STANDARD OPERATING PROCEDURES
FOR
INSTITUTIONAL REVIEW BOARD (IRB)
International Institute for Population Sciences (IIPS)
(Deemed-to-be-University)

(स्थापना/ Established in 1956)
बेहतर भविष्य के लिए क्षमता निर्माण
Capacity Building for a Better Future

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INTRODUCTION ABOUT THE INSTITUTE

Started in 1956 under the joint sponsorship of Sir Dorabji Tata Trust, the Government of India and the United Nations, International Institute for Population Sciences (IIPS) has established itself as the premier Institute for training and research in Population Studies for developing countries in the Asia and Pacific region. IIPS holds a unique position among all the regional centres in that it was the first such centre to be started and serves a much larger population than that served by any of the other regional centres. On August 19, 1985, the Institute was declared a 'Deemed to be University' under Section 3 of the UGC Act, 1956, by the Ministry of Human Resource Development, Government of India, to facilitate the expansion of its academic activities. The Institute is under the administrative control of the Ministry of Health and Family Welfare, Government of India. Apart from teaching activities, the institute also conducts a large amount of research on various aspects of the population. Emphasis is given to studies related to the inter-relationship of various components of population change, such as Fertility, Mortality and Migration with various factors. The Institute also undertakes evaluative studies and large-scale surveys. The research projects of the Institute are mostly funded by the Ministry of Health and Family Welfare, Government of India and also by the State Governments, the World Bank, the United Nations Population Fund, the World Health Organization, the International Labour Organization and other Government and Non-Government organizations.

Ethical approval is mandatory for research projects involving human participants, human samples, or anonymized data/medical records. This approval ensures that the research is conducted ethically and participants' well-being is protected at all stages of the research process. IIPS is sincerely committed to upholding these ethical standards. The document on Standard Operating Procedures (SOP) of the IIPS-IRB has been prepared in adherence to the ethical guidelines established by the Indian Council of Medical Research (ICMR) and the World Health Organization (WHO). The document is divided into four broader sections. Section A outlines the features of IIPS-IRB, Section B details the submission process to IRB. Additionally, norms specific to Social Science Research are described at Section C and Section D, encompassed Audit/Inspection related rules of IIPS-IRB.

SECTION-A: FEATURES OF IIPS-IRB

Name of the ethics committee: This Ethics Committee is known as the Institutional Review Board, International Institute for Population Sciences, in short IIPS-IRB.

Authority under which the ethics committee has been constituted: The Director, IIPS shall constitute the IRB in accordance with the SOP.

Purpose of IRB: The primary purpose of an IRB is to ensure the rights, welfare, and well-being of all research participants. They ensure research is conducted ethically, by minimizing or no risks of physical, psychological, social, or financial harm throughout the research process.

Membership Requirements of the Ethics Committee

a) **Roles and Responsibilities**: The basic responsibility of the Institutional Review Board (IRB) is to ensure a competent review of all ethical aspects of the project proposals received by it objectively. The other major objectives include:

- To preserve the possible research participants' rights, dignity, and well-being.
- To guarantee that global scientific norms and universal ethical principles are articulated in terms of regional values and traditions.
- To support the formation and instruction of a research community receptive to regional health care needs.
- To ensures transparency in the research process by reviewing informed consent documents and ensuring participants are fully informed about the research

The meetings of IRB are scheduled once every quarter or upon receiving at least three applications for reviewing project proposals for human subject protection strategies. The project should either be funded by the Institute or from an outside research agency/organization, where any faculty of the Institute is associated either in the capacity of PI or Co-PI or consultant or from Population Research Centers. Outside Project approval can be granted with IIPS director permission.

b) **Composition**: The IRB consists of multidisciplinary members, including experts in ethics, law, medicine, social sciences, and laypersons. The IIPS-IRB, comprising internal and external members, has been set up to ensure that the research is conducted ethically and that the well-being of the participants is protected. Independence and competence are the two hallmarks of an effective IRB, ensuring an unbiased and thorough review of the research proposal. The number of persons in an ethics committee should be kept fairly small (8 - 12

members). It is generally accepted that a minimum of five persons is required to form the quorum, without which a decision regarding the research should not be taken. IIPS follows the following composition of IRB: -

1. Chairperson
2. One - two persons from the basic medical science
3. One - two clinicians from other institutes
4. One legal expert or retired judge
5. One - two social scientists
6. One representative of a non-governmental voluntary agency and community
7. Convener from the Institute with an understanding of the Institute and
8. Member Secretary

c) Criteria for Selection of Members

a. **Chairperson:** The Chairperson must be external member and shall be a person of high standing in society, with demonstrable expertise in ethics and research. The Chairperson must have a minimum of 1-3 years of prior experience serving on an ethics committee. The Chairperson shall be responsible for decision-making processes. Their independent status is critical for the integrity of the IRB's operations.
b. **Medical Experts/Clinicians:** All clinicians and medical experts appointed to the IRB must possess a recognized postgraduate qualification in their respective fields. They must demonstrate expertise in both medical research and the ethical aspects of clinical studies. Their role is to provide expert input on the scientific validity of research proposals and the ethical management of clinical interventions.
c. **Legal Expert:** The legal expert must be either a practicing lawyer or a retired judge with substantial experience in legal matters related to health or social issues, research, and ethics. The legal expert ensures that all research complies with relevant laws and regulations.
d. **Social Scientist:** The social scientist must have expertise in representing vulnerable populations or community interests. Their primary role is to ensure that the research is aligned with social welfare and ethical standards.
e. **NGO Representative and community person:** NGO representatives must have expertise in community interests. The research and current activities are aligned with social welfare and of high ethical standards. S/he must be aware of the community profile and linked to different activities in the community.
f. **Convener:** The Convener must be from IIPS and be linked to different research activities. His/her responsibility is to ensure the researcher's welfare. S/he must have expertise in ethics, research, and administrative functions and will guide the member secretary.
g. **Member Secretary:** The Member Secretary shall be a staff member of IIPS with expertise in ethics, research, and administrative functions. They are responsible for maintaining IRB records, scheduling meetings, and ensuring compliance with the SOP.

d) Tenure and Terms of Appointment

All members shall be appointed by the Director of IIPS in consultation with the Chairperson.

The Director has the authority to approve or reject proposed members based on their qualifications and the needs of the IRB. New members may be recommended by existing IRB members, but their appointment must be formalized by the Director. All appointed members must submit a current Curriculum Vitae (CV) and any relevant training certifications in ethics or Good Clinical Practice (GCP). If training certificates are not available at the time of appointment, the member must complete the required training within six (6) months. Members must also provide a written agreement to adhere to confidentiality and conflict of interest policies. Members shall be appointed for a period of three (3) years, with the possibility of an extension for a second term. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on a regular basis (the members are typically appointed for a defined term with the possibility of extension and periodic rotation of a certain percentage of members to ensure continuity of expertise and fresh perspectives).

e) Policy Regarding Training for New and Existing Committee Members

a) Training for New Members: All newly appointed members must undergo an introductory training program before actively participating in IRB meetings. This training will focus on national and international ethical guidelines such as ICMR guidelines and Good Clinical Practice (GCP) standards. It will also cover the functioning of the IRB, including its SOPs, conflict of interest policies, confidentiality requirements, and member responsibilities. The Member Secretary, convener in consultation with the Chairperson, will arrange training sessions and ensure that new members complete the program within three months of their appointment. If a new member lacks a certification in research ethics or GCP, they will be required to obtain this certification within six months. The completion of training must be documented and filed by the IRB secretariat.

b) Training for Existing Members: Existing members of the IRB are expected to participate in refresher training sessions at least once every two years to stay updated on the latest developments in research ethics and IRB operations. These sessions will be organized by the Member Secretary or convener and may include workshops, online training modules, or participation in relevant conferences.

c) Members will also receive training whenever there are significant updates to national regulations, international guidelines, or changes to the IRB's SOPs. The Member Secretary, or convener will notify members of mandatory training sessions, and attendance will be required. Any member failing to attend required training may be subject to review by the IRB, and non-compliance could affect their continued participation in the committee.

d) Documentation of Training: All training, whether for new or existing members, must be documented. This includes attendance records, completion certificates, and a brief description of the training content. The IRB secretariat is responsible for maintaining these records and ensuring that all members are compliant with the training policy.

e) Ongoing Development: Members will be encouraged to pursue additional training opportunities, including specialized training in areas relevant to the research topics reviewed by the IRB. The IRB may recommend specific courses or workshops, and in some cases, the IIPS may provide support for members to attend national or international training programs.

f) The Terms of Reference of the Committee (IIPS-IRB)

Chairperson: The Chairperson of the IRB plays a pivotal role in ensuring the ethical and efficient functioning of the committee. The Chairperson's responsibilities are legally binding and aim to uphold the integrity and impartiality of the IRB's operations. The Chairperson's primary duties include but are not limited to:

- **Presiding over Meetings:** The Chairperson shall convene and preside over all IRB meetings, ensuring the quorum is met, discussions are inclusive, and decisions are made with due regard to all ethical principles. The Chairperson must ensure all protocols are reviewed objectively and thoroughly before approval.
- **Decision-Making:** As the final authority, the Chairperson is responsible for approving, requesting modifications, or rejecting research proposals after due consultation with the IRB members. The Chairperson must ensure that all decisions align with the national guidelines, including ICMR's National Ethical Guidelines.
- **Conflict of Interest Management:** The Chairperson must actively ensure that no member participates in reviews where they have a conflict of interest. All members, including the Chairperson, must declare any potential conflicts at the start of each meeting, and the Chairperson shall facilitate appropriate action.
- **Oversight and Reporting:** The Chairperson must oversee the ethical review process and ensure compliance with all relevant ethical standards and regulations. This includes monitoring ongoing research, reviewing adverse event reports, and ensuring prompt and accurate documentation of the IRB's decisions.
- **Capacity Building:** The Chairperson is responsible for promoting continuous professional development and capacity building of IRB members by encouraging participation in relevant training programs, workshops, and updates on ethical guidelines.

