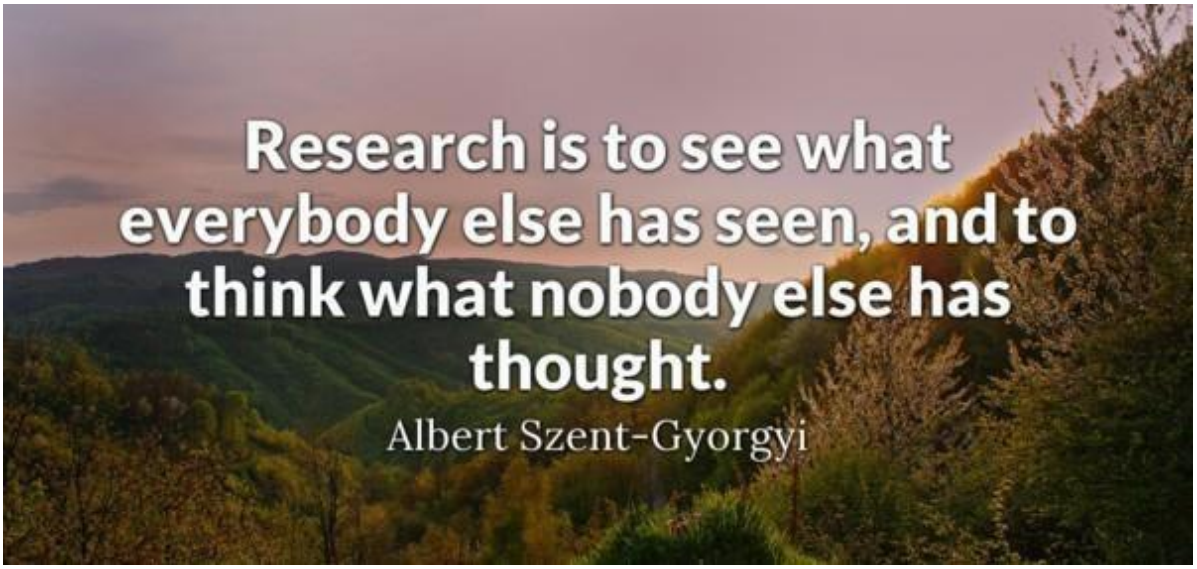
RESEARCH POLICY

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH,
Plot No 3, Sector - 18 A Dwarka, New Delhi-110075, INDIA.
(Dated 23rd December 2019)


Research is to see what everybody else has seen, and to think what nobody else has thought.
Albert Szent-Gyorgyi

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1. Preamble

The International Institute of Health Management Research (IIHMR Delhi), a part of the IIHMR Society, was established in 2008, with a mandate to focus on national and international health priorities of the country and the Asia-Pacific region. It is a premier and a pioneering health management research organization in policy, program management and evaluation research in the health sector in India. The Institute has been instrumental in a paradigm-shift in management of health care and hospitals in India. A critical mass of professionally trained health and hospital managers has been produced by IIHMR.

The IIHMR has a unique organization culture that enshrines core values and ethos of autonomy, accountability, openness, and transparency. The interdisciplinary teams of faculty and research staff constitute an enabling environment for learning and professional growth and development. The faculty is multidisciplinary that represents public health, management, economics, statistics, demography, and social and behavioral sciences.

Vision: To establish IIHMR Delhi as one of the hubs for research and practice that will help attain academic excellence in public health and hospital management

Goal:

As per international norms, academic Institutions are ranked based on the research influence. i.e research output that is relevant to the growth of a country and community at large. It is therefore important to showcase how academics and research can be translated into effective policies and programs.

The guiding principles for achieving this goal are the following:

- Introduce academic programs based on research needs of the country
- Review, strengthen and establish national and international collaborations
- Participate in program and policy relevant research and enhance research output
- Participate in programs and events of public health importance
- Establish field action/demonstration sites through research programs
- Disseminate research findings among professionals, researchers, academia, policy makers, students and community

This document outlines the activities to be undertaken by the faculty members and students of IIHMR Delhi to facilitate conduct of research in accordance with the principles of ethics.

2. Goal and Objectives of the Research Policy

The overall purpose of Research Policy is to provide a framework for the governance and conduct of research, as well as, promote the positioning of research as a priority pursuit in the institute.

The specific objectives are to:

- Streamline research activities;
- Create an enabling environment for the conduct of research;
- Strengthen research management and coordination;
- Improve research culture and practice;
- Enhancing Research Capability of Students and Faculty;
- Mobilize and manage funds for good quality research and
- Increase the returns for the conduct of research in terms of increased institutional visibility

3. Research Policy Framework

Types of research

The Institute instructively acknowledges and more importantly, takes stance of the explicit relationship between research and consultancy. In this respect, providing operational definitions to demarcate the areas of overlap and independence are important for developing its Research Policy. Thus, for the avoidance of doubt, the following definitions/explanations have been adopted for the operationalization of the Research Policy.

- **Unsolicited Research:** The first relates to scientific inquiry initiated and wholly funded by an academic faculty in the Institute.
    - IIHMR society announces internal Grant support to faculty on piloting their innovative research idea or intervention. Dean (Research) with support from faculty coordinator will track for such opportunities. They will be encouraged to submit brief proposals in consultation with the Director.
    - Faculty members are also encouraged to submit concept notes with organizations (both Governmental and non Governmental, UN agencies) in consultation with Dean and Director

- **Research Grant**: This refers to contractual funds received to conduct scientific inquiry from an external institution through any one of the following.
    - There are Request for proposals (RFPs) or Call for proposals by government, UN and national/international development agency. They announce/advertise funding opportunities (Grant or Request for proposal) on their research theme/priority.
    - Sometimes certain agencies approach the organizations independently to undertake specific tasks based on their Terms of Reference (TOR)

- IIHMR will build strategic alliances with institution through partnership agreement with them and bid the project by through consortium

- **Consultancy:** This refers to services including research, training and advisory activities demanded by an external entity from a faculty in the Institute. The engagement in this service attracts a commercial fee for both the faculty involved and the Institute. Faculty using resources of the Institute shall expressly seek permission from the Institute. In such a circumstance, the entity demanding the service shall financially compensate the Institute for the use of its resources as enshrined in the Institute's Consultancy Policy. In a separate document, the guidelines on the consultancy engagements in the Institute have been documented (IIHMR Consultancy Policy).

