Hamdard Institute of Medical Sciences & Research and Associated HAH Centenary Hospital, Guru Ravidas Marg, Hamdard Nagar, New Delhi-110062.

Standard Operating Procedures (SOP) For Institutional Ethics Committee Version- 2.0

Date: 06th May-2025

Approved by

Dr. Arun Aggarwal **Chairperson IEC**	**Dr Yasir Alvi** **Member Secretary IEC**

GLOSSARY

CDSCO	Central Drugs Standard Control Organization
CRO	Contract Research Organization
CTRI	Clinical Trial Registry of India
CV	Curriculum Vitae
DCGI	Drugs Controller General of India
GCP	Good Clinical Practice
HAHC	Hakeem Abdul Hameed Centenary Hospital
HIMSR	Hamdard Institute of Medical Sciences And Research
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome
ICH	International Council For Harmonisation
ICD	Informed Consent Document
ICJME	International Committee of Medical Journals Editors
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
LAR	Legally Acceptable/Authorized Representative
MoU	Memorandum of Understanding
NGO	Non Governmental Organization
PI	Principal Investigator
PIS	Patient Information Sheet
RPAC	Research Project Advisory Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedures
TOR	Terms of Reference

1. Objectives of Standard Operating Procedures (SOPs):

International Council for Harmonization Good Clinical Practice (ICH-GCP) guideline defines Standard Operating Procedure (SOP) as "Detailed, written instructions to achieve uniformity of the performance of a specific function". The basic objective of this SOP of the Institutional ethics committee (IEC) is to maintain effective functioning of the IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the Indian Council of Medical Research (ICMR) and national ethical guidelines for biomedical research on human subjects to ensure the protection of the rights and welfare of human participants.

2.1 : Composition of Institutional Ethics Committee:

Institutional Ethical Committee will be multidisciplinary and multi-sectional in composition. The number of members will be 7 to 15. Minimum 50% member will not be affiliated to the institute in any way.

The chairman of the Institutional Ethical Committee will be from outside the HIMSR and will be nominated by the Honorable Director General, HIMSR. The Member Secretary (nominated by the Dean) will be from HIMSR, will conduct the business of committee. Others members will be from pool of doctors & Basic Medical Scientist (Non-medical or medical person with qualifications in basic medical sciences, preferably a pharmacologist), legal expert and a non- medical person (lay person) from society. There shall be adequate representation of age, gender, community etc. in the Committee to safeguard the interests and welfare of all sections of the society. (Ref. Schedule Y, Central Drugs Standard Control Organization (CDSCO) 2005 Appendix VIII). Every appointed member/ special invitee is expected to remain present and participate in the discussion / decision making process.

The representation on the IEC shall be:

a. Chairperson (from outside institution)
b. Member Secretary from Institute
c. Medical scientist (preferably a pharmacologist)
d. Clinicians
e. Legal expert
f. Social scientist or representative of non-governmental voluntary agency.
g. Lay person from society.

2.2. Authority for constituting the IEC at HIMSR and associated HAHC Hospital:

a. Honorable Director General, HIMSR and associated HAHC hospital will appoint the Chairperson from outside the Institute.

b. The member secretory (from the institute) and other members of IEC will be constituted by the Dean/Principal, in consultation with the Chairman IEC.

c. The committee members will be appointed based on their competence, experience and integrity by request

d. Members will confirm their acceptance to the Dean/Principal providing all the required information for membership including consent **(Annexure 10)** Conflict of interest form **(Annexure 11)**, latest CV and certification of GCP & Clinical trials rules training.

e. List of members appointed w.e.f 30th July, 2024 **(Annexure 13)**

2.3 Membership requirements for IEC:

a. Chairperson will be a well-respected person from any background with prior experience of having served/serving in an ethics committee.

b. Member/s should be sufficiently qualified through the experience and expertise and sensitive to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects

c. In addition to possessing the professional competence necessary to review the specific research activities, the member/s should be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice.

d. Each member of the committee will submit a declaration to maintain the confidentiality of the documents reviewed by them during their membership period. Members should sign confidentiality agreement regarding IEC activities and submit Conflict of interest form when then join the IEC membership **(Annexure 11)**, and in case of any conflict of interest in any particular meeting, they should declare to the IEC and submit **(Annexure 12)** at the beginning of that meeting.

e. Each member should submit recent signed CV and training certificates including Good Clinical Practice (GCP), at the time of induction, or must undergo training within 6 months of appointment.

2.4 Tenure of appointment of IEC members:

a. All members will serve for a period of 3 years on renewable basis.

b. There will be no bar on the members serving for more than one term, but it is desirable to have approximately one third fresh members.

c. New members will be included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.

d. All the members will be eligible for an Honorarium of Rupee 5000/- per sitting (or as per HIMSR rules).

2.5 Policy for removal of member:

a. A member may be relieved or terminated of his/her membership in case of conduct not suitable for a member of the Ethics Committee.

b. A member can be replaced in the event of long-term non-availability (three consecutive meetings). The membership shall be reviewed by the Dean and chairman, if the member is a regular defaulter. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Chairman IEC for necessary action. In all such situations/circumstances, member secretary will serve a letter of termination to the member. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership circular/roster will be revised

c. Dean/Principal of the Institute can replace the member of IEC as and when required.

2.6 Resignation / Replacement procedure:

a. A member can tender resignation of his office of membership from the IEC to the Dean of Faculty through the Chairperson after serving one month advance notice.

b. In case of resignation, chairman & member secretary would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative.

2.7 Training and updating members of IEC members

a. All IEC members should be conversant with Guidelines for Research involving Human Subjects.

b. All IEC members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements.

c. A team of trainers chosen for this purpose by Member Secretary will ensure that new members get trained with in fortnight after being inducted.

d. Institutional Ethics Committee will hold retraining for all the members of IEC once in 6 months for 2-3 hours on roles & responsibilities of IEC and its members.

e. All relevant new guidelines will be brought to the attention of the members

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

g. Any change in the regulatory requirements will be brought to the attention and the members will be made aware of local, social and cultural norms, as this is the most important social control mechanism.