Convener and Member Secretary: The Convener and Member Secretary hold a critical operational role in ensuring that the IRB functions smoothly and in compliance with all relevant standards. The Member Secretary is guided by the convener and his/her duties include:

- **Administrative Responsibilities:** The Member Secretary is tasked with the administration and coordination of IRB meetings, including organizing agendas, circulating relevant research protocols, and ensuring that all necessary documentation is complete and available for review before meetings.
- **Record Keeping:** The Member Secretary is responsible for maintaining all IRB records in compliance with legal requirements. This includes minutes of meetings, research proposals, ethical approvals, correspondence with researchers, and any reports submitted during the course of approved research. Records must be securely archived and available for audits or inspections.
- **Communication with Researchers:** The Member Secretary serves as the primary point of contact between the IRB and the researchers. They must communicate decisions made by the IRB to the respective researchers, including any requests for modifications or additional information.
- **Monitoring Research Compliance:** The Convener & Member Secretary must ensure that ongoing research complies with the IRB's stipulations, including the timely submission of progress reports, adverse event reports, and protocol amendments. The Member Secretary must ensure periodic review of ongoing research projects to verify

compliance.

- **Ensuring Quorum and Timely Meetings:** The Convener & Member Secretary must ensure that the quorum requirements, as set out in relevant guidelines, are met for every meeting. The Member Secretary must also coordinate the scheduling of meetings in a timely manner, especially for urgent matters requiring expedited reviews.
- **Confidentiality and Ethics Compliance:** The Convener & Member Secretary is responsible for ensuring that all members sign confidentiality and conflict of interest agreements as part of their appointment to the IRB.
- **Issuance of the Certificate:** It is the responsibility of the Convener to issue the certificate within two weeks of the IRB approval.

Members: Each member of the IRB plays a crucial role in reviewing research proposals to ensure that ethical and scientific standards are met. The responsibilities of members include:

- **Review of Proposals:** Members must independently review all research proposals assigned to them before the IRB meetings. This includes reviewing the scientific validity, risk-benefit ratio, consent procedures, and compliance with relevant ethical guidelines.
- **Participation in Meetings:** Members are expected to actively participate in all IRB meetings. This includes contributing their expert opinions during discussions, voicing concerns where appropriate, and voting on decisions related to the approval or rejection of proposals.
- **Declaration of Conflicts of Interest:** Members must declare any potential conflict of interest at the beginning of each meeting. If a member is involved in a research proposal either as a principal investigator or co-investigator or has any other form of conflict, they must recuse themselves from discussions and voting on the proposal.
- **Monitoring and Reporting:** Members are responsible for monitoring the progress of approved research. This includes reviewing interim reports, serious adverse event (SAE) reports, and protocol deviations submitted by the researchers. Members may be required to participate in site visits if deemed necessary to ensure ethical compliance.
- **Confidentiality:** All members must sign a confidentiality agreement, ensuring that sensitive information about research protocols and participants is not disclosed outside of the IRB.
- **Training and Capacity Building:** Members are expected to undergo continuous training on ethical guidelines and research methodologies, particularly if new regulatory changes or updates to national or international ethical standards arise.
- **Honorarium:** The external IRB members will be getting reasonable honorarium as per government rule.

g) Conditions of Appointment, the Quorum Required, and Resignation

a) Conditions of Appointment: Appointment of New Members: New members will be appointed under the following circumstances:

- When a regular member completes his/her tenure.
- If a regular member resigns or drops out before the tenure is completed.
- If volume of proposals and frequency of review demands the appointment of new members.

When a new member shall be appointed, it is advisable to induct a member in the same category to fulfill the norms of the same category.

- **Eligibility and Qualifications:** Each appointed member of the IRB must possess

the necessary expertise and qualifications pertinent to their role. The selection must adhere to ethical standards, ensuring that members are capable of reviewing research proposals in compliance with legal and institutional guidelines. Members must demonstrate relevant experience and ethical competence, and they must not have any record of professional misconduct.

- **Independence:** At least fifty percent (50%) of the IRB members shall be independent and not affiliated with IIPS. This ensures unbiased decision-making and integrity of the review process. Appointees who are affiliated with IIPS must have no direct or indirect conflicts of interest concerning the research they are tasked to review.
- **Conflict of Interest:** All members shall declare any potential conflicts of interest at the time of their appointment and throughout their tenure. Members involved in research projects that come before the IRB, either as principal investigators or in any other significant capacity, must disclose this and recuse themselves from discussions and decision-making on those projects.
- **Confidentiality:** Each IRB member must sign a Confidentiality Agreement before commencing their duties. This agreement obligates them to protect sensitive and confidential information related to research protocols, deliberations, and participant information, in accordance with institutional and national guidelines.
- **Tenure of Appointment:** The standard tenure for all IRB members shall be three (3) years, with the possibility of reappointment for an additional term, based on performance and the needs of the IRB. This ensures a balance between continuity and the introduction of fresh perspectives in ethical review.
- **Training Requirements:** Appointed members must undergo mandatory ethics training within six (6) months of their appointment. This training should include Good Clinical Practice (GCP) and other relevant ethical guidelines to ensure the competence of the board in handling complex ethical issues in human research.
- **Performance and Evaluation:** IRB members are expected to actively participate in meetings and contribute meaningfully to the review process. Failure to fulfill duties or attend meetings regularly may result in termination of membership, following review by the Chairperson and Member Secretary.

b) Quorum Requirements for IRB

- **Minimum Quorum Requirement:** The quorum is critical to ensure balanced and fair decision-making, reflecting a variety of expertise and perspectives. A minimum of five (5) members is required to form a quorum, without which no decision regarding any project can be made.
- **Composition of the Quorum:** The quorum must reflect the multidisciplinary nature of the IRB, ensuring that both scientific and non-scientific perspectives are represented. Additionally, efforts should be made to ensure that the quorum reflects diversity in terms of gender, community representation, and expertise. The quorum must include the following types of members to ensure a well-rounded review process:
    - **Medical Experts:** At least one basic medical scientist (preferably a pharmacologist) or clinician must be present.
    - **Non-Medical Experts:** At least one member must be a legal expert, social scientist, or representative from a non-governmental voluntary agency, philosopher, ethicist, theologian, or a similar expert.
    - **Layperson:** At least one layperson from the community or public health institute who is unaffiliated with the institution.
    - **Chairperson or Acting Chairperson**: Either the Chairperson or a designated member, who is independent of the institution, must preside

over the meeting.
    - **Non-Affiliated Member:** At least one non-affiliated member must be present in every quorum to ensure independence and impartiality in decision-making.
    - **Affiliated members, Convener**
    - **Member Secretary**
- **Absence of Quorum:** If the quorum is not met, the meeting cannot proceed, and any decisions made will be invalid. The Member Secretary shall reschedule the meeting at the earliest opportunity and notify all members in advance.
- **Role of the Chairperson in Quorum:** The Chairperson must preside over all meetings where the quorum is present. In their absence, an alternate member (non-affiliated to IIPS), appointed by the Chairperson may preside. The acting Chairperson must ensure that all decisions are made following ethical and procedural standards.
- **Conflict of Interest Impact on Quorum:** Members who have declared a conflict of interest for a particular project under review must recuse themselves from the decision-making process. Their recusal does not count toward the quorum, and other members must still meet the quorum.

c) Procedure for Resignation, Replacement, or Removal of Members

i. **Resignation:** In the case of resignation, an IRB member must submit a formal written notice to the Chairperson. The member is required to provide a one-month notice period, unless the Chairperson approves an immediate resignation. The resignation will take effect from the date it is accepted by the Chairperson. Members who resign are expected to complete any pending responsibilities before their departure.

ii. **Replacement:** Replacement of an IRB member may occur due to resignation, retirement, incapacity, death, or an increase in the committee's workload that necessitates additional expertise. When such a situation arises, the Chairperson, in consultation with other committee members, will recommend a suitable candidate to the Director for approval. The new member must submit an updated Curriculum Vitae (CV), complete any required ethics training, and sign a Confidentiality Agreement prior to joining the committee.

iii. **Removal/Disqualification:** A member may be removed or disqualified if they fail to attend three consecutive IRB meetings without prior intimation or are involved in misconduct, a breach of confidentiality, or conflicts of interest that undermine the functioning of the committee. Additionally, relocation or any inability to perform assigned duties may result in removal. Any such case will be brought before the IRB for review in the next scheduled meeting, where the concerned member will be given an opportunity to provide an explanation, either in writing or in person. The removal of a member requires a two-thirds majority vote of the members present. In cases of serious misconduct, the Chairperson has the authority to suspend the member until a formal review is conducted.

h) Policy to Monitor or Prevent the Conflict of Interest

- **Definition of 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, EC 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. (ICMR, 2017).

- **Disclosure of Conflict of Interest:** All members of the IRB are required to disclose any actual, potential, or perceived conflict of interest in writing using the Conflict of Interest Declaration Form prior to the review of research protocols. This disclosure must include any financial interest, personal relationship, academic rivalry, or any other factor that might influence the impartiality of the member's judgment. It is the responsibility of the IRB Chairperson to review these disclosures and determine the appropriate course of action. In cases where a conflict of interest is identified, the Chairperson shall ensure that the concerned member does not participate in the review, discussion, or voting process related to the proposal in question.
- **Management of Conflict of Interest:** When a conflict of interest is disclosed, the Chairperson shall evaluate the severity and nature of the conflict. If deemed necessary, the concerned member may be permitted to provide factual information regarding the research project but must refrain from participating in any further discussion or voting. In cases where the Chairperson is directly involved in the conflict, the Vice-Chairperson or an alternative senior member of the IRB shall assume the responsibility of reviewing the COI and making the necessary decisions.
- **Exclusion of any IRB member**: The investigator submitting the research proposal has the right to request the exclusion of any IRB member from the review process if they believe that the member may have a conflict of interest. Such requests must be made in writing and submitted along with evidence to substantiate the claim. The Chairperson shall review such requests and, if valid, shall exclude the member from the review process.
- **Confidentiality and Documentation**: All disclosures of conflicts of interest shall be treated with strict confidentiality. The IRB Secretariat is responsible for maintaining comprehensive records of all disclosures and decisions related to conflicts of interest. These records will be included in the official meeting minutes, and any actions taken to manage or prevent the conflict shall be clearly documented.
- **Recusal and Exclusion Procedures**: In the event of a disclosed or identified conflict of interest, the affected member shall be recused from participating in the protocol review, discussion, and decision-making process. The Chairperson will inform the IRB members of the recusal at the commencement of the meeting. Should a member fail to disclose a conflict of interest, and the conflict is identified later, the Chairperson has the authority to invalidate any prior decision or action taken by the conflicted member, if necessary.
- **Appeals and Resolution**: In instances where an investigator or IRB member disputes the existence of a conflict of interest or its management, an appeal may be submitted to the Chairperson for reconsideration. The Chairperson shall convene an independent subcommittee to review the appeal and render a final decision.

i) Functions of IIPS IRB

The key functions of IRB are:

- **Protecting the rights, safety, and well-being of research participants*:*** The primary function of the IRB is to safeguard the rights, welfare, and safety of research participants. They achieve this by reviewing research proposals to ensure they adhere to ethical principles and minimize potential risks of physical, psychological, social, or financial harm to participants.
- **Reviewing Research Proposals**: The IRB meticulously examines to ensure that research proposals:
- **Maintain ethical standards**: Adhere to the principles of informed consent is appropriately

obtained and documented. The research participants voluntarily agree to participate after fully understanding the study's aims, procedures, risks, and benefits.