Research Budget Planning: Faculty are expected to prepare annual research plan with tentative budget at beginning of the financial year. Review of faculty research plan shall be reviewed quarterly and amendments made if any.

Sources of Funding for Research

Funds for the conduct and enhancement of research skills as well as management/administration of research-related activities shall be generated both within and beyond the institute.

Internally Generated Funds for Research

- The institute management, through IIHMR society, shall provide 'small' research grants to faculty on their interested area of research or any innovative research ideas.

- Funds for research skills enhancement of faculty and student and management/administration of research-related activities shall be provided by the Institute.

External Sources of Funds for Research

- Dean Research, with support from faculty, shall maintain a database of regular grants and regularly furnish faculty with information on calls for research grants and RFP for timely action.
- Director's office shall register the Institute on all external research-funding platforms.
- Faculty shall approach external agencies such as development partners, Government of India, state governments, UN and private organizations/individuals to attract research funds.

Research Contract: This refers to funds received by institute from an external agency based on a mutually decided agreement. The agreement should clearly spell out the terms of reference and deliverables covering both technical and financial aspects. Failure to deliver has legal implications both for the academic faculty involved and the Institute.

Publication/Sharing the research finding: IIHMR Delhi shall showcase research activity of Faculty and student of IIHMR through organizing Research Day and develop a compendium of abstract of research project implemented by IIHMR Delhi, student dissertation and summer training, call as "Anusandhan". Faculty are expected to publish their work in any approved journal by UGC or any reputed national/international journal. They also encourage to developed policy papers, working paper, research briefs and circulate to different stakeholders/potential clients and post on IIHMR website for wider dissemination.

Students will be encourage by faculty to present paper in the conference and subsequently publish paper jointly. In all students related research work, corresponding author will the faculty (mentor) under whose guidance the work has been carried out. Cash award with certificate for best dissertation and summer training shall be given to 1st year and 2nd year student at Research Day.

IIHMR will organize dissemination workshops once in a year and share the research findings of all research projects implemented by IIHMR Delhi to students for knowledge sharing and dissemination.

Cash awards with certificate shall be given to the faculty for publication.

Enhancing Research Capability of Students and Faculty: IIHMR Delhi will organize week-end workshops on proposal writing, data analysis (using statistical softwares such as SPSS/AtlasTi etc.), academic writing, publication etc for students. The areas that are not normally covered during the routine course work will be identified.

In addition, Research Skill building workshops and trainings will be organized to hone and develop skills of faculty and strengthen the in-house capacities to manage and implement research projects/interventions and to enhance quality.

IIHMR Delhi shall organize lectures by Eminent Scientists from various R&D Organizations. The institute library will equip with information to support research and development of student and faculty.

Provision of Research Support Services

The IIHMR management recognizes the need to offer support to promote research activities and therefore seeks to create an enabling environment for the conduct of research and use of research findings and to strengthen research management and coordination.

The Institute, through Dean Research and in collaboration with other relevant Sections-Academic in the Institute, will provide the following research support services:

i. Set University-wide research agenda;
ii. Ensure that all research protocols go through ethical clearance at the Institute

Implementation and Amendment

Dean Research has the oversight responsibility of monitoring and enforcing the implementation of the Research Policy in the Institute.

- The policy shall become operational as soon as it is approved by Director.
- This policy shall be implemented in a manner consistent with the mandate, mission, vision and the strategic plan of the Institute.
- Director IIHMR shall review the Policy periodically.
- Any amendment to the policy shall be done on the advice of the Director, IIHMR Delhi.

Operationalization of the Research Policy

Dean Research is obliged to play a key role in providing information on the contextual environment to ensure the operationalization of the Research Policy. For the Research Policy to be binding on faculty in the Institute, Dean Research will collaborate with Principle Investigator of Project/Faculty coordinator to track opportunity /Account and Admin sections/Committees of Institutes such as project steering committee to provide oversight, guidance and support for the project.

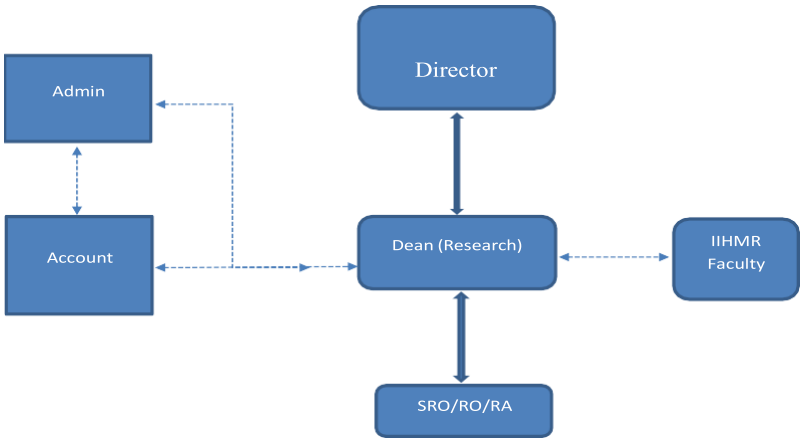
Dean Research through the Director's office has the responsibility to provide institutional-level support for research and consultancy programmes, within the framework of the relevant Institute policies and regulations. Dean Research will encourage the faculty to undertake research projects and Coordinate/ help faculty and ROs in writing winning Grants/Research proposals for clients. In a separate document, SOPs for tracking & responding to research/grant/consulting opportunities have been documented.