2.8 Basic role and responsibilities of institutional Ethics committee:

a. To **review and arrive at appropriate decision** on all types of research proposals involving human participants (clinical Trial/ Study/ Research Proposal etc.) and to intimate it in writing.

b. To ensure the competent review and evaluation of all ethical aspects of research projects received in an objective manner.

c. **To protect the safety, rights and wellbeing of the potential research participants**, the goals of research, however important, should never be permitted to override the

health and wellbeing of the human participants.

d. To conduct scientific evaluation and ensure technical appropriateness of the proposed study.

e. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

f. To take all steps such as enquiring into a particular issue, monitoring the on-going study, seeking progress and reports from the PI in the interest of the study as well as Institution.

g. Where any serious adverse event (SAE) occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee will analyze the relevant documents pertaining to such event and forward its report to the Central Licensing Authority, (along with the its opinion on the financial compensation, if any)

h. To recommend appropriate compensation for research related injury, wherever required.

i. Where at any stage of a clinical trial, it concludes that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the committee will order discontinuation or suspension of the clinical trial and the same will be intimated to the head of the institution conducting clinical trial and the Central Licensing Authority

j. IEC will allow any officer authorized by the Central Licensing Authority to enter, and inspect the premises, any record, or any documents related to clinical trial, and will

furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

k. To recommend all the relevant matters to the Head of the Institution (Dean/Principal), especially in furtherance of cause of research.

l. To assist in the development and the education of a research community responsive to local health care requirements in the institute

m. Creation, developing revising and implementing ethical guidelines (SOPs)

3.1 Procedure for convening and conducting IEC meetings:

a. The Member Secretary in consultation with the chairman will convene the IEC meeting at least once in every three months (Additional review meeting can also be held with short notice as and when required)

b. All members will receive notification of meeting schedules in advance.

c. The Chairperson will conduct all meetings of the Institutional Ethical Committee. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson (Non-affiliated) will be elected by the members present from among themselves for that meeting only.

d. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare minutes of the meetings and get them approved by the Chairperson before communicating to members and Principal Investigator.

e. Minutes of the IEC meetings, all the proceeding and deliberation will be documented.

f. Applicant investigator may be invited to present the proposal or elaborate on specific issue.

g. The IEC 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 will be required to give their specialized views but should not take part in the decision making (or voting) process which will be made by the members of the IEC.

3.2 Quorum Requirements for conducting IEC meeting:

A minimum of 5 members are required to constitute the quorum for the meeting of which **at least one member must be from outside the institution**, and one member will be a

nonscientific member & one from **opposite gender**. All decisions will be taken in meetings and not by circulation of project proposals. For clinical trial, quorum will include at least one representative from all the following:

a. One basic medical scientist (preferably one pharmacologist).

b. One clinician

c. One legal expert

d. Social scientist

e. One lay person from the community

The chairperson and member secretary may have dual roles, ie as chairperson as well as clinician.

4.1 Procedure for submission of research project

a. **Institutional Project Committee Submission (RPAC):** All proposals **along with duly signed by involved investigators,** should be submitted, first to Research Project Advisory Committee (RPAC), HIMSR for scientific review and institutional permission on prescribed format **(Annexure 1). Hard and Soft Copies:** Submit two hard copies of the protocol to RPAC office/secretariat**,** HIMSR**,** and a soft copy (pdf) via email to ***rpac@himc.co.in***, along by RPAC cover letter and protocol checklist filled by the investigator (**Annexure 3**). **For MD/MS Thesis only:** Thesis of MD/MS students would be submitted to **Thesis Protocol Committee, HIMSR** for scientific review. Thesis Protocol Committee will have at least two members from Intuitional Ethics Committee who may also perform the expedited review of all the MD/MS Thesis protocol (except studies involving more than minimal risk/ High risk / Interventional studies) and submit their assessment for Ethics committee.

b. **IEC Submission**: After the RPAC approval, the protocol needs to be submitted to the **IEC office/secretariat, HIMSR**, two weeks in advance of scheduled meeting along with study related document necessary for review by IEC. **Hard and Soft Copies:** Submit one hard copies of the protocol **forwarded by RPAC secretory**, and a soft copy (pdf) via email to ***iec-himsr@himsr.co.in***, along with IEC cover letter (**Annexure 2**) and protocol checklist filled by the investigator (**Annexure 1 and 3**).

c. Cover letter to the Member Secretary IEC for initial review (**Annexure 2**), should 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 exemption from review or expedited review, the justification should be mentioned in the application along with the cover letter (**Annexures 4 & 5**).

d. IEC academic assistant will verify the proposal for completeness as per check list **(Annexure3)**

e. The date of meeting will be intimated to the PI who should be available for protocol presentation and offer clarifications if necessary.

f. The decision of Institutional Ethical Committee will be communicated in writing.

g. If revision is to be made, the revised document (1 printed and signed hard copy) and the softcopy (pdf) along with cover letter (**Annexures 7)** with pointwise reply to the comments/observations of the IEC should be submitted within a stipulated period as

specified in the communication.

h. In case of Research Proposal where the Principal Investigator (PI) happens to be the Member-Secretary of IEC-HIMSR, the approval letters and routine correspondence shall be signed/counter-signed by the Chairperson of IEC.

i. IEC-HIMSR charges a review fee of Rs 50,000 (Fifty thousand) for initial review and Rs 25,000 (twenty-five thousand) for subsequent reviews from funded projects by Pharmaceutical Industry and Contract Research Organization (CRO). The fees are deposited in the HIMSR account. EC may allow waiver of this fee from the funded projects supported by government agencies and WHO.