- Maintain participant confidentiality throughout the research process.
- Ensure the research design is scientifically sound and maximizes potential benefits for participants and society.
- **Providing Oversight**: The IRB provides ongoing oversight of the research process. The IRB may conduct audits or inspections of ongoing research to verify adherence to the approved protocol and ethical principles. This could involve reviewing research records, interviewing participants, or observing research procedures.
- **Maintaining Records**: The IRB is responsible for maintaining detailed records of all reviewed research proposals, their decisions, and any subsequent communication with researchers. Review reports will be updated and made available from time to time crucial for ensuring transparency, accountability, and audibility of the IRB process.

j) **Principles of IIPS- IRB:** As recommended by ICMR, IIPS-IRB follows the four basic principles namely, a) respect for persons (autonomy), b) beneficence, c) non-maleficence and d) justice must guide research to protect the dignity, rights, safety a well-being of research participants while conducting Biomedical and Health Research (ICMR, 2020) These basic principles have been further expanded into 12 general principles:

- **Principle of Essentiality:** Research must be necessary to answer a significant question and contribute to knowledge. There should be no alternative way to achieve the same results with less risk to participants.
- **Principle of Professional Competence:** Researchers must possess the necessary qualifications and experience to conduct the research safely and ethically.
- **Principle of Voluntariness:** Participation in research must be entirely voluntary. Participants must be free to withdraw from the study at any time without consequences.
- **Principle of Maximization of Benefit:** The potential benefits of the research for participants and society should outweigh the risks involved.
- **Principle of Non-exploitation:** Participants should not be exposed to any undue influence or coercion to participate. The research should not exploit them financially, socially, or otherwise.
- **Principle of Institutional Arrangements:** The research institution must have a robust ethical review process (IRB) to ensure the study adheres to ethical principles. (Ref: ICMR Guidelines)
- **Principle of Social Responsibility:** Research should be conducted considering its broader impact on society. It should not contribute to social injustice or discrimination.
- **Principle of Transparency & Accountability:** Researchers must be transparent about the research process and accountable for their actions. Participants have the right to be informed about the study and their rights.
- **Principle of Ensuring Privacy & Confidentiality:** The privacy and confidentiality of participants' data must be protected throughout the research process.
- **Principle of Totality of Responsibility:** Everyone involved in the research, from researchers to sponsors, has a shared responsibility to ensure the study is conducted ethically.
- **Principle of Risk Minimization:** All potential risks to participants must be

identified, minimized, and managed effectively.

- **Principle of Environmental Protection:** Research should be conducted in a way that minimizes any negative impact on the environment.

By adhering to these principles, researchers can ensure their work is conducted ethically and protects the well-being of research participants.

Risks and Benefits: For all biomedical/health/socio-behavioral research involving human subjects, the investigator must ensure that potential benefits and risks are reasonably balanced and risks are minimized.

In ethically acceptable research, risks have been minimized (both by preventing potential harms and minimizing their negative impacts should they occur) and are reasonable in relation to the potential benefits of the study. The nature of the risks may differ according to the type of research to be conducted.

k) IRB members should be aware that risks may occur in different dimensions (e.g. physical, social, financial, or psychological), all of which require serious consideration. Further, harm may occur either at an individual level or at the family or population level. The PI should inform the IRB any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a subject's spouse or partner and the direct benefits, if any, expected to result to subjects from participating in the research as well as the expected benefits of the research to the community or to society at large, or contributions to scientific knowledge.

l) **Benefit-risk assessment**: The IRB must decide about the type of review required (exempted, expedited, full committee) based on the type of risk involved. As per WHO ERC Guidelines for Principal Investigators, the following are examples of the potential risks/harms and benefits that may occur to research participants as a result of taking part in research.

Risks/Harms	Benefits
Physical harm	Access to treatment / Free treatment
Social harm / social risk	Emotional support
Emotional harm / risk	Psycho-social support
Stigmatization	Humanitarian
Loss of privacy	Contribution to society
Insensitivity to vulnerabilities, exposing individuals to various types of harms/risks	Others
Sharing of confidential information resulting in tangible or intangible losses	
Perpetuation of gender and other biases	
Others	

Source: WHO ERC Guidelines for Principal Investigators

Types of Risks: As per the National Ethical Guidelines for Bio-medical and health research involving human participants, ICMR, 2017 has classified the risk into four categories as given below:

Type of Risk	Definition/Description
Less than minimal risk	The 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	The probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where the occurrence of serious harm or an adverse event (AE) is unlikely. 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.

Source: National Ethical Guidelines for Bio- medical and health research involving human participants, ICMR, 2017

Source: National Ethical Guidelines for Bio- medical and health research involving human participants, ICMR, 2017

m) Review Process for Research Involving Vulnerable Populations

i) All research proposals involving vulnerable populations must undergo full board review. Expedited reviews or exemptions are not permitted for studies involving these groups. The review process will include the following steps:

ii) Appointment of Reviewers: The Chairperson will appoint at least two members with expertise in the ethical review of research involving vulnerable populations to assess the protocols. These reviewers will ensure that adequate justification is provided for including such groups and that additional protections are in place.

a) Informed Consent: The IRB will review the informed consent process, ensuring that appropriate measures are in place for obtaining consent from legal guardians, caregivers, or next of kin where required. Assent will be obtained from minors, and special attention will be given to ensuring voluntariness and understanding in the consent process.

b) **Risk-Benefit Analysis:** The reviewers will assess the risk-benefit ratio of the research, ensuring that vulnerable populations are not exposed to unnecessary risk or disproportionate burden. Special consideration will be given to whether the research could be conducted with non-vulnerable populations.

c) **Privacy and Confidentiality:** The IRB will ensure that the privacy of participants and the confidentiality of their data are protected throughout the research, especially in studies involving sensitive populations such as those with disabilities, cognitive impairments, or socio-economic disadvantages.

d) **Special Considerations for Specific Vulnerable Groups**

- **Children and Cognitively Impaired Individuals:** Research involving children and individuals with cognitive impairments will require consent from legal guardians or authorized representatives, with additional assent from participants when appropriate. The research must be designed to provide direct health benefits or minimal risk to the participant.
- **Pregnant Women and Disabled Persons:** Research involving pregnant women or disabled persons must include provisions to minimize risks, ensuring that the research is necessary to improve health outcomes or advance knowledge relevant to these groups.
- **Economically or Socially Disadvantaged, Migrants, Refugees, and Conflict-Affected Populations:** Research involving these populations must ensure that participants are not coerced by the offer of undue incentives. Additional mechanisms for consent, language support, and legal protection may be necessary, especially for refugees and displaced individuals.

e) **Use of Checklists and Forms**: The IRB will use specific checklists and forms tailored to vulnerable populations to ensure that all ethical considerations are addressed. The Secretariat will maintain these checklists, and the Member Secretary will ensure their distribution to reviewers as needed.

f) **Ongoing Monitoring and Review**: Studies involving vulnerable populations will be subject to ongoing monitoring, including more frequent reviews and site visits. Any changes in participant vulnerability, such as recovery from illness, will require re-evaluation and adjustment of the consent process.

n) **Type of Reviews**: Based on a certain set of criteria, a proposal can be submitted for one of the following types of review:

A. **Exemption from review**:
Proposals that present less than minimal risk fall under the category of exemption from Review. Following are the examples of situations where exemption from review may be applied:

- 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; Public health programmes by Government agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)

The IRB certificate for project proposals exempted from review may be issued by the IRB secretariat within 20 days of submission, following scrutiny by the Chairperson and the Member-Secretary.

B. **Expedited Review**

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. Once submitted for expedited review, the proposal will be reviewed within 15 days. The convener and the Chairperson of the IRB or designated members of the Committee or Subcommittee of the IRB may do expedited review only if the protocols involve:

- Minor deviations from originally approved research during the period of approval (usually of one-year duration).
- Revised proposal previously approved through full review by the IRB or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
- Research activities that involve only procedures listed in one or more of the following categories:
- Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
- When in emergencies like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IRB may be taken before use of the test intervention.

C. Full Committee Review: All research proposals that present more than minimal risk to human subjects, and are not covered under the exempt or expedited review category should be submitted for full committee review. These are reviewed by IRB Committee members, presentation of the proposal to the IRB Committee followed by a general discussion and a consensus decision. Some examples of the proposal for full committee reviews are:

- Research involving vulnerable populations, even if the risk is minimal
- Research with minor increase over minimal risk like studies involving the 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 and 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 given 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 Convener 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

Review procedures: A primary review of a new research proposal submitted to the IRB will be conducted. The IRB assesses the proposal against ethical principles, scientific merit, and participant protection. The committee may request modifications or clarification from the researcher before granting approval. For minimal-risk research that meets specific criteria, the IRB may conduct an expedited review.

