute of Human Behaviour & Allied Sciences, Delhi

Version 2; 31 May, 2022

General Instructions:

a) Tick one or more as applicable. Mark NA if not applicable

b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1.

a) Name of Organization:

b) Name of the Ethics Committee:

c) Name of Principal Investigator:

d) Department/Division:

e) Date of Submission:

f) Type of review requested:

Exemption from Review	Expedited Review	Full Committee Review

Refer to Table 1 & 2 above of SOPs and National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017on Page 36 Table 4.2. for the types of review

g) Title of the study:

Acronym/ Short title, (If any):

h) Protocol number (If any): Version number:

h) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication

			including telephone/mobile, and email id
Principal Investigator/Guide			
Co-investigator/student/fellow			

i) Number of studies where applicant is a:

Principal Investigator at time of submission	Co-Investigator at the time of submission

j) Duration of the study:

2. FUNDING DETAILS AND BUDGET

a) Total estimated budget for site:

At site	In India	Globally

b) Funding details

Self-funding	Institutional funding	External Funding agency

Specify, if any other

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay Summary of study (within 300 words)

b) Type of study:

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

4. METHODOLOGY

a) Sample size/ No. of Participants (as applicable)

At site	In India	Globally

Control group	Study Group

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation (*Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it)*

b) Is there an external laboratory/ outsourcing involved for investigations?

Yes	No	NA

c) How was the scientific quality of the study assessed?

Independent external review	Review by Sponsor/Funder	Review within PI's institution
Review within multi-centre research group	No Review	

Date of review:

Comments of Scientific Committee, if any (100 words)

SECTION C - PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

a) Type of participants in the study:

Healthy volunteer		Patient		Vulnerable person/ Special groups	
Others (Specify)					

Who will do the recruitment?

Participant recruitment methods used:

Posters/ leaflets/Letters		TV/Radio ads/social media/Institution website		Patients / Family/Friends visiting hospitals	
Telephone		Any other (Specify)			

b)

Children under 18 y		Pregnant or lactating women	
Differently abled (Mental/Physical)		Employees/Students/Nurses/ Staff	

Elderly		Institutionalized	
Economically and socially disadvantaged		Refugees/Migrants/Homeless	
Terminally Ill (stigmatized or rare diseases)		Any other (Specify):	

If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/ MoU etc.

i. Will there be vulnerable person/special groups involved?

Yes	No	NA

ii. If yes, type of vulnerable person /special groups

iii. Provide justification for inclusion/exclusion

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

c) Is there any reimbursement to the participant?

Yes	No

If yes, provide details

Monetary	Non-monetary

d). Are there any incentives to the participant?

Yes	No

If yes, provide details

Monetary	Non-monetary

d) Are there any participant recruitment fees / incentives the study provided to the PI/ Institution?

Yes	No

If yes, provide details

Monetary	Non-monetary

6. BENEFITS AND RISKS

a) 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	

For categories of risk refer to Table 1 of SOPs and for further details National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017. Page 6 in Table 2.1

ii. Describe the risk management strategy:

b)

What are the potential benefits from the study?	**Yes**	**No**	**If yes,**	**Direct**	**Indirect**
For the participant					
For the society/community					
For improvement in science					

Please describe how the benefits justify the risks

c) Are Adverse Events expected in the study?

Yes	No	NA

The term adverse events in this regard encompass both serious and non-serious adverse events.

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

Yes	No

If yes, Specify

7. INFORMED CONSENT

a) Are you seeking waiver of consent? If yes, please specify reasons and skip to question 8.

Yes	No

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

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

c) Type of consent planned for:

Signed consent		Verbal/ oral consent		Witnessed consent		Audio-Video (A/V) consent	
Consent from LAR (If so, specify from whom)		For children<7 y parental/LAR consent		Verbal assent from minor (7-12 y) along with parental consent		Written Assent from Minor (13-18 y) along with parental consent	
Other *(specify)*							

d) Who will obtain the informed consent?