4.2 Procedure for review of Projects:

a. The IEC's member-secretary shall screen the research proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full review.

b. 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.

c. The meeting of the IEC-HIMSR is held whenever enough projects/proposals are there for review and about usually once in 3 months meetings are held.

d. The proposals (as soft copy) will be sent to members one weeks in advance by e-mail.

e. Principle Investigator should be available during the meeting and will give brief presentation of his proposal. He may be asked for any clarifications

f. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.

g. Decisions will be taken by consensus after discussions, and voting will be done if necessary.

h. The decisions of the meeting shall be recorded in the form of minutes and approved by Chairperson in writing by email.

4.3 Element of Review of Proposed Projects:

The submitted proposal shall be reviewed both for scientific content and ethical principles. Every proposal will be evaluated by IEC members on ethical issues as per ICMR Ethical Guidelines 2017 as amended thereafter, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC interview. All members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue. The IEC review will be done through formal meetings and will not resort to decision through circulation of proposal.

The committee members shall review the proposal with reference to the following:

a. **Approval of scientific review committee/Research committee and other regulatory agencies.**
b. **Social values**
c. **Scientific design of the study**
d. **Assessment of predictable risks & harms and potential benefits**
e. **Justification and rationale of the study**
f. **Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.**
g. **Payment for participation**
h. **Justification for placebo in control arm, if any.**
i. **Community considerations including permission to conduct research in schools, or another vulnerable group of populations.**
j. **Monitoring of serious adverse events**
k. **Compensation to subjects for participating in the study**
l. **Compensation for study related injury**
m. **Patient retention activities.**
n. **Protection of privacy and confidentiality**
o. **Plans for data analysis and reporting**

p. **Informed consent document** in English and regional languages: 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.

- 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.
- Circumstances where audio/audio-visual recording of the informed consent process may be required, in certain clinical trials as notified by CDSCO.
- Verbal/oral consent/waiver of consent/re-consent as required under certain conditions after due consideration and approval by the IEC.

q. **Competence of investigators**, supporting staff and infrastructure facility

- Qualification of researchers, number and status of the ongoing 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-HIMSR for approval while justifying the same. IEC-HIMSR may approve more projects for individual researcher on a case-to-case basis.

r. **Approval of regulatory authorities** wherever applicable

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

t. **Plan for medical management and compensation for study related injure**

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

v. **Criteria for withdrawal of patients**, suspension or premature termination of a study.

w. **Involvement of the community**, wherever necessary.

4.4 Decision-making on the research proposal by IEC:

a. A member shall 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). This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.

b. Only members will make the decision. The decisions shall be taken in the absence of Investigators, representatives of sponsors and consultants.

c. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.

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

e. Decision may be

- **Approval** –with or without suggestions or comments,
- **Revision** with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be,
- **Revision** with major modifications for resubmission – this will be placed before the expedited review / full committee for reconsideration for approval, as the case may be,
- **Not approved** (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/ terminating/revoking of permission. Specific suggestions for modifications and reasons for 'non approval' should be given.

f. Revised proposals may be subjected to an expedited review.

g. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified

h. 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) (**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.

4.5 Communicating the decision of IEC:

a. Decision of the meeting on the proposals will be communicated to Principal Investigator/ Research Scholar by the Member Secretary in writing (by printed letter on paper or by email to the PI). within two weeks of meeting at which the decision was taken.

b. The communication letters with IEC reference number shall be collected by the PI/ Research Scholar from IEC office (member secretory office).

c. In case of Research where the Principal Investigator (PI)/Co-PI happens to be the Member-Secretary of IEC-HIMSR, the decisions shall be signed/counter signed by the Chairperson IEC-HIMSR.

d. All the approvals will be valid for two year or for the duration of the project whichever is earlier (validity period of permission to initiate a clinical trial will be two years). Investigator has to get his or her project re- approved after one year, where required.

e. Suggestions for modifications and reasons for rejection shall also be communicated to the Principal Investigator.

4.6 Expedited Review Procedures:

a. The proposal that can be considered for **Expedited Review are listed in Table 2.**

b. The cover letter to IEC at the time of proposal submission need to be request for expedited review with appropriate reasoning along with Application Form for Expedited Review (**Annexure 5**)

c. 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.

d. An expedited review, when designated for a particular proposal during its original discussion, requires the Chairperson/Member-Secretary, one/two 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.

e. The committee may use expedited review procedure in case of minor changes/ amendments in the previously approved research proposal that appear to involve no more than minimal risk to the study subjects.

f. Only the Chairperson and Member Secretary shall make the decision to allow an expedited review.

g. Under an expedited review procedure the reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.

4.7 Post approval follow-up procedures:

a. IEC will review the progress of all the studies which are cleared by it from the time of decision till the termination of the research.

b. Progress of all the research proposals will be followed at a regular interval.

- Clinical trial: at least six monthly, or as per the New Drugs and Clinical Trials Rules, 2019
- Non-thesis projects: at least six monthly
- Thesis/dissertation projects: at least once a year.
- In special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.

c. Investigators are required to submit regular report to IEC apart from the final report (**Annexure 8 and 9**).

d. Protocol deviations shall not be permitted. In exceptional cases where a deviation is deemed unavoidable, protocol deviation must be duly documented and reported to IEC, with adequate justifications (**Annexure 8**).

e. Change of Principle investigators/ Co -PI must be informed to the office of IEC within one month.

f. Any new information related to the study should be communicated. (**Annexure 8**).

g. The IEC reserves the right to review the study or inspect the study site during the study period. The decision can be continuation, suspension or termination of study.

h. PI must inform the completion of study within 15 days and must submit the result summary to IEC within 90 days.

i. Investigators are required to report any Serious Adverse Events (SAE) or Suspected Unexpected Serious Adverse Reaction (SUSAR) to the study subject to the IEC within 24 hours of their occurrence/ awareness to IEC-HIMSR, Head of the Institute, and Sponsor.

j. In next 14 days the sponsor must submit due analysis report of causality assessment to the IEC, DCGI and Head of Institution.

k. IEC-HIMSR reviews it over next 30 days and decide on causality of injury, quantum of injury and compensation to research subject (as per the 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, their representative, or the investigator, leading to a serious adverse event.