The IIPS-IRB provides a complete and adequate review of the research proposals submitted. Once the member secretary of the IIPS-IRB, in consultation with the chairperson and other members decides on a date, the PI or Co-PI of the project is requested to make a brief presentation and explain the issues of human subject protection and strategy to address it. IIPS-IRB reviews human subject issues and strategies for protecting it, irrespective of qualitative or quantitative data.

In special cases, the chairperson of IRB, in consultation with members, may decide to review the applications through circulation or even provide an exemption from review if there are negligible chances of violating human subject rights, safety and threats to their life.

The meeting of IRB can be scheduled thrice a year preferably in the second week of April, August and December depending on the availability of members. The exact date will be notified on the IIPS website. However, the PIs are required to submit the proposal along with other necessary documents one month ahead of the meeting schedule (before the first week of March, July and November).

Time frame for Review

- Initial Screening of the proposal to be done within 2 weeks of the receipt of the application for screened for completeness and adherence to submission guidelines.
- A detailed technical screening at the Secretariat level will be done within one week by the internal members of the committee after the initial screening.
- Based on the type of the proposal, the review will be scheduled within four weeks.
- In case of a full committee review, the meeting will be held in the second week of April, August and December.
- Feedback and decisions are communicated to the researcher within a specified timeframe, usually within four to seven weeks.

Certificate

Once the IRB is satisfied that the study is in no way harmful to the subjects under study, IRB Member Secretary includes it in the minutes of the meeting and shares it with all the members. Once it is ensured that all the points discussed in the meeting are included in the minutes, it is signed by the Convener and Chairperson and uploaded on the Institute's website. The committee will issue an Ethical Clearance Certificate, valid for the period of study specified signed by the chairperson. It is the responsibility of the Convener and Member Secretary to issue the certificate within two weeks of the meeting of IRB.

SECTION B: PROCESS OF SUBMISSION TO IIPS-IRB

Process of submitting applications: Principal Investigator(s) should submit a duly filled-in IIPS-IRB application providing detailed information about the study objectives, methodology, participant recruitment, and data handling. Supporting documents like proposal and review type format (pdf), Proposal (pdf), Coordinator/s CV (pdf), Consent form, and Tools (pdf) to the Member Secretary, IIPS-IRB. In the case of proposals, where IIPS faculty is involved as the PI/Co-PI, the file should be rooted through the Director and Senior Professor, IIPS, Mumbai through e-office. For PRCs, the proposal should be submitted through the proper channel with a forwarding letter of the Head of the PRC to the IIPS-PRC coordinator.

a) Submission of proposal

- Submissions for full board review must be made Six weeks before the scheduled IRB meeting.
- Expedited and exempt review submissions are accepted on a rolling basis.
- The IRB office acknowledges receipt of the submission and screens it for completeness within 4 working days of the receipt. Incomplete submissions are returned to the researcher for revision.

Ensure the following before submission:

- **Project Information**

  Title: Title of the research project.
  Principal Investigator (PI): Name, designation, and contact information of the lead researcher.
  Co-Investigators (Co-I) and Research Team: List team members with their roles and responsibilities clearly defined.

- **Research Background and Justification**

  Rationale: Explain the reasons for conducting the research. This includes a well-documented statement of the need or problem the project addresses, its potential causes, and possible solutions.
  Objectives: Clearly state the specific research questions or objectives. They should be simple, specific, and measurable.

- **Research Design and Methodology**

  Study Design: Describe the type of study (e.g., survey, case study, experiment) and its justification for addressing the research question(s).
  Sampling: Explain the sampling frame and criteria for participant selection (inclusion/exclusion criteria).
  Methodology: It should include information on the research design, the research subjects, interventions introduced, observations to be made and sample size. Detail the procedures to be used, data collection methods (e.g., interviews, questionnaires), observations, and any laboratory analyses. Include a table outlining the study schedule for both qualitative and quantitative studies.

- **Ethical Considerations**

  Participant Selection: Describe the criteria for selecting participants and their right to withdraw from the study.
  Informed Consent: Explain the informed consent process and attach copies of the

consent forms in both English and the local language as required by ethical research principles.
Data Security and Confidentiality: Outline how you will ensure data security, privacy, and confidentiality throughout the research process.

- ***Data Analysis and Dissemination***

Statistical Analysis (Quantitative Studies): Describe the statistical methods planned for data analysis. Include justification for the sample size, power of the study, and significance level.
Analysis Tools (Qualitative Studies): Explain the tools or instruments used to analyze qualitative data.
Publication Policy: Clearly state the authorship policy and who will be acknowledged in publications. Follow ethical guidelines for authorship.

- ***Additional Information***

Budget: Provide a detailed breakdown of the research budget with justifications for each item.
Funding Sources: Disclose any funding received or anticipated from other sources.
Collaborations: Mention collaborations with other institutions and attach any relevant ethical clearance documents from them (if applicable).
References: Include a list of relevant studies cited within the protocol (minimum number may vary).

- ***Compliance and Signatures***

Statement of Ethical Conduct: Include a statement confirming adherence to ethical research principles.
Signatures: Obtain signatures from the PI, supervisor/research scholar, co-investigators, and the head of the relevant department/school.
IRB form, consent form, assent forms and CV Format are available in the IIPS IRB Website; https://www.iipsindia.ac.in/content/institutional-review-board
PIs are required to submit both hard and soft copies of the completed IRB application with the proposal and other required documents through proper channels to the Director and Senior Professor, IIPS, Mumbai. IIPS faculty PIs should submit their application through the e-office file system to the Director and Senior Professor of IIPS, through project cell, email id: projectcell@iipsindia.ac.in.
Four copies of the IRB application form, proposal and all other required documents should be sent to the IIPS IRB office by post at least 45 days prior to the meeting date.

- **Continuing Review:** Once the research is approved, the certificate will be issued and the IRB conducts periodic reviews to ensure the study continues to adhere to ethical principles and participant protection. The frequency of these reviews depends on the potential risks involved in the research.

- **Periodic Review:** The IRB periodically reviews any amendments to the protocol, assesses ongoing participant safety, and ensures informed consent remains valid.

- **Interim Review:** In case of any adverse events, protocol deviations, or complaints. an unscheduled review will be initiated by the IRB due to concerns about the ethical conduct of the research or participant safety

b) Dos and Don'ts for submission of application

Dos:

- Application should be submitted in proper template
- Application should be submitted through the proper channel
- Clearly and concisely describe your research project, including study objectives, methodology, participant recruitment, data handling, and risks and benefits.
- Explain how you will obtain informed consent from participants.
- Outline your data collection, storage, and security procedures.
- Include documents mentioned in the checklist should be submitted.
- All pages should be numbered
- Proofread your application carefully before submission.

Don'ts:

- Don't use jargon or technical language that laypeople wouldn't understand.
- Don't submit an incomplete application.
- Don't provide inaccurate or misleading information.

c) Attachments: Checklist for attached documents:

i. Cover letter
ii. Forwarding letter by the competent authority for Non-IIPS proposals
iii. Copy of filled-in and duly signed IRB Form (4 copies)
iv. Project proposal – (4 Copies)
v. Brief description of the proposal
vi. Curriculum Vitae of Investigators in prescribed format – (4 Copies)
vii. In case of collaborative research, attach the MOU with the collaborating organization
viii. Format of review type,
ix. Participant information sheet-cum-Informed Consent form, (if multiple respondents, consent should be taken from each respondent)
x. Informed Assent form (If applicable)
xi. Investigator self-declaration form,
xii. Questionnaire and/or Copy of clinical trial protocol and/or interview guidelines

d) Adherence to Informed Consent Principles

- Assent refers to agreeing or approving after thoughtful consideration an idea or suggestion to participate in research by a young person below the age of 18 years, who is old enough to understand the implications of any proposed research but not legally eligible to give consent. The assent has to be corroborated with the informed consent of the parent.

- Obtaining Informed Assent from Children or Minor's Parents, legal guardians, or a legally authorized official must sign consent forms permitting children or minors to participate in research projects. In addition, children and minors are required to sign an Assent Form.

- The content of an assent form for children participating in research should be tailored to their age and understanding. It should be written in simple, clear language that aligns with their cognitive, social, and emotional development. Here's a breakdown of key points to include:

A. Key components of Informed Consent to be included:

a. **Explanation of the Study (Benefit & Purpose)**:
- ***i.*** briefly explain the research project and how it might benefit children like them in a child-friendly way.
- ***ii.*** Mention the activities involved in the study, including any potential discomfort the child might experience.

b. **Study Procedures and Potential Discomfort:**
- i. Describe the activities involved in the study, using simple language and avoiding medical jargon.
- ii. Mention any potential discomfort the child might experience and assure them it will be minimized.

c. **Right to Ask Questions and Contact Information:**
- i. Emphasize that the child can ask questions about the research at any time.
- ii. Provide contact information for a person the child can reach with questions or concerns (e.g., researcher, parent liaison).

d. **Voluntary Participation and Confidentiality:**
- i. Clearly state that the child's participation is voluntary and they can refuse to participate or withdraw at any point without impacting their treatment or care.
- ii. Assure them that refusing will not affect their treatment or care at the center (If applicable).

e. Consent and Contact Information:
- **i.** Provide contact information for a person the child can reach with questions or concerns.

The committee advise the researcher on obtaining "informed consent" from the subjects, and ensure "confidentiality" concerning their information. In the case of surveys involving different methods and multiple respondents, consent forms should be taken from each respondent, along with the assent forms, if minors are involved.

B. Guidelines

i. The title with the signature of the Principal Investigator (PI) and Co-investigators as an attestation for conducting the study.

ii. Clear research objectives and rationale for investigating in human participants in the light of existing knowledge.

iii. Precise description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures.

iv. All other relevant documents related to the study protocol like investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances.

v. The projects are to be presented before the IRB Committee, 15 minutes for presentation and 15 minutes for question-and-answer session.
vi. Please submit the properly filled-in form. Partially filled-in/Incomplete IRB form will not be entertained.