The institute will focus on research through

i. Writing grant proposals by Faculty in the institute's priority area such as Reproductive and Child Health, Climate Change, Health Economics, Financing for Universal Health Coverage, Use of information technology, Evaluation of National Program,
ii. Building strategic alliances and consortium to bid for project and drive partnerships and alliances complementing IIHMR's capabilities
iii. Developing and nurturing national and international linkages for research and development
iv. Bidding for large scale projects/survey/assessment
v. Translating research into papers/ documents/ research articles

Organogram of Research department of IIHMR Delhi is as follows:

RESEARCH DEPARTMENT: ORGANOGRAM, IIHMR, DELHI



4. Conduct of Research

The conduct of research is one of the three core activities undertaken by faculty in the University hence this Research Policy provides guidelines with the aim of promoting adherence to good practices in the industry and to systematically track research engagement undertaken in the University. With reference to section four of this Research Policy document, research can be classified into unsolicited research, research grants and research contracts. These research engagements are expected to lead to the following: peer reviewed journal articles, working papers, publication in either reviewed or non-reviewed conference proceedings, news briefs, policy briefs and technical reports.

Faculty members engaging in research activities are expected to:

- Once a faculty members gets to know about any RFP, s/he will inform the Dean (Research) and the Director expressing an interest to apply for the same
- S/he will form a team based on mutual interest and requirement of the RFP
- Prepare a technical proposal as per the specifications given in the RFP/grant/consulting assignment
- Prepare a study budget in consolation with finance person (Assistant Account Manager-A & F) of the Institute. Faculty should follow the financial norm (e.g. rate of professional fee, institutional overhead of institute) for preparing the budget.
- The draft technical proposal and study budget should be submitted to the director's office through Dean (Research 72 hours) before the last date of submission for review and feedback.
- The Dean Research/Director must revert back with feedback on the proposal quickly. This might be really quick as more often than not the time available to respond to RFP is very short.
- The Dean Research should ensure that the technical proposal is sound and financial proposal is competitive.

The following expectations are specific to faculty engaging in research contracts:

- Ascertain clearance from the Institute legal team through Dean research/admin on the terms of the research contract;
- Include 20 percent as institutional overheads in the project budget at the time of submission of grant proposal to the funder. In not feasible then Include 20 percent as institutional overheads in the internal budget of project with the permission from Director IIHMR
- Include GST as per GOI rule in the project budget
- Coordinate with client and account/admin section of IIHMR Delhi for installment of project fund, project requirement such as Utilization certificate, Invoice and closure of project.

If the project comes through, the PI should do the following:

- Brief the Dean (Research) and the Director about the plan of activities
- Initiate the process of recruiting project staff (if any) in consultation with Dean and Administrative officer
- Get approval from IRB following the formal procedures
- Update the progress of the project to the Dean on a quarterly basis
- Submit a completion report (technical and financial) to the Dean and the Director

5. General Ethical Issues

- Researchers must protect the dignity, rights, safety and well-being of research participants.
- They should have appropriate qualifications, competence in research methodology and be compliant towards the scientific, medical, ethical, legal and social requirements of research.
- The researcher, sponsor and IRB must conduct a benefit–risk assessment and actively attempt to maximize benefits and minimize risks to participants.
- Benefits to the individual, community or society refer to any sort of favourable outcome of the research, whether direct or indirect. The social and scientific value of research should justify the risk, which is the probability of causing discomfort or harm anticipated as physical, psychological, social, economic or legal.
- Risk can be categorized as less than minimal risk, minimal risk, minor increase over minimal or low risk and more than minimal or high risk.
- The IRB must decide about the type of review required (exempted, expedited, full committee) based on the type of risk involved.
- The researcher must obtain informed consent from the participant/legally acceptable/ authorized representative (LAR) in writing.
- Informed consent documents (participant information sheet and informed consent form) should carry the specified elements in simple, layman's language. These documents should be approved by the IRB.
- Oral consent/waiver of consent/re-consent may be obtained under certain conditions, after due approval by the IRB.
- Researcher(s) should safeguard the privacy and confidentiality of participants and research- related data from unauthorized access.
- Benefits and burdens of research should be equitably distributed among the participating individuals or communities.
- Participants should not be made to pay for research-related expenses incurred beyond routine clinical care. Reimbursement for expenses incurred can be made in cash or kind or both.
- In case of a clinical trial or any intervention study, the researcher must report all serious adverse events (SAEs) to the IRB within 24 hours of knowledge and submit a report on SAE relatedness to research within 14 days.
- Research participants who suffer direct physical, psychological, social, legal or economic harm are entitled to financial compensation or other forms of assistance.
- It is the responsibility of the sponsor (whether a pharmaceutical company, government or non-governmental organization (NGO), national or international/bilateral/multilateral donor agency/institution) to include insurance coverage or provision for possible compensation for research related injury or harm within the budget.
- In investigator initiated/student research, the investigator/institution where the research is conducted becomes the sponsor and must provide compensation for research-related injury through insurance, corpus funds or grants.
- Free medical care may be offered as ancillary care for non-research-related conditions or incidental findings if it does not amount to undue inducement as determined by IRB.

- Policies for declaration and management of financial or non-financial (personal, academic or political) conflict of interest for researchers, IRB, institution and sponsor must be implemented by research institutes.
- The selection of vulnerable and special groups needs careful consideration, with provisions for additional safeguards and close monitoring.
- Engaging with the community from the beginning of research till after its completion helps to improve design and conduct of research and ensures greater responsiveness to health needs. However, every individual participant's consent is essential.
- Post-research access and benefit-sharing may be done with individuals, communities and populations, wherever applicable after completion of study
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General Ethical principles

Benefit–risk assessment	Informed consent process	Privacy and confidentiality
Distributive justice	Payment for participation	Compensation for research related harm
Ancillary care	Conflict of interest	Selection of vulnerable and special groups as research participants
Community engagement	Post-research access and benefit sharing	

6. Standard Operating procedures (SOPs) for conduct of research

Integrity of research is the responsibility of the organization. In order to promote and maintain it, an Institutional Review Board (IRB) has been constituted. The following sections will describe the Standard Operating Procedures (SOPs) of IRB.

A) Institutional Review Board (IRB)

Objective

The objective of the Institutional Review Board (IRB) of IIHMR Delhi is to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

Authority under which IIHMR Delhi IRB is constituted

The Director appoints the Chairperson and all the committee members based on their competence, experience and integrity by sending an official request letter (***Annexure 1***). Members will confirm their acceptance to the Dean by providing all the required information for membership (***Annexure 2***).