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

    iv. Failure to provide the required standard care—though available—to the subject as per the clinical trial protocol in a placebo-controlled trial

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

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

    vii. Any clinical trial procedure involved in the study that leads to a serious adverse event

l. If the adverse event was anticipated in the protocol and the subject was informed about the possibility of event in the Informed Consent Form (ICF) there is no need to inform IEC unless the adverse event was unexpectedly serious, life threatening or fatal.

m. In case of premature suspension/termination of study, the applicant must notify the IEC of the reasons for suspension/termination

4.8 Obligations of ethics committee regarding new research directly related to pandemic

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

a. To ensure that there no barriers to research even during emergencies like the COVID-19 pandemic, the IEC-HIMSR 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. 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-HIMSR. 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.

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

f. 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.

g. 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.

h. Common review of multi-centric research is carried out by expedited committee for fast-track decision making. IEC-HIMSR may choose to accept the decision or full committee review. The IEC-HIMSR ensures ethics review with reference to site-specific issues.

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.

5. Record keeping and archiving at the office of IEC:

The office of the member secretary is responsible to archive the study related documents, proceedings and communications

Procedure:

I. An dedicated academic assistant will help the IEC Member Secretary in executing functions of the IEC, documentation & archiving documents.

II. All the documents and communications of IEC will be dated, filed and archived in a secure place.

III. Only the member secretary or persons, who are authorized by the Chairman of IEC will have the access to the various documents.

IV. All documents related to research project will be archived for a minimum period of five years in the Institute following completion or termination of project, unless there is a specific requirement for a longer time. All the agenda & minutes of meeting will be filed & archived.

V. At the end of each meeting, every member must return the research proposals, no document (except agenda) will be retained by any IEC member.

VI. List of documents that will be filed and archived with proper label on the top of file for easy identification:

a. Constitution and composition of IEC-HIMSR.

b. Curriculum Vitae (CV) of all members of IEC

c. GCP, Clinical Trials rules and other training in Human ethics of all members of IEC.

d. Standard Operating Procedures of IEC.

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

f. Agendas and Minutes of all IEC meetings duly signed by the Chairperson /Member secretary

g. Copy of all correspondence with members, Principal Investigators and other regulatory

bodies.

h. Copies of decisions communicated to applicants for research project.

i. Record of all notification issued for premature termination of a study with a summary of the reasons.

j. Final report of the approved projects.

k. Records relating to the serious adverse event, medical management of trial subjects and compensation paid.

l. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members.

m. The published guidelines for submission established by the EC.

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

o. Annual reports

6. Terms of reference (TOR):

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

1. Membership Requirements
2. Terms of Appointment with reference to the duration of the term,
3. The policy for removal, replacement, resignation procedure,
4. Frequency of meetings, and
5. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts / scientific review members etc.

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members (minimum 1/3rd) could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.

7. Standard Operating Procedures (SOP) for vulnerable population:

Definition of vulnerable population: Individuals/ groups/ populations who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or other reasons.

Examples of vulnerable population are:

1. Socially, economically or politically disadvantaged and susceptible to exploitation e.g. unemployed or impoverished persons, homeless persons, abandoned, orphans, refugees and patients in emergency situation, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.
2. Incapable of giving voluntary informed consent e.g. children, unconscious, differently abled persons.
3. Able to give consent, but their voluntariness or understanding is compromised due to their situational conditions or being under a hierarchical system e.g. prisoners, staff and students of medical, nursing and pharmacy academic institutions etc.
4. Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare)
5. terminally ill or are in search of new interventions having exhausted all therapies
6. Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate, which may lead them to give consent
7. Persons with diminished autonomy besides issues pertaining to commercialization of research and international collaboration

Procedures:

While all the requirements are applicable to biomedical research as a whole, irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safeguards / protection and specific considerations for the IEC. The IEC-HIMSR will follow the ICMR guidelines-2017 for vulnerable groups:

1. Researchers must justify the inclusion/exclusion of a vulnerable population.
2. A community representative will be invited to IEC meetings to make sure the research is responsive to their needs and the informed consent process is appropriate.

3. Additional precautions will be taken by all stakeholders such as researchers, ECs and sponsors to avoid exploitation of vulnerable participants.
4. Informed consent process will be well documented and additional measures adopted if required, such as audiovisual/audio recording of assent/consent/reconsent.
5. **Research proposals will undergo review in a full committee meeting.**
6. Protection of privacy and dignity as well as provision of quality health care will be provided in dealing with vulnerable people, especially the minorities.
7. Research involving children, in addition, will follow the National Ethical Guidelines for Biomedical Research Involving Children, ICMR, 2017.
8. Due approvals will be taken from competent authorities before entering **tribal areas.**
9. Research involving cognitively impaired individuals or those with mental illness will be done carefully, especially if there is risk to themselves, to others or suicidal ideation.
10. The EC should carry out the benefit–risk analysis and examine risk minimization strategies.
11. Effort will be made to ensure that individuals or communities invited for research is selected in such a way that the burdens and benefits of the research are equally distributed.
12. Persons who are economically or socially disadvantaged are not used to benefit those who are better off than them.
13. Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders will be protected. Appropriate proxy consent from the legal guardian will be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process will be properly documented.
14. Adequate justification will be made for the involvement of subjects such as prisoners, students, subordinates, employees, and service personnel etc. who have reduced autonomy as research subjects.
15. Research on genetics will not lead to racial inequalities.

8. Standard Operating Procedures (SOP) to monitor or prevent the conflict of interest

Purpose: The purpose of this SOP is to describe the process to identify and manage confidentiality / Conflict of interest among Institutional Ethics Committee (IEC) members.