PI/Co-I		Nurse/Counselor		Research Staff		Other (Specify)	

Any tools to be used (Specify)

e) Language of the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English	Local language	Other (Specify)

List the languages in which translations were done

If translation has not been done, please justify

f) Provide details of Consent requirement for previously stored samples, if used in the study (*Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 54 in Section 5.8; Enclose undertaking from PI confirming the same)*

g) 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)*					

8. PAYMENT/COMPENSATION

a) Who will bear the costs related to participation and procedures?

PI	Institution	Sponsor	Other agency (Specify)

b) Is there a provision for free treatment of research related injuries?

Yes	No	NA

If yes, then who will provide the treatment?

c) Is there a provision for compensation of research related SAE?

Yes	No	NA

If yes, specify.

Sponsor	Institution/Corpus funds	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	NA

If yes, specify.

e). Is there a provision for ancillary care for unrelated illness during the study period?

Yes	No	NA

If yes, please specify.

9. 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 (*For example, a data entry room, a protected computer etc.*)?

Yes	No	May be

If yes, explain how you might use stored material/data in the future?

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

	Publication, Benefit Sharing and IPR Issues	Yes	No	NA
a)	Will the results of the study be reported and disseminated? If yes, specify.			
b)	Will you inform participants about the results of the study?			
c)	Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words)			

d)	Is there any plan for post research benefit sharing with participants? If yes, specify			
e)	Is there is any commercial value or a plan to patent/IPR issues. 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? If yes, provide the 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 including responsible.
	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, 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 EC approved protocol.
	I/We declare that the expenditure in case of injury related to the study will be taken care of.
	If applicable, 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 (if required) 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 safety and confidentiality of study 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 study.
	I/We have the following conflict of interest (PI/Co-PI):
	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI:		Signature:	Date:
Name of Co-PI:		Signature:	Date:
Name of Guide:		Signature:	Date:
Name of HOD:		Signature:	Date:

12. CHECKLIST

S.No	Items	Yes	No	NA	Enclosure No.	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
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.	EC 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 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 Registration/ permissions	**Required**	**Not required**	**Received**	**Applied dd/mm /yy**	**EC Remarks**
18.	CTRI					
19.	DCGI					
20.	HMSC					
21.	NAC-SCRT					
22.	ICSCR					
23.	RCGM					

24.	GEAC					
25.	BARC					
26.	Tribal Board					
27.	Others (Specify)					

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28.						
29.						

*****_For multicentric research. MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre_

Annexure 6. Application Form for Clinical Trials

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

   CTRI registration number:
   NABH accreditation number EC registration number:

2. If regulatory trial, provide status of CDSCO permission letter
   Approved and letter attached ☐
   Applied, under process ☐
   Not applied (State reason)

3.

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

Tick all categories that apply to your trial

4. Trial design of the study (May choose more than one)

I.

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

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

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

5. List the primary / secondary outcomes of the trial.

6. 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:

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	☐	Audits, quality control, quality assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others (specify)	☐

Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; If yes, provide regulatory approval details
Yes ☐ No ☐ NA ☐

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

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

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

8. Describe in brief any preparatory work or site preparedness for the protocol?
Yes ☐ No ☐ NA ☐
If yes, (100 words)

9. Is there an initial screening/ use of existing database for participant selection?
Yes ☐ No ☐ NA ☐
If Yes, provide details (*In order to select participants for your protocol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same)*

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

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

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

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

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

Does the study have a Data and Safety Monitoring Plan? If no, please justify.

Yes☐ No☐

. 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)

List the languages in which translations were done

Justify if translation not done

17. Involvement/consultation of 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 Medical Council of India (MCI) or the State Medical Council registration? Please provide details.
Yes☐ No☐

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

Signature of PI: Click here to enter a date.