Roles and Responsibilities of IIHMR Delhi IRB

The IRB reviews all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The IRB will ascertain whether all the cardinal principles of research ethics viz., Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons , Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit analysis, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations. It will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the study sites.

The mandate of the IRB shall be to review all research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of the funding agency.

It will provide advice to the researchers on all aspects of the welfare and safety of the research participants. In case an ethics committee revokes its approval accorded to a proposal, it will record the reasons for doing so and at once communicate such a decision to the Investigator.

Composition of IIHMR Delhi IRB

The IRB is multidisciplinary and multi-sectoral in composition and an independent body. It follows the norms laid down by ICMR. The total number of members of IRB will range between 8-15.

The chairperson of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the business of the Committee. Other members will be a mix of medical / non-medical, legal, scientific and non-scientific persons and may also include members of public to reflect the differed points of view.

There will be representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. Member should be aware of local, social and cultural norms, as this is an important social control mechanism. IEC may invite subject experts to take their views, whenever it is needed.

The IRB will comprise of the following members:

Chairperson Non-affiliated	• A well-respected person from any background with prior experience of having served/serving in an Ethics Committee
Member Secretary Affiliated	• Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills • Should be able to devote adequate time to this activity which should be protected by the institution
Basic Medical Scientist(s) Affiliated/ non-affiliated	• Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist
Clinician(s) Affiliated/ non-affiliated	• Should be individual/s with recognized medical qualification, expertise and training
Legal expert/s Affiliated/ non-affiliated	• Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.
Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated	• Should be an individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities

Lay person(s) Non-affiliated	• Literate person who has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community and aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities

The IIHMR IRB comprises of the following members:

1. Chairperson
2. One person from basic medical sciences
3. One clinician
4. One medico legal person
5. One or two social scientists
6. One or two public health specialists
7. One monitoring and evaluation specialist
8. One or two lay persons from the community
9. Member Secretary

Membership requirements

- All members will serve for a period of 3 years on renewable basis. 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.
- During the term, Dean in consultation with the Director can disqualify any member if, the contribution is not adequate and/or there is long period of (member) non availability.
- A member can tender resignation of his office of membership from the IRB to the Dean through the Chairperson after serving one month advance notice.
- Dean can replace the member of IEC as and when required.
- Each member is required to sign the declaration and confidentiality agreement regarding IRB activities (***Annexure 2***)
- Conflict of interest should be declared by members of the IRB prior to review meeting.

Quoram requirements

Minimum of 50% of committee strength + 1 member and not less than 5 members will be required to compose a quorum for the meeting of which at least one member will be from outside the institution, and one member will be a non-scientific member & one from apposite gender. All decisions will be takenin meetings and not by circulation of project proposals. Quorum will have 5 members with following representations:

(a) Public Health specialist

(b) Clinician
(c) Legal expert
(d) Social scientist
(e) Lay person

Conduct of IEC meetings

The Chairperson will conduct all meetings of the IRB. In the absence of the chairperson an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. S/he will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.

Independent consultants

The IRB 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. They will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the IRB.

Process of submission of application

All proposals should be submitted 2 weeks in advance of scheduled meeting in the prescribed application form. All relevant documents should be enclosed with application form. (Documents will be available with Member - Secretary, IIHMR Delhi IRB)

Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators / Research Scholars shall be guided to the Chairperson IIHMR Delhi IRB, through member secretary. In his/ her absence via any person nominated by chairperson. Receipt of the application will be acknowledged by the IRB office.

Every application will be allotted an IRB registration number to be used for all future correspondence and reference. The date of IRB meetings will be intimated to the Principal Investigator to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.

The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

Assessment of proposals

- Based on the assessment of risks involved, the IRB Member secretary will give the review (Exempted from review/ expedited review/ full committee review) ***(Annexure 3,4)***

- ✓ **Exempted from review**: for those research that fall under **less than minimal risk** category:
  - for projects involving secondary data, data available in public domain, or is a part of health programs with the sole purpose of monitoring of the program
  - primary data based on interviews or routine observations on people aged more than 18 years and on those who are not vulnerable population with ***no identifiers*** such as name, address, contact details ***(Annexure 5)***

- ✓ **Expedited review:** for those research that involves **minimal risk**
  - For projects that involves primary data collection on people aged more than 18 years, on those who are not vulnerable population and ***with identifiers*** such as name, address, contact details
  - Decision of the Member Secretary would be "*Ethical concerns present/ absent*"

- ✓ **Full committee review:** for those research that involves **low or high risk**
  - For projects on vulnerable population, where data on identifiers are collected
  - Intervention studies/ trials

Proposals falling under Expedited or full committee review will be taken up for IRB meeting.

Review procedures:

1. The meetings of IRBs will be held periodically. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.
2. The proposals should be sent to the IRB at least 2 weeks in advance of schedule meeting.
3. The IRB member-secretary or 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 review (explanation is given below).
4. The Principal investigator will present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co PI will present the proposal.
5. The decisions will be minuted and Chairperson's approval taken in writing.
6. The IRB shall look into the Ethical issues while reviewing any proposal

Ethical issues to be considered while reviewing any proposal

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 IRB 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 IRB 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 research 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 adequacy assessment of 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	- The EC should review any declaration of COI by a researcher and suggest ways to manage these.

of potential COI	- 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 for study related injury	- 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: o the process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations; o 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 o back translations of the informed consent document in English, wherever required; o 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.

Decision making

1. Members will discuss the various issues before arriving at a consensus decision.
2. Decisions will be taken by consensus after discussion, and whenever needed voting will be done.
3. When consensus is not arrived at, the decision will be made by voting procedure.
4. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
5. Decision will be made only in meetings where quorum is complete.
6. Only member can make the decision. The expert consultants will only offer their opinions.
7. Decision of chairperson will be final.
8. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
9. Modified proposals will be reviewed by an expedited review through identified members.
10. Procedures for appeal by the researchers will be clearly defined.
11. The IEC can give one of the following decisions:
    - ✓ **approved** – 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 full committee for reconsideration for approval; or
    - ✓ **not approved** (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission

Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member Secretary in writing to the PI within 2 weeks after the meeting at which the decision was taken in the specified format (Annexure-6). All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after one year if necessary.
2. The communication of the decision will include:
    - Name and address of IRB
    - The date, place and time of decision.
    - The name and designation of the applicant.
    - Title of the research proposal reviewed.
    - The clear identification of protocol no., version no., date, amendment no., date.
    - Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.
    - A clear statement of decision reached.
    - Any advice by the IRB to the applicant including the schedule / plan of ongoing review by the IRB
    - In case of conditional decision, any requirement by IRB, including suggestions for revision, and the procedure for having the application re-reviewed.
    - In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
    - Signature of the Chairperson with date.