Procedure for New members: (Annexure 11).

a. The newly appointed IEC member, before the beginning of their tenure, Guests /observers for IEC meetings, Independent Consultants / advisory committee/ board member will sign and date the conflict of interest form before a member of the Secretariat.

b. They will give the signed form back to the Secretariat.

c. The Secretariat will obtain the signature of the IEC Chairperson on the Conflict of Interest Agreement Form.

d. The secretariat will provide IEC member, Guests or observers for IEC meetings, Independent Consultants a photocopy of the Conflict of Interest Agreement Form for their records (duly signed and dated by them and IEC Chairperson).

e. The Secretariat keeps the original copies of the signed Agreements at the Institutional Ethics Committee office in the files entitled Conflict of Interest Agreement file for members, guests, observers, Independent Consultants.

f. The Secretariat will store the file in a secure cabinet with limited key holders.

Procedure for existing member:

a. The members shall voluntarily withdraw from the Ethic committee meeting while making a decision on an application which evokes conflict of interest which may be indicated in writing to the chairman prior to the review and to be recorded so in the minutes. (**Annexure 12).**

b. A member must voluntarily withdraw from the IEC while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the chairperson prior to the review and should be recorded so in the minutes. If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed.

c. No Institutional Ethics Committee may have a member participate in the IEC's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IEC

d. Every member at beginning of the tenure and before he/she commences to review research projects submitted to IEC and before he/she starts to function as an IEC member and before he/she starts attending IEC meeting will read the and sign (with date) the Conflict of Interest Agreement Form (**Annexure 11 and 12**).

e. If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

Table 1: Categories of Risk involved in research

Type of Risk	Description
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. Examples: • Research on anonymous or non-identified data/samples • Data in the public domain • Meta-analyses
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 • Observation, physical exams, chest X-rays • Non-invasive sample collection (e.g., hair, saliva, urine)
Minor increase over minimal risk or Low risk	There is a slight increase in the probability of harm or discomfort above the minimal risk threshold. This may include: • Routine research on children or adolescents • Research on individuals incapable of giving consent • Withholding or delaying proven treatments in control/placebo groups • Minimally invasive procedures causing only mild discomfort (e.g., blood sampling, minor bruises) • Research involving psychological, social, or indirect risks • Such studies must have a clear social value and ensure the use of identifiable data is minimized.
More than minimal risk or High risk	Research poses a higher probability of harm or discomfort and typically involves invasive or high-risk procedures. Examples include: • Interventional studies using drugs, devices, or invasive procedures (e.g., lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc. These are greater than minimal risk and require comprehensive ethical justification and safeguards.

(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 including systematic reviews and meta-analysis • 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 government agencies such as programme evaluation, where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)
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 leftover 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 (See 4.8: Obligations/duties of ethics committee regarding new research directly related to pandemic)
Full committee review	All research proposals presenting more than minimal risk that are not covered under exemption 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 – Categories of Risk). • 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, should be ratified by the full committee, which has the right to reverse or modify any decision taken by the expedited committee. • Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment materials, etc.) involving 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)

Table 3: Ethical issues related to reviewing a protocol

Social values	• The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value.
Scientific design and conduct of the study	• Valid scientific methods are essential to make the research ethically viable as poor science can expose research participants or communities to risks without any possibility of benefit. • Although ECs may obtain documentation from a prior scientific review, they should also determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy. • The EC can raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants.
Benefit-risk assessment	• The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research. • Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole. • The EC should review plans for risk management, including withdrawal criteria with rescue medication or procedures. • The EC should give advice regarding minimization of risk/ discomfort wherever applicable. • Adequate provisions must be made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board (DSMB) if applicable (for example in clinical trials)
Selection of the study population and recruitment of research participants	• Recruitment should be voluntary and non-coercive. Participants should be fairly selected as per inclusion and exclusion criteria. However, selection of participants should be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit. • Participants should be able to opt out at any time without their routine care being affected. • No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits. • Vulnerable groups may be recruited after proper justification is provided.

Payment for participation	• Plans for payment for participation, reimbursement of incurred costs, such as travel or lost wages, incidental expenses and other inconveniences should be reviewed. • There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against their better judgement. No undue inducement must be offered.
Protection of participants' privacy and confidentiality	• ECs should examine the processes that are put in place to safeguard participants' privacy and confidentiality. • Research records to be filed separately than routine clinical records such as in a hospital setting.
Community considerations	• The EC should ensure that due respect is given to the community, their interests are protected and the research addresses the community's needs. • The proposed research should not lead to any stigma or discrimination. Harm, if any, should be minimized. • Plans for communication of results to the community at the end of the study should be carefully reviewed. • It is important to examine how the benefits of the research will be disseminated to the community.
Qualifications of researchers and study sites	• The EC should look at the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants.
Disclosure or declaration of potential COI	• The EC should review any declaration of COI by a researcher and suggest ways to manage these. • The EC should manage COI within the EC and members with COI should leave the room at the time of decision making in a particular study.
Plans for medical management and compensation	• The proposed plan for tackling any medical injuries or emergencies should be reviewed. • Source and means for compensation for study related injury should be ascertained.
Review of the informed consent process	The informed consent process must be reviewed keeping in mind the following: • the process used for obtaining informed consent, including the • identification of those responsible for obtaining consent and • the procedures adopted for vulnerable populations; the adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs; • contents of the patient/participation information sheet including the local language translations (See section 5 for further details); • back translations of the informed consent document in English, wherever required.

	• provision for audio-visual recording of consent process, if applicable, as per relevant regulations; and • if consent waiver or verbal/oral consent request has been asked for, this should be reviewed by assessing whether the protocol meets the criteria. See section 5 for further details.