Annexure 7. Application Form for Human Genetics Testing Research

Title of study: Principal Investigator (Name, Designation and Affiliation)

. Describe the nature of genetic testing research being conducted.
(e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

2. Does the study involve pretest and post-test counselling? If yes, please describe.
Yes ☐ No ☐ NA ☐

3. Explain the additional safeguards provided to maintain confidentiality of data generated.

4. If there is a need to share the participants' information/investigations with family/community, is it addressed in the informed consent?
Yes ☐ No ☐ NA ☐
If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)

5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐
If yes, will informed consent be obtained? State reasons if not. Yes ☐ No ☐ NA ☐

6. What measures are taken to minimize/ mitigate/eliminate conflict of interest?

7. Is there plan for future use of stored sample for research? Yes ☐ No ☐
If yes, has this been addressed in the informed consent. Yes ☐ No ☐

Signature of PI: Click here to enter a date.

Annexure 8. 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 considered 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: Click here to enter a date.

Annexure 9. Format for Curriculum Vitae for Investigators

Name:	
Present affiliation *(Job title, department, and organisation)***:**	
Address *(Full work address)***:**	
Telephone number:	**Email address:**
Qualifications:	
Professional registration *(Name of body, registration number and date of registration)***:**	
Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations)***:**	

Projects undertaken in the last 5 years:

Relevant research training/experience in the area[25]:
Relevant publications *(Give references to all relevant publications in the last five years)***:**

Signature	**Date:** Click here to enter a date.

[25]*Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*

Annexure 10. Undertaking by the investigator in case of a clinical trial

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

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

3. Commitments:

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

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

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

iv) I agree to inform all Subjects; that the intervention/drugs/device 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 OCP guidelines are met.

v) I agree to report to the 'Sponsor all adverse experiences that occur during the investigation(s) in accordance with regulatory and GCP 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 / inspection by the Sponsor, Ethics Committee, Licensing Authority, or their authorized representatives, in accordance with regulatory and OCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

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

x) I agree to inform all unexpected serious adverse events to the Sponsor as well as the Ethics Committee within 24 hours of their occurrence.

xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

xii) I agree to comply with all other requirements, guidelines, and statutory obligations as applicable to clinical Investigators participating in clinical trials including the provisions contained in National Ethical Guidelines for Biomedical and Health Research involving Human Participant, 2017 by ICMR and The New Drugs and Clinical Trial Act, 2019.

Signature

Name of the PI

Affiliation

Annexure 11. Continuing Review/Annual Report

EC Ref. No. (*for office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval: Click here to enter a date. Validity of approval: Click here to enter a date.
2. Date of Start of study: Click here to enter a date. Proposed date of Completion: Click here to enter a date.

   Period of Continuing Report Click here to enter a date. ---- to ------ Click here to enter a date.
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected No. Screened: No. Enrolled:

   Number Completed: No. on followup: .

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB* *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

   Yes ☐ No ☐ NA ☐

   (d) Any other remark

   (e) Have any participants withdrawn from this study since the last approval?

   Yes ☐ No ☐ NA ☐

   If yes, total number withdrawn and reasons:
4. Is the study likely to extend beyond the stated period?
   (Mention problems if encountered) Yes ☐ No ☐

   If yes, please provide reasons for the extension

5. Have there been any amendments in the research protocol/informed consent document (ICD) during the past approval period?
If No, skip to item no.6 Yes ☐ No ☐

(a) If yes, date of approval for protocol and ICD : Click here to enter a date.

(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No ☐
If yes, when / how:

6. 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:

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

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief:

(b) Have any SAE's occurred since last review? Yes ☐ No ☐
If yes, number of SAE's : Type of SAE's:

(c) Is the SAE related to the study? Yes ☐ No ☐
Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

9. Has there been any protocol deviations/violations that occurred during this period?
If yes, number of deviations

Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

10. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC

    Yes ☐ No ☐ NA ☐

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

    Any other comments:

Signature of PI:

Click here to enter a date.

Annexure 12. Application Form for Amendments

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.
2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD[18]

3. Impact on benefit-risk analysis Yes ☐ No ☐ If yes, describe in brief:

4. Is any re-consent necessary? Yes ☐ No ☐
   If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. 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) ☐

6. Version number of amended Protocol/Investigator's brochure/Informed consent document (ICD):

Annexure 13. Protocol Violations/Deviations Reporting

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.

   Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.

2. Participant ID: Date of occurrence: Click here to enter a date.

3. Total number of deviations /violations reported till date in the study:

4. Deviation/Violation identified by: Principal Investigator/study team ☐
   Sponsor/Monitor ☐ SAE Sub Committee/EC ☐

5. Is the deviation related to (Tick the appropriate box):

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

6. Provide details of Deviation/Violation:

7. Corrective action taken by PI/Co-PI:

8. Impact on (if any): Study participant ☐ Quality of data ☐

9. Are any changes to the study/protocol required? Yes ☐ No ☐
   If yes, give details

Signature of PI: Click here to enter a date.

Annexure 14. Serious Adverse Event Reporting Form (Biomedical Health Research)

Title of study:

Principal Investigator (Name, Designation and Affiliation)

Participant details:

Initials and ID	Age at the time of event	Gender	Weight: (Kg)
		Male ☐ Female ☐	Height: (cm)

Suspected SAE diagnosis:

Date of onset of SAE: Click here to enter a date.

Date of reporting SAE: Click here to enter a date.

Describe the event (*Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious)*:

Details of suspected intervention causing SAE (*Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

Report type: Initial ☐ Follow-up ☐ Final ☐
If Follow-up report, state date of Initial report Click here to enter a date.

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

In 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).

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.

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

In case of death, state probable cause of death:

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

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

Provide details of compensation provided/ to be provided to participants (include the information on who paid, how much was paid and to whom)

Outcome of SAE

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Others	☐

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

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

Signature of the PI

Date

Annexure 15. Serious Adverse Event Reporting Form (Clinical trials)

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Participant details:
   Initials and Case No./Subject ID | Age at the time of event | Gender Male ☐ Female ☐ | Weight: (Kg) Height: (cm)

2. Report type: Initial ☐ Follow-up ☐ Final ☐

   If Follow-up report, state date of Initial report Click here to enter a date.

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

   By PI- Related ☐ Unrelated ☐

   By sponsor - Related ☐ Unrelated ☐

   By EC - Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:

4. Date of onset of SAE: Click here to enter a date. Date of reporting: Click here to enter a date.

5. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other)

6. Details of suspected study drug/device/investigational procedure causing SAE:
   I. Suspect study drug (include generic name) device/intervention:
   II. Indication(s) for which suspect study drug was prescribed or tested:

III. Route(s) of administration, daily dose and regimen, dosage form and strength:

IV. Therapy start date: Click here to enter a date. Stop date: Click here to enter a date.

7. Was study intervention discontinued due to event? Yes ☐ No ☐

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

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

10. Concomitant study drugs history and lab investigations:
I. Concomitant study drug (s) and date of administration: Click here to enter a date.

II. Relevant test/laboratory data with dates:Click here to enter a date.

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

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

12. Seriousness of the SAE:

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

13. 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).

14. Outcome of SAE:

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

15. Was the research subject continuing the trial? Yes ☐ No ☐ NA ☐

16. Provide the details about PI final assessment of SAE relatedness to trial.

17. Has this information been communicated to sponsor/CRO/regulatory agencies?
Yes ☐ No ☐
Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol?
Yes ☐ No ☐

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

Signature of PI: Click here to enter a date.

Annexure 16. Premature Termination/ Suspension/ Discontinuation Report Form

Title of study:

Principal Investigator (Name, Designation and Affiliation)

Date of EC Approval: Click here to enter a date. Date of start of study: Click here to enter a date.