SECTION C: ETHICAL ISSUES IN SOCIAL SCIENCE RESEARCH

In the Indian context, socio-behavioral research must consider the diverse and complex social fabric characterized by multi-religious society, caste system, class dynamics, endogamy, gender issues and geo-ethnic variations as its impact on social behaviour and attitudes is crucial. Here are the guidelines for ethical adherence in social science research:

- **Risks are non-measurable and dynamic:** Risks in social and behaviour sciences studies are non-measurable and dynamic in nature. Therefore, it is often difficult to quantify and might be misinterpreted as no/minimum risk research potentially leading to inadequate protections for participants.
- **Data sharing, incidental findings and post-research benefits**: The PI's responsibilities related to data sharing, incidental findings and post-research benefits to the study population need to be carefully reviewed by the IRB on a case-by-case basis and any exemptions from these obligations must receive prior approval from IRB
- **Ancillary care**: Ancillary care refers to additional medical care provided to participants beyond what is required for the study itself should be evaluated on a case-by-case basis by the IRB carefully.
- **Discovery of Unacceptable Practices:** As part of the research protocols, socially, legally, medically and technically unacceptable practices and behaviour may be discovered or observed. While researchers are not required to interrupt such behaviours to determine the truth. They must document these in the research findings and responsibly disseminate the findings for the larger social good.
- **Reporting Harmful Behaviour:** researchers have duty to report patterns of harmful behaviours (e.g., suicidal tendencies, infanticide) to appropriate authorities. Researchers must maintain the privacy and confidentiality of the respondent's identity.

a) **Ethical challenges are more pronounced in collaborative research**: Ethical challenges are more pronounced in collaborative research (national or international) due to possible inequity of expertise and knowledge access. Ensuring transparency and equity in funding relationships, is crucial to maintaining ethical standards. Clear agreements on data management, sharing, and intellectual property rights should be established at the outset. As collaborative research often involves multiple cultural contexts, requiring sensitivity to different ethical norms and practices. It must comply with the regulatory requirements of all participating countries or regions.

b) **Consideration for appropriate design and conduct of study**: Like any other research, the researchers must ensure that the proposed studies are scientifically sound, built on an adequate prior knowledge base, and are likely to generate valuable information.
    - In socially stratified groups and communities, researchers must spend time to become conversant with cultural norms and practices in order to develop strategies to build trust and negotiate power in ways that do not put research participants at risk.
    - In some types of research within communities, appropriate interpreters would be required. They need to be carefully selected, keeping in mind the hierarchies existing in the context. A local person from the same village in which the research is to be conducted should not be used as an interpreter. Instead, an interpreter should be chosen from some other nearby village so that her/his vulnerability and perceived threat from other participants can be mitigated. Institutions should develop or have SOPs for handling deteriorating situations, including a pre-tested communication plan.
    - The information about these norms/practices should be collected from reliable and

multiple sources including multiple persons/groups, which should be mentioned in detail. This knowledge should be considered while deciding the group of participants and style of interview/investigation. However, the final decision about recruiting the participant should be based on the participant's and her/his family's opinion about norms/practices. These issues become particularly pertinent in cases of research that involve patriarchal or restrictive communities.

- Field work challenges for research team – Research team members may sometimes be subjected to unforeseen situations which may involve trauma, humiliation and threats of violence. Training should be given to the research team to meet such challenges.

c) **Considerations by the IIPS-IRB for Ethical Review**: Social and behavioural sciences research approaches are not always positivist and, therefore, articulation of a hypothesis may not be possible at the beginning of the research. Instruments/documents are developed during the course of the research; are reflective; and may keep changing as the research progresses. The IRB must be kept informed about these changes and appropriate re-consent taken from participants. The researcher must take prior permission from the IRB with justifiable reasons for audio/ video recording of participants' interviews.

d) Risk assessment: Participants of research in behavioral and social science face the potential of being exposed to significant and unique harm which may not be limited to physical harm. The researchers, research team and IRB must recognize the cultural context and associated harm related to dignity as well as social and informational harm. This will avoid hurting or transgressing rights of the participants/community.

- **Harm to dignity** is likely to occur when individuals are not treated as persons with their own values, preferences, and commitments, but rather as mere means not deserving of respect. This is also sometimes classified as another form of negligence. It may result in individuals feeling hurt, humiliated, excluded, dismissed or unfairly treated.
- **Psychological and emotional harm** may result from participating in a study where memories of traumatic experiences such as disasters (natural or otherwise), violence, conflict, abuse, assault and other such conditions need to be revisited by the participants. This may also affect and compound the vulnerabilities of participants already experiencing post-traumatic stress disorder (PTSD).
- **Social harm** is a non-medical adverse consequence of study participation, including difficulties in personal relationships and stigma or discrimination from family or community. Social harm can be related to personal relationships, travel, employment, education, health, housing, institutions (government/nongovernment) and others.
- **Informational risk** is the potential for harm from disclosure of information about an identified research participant to others. For much of social and behavioural research, informational risk is one of the primary risks.
- **Risk mitigation** Measures should be employed to minimize potential risks and their negative impact, such as short- and long-term adverse impacts on participants of studies on abortion, sexual abuse and other sensitive subjects. These measures should be incorporated into research methods, with special reference to hierarchies that exist in the social context where the research is undertaken.

e) Community engagement: While devising methods and interpreting observations, researchers should engage potential participants and communities in a meaningful participatory process that involves them in an early and sustained manner in the design, development, implementation and monitoring of research, and in the dissemination of its results.

f) Informed consent: Human participants in a proposed research study must be informed about the nature of the research project, and researchers/research teams must obtain their voluntary consent prior to their participation in the study. The different types of informed consent processes in social and behavioural sciences research are provided as below:

- **Community consent/gatekeeper consent/individual consent:** Individual informed consent has to be taken after obtaining the permission of gatekeepers, such as community heads or leaders/ culturally appropriate local authorities/healthcare providers/institutions or organizations responsible for community welfare or their appointed advocates. Consent procedures must respect local cultural customs, however, community traditions do not substitute for individual consent unless a waiver has been granted.
- **Participant consent:** Researchers must develop culturally appropriate ways to communicate information necessary for adherence to the standard required in the informed consent process.
- **Selective withholding of study information:** IRB may permit selective withholding of information/hypothesis of the study in the consent form for achieving overall social and public good, without influencing the outcome of the study. On completion of the research, the participants should be de-briefed, if applicable.
- **Participant refusal:** Often the power differences between participants and researchers in India make it difficult for people to explicitly refuse to participate. Researchers should be alert to cultural symbols of refusal, such as body language, silence, monosyllabic replies, or restlessness that communicate discomfort. They must not persist with the research under these circumstances.
- **Relational autonomy:** Individuals are socially embedded wherein the person's identity is shaped by social determinants, such as caste, class, ethnicity and gender. Therefore, the participant may not be autonomous in decision making. Right to autonomy must be understood in relation to substantive equality of opportunity, sufficient social support and conditions for self-respect. Accordingly, concerns about social justice must be central to any adequate conception of individual autonomy. The IRB may take into account this context with due diligence regarding the vulnerable status of prospective participants during review, for example, a woman asking her husband or family before giving consent.
- **Waiver of informed consent:** If the research has important social and public health value and poses no more than minimal risks to participants, the IRB may waive the requirement for individual informed consent if it is convinced that the research would not be feasible or practicable to carry out without a waiver, for example, research on harmful practices.

g) **Privacy and confidentiality**: Privacy and confidentiality of research participants should be considered while selecting sites for data collection, choosing sensitive research areas, specific contexts and settings. In some circumstances participants become more vulnerable in research because of heightened psychological, social, physical or legal risks. Breach of confidentiality in these types of research may cause serious harm to vulnerable participants. It is important to protect study participants from potential future risks and harm by establishing culturally sensitive and context specific safeguards.

h) **Duty to disclose sensitive information**: Researcher(s) may come across certain facts detrimental to a participant's self or others, such as suicidal tendency/ideation, notifiable diseases. In such a situation, researchers have a responsibility to disclose this information to relevant persons/authorities to save life or prevent damage contemplated by the participant. Measures to be taken in such instances are given below:

- If there is a high likelihood of getting sensitive incidental findings during the research process, then the ways to handle these at individual, family and community levels should be discussed and mentioned in the protocol.
- Researchers and the IRB should have a basic understanding of the legal provisions in the related area. Persons with the necessary domain knowledge and experience can be special invitees to IRB meetings.

i) **Studies Using Deception**: Deception occurs when researchers provide false or incomplete information to participants for the purpose of misleading them so as to achieve the study objectives and for larger public good. Research employing any type of deception should undergo full committee review. Research involving any kind of deception should:

- pose no more than minimal risk;
- not adversely affect the welfare and safety of the participants;
- be conducted only when the research cannot be carried out without deception;
- have an adequate plan for debriefing the participants after completion of the study, if appropriate;
- disseminate results of research to the participants, if applicable; and be carefully reviewed by the IRB.

j) **Safety of participants**: Support systems, such as access to counselling centres, rehabilitation centres, police protection, etc., should be in place when research is on a sensitive issue, such as mental health, gender-based violence and social exclusion and discrimination.

k) **Safety of research teams in the field**: The safety of the research team is the responsibility of the institution, sponsors and local authorities, particularly in research on sensitive topics or in sensitive research settings since there would be a possibility of the researcher or research team being subjected to disturbing instances while conducting the research. Besides providing safety, including insurance coverage, and giving training to the researcher or research team to meet such challenges, setting up community advisory boards could be helpful to ease the situation.

l) **Qualitative research**: The knowledge gathered through qualitative research is interpretative based on the observation and its analysis by the researcher or research team which is socially constructed at individual and socio-cultural levels.

a. Informed consent is very often dynamic in nature and negotiable. When written consent may not be possible, other means could be used and documented.
b. The IIPS-IRB may look at issues that pertain to the design involving researcher–participant relationships, informed consent process and conduct of the research.
c. Preliminary activity of observation for preparing notes, before actually initiating research based on the observation, need not be submitted for IRB's review. However, any ethical issues arising even during that preliminary phase, before actual collection of data, should be included in the research proposal for review by the IRB.
d. On some occasions/in some observational research the IRB may approve waiver of consent, provided mechanisms for maintaining privacy and confidentiality are justified.
e. In collaborative research, it is desirable to establish a rapport with the community to be engaged in research through the gatekeepers or community advisory boards.
f. Sharing raw data and notes with repositories, researchers, peer communities, institutions, and funders is increasingly becoming a requirement for transparency in research.
g. Sharing raw data including audio-visual material should protect the confidentiality of the individual and research setting by sufficiently processing data to mask identifiers before sharing.
h. Researchers have a duty of disclosure to share research findings in aggregated form and relevant information in a user-friendly format with community leaders, gatekeepers and communities without disclosing individual identities. They must also share these findings and relevant information with the participants.