Annexure 1: Proforma for submitting research proposal to IEC

(Bellow information and enclosures should be furnished wherever necessary depending upon the nature of study proposal) Please download and use - **Faculty protocol format / Student protocol format from HIMSR website**	
1	Covering letter (and Forwarding letter from Guide in case of thesis proposal through proper channel (Head of the Department) (**Annexure XX**)
2	Title of the Project
3	Name with signature of the principal investigator & qualification, designation and department
4	Name with signature of co-investigator (s) & qualification, designation and department
5	Name of the Institute/ department/ field area where research will be conducted.
6	Protocol of the proposed research: (includes and not limited to) • The first page carrying the title of the proposal with names and signatures of the investigators • Brief summary/ lay summary • Background with rationale for undertaking the investigations in human participants in the light of existing knowledge, • Justification of inclusion/exclusion of vulnerable populations. • clear objectives, hypothesis • detailed description of methodology • Eligibility criteria (inclusion and exclusion) and participant recruitment procedures (sampling) • sample size (with justification), • type of study design (observational, experimental, pilot, randomized, blinded etc), • Duration of the study • intended intervention, dosages of drugs, route of administration, duration of treatment, • details of invasive procedures if any, • Justification for placebo, benefit–risk assessment, plan to withdraw or withhold standard therapies in the course of research with justification • plan for statistical analysis of the study, • ethical issues in the study and plans to address these issues • 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 • Plan to maintain the privacy and confidentiality of the study participants • For research involving more than minimal risk, an account of management of risk or injury • 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. • Plans for publication of results – positive or negative – while maintaining

	confidentiality of personal information/ identity. • authorship criteria incase more than one investigator
7	Proposal should be submitted with relevant enclosures like • case report forms, • questionnaires, • follow-up form, • participant recruitment procedures and brochures, if any. • Informed consent process, including o patient information sheet and o informed consent form in English and local language(s) are mandatory. • Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and • statement of relevant regulatory clearances should be attached. • Source of funding and financial requirements for the project has to be detailed.
8	Expected benefits to subjects/volunteers/community. Benefits to other categories if any
9	Explain all anticipated risks (adverse events, injury, and discomfort) of the project. Efforts taken to minimize the risks.
10	For any drug/ device trial, relevant pre-clinical animal data and clinical trial data from other centers within the country/ other countries, if available.
11	For trials, proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.
12	Agreement to report all Serious Adverse Events (SAE)/death to IEC-HIMSR within the stipulated duration as per Schedule Y.
13	Agreement to comply with the relevant national and applicable international guidelines, Schedule Y guidelines, ICMR guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
14	Details of Regulatory clearance if required, if applicable
15	Consent form in local language
16	Conflict of interest for any other investigator, if any
17	Agreement to inform the completion of study (within 15 days) and the result summary (within 90 days) to IEC-HIMSR
18	Curriculum vitae of principal investigator with relevant publications.
19	Any other information that ethics committee may require to fulfil its responsibilities
20	Signature of Principal investigator and Co- investigators

Annexure 2. Covering letter for initial IEC Review

To,
The Member Secretary,
Institutional Ethics Committee,
HIMSR, New Delhi

Subject: Request for **Exemption/Expedited Ethical/ Full Review** (select one) of Research Proposal

Respected Sir/Madam,

I, ……., (designation) at Department of …….., wish to submit my research proposal titled "……." for consideration under **Exemption/Expedited Ethical/ Full Review** (select one) by the Institutional Ethics Committee of HIMSR.

My research proposal has been duly reviewed and approved by the Research Project Advisory Committee (RPAC) on ..../…../.. (attach RPAC approval letter)

Given the ***Less than minimal risk/ minimal risk/ Low risk/ More than minimal risk or High risk*** (select one) involved in my study and its compliance with ethical guidelines, I kindly request an ***Exemption/Expedited Ethical/ Full Review*** (select one) under the applicable ethical framework. (Kindly give reason for your selection of risk – See table 1)

The study will be conducted at …….. (mention study site) and involves the collection of (mention samples).The procedure ***dose/does not*** involve the collection of any additional samples beyond routine collection.

Enclosed with this application are the following documents for your kind perusal:
1. Copy of RPAC approval letter
2. Study Protocol
3. Participant information sheet and informed consent form (English & Hindi)
4. Case Report Form / Questionnaire
5. Check List for Protocol Submission
6. Copy of approval letter from other IEC (If present)

I assure you that the study will be conducted in strict adherence to ethical guidelines and with utmost regard for participant safety and confidentiality.

Thank you
PI name and designation
Sign with date

PI Email:
PI Contact No.:

Annexure 3. **Check List of Documents for Protocol Submission to IEC to be filled by PI.**

SN	Document	Yes	No	NA	Comments
1	*Cover Letter to Member Secretary/ Chairperson.				
2	* Hard copies and soft copy Project Protocol in prescribed format				
3	Protocol duly signed by the investigators				
4	*Summary/Abstract of protocol (in not more than 500 words).				
5	*Ethical Consideration & justification (Benefits, risk, Confidentiality)				
6	*Data management				
7.	*Informed consent Part 1 (Patient information sheet) in English,				
8.	*Informed consent Part 1 (Patient information sheet) in Regional languages (Hindi and/or Urdu)				
9.	*Informed consent document Part 2 in English,				
10.	*Informed consent documents Part 2 in regional languages				
11	*Research participants Questionnaire/s				
12	A statement of agreement to comply with ethical principles set out in relevant guidelines				
13	Current Status of Ongoing Studies approved by IEC and conducted by PI (title, no of participant, SAE at the site)				
14	Ethics Committee clearance of other centers				
15	Brief current curriculum vitae of PI and Co PI. (Compulsory for regulatory studies)				
16	Case Record Form (Compulsory for Clinical trials)				
17	Research participants recruitment procedures: advertisement,				
18	GCP training certificates of all PI and Co-PI (last 3years, (Compulsory for Clinical trials, highly suggested for all studies)				
19	Log of delegation of responsibility of the study team members (Compulsory for regulatory studies)				
	In case of Clinical Trial / interventional studies				
20	Information on Clinical Trials				
21	Contact Address of Sponsor				
22	Total Budget				
23	Research participants selection				
24	Privacy and confidentiality				
25	Use of biological/ hazardous materials				
26	Risks & Benefits				
27	Data Monitoring				
28	Consent				
29	Compensation for participation				
30	Undertaking by Principal Investigator regarding compensation for study related injury				
31	Statement on conflict of interest				
32	Insurance				
33	Clinical Trial Agreement for drug trial / MoU as applicable, for collaborator & Govt sponsored trials				