Record keeping and archiving at the office of IIHMR Delhi

1. All the documents and communications of IRB will be dated, filed and archived in a secure place.
2. Only persons, who are authorized by the Chairman of IRB will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
4. No document (except agenda) will be retained by any IRB member.
5. Following documents will be filed and archived with proper label on the top of file for easy identification
    - Constitution and composition of IRB
    - Curriculum Vitae (CV) of all members of IRB with records of training in Human ethics if any.
    - Standard Operating Procedures of IRB
    - Annual reports
    - A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members
    - The published guidelines for submission established by the EC
    - Copy of all study protocols with enclosed documents, progress reports
    - Agendas and Minutes of all IRB meetings duly signed by the Chairperson / Member secretary
    - Copy of all existing relevant national and international guidelines on ethics and laws along with amendments

- Copy of all correspondence with members, Principal Investigators and other regulatory bodies
- Record of all notification issued for premature termination of a study with a summary of the reasons
- Final report of the approved projects, including microfilms, CDs and Video recordings

Updating IRB members:

1. All relevant new guidelines should be brought to the attention of the members.
2. The IRB members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ (ies), so that they become aware of their role and responsibilities.
3. For interventional studies, it is preferable to train the members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism.

Terms of reference

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

A. Membership Requirements

B. Terms of Appointment with reference to the duration of the term,

C. The policy for removal, replacement, resignation procedure,

D. Frequency of meetings, and

E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts *etc.*

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IRB 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.

B) Informed consent process

- Voluntary written informed consent should be obtained in an informed consent document (ICD) from each participant to protect each individual's freedom of choice.
- Informed consent is a continuous process involving three main components:
    - Providing relevant information to potential participants
    - Ensuring competence and comprehension of the information and
    - Voluntariness of participation

- The ICD has two parts – patient/participant information sheet (PIS) and the informed consent form (ICF). Information on known facts about the research, which has relevance to participation, is included in the PIS. This is followed by the ICF in which the participant acknowledges that she/he has understood the information given in the PIS and is volunteering to be included in that research.

- Adequate time should be given to the participant to read the consent form, if necessary discuss it with family and friends, and seek clarification of her/his doubts from the researchers/research team before deciding to enroll in the research.

Characteristics of an Informed Consent Document/ Form

Elements of an ICD	**Additional elements (optional)**
1. Statement mentioning that it is research	1. Alternative procedures or treatment
2. Purpose and methods	2. Insurance coverage
3. Duration, frequency, methods	3. Possible stigmatizing condition
4. Benefits to participant, community or others	4. Biological material and data, including:
5. Foreseeable risks, discomfort or inconvenience	i) Current and future uses
6. Confidentiality of records	ii) Period of storage and secondary use
7. Payment/reimbursement for participation	iii) Sharing of data and biological materials
8. Treatment and/or compensation for injury	iv) Right to prevent use of biological sample
9. Freedom to participate/withdraw	v) Provisions to safeguard confidentiality
10. Identity of research team and contact persons	vi) Post-research plan/benefit sharing
	vii) Publication plan/photographs/pedigrees

- Researchers should only use the IRB approved version of the consent form and its translation in local languages.
- Informed consent should be voluntary and be signed by the participant after receiving information, understanding it and discussing with family/friends (if required).
- Verbal/oral consent/waiver of consent/reconsent may be obtained only after approval by the IRB.

Conditions for granting waiver of consent

The EC may grant consent waiver in the following situations:
- research cannot practically be carried out without the waiver and the waiver is scientifically justified;
- retrospective studies, where the participants are de-identified or cannot be contacted;
- research on anonymized biological samples/data;
- certain types of public health studies/surveillance programmes/programme evaluation studies;
- research on data available in the public domain; or
- research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

- Appropriate ICD should be prepared for differently abled participants.
- In case of research involving children, in addition to parental consent, verbal (7-12 years) or simplified written (>12 – 18 years) assent should also be taken from the participant.
- The LAR's consent is required in case a participant is incompetent (medically or legally). It shouldbe documented appropriately
- Documentation of the informed consent process is an essential part of this exercise. Each prospective participant should sign the informed consent form after going through the informed consent process of receiving information, understanding it and voluntarily agreeing to participate in the research.
- The process of consent for an illiterate participant/LAR should be witnessed by an impartial literate witness who is not a relative of the participant and is in no way connected to the conductof research, such as other patients in the ward who are not in the study, staff from the social service department and counsellors. The witness should be a literate person who can read the participant information sheet and consent form and understand the language of the participant.
- If the participant cannot sign then a thumb impression must be obtained.
- The researcher who administers the consent must also sign and date the consent form.
- In the case of institutionalized individuals, in addition to individual/LAR consent, permission for conducting the research should be obtained from the head of that institution.

- Electronic/online consent may be obtained for research involving sensitive topics while safeguarding information and data and also if required for regulatory clinical trials. The electronicconsent must contain all elements of informed consent in a language understood by the people
- The process, electronic materials, method of documentation (including electronic/ digital signatures), methods used to maintain privacy of participants, confidentiality, and security of the information as well as data use policies at the research site must be reviewed and approved by the IRB a priori.
- Permission of the gatekeepers, that is, the head/leader of the group or culturally appropriate authorities, may be obtained in writing or audio/video recorded on behalf of the group and should be witnessed.
- Community consent: In certain populations, the community plays an important role in the consent process. Some participants may not participate in the research unless the community's consent is available. There may be situations when individual consent cannot be obtained as it will changethe behaviour of the individual. In such situations community consent is required. When permission is obtained from an
- organization that represents the community, the quorum required for such a committee must be met. For example, in a village panchayat the number of members ordinarily required to conduct a meeting must be present while giving consent. Individual consent is important and required even if the community gives permission.
- Re-consent is required in the following situations when:
  - new information pertaining to the study becomes available which has implications for participant or which changes the benefit and risk ratio;

- a research participant who is unconscious regains consciousness or who had suffered loss of insight regains mental competence and is able to understand the implications of the research;
- a child becomes an adult during the course of the study;
- research requires a long-term follow-up or requires extension;
- there is a change in treatment modality, procedures, site visits, data collection methods or tenure of participation which may impact the participant's decision to continue in the research; and
- there is possibility of disclosure of identity through data presentation or photographs (this should be camouflaged adequately) in an upcoming publication.