Date of Last Progress Report Submitted to EC: Click here to enter a date.
Date of Termination/suspension/discontinuation: Click here to enter a date.
Tick the appropriate
Premature Termination ☐ Suspension ☐ Discontinuation ☐
Reason for Termination/Suspension/Discontinuation:
Action taken Post Termination/ Suspension/Discontinuation:

Plans for post study follow up/withdrawal (if any, *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study):*

Details of study participants:
Total participants to be recruited: Screened: Screen failures:

Enrolled: Consent Withdrawn: Reason(Give details):

Withdrawn by PI: Reason(Give details):

Active on treatment: Completed treatment : Participants on Follow-up:

Participants lost to follow up: Any other: No. of drop outs:

Reasons for each drop-out:

Total Number of SAEs reported till date in the study:
Have any unexpected adverse events or outcomes observed in the study been reported to the EC?

Yes ☐ No ☐

Have there been participant complaints or feedback about the study? Yes ☐ No ☐
If yes, provide details

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

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): If yes, provide details

Yes ☐ No ☐

Summary of Results (if any):

Signature of PI: Click here to enter a date.

Annexure 17. Study Completion

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval: Click here to enter a date.
2. Date of Start of Study: Click here to enter a date. Date of study completion:Click here to enter a date.
3. Provide details of:
   a) Total no. of study participants approved by the EC for recruitment:
   b) Total no. of study participants recruited:
   c) Total number of participants withdrawn from the study (if any):
   Provide the reasons for withdrawal of participants (*Explanation for the withdrawal of participants whether by self or by the PI)*:
4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)
5. Describe the main Ethical issues encountered in the study (if any)
6. State the number (if any) of Deviations/Violations/Amendments made to the study protocol during the study period

   Deviations: Violation: Amendments:
7. Describe in brief Plans for archival of records / Record Retention:
8. Is there a plan for post study follow-up Yes ☐ No ☐

   If yes, describe in brief:
9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes ☐ No ☐

   If yes, describe in brief:

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No ☐

    If yes, describe in brief:

11. Describe results (summary) with Conclusion (*For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready)*

12. Number of SAEs that occurred in the study:

13. Have all SAEs been intimated to the EC: Yes ☐ No ☐

14. Is medical management or compensation for SAE provided to the participants?

    Yes ☐ No ☐

    If yes, provide details

Signature of PI: Click here to enter a date.

Annexure 18. Reporting of Site Visits by Team from Ongoing Studies Review Sub-committee

Title of study:

Principal Investigator (Name, Designation and Affiliation):

Names of the Team Members

Date of visit Time of visit

Date of EC approval:

Date of start of study: Date of study completion (proposed):

Provide details of:

i. Total number of study participants approved by the EC for recruitment:

ii. Total number of study participants recruited till date:

iii. Total number of participants withdrawn from the study (If any):

Check whether the following are being done according to the method described in the protocol

i.	Sampling process	Yes/No/Remarks
ii.	Consent process	Yes/No/Remarks
iii.	Consent form signatures	Yes/No/Remarks
iv.	Allocation Concealment	Yes/No/Not applicable/Remarks
v.	Randomization	Yes/No/Not applicable/Remarks
vi.	Storage of intervention medicines	Yes/No/Not applicable/Remarks

vii.	Case/Participant Record Form	Yes/No/Remarks
viii.	Data storage & safety	Yes/No/Remarks
ix.	Payment to participants for visits	Yes/No/Not applicable/Remarks
x.	Study Coordinators or Research Officers	Yes/No/Not applicable/Remarks
xi.	Any other (as decided by the team)	
xii.	Remarks on the quality of above processes, their methods and the documentation, etc.	

Ensure that the PI provides the following:

a. List of study participants enrolled in the study (name, age, Sex, CR No./OPD No./Study Registration Number, and contact number).

b. Names, designation, qualifications, research experience and contact details of the Study Coordinators, Research Officers and other study staff.

c. Any other documents as deemed necessary by the Team.

Remarks

a. Findings suggesting deviation from the approved protocol

b. Any suggestion given to the PI

c. Suggestions regarding the process of inspection/site visits

Recommendations, if any.

Name and signatures of the members of the Team

NOTE: Kindly, submit this report to the Convener of Ongoing Projects Sub-Committee and the documents received from PI as early as possible and within 5 days of completion of the visit.