SECTION D: PREPARATION FOR AUDIT/INSPECTION OF IIPS-IRB

a) **Inspection**: An inspection is an official review or examination conducted by regulatory authority(ies) of documents, facilities, records, and any other resources deemed relevant to the

study. In the context of a social research institute, such as one focusing on studies related to fertility, migration, gender, or other socio-demographic issues, inspections ensure compliance with ethical and research standards. These inspections may take place at the research institute, sponsor's offices, or the IRB to verify adherence to Good Research Practices.

- The IRB may periodically review the progress of approved studies until their completion. This can be done through periodic study progress reports, internal audits, or ongoing monitoring.
- An annual audit may be performed by external auditors from relevant government bodies.
- Study files and administrative records will be made available for inspection or audit, and photocopies may be provided upon request by the investigator, provided it is authorized by the Member Secretary or Chairperson of the IRB. This also applies to other purposes, such as reviews of adverse events or research conducted on sensitive topics, ensuring that ethical standards are maintained throughout the research process.

b) **Auditors:** The auditors will be from the government institution/body who are well familiar with the ICMR Biomedical and Health Research guidelines. A maximum of 2 auditors will be notified prior to the finalization of date of audit.

c) Notification regarding an audit/Inspection: Upon receiving a written or emailed communication regarding an audit or inspection visit, the Member Secretary & convener of the IRB will promptly inform the Chairperson, IRB members, and, if applicable, the Head of the Institution about the date, purpose, and scope of the audit or inspection.

d) Preparing for Audit

- Once the information about the upcoming audit or inspection is received, the Chairperson
- will assign the Member Secretary and/or designated IRB members the responsibility to prepare for the visit, with the assistance of the project cell.
- The preparation process will follow the steps outlined in the official checklist, ensuring that all necessary documentation is reviewed, organized, and readily accessible. Studies with incomplete or missing documents will be addressed separately, with actions taken to resolve any issues being thoroughly documented.
- Care should be taken to ensure that all documents are kept in the right order for easy and quick access.

e) On the Day(s) of the Visit

- The Chairperson, Member Secretary, convener or designated IRB members should welcome and accompany the auditors/inspectors to the reserved meeting room. All designated team members must be present in the meeting room at the scheduled time.
- The visit will begin with the auditors/inspectors explaining the purpose of the inspection and specifying the type of information or documentation they require. During the interaction, the Chairperson, Member Secretary, convener or IRB members should respond to the auditors' or inspectors' questions clearly, politely, truthfully, and concisely.
- Any files or information requested by the auditors/inspectors will be promptly provided by the Secretariat. Additionally, the Member Secretary, convener designated IRB member, or project cell will carefully record any comments or recommendations made by the auditors/inspectors for future reference and action.

f) Correction of Deficiencies Observed During Audit/Inspection

- The Member Secretary, convener designated IRB member, or project cell will carefully review the comments and recommendations provided by the auditor/inspector. Upon receipt of the formal Audit/Inspection Report, the Chairperson will implement the necessary corrective and preventive measures and set a timeline for completing the corrections, in accordance with the auditor's/inspector's guidelines.
- The action plan, outlining the corrective steps, will be communicated to the auditor/inspector by the Member Secretary or designated IRB member after obtaining approval from the Chairperson.
- If applicable, the Chairperson will decide on a date for an internal follow-up audit to assess the effectiveness of the corrective actions. The Member Secretary or designated IRB member will then report the results of the internal follow-up audit to the Chairperson for further review.

g) Recording the Audit/Inspection Visit

- The Member Secretary, convener, designated IRB member, or project cell must maintain a comprehensive record of all audit/inspection visit reports and corresponding action plans in a dedicated audit/inspection file.
- Additionally, the completed checklist, along with any findings from an internal follow-up audit (if applicable), should be documented and stored in a separate internal audit file for future reference and compliance tracking.

h) **Audit Schedule**: The audit will be scheduled annually as per the Director's approval.

i) **Honorarium:** The external auditors will be getting reasonable honorarium as per government rule.

References

- ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf
- World Health Organization (WHO), https://www.who.int/teams/health-ethics-governance/governance/research
- Department of Health Research (DHR) Guidelines for Ethics Committees
- Institutional Policies of IIPS

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Annexures

Annexure 1: IIPS IRB Application form
Annexure 2: IIPS IRB CV format
Annexure 3: IIPS IRB Expedited Review
Annexure 4: IIPS IRB Exemption From
Annexure 5: IIPS IRB Informed Assent form and guidelines
Annexure 6: IIPS IRB Informed Consent form guidelines
Annexure 7: IIPS IRB Self Declaration Form
Annexure 8: IIPS IRB certificate
Annexure 9: Audit and Inspection Checklist

Annexure 1: IIPS-IRB Application form

INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES

Deemed-to-Be-University
B. S. Devashi Marg (Govandi Station Road)
Deonar, Mumbai, Maharashtra 400088,
https://www.iipsindia.ac.in/

IIPS-IRB Application form

Serial No of IIPS-IRB Management Office:
_____

International Institute for Population Sciences -Institutional Review Board
(IIPS-IRB) Application form for the review of the proposal

General instructions:

a)To be filled by the Principal Investigator (PI);
b) Please tick mark the appropriate one, mark NA if not applicable; and
c)Attach a separate sheet if required

Title of the Proposal:
……
……..……..

Name of the Applicant ……
Name of the Principal Investigator ……
Designation:
……
……
Department:
……
……
Date of submission
Type of review

Exemption from Review …. ☐ Expedited Review . ☐ Full Committee Review .. ☐

Status of Review: New ☐ Revised ☐

SECTION A: ADMINISTRATIVE INFORMATION				
Project Investigators	**Name, Qualifications and Designation**	**Department and Organization Address and contact details**	**Roles and responsibilities**	**Signature**
PI:				

SECTION A: ADMINISTRATIVE INFORMATION				
Project Investigators	**Name, Qualifications and Designation**	**Department and Organization Address and contact details**	**Roles and responsibilities**	**Signature**
Co-PI:				
Please attach a brief bio and CV for all investigators (PIs and Co-PIs) involved in the study (with subject specific publications limited to the previous 5 years).				

Funding Details

Project Duration:
Total Budget:
Share of the sponsor/s in total budget
Sponsor Information: 1. Indian a) Government ☐ i.Central ☐ ii.State ☐ iii. Institutional ☐ b) Private ☐ i.Industry ☐ ii.Development agency ☐ iii. Self-sponsored ☐
2. International Government ☐ Private ☐ UN agencies Other ☐
3. Industry National ☐ Multinational ☐
Specify the funding agency
Contact Address of Sponsor:

SECTION B: RESEARCH RELATED INFORMATION
1. **Brief description of the study** –background, research question aim(s) & objectives, methodology describing the potential risks & benefits, monitoring and auditing, outcome measures, statistical analysis and implication of the research findings (maximum 500 words):
2. **Objectives of the study**
1. **Type of Study:**

Socio-Behavioural Science ☐ Clinical Single center ☐ Clinical Multi- centeric ☐ Epidemiological and Public health ☐ Basic science ☐ Biological sample ☐	Retrospective ☐ Prospective ☐ Quantitative ☐ Qualitative ☐ Mixed method ☐	Cross sectional ☐ Longitudebnal/cohort ☐ Case control ☐ Systematic review ☐ Baseline ☐ Endline ☐ Formative ☐

3. Clinical Trials:

Drug /Vaccines/Device/Herbal Remedies:

i. Does the study involve use of:

Drug ☐ Devices ☐ Vaccine ☐

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐

ii. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐

Other countries, specify ☐

iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No

d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐

4. **Are you aware if this study/similar study is being done elsewhere?**	Yes	No
If Yes, provide details		

SECTION C: PARTICIPANT RELATED INFORMATION

5. Subject selection:

i. Number of Subjects: Sampling design and Sample Size

The rationale for the selection of sample six in 100 words. In case of qualitative study describe the number and type of respondents.

ii. Duration of fieldwork :

iii. Will subjects from both sexes be recruited — Yes / No

iv. Please provide the inclusion and exclusion criteria of the selection of respondents

v. Type of subjects — Volunteers ☐ Patients ☐

vi. Vulnerable subjects — Yes ☐ No ☐

If Vulnerable subjects, Tick the appropriate boxes

Pregnant Women ☐	Children ☐	Elderly ☐
Fetus ☐	Illiterate ☐	Handicapped ☐
Terminally ill ☐	Seriously ill ☐	Mentally challenged ☐
economically & socially backward ☐		Any other (Specify) ☐

iv. Special group subjects — Yes ☐ No ☐

If yes in special subject group, tick the appropriate boxes)

Captives ☐	Institutionalized ☐	Employees ☐
Students ☐	Nurses/Dependent	Armed
Any Other ☐	Staff ☐	Forces ☐

6. Privacy and confidentiality

i. Study involves -
- Direct Identifiers ☐
- Indirect Identifiers/coded ☐
- Completely anonymised/ delinked ☐

	Yes	No	NA
ii. Confidential handling of data by staff			
7. Use of biological/ hazardous materials	Yes	No	NA
i. Use of fetal tissue or abortus			
ii. Use of organs or body fluids	Yes	No	NA
iii. Use of recombinant/gene therapy	Yes	No	NA

If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?	Yes	No	NA
iv. Use of pre-existing/stored/left over samples	Yes	No	NA
v. Collection for banking/future research	Yes	No	NA
vi. Use of ionising radiation/radioisotopes **If yes,** has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No	NA
vii. Use of Infectious/biohazardous specimens	Yes	No	NA
viii. Proper disposal of material	Yes	No	NA
ix. Will any sample collected from the patients be sent abroad?	Yes	No	NA