C) Research on vulnerable population

Individuals/ groups/ populations are considered vulnerable if they 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. Individuals are considered to be vulnerable if they are:

- Socially, economically or politically disadvantaged and susceptible to exploitation
- Incapable of making a voluntary informed decision for themselves or if their autonomy is compromised temporarily or permanently (e.g., people who are unconscious, differently abled)
- Able to give consent, but their voluntariness or understanding is compromised due to their situational conditions
- 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

- Researchers must justify the inclusion/exclusion of a vulnerable population.
- A community representative may be invited to IRB meetings to make sure the research is responsive to their needs and the informed consent process is appropriate.
- Additional precautions should be taken by all stakeholders such as researchers, IRBs and sponsors to avoid exploitation of vulnerable participants.
- Informed consent process should be well documented and additional measures adopted if required, such as audiovisual/audio recording of assent/consent/reconsent.
- Research proposals should undergo review in a full committee meeting.
- Protection of privacy and dignity as well as provision of quality health care is required in dealing with vulnerable people, especially the minorities.
- Research involving children, in addition, should follow the National Ethical Guidelines for Biomedical Research Involving Children, ICMR, 2017.
- Due approvals are needed from competent authorities before entering tribal areas.
- Research involving cognitively impaired individuals or those with mental illness must be done carefully, especially if there is risk to themselves, to others or suicidal ideation.

- In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making
- Consent of the parent/LAR is required when research involves children.
- Assent: In addition to consent from parents/LARs, verbal/oral or written assent, as approved by the EC, should be obtained from children of 7–18 years of age. As children grow, their mental faculties develop and they are able to understand and respond. Respecting the child's reaction, the child is made a party to the consent process by the researcher, who explains the proposed research in a very simple manner, in a language that ensures, that the child understands the request to participate in the research. A child's agreement to participate in research is called assent. If the child objects, this wish has to be respected. At the same time, mere failure to objectshould not be construed as assent. However, if the test intervention is likely to be lifesaving and is available only if the child participates in the study, the dissent by the child may be disregardedprovided parental consent and prior approval from the EC is obtained.
- The IRB should carry out the benefit–risk analysis and examine risk minimization strategies.

D) Interventional studies (including clinical trials)

- Clinical trials must be conducted in accordance with the Indian GCP guidelines, Declaration of Helsinki, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), amendments to the Drugs & Cosmetics Act (1940), and Rules (1945) and other applicable regulations and guidelines.
- Clinical trial interventions could be of drugs, vaccines, biosimilars, biologics, phytopharmaceuticals, radiopharmaceuticals, diagnostic agents, public health or socio- behavioural interventions, technologies, devices, surgical techniques or traditional systems of medicine, etc.
- An investigator should determine if the clinical trial is within the regulatory ambit and if so, all Central Drug Standards and Control Organisation (CDSCO) requirements should be followed.
- If students are conducting clinical trials as part of their thesis, guides/and institutions should take the responsibilities of sponsor.
- Clinical trials must be prospectively registered with CTRI, which is mandatory for trials under the purview of CDSCO.
- IRBs should register and follow the quorum requirements specified by CDSCO before reviewing clinical trials on 'new drugs' as per Schedule Y and its amendments.
- Patients should not be charged for trial interventions that are added on as part of research.
- Ancillary care may be provided to clinical trial participants for non-study/trial related illnesses arising during the period of the trial.
- Adverse effects of drugs should be reported in a timely manner.
- Institutions must obtain grants, insurance coverage or set up corpus funds to meet the costs related to treatment/management and payment of compensation as decided by IRB.
- Clinical trials should be scientifically and ethically sound and preclinical studies should precede trials on humans.

- Precautions should be taken to protect participants from harm when a placebo is used.
- Community trials may be conducted to evaluate preventive strategies like mass drug administration.
- Research that involves sexual minorities or intravenous drug users should ensure community engagement for the duration of the project as well as for dissemination of results after completion.
- Research on traditional medicine interventions, such as Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) should be conducted in accordance with ethical guidelines, ASU-GCP (Ayurveda, Siddha, Unani GCP) guidelines as well as other applicable regulations.
- Trials using diagnostic agents should follow the same protocols as for trials on new drugs.
- Radioactive materials and X-rays should be used with more precaution in persons who have not completed family.
- Clinical trials among women for contraceptives or if they are pregnant or lactating should involve abundant precautions and care.
- Therapeutic misconception is high in oncology trials; therefore, due care should be taken to address this issue.
- Any product using new technology should be GLP (Good Laboratory Practices), GMP (Good Manufacturing Practices) and GCP compliant, which should be duly approved by appropriate authorities.

E) Public health research/ social and behavioral sciences research for health

- Benefits and risks in public health research may not be limited to an individual, but may influence communities, populations and the environment.
- Social and behavioural studies must ensure social equity and inter sectionality. Ethical relativism applies to moral diversity among different cultures and societies.
- ECs must review different types of research such as programme evaluations, demographic surveillance, registries, implementation research, demonstration projects, community trials, surveys, etc.
- Based on specific research, appropriate consent processes may be considered by the IRB, such as verbal/oral consent; broad consent; group consent; waiver of consent and reconsent.
- Special provisions should be provided in design and execution of research if they are likely to havea potential to exploit socioeconomically deprived people.
- Stakeholders (researchers, health providers/ sponsors, Govt. agencies, participants, IRBs, institutions, NGOs, etc.) must make every effort to provide post-research public health interventions, use of findings for sustainability of public health action.
- The IRB may require appropriate experts to address the specific ethical challenges related to socio-behavioural or public health research.
- Safety measures should be in place to protect the privacy and confidentiality of research participants and/or research teams in the field collecting sensitive data.