* Compulsory documents

Annexure 4. Application Form for Exempted Review

Title of study:

Principal Investigator (Name, Designation and Affiliation):

Choose reasons why Exempted review from EC 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 (where there are no individual identifiers)	
vii. Any other (please specify in 100 words):	

Signature of PI:

Comments of EC Secretariat:

Signature of Member Secretary:

Annexure 5. 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:		

PI name and designation
Sign with date
PI Email:
PI Contact No.:

Annexure 6: Covering letter for submitting revised protocol after initial IEC Review

To,
The Member Secretary,
Institutional Ethics Committee,
HIMSR, New Delhi

Subject: Submission of Revised Research Proposal for IEC

Respected Sir/Madam,

I am hereby submitting 1+1 copies of the revised protocol titled " ……..." for the kind approval by the Institutional Ethics Committee of HIMSR.

As per the suggestion of the initial IEC held on ..../…../.., following changes have been made in the revised protocol:
1. …. at page no ….
2. … at page no ….
3. … at page no ….

The study will be conducted at …….. (mention study site) and involves the collection of (mention samples).The procedure ***dose/does not*** involve the collection of any additional samples beyond routine collection.

Enclosed with this application are the following documents for your kind perusal:
1. Copy of RPAC approval letter
2. Study Protocol
3. Participant information sheet and informed consent form (English & Hindi)
4. Case Report Form / Questionnaire
5. Check List for Protocol Submission
6. Copy of approval letter from other IEC (If present)

I assure you that the study will be conducted in strict adherence to ethical guidelines and with utmost regard for participant safety and confidentiality.

Thank you
PI name and designation
Sign with date

PI Email:
PI Contact No.:

Annexure 7: Criteria for authorship (ICMJE)

According to the ICMJE, authorship entails the following criteria: (all four must be fulfilled)

1. substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work;

2. drafting the work or revising it for important intellectual content;

3. final approval of the version to be published;

4. agreement to be accountable for all aspects of the work and ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Annexure 8. Continuing Review/Annual Report

HIMSR IEC Ref No:

Title of study:

Principal Investigator (Name, Designation and Affiliation)
Student Investigator (If applicable)

1.	Date of EC Approval:	…/…/….
2.	Date of Start of study:	…/…/….
	Study duration in month	
	Period of Continuing Report	…/…/…. To …/…/….
3.	Does the study involve recruitment of participants?	Yes / No
	(a) If yes, Total sample size	
	(b) No. Enrolled	
	(b) Enrolment status	ongoing / completed/ stopped
4.	Is the study likely to extend beyond the stated period?	Yes / No
	(Mention problems if encountered)	
	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?	Yes / No
	(a) If yes, date of approval for protocol and ICD :	
	(b) In case of amendments in the research protocol/ ICD, was re-consent sought from participants?	
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
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?	Yes / No
	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:

Annexure 9. Study Completion Report

HIMSR IEC Ref No:

Title of study:

Principal Investigator (Name, Designation and Affiliation)
Student Investigator (If applicable)

1.	Date of EC Approval:	…/…/….
2.	Date of Start of study:	…/…/….
	Date of completion of study:	…/…/….
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	
7	Describe in brief Plans for archival of records / Record Retention:	
8	Is there a plan for post study follow-up?	Yes / No
9	Do you have plans for ensuring that the data from the study can be shared/ accessed easily?	
	If yes, describe in brief:	
10	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)	
11	Number of SAEs that occurred in the study:	
	Have all SAEs been intimated to the EC:	Yes / No
12	Is medical management or compensation for SAE provided to the participants?	Yes / No
	If yes, provide details	

Signature of PI:

Annexure 10. **Members Consent letter for accepting IEC membership**

Date:

From

……

……
……

To

The Dean/Principal
HIMSR and Associated HAHC hospital

New Delhi-110062

Subject: Consent to be a member of Institutional Ethics Committee-

Dear Sir/Madam.

Ref: Your Letter No: dated……: I give my consent to become a member (as.....) of IEC of HIMSR and associated HAHC hospital. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

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

I am enclosing my CV.

Thanking

Yours sincerely,

Signature with Date

Annexure 11. Conflict of Interest Agreement Form for Ethics Committee Members

Conflict of Interest Agreement Form for IEC Members

1. It is the policy of the IEC 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.
2. The Undersigned will immediately disclose to the Chairperson of the IEC 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 or decision making in respect of such proposals.(Annexure IV)
3. When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC review or approval except to provide information requested by the Committee.
4. Examples of conflict of interest cases may be any of the following:
   a. A member is involved in a potentially competing research program.
   b. Access to funding or intellectual information may provide an unfair competitive advantage.
   c. 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. A copy will be given to you for your records.

To
The Chairperson
Institutional Ethical Committee, HIMSR and associated HAHC hospital
Jamia Hamdard, New Delhi-62

Sir**,**
I have read and accept the aforementioned terms and conditions as explained in this Agreement. Whenever I have a conflict of interest, I shall immediately inform you not to count me for discussion or decision making in respect of such proposal.
Name…….

Signature with Date

Signature of Chairperson with Date

Annexure 12: Declaration of Conflict of Interest Form for IEC Members to be submitted before IEC meeting

Declaration of Conflict of Interest

To
The Chairperson
Institutional Ethical Committee, HIMSR and associated HAHC hospital
Jamia Hamdard, New Delhi-62

Sir

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 HIMSR. 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:

Name…….