If Yes, justify with details of collaborators:

a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. ☐
If so, reasons…

Informed Consent
Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes ☐ No ☐

Type of consent planned
*Written/Signed ☐ Oral/Verbal ☐ Audio-visual

In case of a minor children
Verbal assent from o minor (7-12 yrs)along with parental consent
Written assent from o minor (13-18 yrs) along with parental consent

List of languages in which translation is done

Details of number of consent or/assent to be obtained in the study

i.: Tick the included elements in the Consent form

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	☐
Compensation for study related injury	☐	eg. genetic basis for drug development	☐
Translated in local language		Need to recontact	

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

8. Payment/Compensation

Will you provide any form of payment/compensation to the participants as a result of their participation?	Yes	No
Ye yes, please give details of the payment/compensation		

9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits:		
ii. Is there physical / social / psychological risk / discomfort?	Yes	No

If Yes, Minimal or no risk ☐
More than minimum risk ☐
High risk ☐

In case if risks are involved, mention the risks and risk addressing mechanism:

Risk

Risk addressal mechanism

ii.Is there a potetial benefit ? a) to the subject ☐ No benefit ☐ Direct benefit ☐ Indirect benefit ☐ b) to the society ☐ No benefit ☐ Direct benefit ☐ Indirect benefit ☐ c) for improvement in knowledge ☐ No benefit ☐ Direct benefit ☐ Indirect benefit ☐		
Mention the benefits:		
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 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		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to: Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long? ☐☐	Yes	No

12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No

SECTION E: CHECK LIST AND DECLARATION			
Cover letter	**Yes**	**No**	**NA**
Copy of filled-in and duly signed IRB Form (4 copies)	**Yes**	**No**	**NA**
Project proposal – 4 Copies	**Yes**	**No**	**NA**
Short bio of the invigilators	**Yes**	**No**	**NA**
Curriculum Vitae of Investigators in prescribed format	**Yes**	**No**	**NA**
In case of collaborative research, attach the MOU with the collaborating organization	**Yes**	**No**	**NA**
Format of review type	**Yes**	**No**	**NA**
Participant information sheet-cum-Informed Consent form, (if multiple respondents, consent should be taken from each respondent)	**Yes**	**No**	**NA**
Informed Assent form (If applicable)	**Yes**	**No**	**NA**
Investigator self-declaration form	**Yes**	**No**	**NA**
Questionnaire and/or Copy of clinical trial protocol and/or interview guidelines	**Yes**	**No**	**NA**
Investigator's brochure for recruiting subjects	**Yes**	**No**	**NA**

Copy of advertisements/Information brochures	**Yes**	**No**	**NA**
Institutional Animal Ethics Committee clearance	**Yes**	**No**	**NA**
Any other specify	**Yes**	**No**	**NA**
CPCSEA clearance, if any	**Yes**	**No**	**NA**
HMSC/DCGI/DBT/BARC clearance if obtained	**Yes**	**No**	**NA**
Survey Protocol on COVID-related Measures	**Yes**	**No**	**NA**

Date: Principal Investigator
Place:

Annexure 2: CV format for Investigators

INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES	
Deemed-to-Be-University B. S. Devashi Marg (Govandi Station Road) Deonar, Mumbai, Maharashtra 400088, https://www.iipsindia.ac.in/	**IIPS-IRB CV Format for Investigators**

Format Curriculum Vitae for Investigators

Name:	
Present affiliation *(Job title, department, and organisation)***:**	
Address *(Full work address)***:**	
Telephone number:	**Email address:**
Qualifications:	
Previous and other affiliations *(Include previous affiliations in the last 5 years*	
Projects undertaken in the last five years:	
Relevant research training/experience in the area:	

Attended Ethical Training (if any):	
Relevant Publications *(Give references to all relevant publications in the last five years)***:**	
Signature	**Date:** Click here to enter a date.

Annexure 3: Expedited Review

INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES

Deemed-to-Be-University
B. S. Devashi Marg (Govandi Station Road)
Deonar, Mumbai, Maharashtra 400088,
https://www.iipsindia.ac.in/

IIPS-IRB Expedited Review Form

Title of study:

Principal Investigator (Name, Designation, and Affiliation):

1. Choose reasons why expedited review from EC is requested[1]?	
i. Involve non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples	☐
ii. Involve clinical documentation materials that are non-identifiable (data, documents, records).	☐
iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s))	☐
iv. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals	☐
v. Minor deviations from originally approved research causing no risk or minimal risk	☐
vi. Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee.	☐
vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modification in the study proposal through full committee meeting/ expedited review depending on the importance of local consent related issues involved specific to the centre.	☐
viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017).	☐
ix. Any other (please specify)	☐
2. Is waiver of consent being requested ?	Yes ☐ No ☐
3. Does the research involve vulnerable person[2]? If Yes give details (attach a separate sheet):	Yes ☐ No ☐

Signature of PI:

Comments of Project Cell:

Signature of Convener:

[1]*Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*
[2]*For details, refer to application for initial review, Section-C, 5(b)*
[*]*In case this is first submission, leave it blank*

Annexure 4: Exemption from Review

INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES	
Deemed-to-Be-University B. S. Devashi Marg (Govandi Station Road) Deonar, Mumbai, Maharashtra 400088, https://www.iipsindia.ac.in/	**IIPS-IRB Exemption from Review Form**

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

4. Choose reasons why exemption from ethics review is requested[1,2]?	
x. Research on data in the public domain/ systematic reviews or meta-analyses	☐
xi. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person	☐
xii. Quality control and quality assurance audits in the institution)	☐
xiii. Comparison among instructional techniques, curricula, or classroom management methods	☐
xiv. Consumer acceptance studies related to taste and food quality	☐
xv. Public health programmes by government agencies	☐
xvi. Any other (please specify in 100 words)	☐

Signature of PI:

Comments of Project Cell:

Signature of Convener:

1 Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2. 2 Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)

**In case this is first submission, leave it blank*

Annexure 5: Informed Assent form and guidelines

General Guidelines

[*Title of your Institute*]

Informed Assent Form (Respondents under age 18)

[Informed assent form should be on the Institute's letterhead]

Assent refers to agreeing or approving after thoughtful consideration an idea or suggestion to participate in research by a young person below the age of 18 years, who is old enough to understand the implications of any proposed research but not legally eligible to give consent. The assent has to be corroborated with the informed consent of the parent.

Obtaining Informed Assent from Children or Minors Parents, legal guardians, or a legally authorized official must sign consent forms permitting children or minors to participate in research projects. In addition, children and minors are required to sign an Assent Form.

The content of an assent form for children participating in research should be tailored to their age and understanding. It should be written in simple, clear language that aligns with their cognitive, social, and emotional development. Here's a breakdown of key points to include:

Key components to include are:

1. **Explanation of the Study (Benefit & Purpose)**:
    a. briefly explain the research project and how it might benefit children like them In a child-friendly way. Mention the activities involved in the study, including any potential discomfort the child might experience.
2. **Study Procedures and Potential Discomfort:**
    a. Describe the activities involved in the study, using simple language and avoiding medical jargon.
    b. Mention any potential discomfort the child might experience and assure them it will be minimized.
3. **Right to Ask Questions and Contact Information:**
    a. Emphasize that the child can ask questions about the research at any time.
    b. Provide contact information for a person the child can reach with questions or concerns (e.g., researcher, parent liaison).
4. **Voluntary Participation and Confidentiality:**
    a. Clearly state that the child's participation is voluntary and they can refuse to participate or withdraw at any point without impacting their treatment or care..
    b. Assure them that refusing will not affect their treatment or care at the center.
5. **Consent and Contact Information**:
    a. Provide contact information for a person the child can reach with questions or concerns.

Sample:

[*Project Title*:]

My name is [*Your Name*], and I'm here to talk to you about a study we're doing about [*Project Title and Brief description of the study in child-friendly language*].

Your parent(s)/guardian(s) have already given their permission for you to participate, but it's completely up to you if you want to be part of it [*explain the voluntary nature of participation and right not to participate and withdraw*]

You may feel some inconvenience because of the time and effort to be a participant. You may also find some questions that we ask to be upsetting or may feel embarrassed to answer them [*mention any potential discomfort in a gentle way*].

You do not have to respond to any question that makes you uncomfortable and you may stop the interview at any time and nothing will happen. There are no direct benefits to participating in the study,

although you will help us understand what children like you want or need.
Your participation is entirely voluntary and you can stop the interview at any point of time even after having agreed to participate. If you decide not to participate it will not affect any benefits to which you are entitled. I want to assure you that the information you provide during the study will be kept private and confidential.
If you have any question, please feel free to ask them to me. Or you can also contact the Project PI on the following address. [*Address questions of the child regarding the survey if any*]

Principal Investigator: [Name, Affiliation, Office, Mobile, Email Address]
[Principal Investigator and Contact Information]

Do you agree to participate in this survey? [*Verification of child's consent*]
Tick the answer:

1. *Consent given along with signature/ thumb impression*
2. *Consent given but without signature/thumb impression*
3. *Consent Refused*

[Interviewer's Declaration]
I confirm that the individual has given consent freely. *I have taken consent from parents (assent from in case of minor) before the interview*

Interviewer's Name and signature: _____ Date: ___ / ___ / ___

Annexure 6 : Informed Consent form and guidelines

Guidelines for the Informed Consent

An informed consent form must include the following:

1. Obtaining an Informed Consent is not simply obtaining a signature on a prescribed format rather, it is a process of sharing information and addressing questions and concerns of the participant.
2. It is based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research.
3. Participants must then give their consent to participate on an informed consent form developed specifically for the research project.
4. There are very few research situations where a participant's signature on informed consent is not required. However, permission from IRB is always required for waving off of the signature.
5. The informed consent form should be submitted in English as well as in local language(s).
6. The goal and objective of research in simple jargon-free language. The language should not only be scientifically accurate and simple, but should also be sensitive to the social and cultural context of the participant.
7. Informed consent is a continuous process involving three main components – a) providing relevant information to potential participants, b) ensuring the competence of the individual, ensuring the information is easily comprehended by the participants and c) ensuring voluntariness.