- The IRB should carefully review studies where the use of deception is necessary to achieve the study objectives for larger public good and consider debriefing after completion of the study.
- Support systems such as counselling centres, rehabilitation centres, police protection, etc. shouldbe in place for sensitive studies.
- The IRB should ensure that the researcher has taken appropriate measures for data security and confidentiality of information and also that disclosure permissions have been taken and appropriate use of the accessed data is stated by the researcher.

F) Student led research

In order to facilitate students research, Student Research Board (SRB) (with four members) has been constituted. The SRB will work under the guidance of the Director IIHMR Delhi.

Steps to be followed by the students

- Every student will undertake research activities as part of or independent of their dissertation/ internship under the guidance/ mentorship of a faculty member of IIHMR Delhi. Mentors should ensure their trainees conduct research honestly, do not interfere with the work of other researchers and use resources judiciously.
- A concept note should be developed in consultation with the mentor and shared with the Dean (Research). The concept note (max 3 pages excluding annexures) would comprise of the following:
  - ✓ Title of the project
  - ✓ Background (introduction to the topic)
  - ✓ Research question and objective
  - ✓ Methodology- study design, setting, study population, method of data collection, analysis
  - ✓ Consent form (as annexure)
  - ✓ Study tool (as annexure)
  - ✓ Ethics form along with a checklist (as annexure)
- Every concept note will be reviewed by the Students Research Board (SRB) ***(Appendix SRB 1)*** to assess the level of risk involved as outlined in the ICMR document. A checklist has been developed for better categorization ***(Appendix SRB 2).*** The research would be categorized as involving Less than minimal risk, minimal risk, low risk or high risk ***(Annexure 3).***
- For studies involving primary data collection, students would have to make a presentation in front of the SRB
- Based on the assessment the SRB will give its review (Exempted from review/ expedited review/ full committee review) ***(Annexure 4)***
  - ✓ **Exempted from review**: for those research that fall under **less than minimal risk** category:
    - for projects involving secondary data, data available in public domain, or is a part of health programs with the sole purpose of monitoring of the program

- primary data based on interviews or routine observations on people aged more than 18 years and on those who are not vulnerable population with ***no identifiers*** such as name, address, contact details ***(Annexure 5)***

✓ **Expedited review:** for those research that involves **minimal risk**
- For projects that involves primary data collection on people aged more than 18 years, on those who are not vulnerable population and ***with identifiers*** such as name, address, contact details
- Decision of SRB could be "***Ethical concerns present/ absent***"
- If the decision is Ethical concerns present, the proposal would be sent for full committee review

✓ **Full committee review:** for those research that involves **low or high risk**
- For projects on vulnerable population, where data on identifiers are collected
- Intervention studies/ trials
- As suggested by SRB if the decision is Ethical concerns present based on expedited review

- The review of SRB would be shared with the Chairperson of the Institutional Ethics Committee (IEC) of IIHMR Delhi by Dean (Research) for final approval. The IEC can give one of the following decisions:
  - ✓ **approved** – 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 full committee for reconsideration for approval; or
  - ✓ **not approved** (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission

G) Conflict of interest

Conflict of interest (COI) is a set of conditions where professional judgement concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, IRB members, institutions or sponsors.

- If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.
- Policies and procedures to identify, mitigate conflicts of interest and educate staff about such conflicts should be there in place.
- Researchers must ensure that the documents submitted to the IRB include a disclosure of interests (financial and non financial) that may affect the research.

- Researchers must guard against conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties
- Researchers must prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students.
- IRBs must evaluate each study in light of any disclosed interests and ensure that appropriate means of mitigation are taken.
- IRBs must make appropriate suggestions for management, if COI is detected at the institutional or researchers level.
- COI within the IRB should be declared and managed

H) Authorship and publication

Authorship – The researchers should follow the guidance of International Committee of Medical Journal Editors (ICMJE) on authorship, which is largely accepted as a standard and is endorsed by the World Association of Medical Editors (WAME).

Authorship should never be gifted and 'ghost' authors are not acceptable. The authorship of research should be considered at the time of its initiation.
The primary author should be the person who has done most of the research work related to the manuscript being submitted for publication. Research performed as part of a mandatory requirement of a course/fellowship/training programme including student research should have the candidate as the primary author. All efforts must be made to provide the candidate with an opportunity to fulfil the second, third and fourth criteria of the ICMJE guidelines

According to the ICMJE, authorship entails the following criteria:

- substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work;
- drafting the work or revising it for important intellectual content;
- final approval of the version to be published;
- 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 1: Office order on reconstitution of Ethics Committee

Dated:

I am pleased to reconstitute the Institutional Review Board (IRB) of International Institute of Health Management Research (IIHMR) Delhi. The IRB with the following members will be functional w.e.f…. (mention date) for a period of 3 years provided the following conditions are met

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

The renewal of your appointment will be by consensus & 1 month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IIHMR Delhi which we shall circulate.

List of IRB members –

Chairperson
Members Secretary
Basic Medical Scientist
Clinician
Legal expert
Social scientist
Lay person
Public Health Experts
Monitoring and Evaluation

We sincerely hope your association with IIHMR Delhi will be fruitful to the Institute & the community we serve.

Director

Annexure 2: Acceptance letter from members

From,

_____

_____

To
The Director,
IIHMR Delhi.

Sub: Consent to be a member of Institutional Review Board (IRB)

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IRB of IIHMR Delhi. I shall regularly participate in the IRB meetings 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 herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature _____

Name of the Member_____Date:

Address:

Telephone No:

(Off)

(Res)

email:

Annexure 3: Categories of risk

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.