Signature with Date

Signature of Chairman with Date

Annexure 13: Members of the Ethics Committee HIMSR

Name	Address	Affiliation with the Institute	Qualifications	Designation
Dr. Arun Aggarwal	Ret. Dean MAMC N-9, Green Park Main New Delhi-16	No	MBBS, MS (ENT)	**Chairperson**
Dr. Arunabha Ray	Former head, Pharmacology, V.P. Chest Institute	No	MBBS, MD Pharmacology	Basic medical scientist
Dr. Prem Kapoor	Professor, Dept. of Medicine HIMSR, New Delhi-110062	Yes	MBBS, MD Medicine	Member Clinician
Dr. Sabina Khan	Professor Dept. of Pathology, HIMSR, New Delhi-110062	Yes	MBBS, MD Pathology	Basic medical scientist
Dr. Iqbal Alam	Professor Dept. Physiology, HIMSR, New Delhi-110062	Yes	MSc, PhD, Medical physiology	Basic medical scientist
Dr. Arifa Anwar Elahi	Professor, Dept. Obst. & Gynae, HIMSR, New Delhi-110062	Yes	MBBS, MD Obst. & Gynae	Member Clinician
Dr. Gaurav Kumar Jain	Associate Professor, Pharmaceutics, DPSRU, New Delhi	No	PhD, Pharmacy	Basic medical scientist
Ms. Panchajanya Batra Singh	1355, 2nd Floor, Sector- 28, Faridabad, Haryana	No	B.Sc. PGDPE, MBA, LL.B.	Member/ Legal Expert
Ms. Farheen Malik	G-2, Hamdard University Campus, Hamdard Nagar, New Delhi	No	B.Sc. BUMS.	Member/ Social Scientist.
Mr. Ajinder Sirohi	H.no 281, sector 2C, Vasundhra, Gaziabaad	No	MA Social science	Member/ Lay person
Dr. Afreen Khan,	Associate Professor, Dept. of Pediatrics HIMSR, New Delhi-110062	Yes	MBBS, MD Pediatrics	Member Clinician
Dr. Yasir Alvi	Associate Professor Dept. of Community Medicine, HIMSR, New Delhi-110062	Yes	MBBS, MD Community Medicine	Member Secretary

Annexure 14: UNDERTAKING BY THE ETHICS COMMITTEE

1. **Full name, address and title of the Chairperson:** Dr. Arun Aggarwal, Ret. Dean MAMC, N- 9, Green Park Main, New Delhi-16.

2. **Name and address of the office of the Ethics Committee:** Institutional Ethics Committee, Hamdard Institute of Medical Sciences and Research and associated HAH. Centenary Hospital, Guru Ravidas Marg, Hamdard. Nagar, New Delhi, South East Delhi, Delhi – 110062, Contact No 01129901148, Fax No.

3. Names, address, qualifications & designation of all the members of the Ethics Committee*

Name	Address	Affiliation with the Institute	Qualifications	Designation
Dr. Arun Aggarwal	Ret. Dean MAMC N-9, Green Park Main New Delhi-16	No	MBBS, MS (ENT)	Chairperson
Dr. Arunabha Ray	Former head, Pharmacology, V.P. Chest Institute	No	MBBS, MD Pharmacology	Basic medical scientist
Dr. Prem Kapoor	Professor, Dept. of Medicine HIMSR, New Delhi-110062	Yes	MBBS, MD Medicine	Member Clinician
Dr. Sabina Khan	Professor Dept. of Pathology, HIMSR, New Delhi-110062	Yes	MBBS, MD Pathology	Basic medical scientist
Dr. Iqbal Alam	Professor Dept. Physiology, HIMSR, New Delhi-110062	Yes	MSc, PhD, Medical physiology	Basic medical scientist
Dr. Arifa Anwar Elahi	Professor, Dept. Obst. & Gynae, HIMSR, New Delhi-110062	Yes	MBBS, MD Obst. & Gynae	Member Clinician
Dr Gaurav Kumar Jain	Associate Professor, Pharmaceutics, DPSRU, New Delhi	No	PhD, Pharmacy	Basic medical scientist
Ms. Panchajanya Batra Singh	1355, 2nd Floor, Sector- 28, Faridabad, Haryana	No	B.Sc. PGDPE, MBA, LL.B.	Member/ Legal Expert
Ms. Farheen Malik	G-2, Hamdard University Campus, Hamdard Nagar, New Delhi	No	B.Sc. BUMS.	Member/ Social Scientist.
Mr. Ajinder Sirohi	H.no 281, sector 2C, Vasundhra, Gaziabaad	No	MA Social science	Member/ Lay person

Dr. Afreen Khan	Associate Professor, Dept. of Pediatrics HIMSR, New Delhi-110062	Yes	MBBS, MD Pediatrics	Member Clinician
Dr. Yasir Alvi	Associate Professor Dept. of Community Medicine, HIMSR, New Delhi-110062	Yes	MBBS, MD Community Medicine	Member Secretary
Ms. Kehkasha Parveen	Office Assistant Mobile: 8700612521 email: kashish31125@gail .com	Yes	M.Sc. Chemistry	Other Supporting Staff
Mr. Bhumshashar K	Office Attendant Mobile:9650665743, email: mubashshirthakur@ gmail.com	Yes	12th (Not Applicable)	Other Supporting Staff

4. Commitments:

a. The Committee shall review and accord its approval to biomedical research and also carry ongoing review of the study at appropriate intervals, as specified in latest edition of National ethical guidelines for biomedical and health research involving human participants - ICMR for safeguarding the rights, safety and well- being of the research participants.
b. In case of any serious adverse event occurring to research participants during the research study, the Committee shall analyze and forward its opinion as per procedures specified under National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.
c. The Committee shall allow experts/officials authorized by Department of Health Research (DHR) to enter its premises to inspect any record, data or any document related to research study and provide adequate replies to any query raised by such experts/officials, as the case may be, in relation to the conduct of biomedical and health research.
d. We agree to maintain adequate and accurate records after the completion or termination of biomedical & health research study for not less than 3 years from the date of completion or termination of the study (both in hard and soft copies).

(Signature of the Chairperson) **(Signature of the Member secretary)**

Date: **Date:**