Annexure 4: Type of review

Type of risk	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; • 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; and • 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; • 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 ; • studies involving deception of participants); • 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 course of 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

Annexure 5: Characteristics of vulnerable population/ individual/ groups

Following are some examples of vulnerable populations or groups:

- economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.)
- 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
- children (up to 18 years)
- women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare)
- tribals and marginalized communities
- refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations
- afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled
- terminally ill or are in search of new interventions having exhausted all therapies
- suffering from stigmatizing or rare diseases
- have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners)

Annexure 6: Application form for IRB

Logo of the Institute

Application Form for Initial Review

..... *(Name of the Institution)* **EC Ref. No.** *(For office use):*

General Instructions : a) Tick one or more options as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

I. ADMINISTRATIVE DETAILS

(a) Name of Organization: .....

(b) Name of Ethics Committee: .....

(c) Name of Principal Investigator: .....

(d) Department/Division: ..... (e) Date of submission: dd mm yy

(f) Type of review requested[1]:

Exemption from review ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study: .....

.....

.....

Acronym/ Short title, (If any): .....

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

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

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

(k) Duration of the study: .....

[1] *Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review*
[2] *Include telephone/mobile, fax numbers and email id*

Version 2.0 *01*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: .....

At site..... In India..... Globally .....

(b) Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

.....

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words): .....

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(b) Type of study:

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

.....

4. METHODOLOGY

(a) Sample size/ number 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 .....

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[3] *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?[4] 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: dd mm yy

Comments of scientific committee, if any (100 words)

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SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers ☐ Patients ☐ Vulnerable persons/ 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 ☐

Others ☐ *(Specify)* .....

(b) i. Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

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

Children under 18 yrs	☐	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)*:	☐	.....	

iii. Provide justification for inclusion/exclusion .....

.....

.....

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

.....

.....

(c) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(d) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

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

If yes, Monetary ☐ Non-monetary ☐ *Provide details* Yes ☐ No ☐

.....

.....

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk[5] :

Less than Minimal risk ☐ Minimal risk ☐

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

ii. Describe the risk management strategy: .....

.....

.....

(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[6] ? Yes ☐ No ☐ NA ☐

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 item no. 8 Yes ☐ No ☐

.....

.....

[5]*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research involving Human Participants 2017, Page 6 Table 2.1*

[6]*The term adverse events in this regard encompass both serious and non-serious adverse events.*

(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 (AV) consent ☐
Consent from LAR ☐ (If so, specify from whom)	For children<7 yrs parental/LAR consent ☐	Verbal assent from minor (7-12 yrs) along with parental consent ☐	Written assent from minor (13-18 yrs) 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 .....

(e) 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 requirements for previously stored samples if used in the study[7]

.....

.....

(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 ☐
Others(Specify) ☐		Secretary of EC

.....

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8] ?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ *(specify)*

.....

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ N/A ☐

If yes, then who will provide the treatment? .....

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐ N/A ☐

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

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

.....

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.

Yes ☐ No ☐ N/A ☐

9. STORAGE AND CONFIDENTIALITY

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

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[9] and by whom? .....

(d) For how long will the data be stored? .....

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

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

.....

.....

.....

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

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

.....

.....

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes ☐ No ☐ NA ☐

.....

.....

(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes ☐ No ☐ NA ☐

.....

.....

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

.....

(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 details. Yes ☐ No ☐

.....

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.....

.....

SECTION E: DECLARATION AND CHECKLIST [10]

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

Name of PI: .....

Signature: ..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

Name of Guide: .....

Signature: ..... dd mm yy

Name of HOD: .....

Signature: ..... dd mm yy

[10] *These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements*

Acknowledgement for Receipt of Application (Copy to be provided to PI)

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 Participant Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/ mm/yy	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 multicentre 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
[¶]Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)

Annexure 7: Communication of Decision of the Institutional Ethics Committee (IEC)

IEC No: Proposal title:
Principal Investigator: Date of review: Type of review: - New review - Revised review - Expedited review Date of previous review if it is revised or expedited review: Decision of the IRB: - **approved** - **revision with minor modifications** - **revision with major modifications** - **not approved**
Suggestions/ Reasons/ Remarks:
Recommended for a period of :

Signature of Chairperson
IRB, IIHMR Delhi

Appendix SRB 1
(Students Research Board (SRB)

In order to facilitate students' research projects, a separate committee (Student's Research Board or SRB) under the chairpersonship of Dean (Research) has been created. SRB will work under the guidance of the Director, IIHMR Delhi. SRB will report to the Chairman, Institutional Ethics Committee (IEC) of IIHMR Delhi.

Roles and responsibilities

- All concept notes pertaining to the topics of dissertation/ independent research will be reviewed by SRB.
- They will assess the level of risk involved as Less than minimal risk, minimal risk, low risk or high risk as per Appendix 3.
- The committee will give its review as Exempted from review/ expedited review/ full committee review
- For proposals that fall under Expedited review, students presentations will be arranged
- For proposals that fall under Full committee review the proposals would be shared with the IEC of IIHMR Delhi
- A summary of the projects with the SRBs decision will be submitted to the Chairperson of IEC for endorsement and approval

Appendix SRB 2
(Checklist for submission to SRB)

Name of the student	
Academic session	
Faculty/ mentor	
Title of the proposal	

Please answer the following questions:

Questions	Response
The study involves secondary data or data available in public domain	Yes/ No/ Not Applicable
The study involves program level data and due permission is taken from the Government	Yes/ No/ Not Applicable
The study design is observational	Yes/ No/ Not Applicable
Participant identifiers (name, contact number, address) will not be collected	Yes/ No/ Not Applicable
Research participants do not belong to vulnerable population (age <18 years/ pregnant/ lactating women/ from tribal areas/ refugees/ ill patients/marginalized	Yes/ No/ Not Applicable
Research participants will be informed about the study mandate	Yes/ No/ Not Applicable
Research participants will be provided an opportunity to decline to take part or withdraw at any stage	Yes/ No/ Not Applicable
Consent form (draft form acceptable) submitted	Yes/ No/ Not Applicable
Study tool (draft form acceptable) submitted	Yes/ No/ Not Applicable

If the responses to all the questions are ‘Yes’ or ‘Not Applicable’, the study would be considered as having ‘less than minimal risk’ and hence would be ***exempted from review.***

If any one response is ‘No’, risk assessment would be done. If it entail ‘minimal risk’, it will be considered for ***expedited review*** or else it will be considered for ***full review***.