Annexure 6: Informed Consent form and guidelines

Part - A

INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES	
Deemed-to-Be-University B. S. Devashi Marg (Govandi Station Road) Deonar, Mumbai, Maharashtra 400088, https://www.iipsindia.ac.in/	**IIPS-IRB Informed Consent Form**

[Project Title:]

1. [Introduction]

Greetings…. Self-introduction
Statement mentioning that it is research

2. [Purpose of Your Study]

- Clear the research objectives and outcome of the study
- [Respondent's Role]-Explain the procedure to participate in the interview/survey. Explanation of all the research tools employed. Reasons or methods for inclusion/exclusion of the particular group or individual(s) in the community or in any other settings, for participation in the survey should be briefed.
- Detailed description of the methodology
- [Time]- Approx. estimated time to complete the survey
    - *The interview will take approximately ------mins to complete.*

3. [Risks or Benefits]-

- Risks: [Describe any potential risks/discomfort/inconvenience associated with participation.]
    - *You may feel some inconvenience because of the time and effort to be a participant. In case of sensitive surveys, including questions on You may also find some questions that we ask to be upsetting or may feel embarrassed to answer them. You do not have to respond to any question that makes you uncomfortable and you may stop the interview at any time and nothing will happen.*

- Benefits: [Explain any potential benefits to participants or community.]
    - *There are no direct benefits to participating in the study, although you will help us understand what children like you want or need*

4. [Privacy/Confidentiality/Data Security]

- It is necessary to maintain the privacy and confidentiality of participants at all stages.
- The extent of privacy, anonymity, and confidentiality that will be provided to participants
    - *The information shared by you will be kept confidential and will not be shared with anyone, and will be used only for research purposes.*
    -
- [Data Sharing- Data collected will be completely anonymized/partially anonymized]
    - *The data will only be used for research and planning purposes without any personal identification.*

  Suppose in the case of Indirect Identifiers, you may give:
    - *All the information you provide will be strictly confidential, and your name will not appear on the questionnaire. Instead, your questionnaire will contain an identification number that is known only by the principal investigator of this study.*
    - *No one including your family members, friends, or other members of the community will ever know that you have not participated in the survey and no one will know what answers you gave since we do not collect information about your name etc.*

- [Information on any follow-ups of survey if any]
    - *The survey team may also re-contact you if it is necessary to complete the information in the survey.*

- [Voluntary nature of participation and Right not to participate and withdraw]
    - *Your participation is voluntary. You may refuse to participate or may discontinue your participation at any time during the survey. You can also choose not to answer any questions.*

- [Importance of the response/survey and future use of the information]
    - *Your responses are very important to us and the community, as these answers will represent many other people. This is an important study and I hope you will participate fully.*

5. [Contact information]

We will leave the necessary contact information with you. If you have any questions or concerns about this study, please contact on the address given below.

6. [Address questions of the Respondent regarding the survey if any]

- Do you have any questions?
    - *Should you have any question about the survey please feel free to ask me or contact the concerned authority.*

[Principal Investigator and Contact Information]

Principal Investigator: [Name, Affiliation, Office, Mobile, Email Address]

7. [Consent] Respondent's willingness to participate in the study

- *Do* you *agree to participate in this survey?*

[Verification of consent]

Tick the answer:

1. Consent is given along with signature/ thumb impression
2. Consent is given but without signature/thumb impression
3. Consent Refused

[Interviwer's Declaration]

I have informed the respondent about the project, risk and benefit and also confidentially risk taken consent from the respondent before the interview.

Interviewer's Name: _____ *Date:* ___ / ___ / ___

Annexure 6: Informed Consent form and guidelines

Part - B

INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES	
Deemed-to-Be-University B. S. Devashi Marg (Govandi Station Road) Deonar, Mumbai, Maharashtra 400088, https://www.iipsindia.ac.in/	**IIPS-IRB Informed Consent Form**

Informed Consent Form

I, _____, have read the Participant Information Sheet for the above-mentioned project. The information provided in the sheet regarding the nature, purpose, safety, potential risks/benefits, and the expected duration of the study, as well as other relevant details, including my role as a study participant, has been explained to me in a language that I understand.

I confirm that:

- I have had the opportunity to ask questions, and all my queries have been answered to my satisfaction.
- I understand that my participation in this research study is entirely voluntary, and I have the right to withdraw from the study at any point without giving any reason and without affecting my current or future medical treatment or relationship with the researchers.
- I understand the risk & benefits of participating in this study.
- I understand that refusing to participate or withdrawing will not result in any penalty or loss of benefits to which I am entitled.
- I understand that my personal information and data collected during this study will be kept confidential. Only the researchers involved in the study, the sponsoring agencies, regulatory authorities, and IRB may access my records if necessary, for monitoring and auditing the study in line with the ethical guidelines.
- I understand that the data will be anonymized for any future use, and my identity will not be revealed in any reports or publications that come out of this research.

By signing this consent form, I willingly agree to participate in this study. I understand that I can withdraw at any time without giving a reason and without any loss of benefit.

For participants with limited or non-readers:
I, [Witness Name], have witnessed the consent procedure of the study participant. The participant had the opportunity to ask questions, and I confirm that the individual has given consent freely and voluntarily after understanding the study's purpose and their role in it.

Name of the Participant/Guardian: _____

Signature/Thumb Impression of the Participant/Guardian: _____

Witness (for non-readers): _____
(Signature and Name)

Name of the Person Administering the Consent: _____

Signature of the Person Administering the Consent: _____
Date: _____

Principal Investigator (PI): _____
Contact Information: [Insert PI's Contact Details]

Co-Principal Investigator (Co-PI): _____
Contact Information: [Insert Co-PI's Contact Details]

Note: All parties signing the consent form must date their own signature

Annexure 7: Self Declaration Form

Part A

INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES	
Deemed-to-Be-University B. S. Devashi Marg (Govandi Station Road) Deonar, Mumbai, Maharashtra 400088, https://www.iipsindia.ac.in/	**IIPS-IRB Self Declaration Form**

DECLARATION BY THE PRINCIPAL INVESTIGATOR

Study Title: _____

I hereby declare that:

1. Voluntary written consent of the human subject will be obtained.
2. In case of children and mentally handicapped subjects-voluntary written informed consent of the parents/guardians will be obtained.
3. The probable risk involved in the project will be explained in full details to the subjects/parents/guardians.
4. Subjects/parents/guardians will be at liberty to opt out of the project at any time.
5. I will terminate the study at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgement required for me that continuation of the experiment is likely to result in injury, disability of death to the experimental subject.

Date: _____

(Signature of Principal Investigator)
Deptt._____

Annexure 7 : Self Declaration Form

Part B

INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES

Deemed-to-Be-University
B. S. Devashi Marg (Govandi Station Road)
Deonar, Mumbai, Maharashtra 400088,
https://www.iipsindia.ac.in/

IIPS-IRB Self Declaration Form

(DECLARATION BY THE PRINCIPAL INVESTIGATOR/DIRECTOR)

Study Title: _____

1. Is The Department/University ready to undertake the responsibility of the human subjects in case of injury? If yes, then will it include — Yes/No/NA

- Transportation charges — Yes/No/NA
- Hospitalization charges — Yes/No/NA

2. Do you think that the study is so designed that they would yield meaningful results that could not be obtained by the other method? — Yes/No/NA

3. Do you think that the animal experiments carried put support the need for clinical experimentation? — Yes/No/NA

4. Do you think that the study would be conducted in a manner to avoid all unnecessary physical and mental suffering and injury? — Yes/No/NA

5. Do you think the experiments have been planned in a manner so that the degree of risk to be taken would never exceed that determined by the humanitarian importance of the problem to be solved by the experiment? — Yes/No/NA

6. Do you think that proper preparations would be made and adequate facilities provided to protect the study subject against even remote possibilities of injury, Disability or death; — Yes/No/NA

7. Do you think that safeguards have been taken to see that the research would be conducted only by scientifically qualified persons who possess the requisite competence, experience and qualities to carry out the research? — Yes/No/NA

Date:

(Signature of Principal Investigator)

(Signature of Director)

Annexure 8 : IIPS-IRB Certificate

अन्तर्राष्ट्रीय जनसंख्या विज्ञान संस्थान
(विश्वविद्यालय समतुल्य)*
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार का स्वायत्त संगठन
गोवंडी स्टेशन रोड, देवनार, मुम्बई- 400 088. भारत

(स्थापना/ Established in 1956)
बेहतर भविष्य के लिए क्षमता निर्माण
Capacity Building for a Better Future

Sr. No.: /

International Institute for Population Sciences
(Deemed University)*
An Autonomous Organization of Ministry of Health & Family Welfare, Govt. of India
Govandi Station Road, Deonar, Mumbai -400 088. INDIA

No. /IIPS/PSC-54/IRB/
Date:

Institutional Review Board
(IRB00013212)

Project title**:**	
Name & Address of Institution:	
Principal Investigator Name: Contact Number: E-mail ID:	Name of Co- PI/s:
Collaborators' Name, Address, Contact. No. & Email:	Sponsor:
Review Status: New Review/ Revised Review	
The following item [√] have been received and reviewed in connection with the above study to be conducted by the above investigator. [ ] Participant Information Sheet [ ] Study Protocol / Synopsis [ ] Summary of Change Document (in case of a revision) [ ] Informed Consent Form [ ] Informed Assent Form (in case minors are involved) [ ] Investigators' CVs And have been [√] [ ] Approved [ ] Conditionally approved (identify item and specify modification below or in accompanying letter) [ ] Rejected (identify item and specify reasons below or in accompanying letter)	
Comments (if any):	
Date of Approval:	
Please note: - **Inform IRB immediately in case of any adverse events and serious adverse events.**	

- **Inform IRB in case of any change of study procedure, site and investigator.** - **Members of IRB have right to monitor the pretesting procedure with prior intimation.** - **Members of IRB have right to monitor the field procedure with prior intimation.**	
Convener **IRB Committee**	**Chairperson** **IRB Committee**

Annexure 9: Audit and Inspection Checklist

1. Date of letter of communication regarding audit/inspection
2. Date(s) agreed upon for the audit/inspection
3. Ensure IRB-IS members and staff have been informed about the date(s) and time
4. Ensure availability of IRB-IS related information (mandate, terms of reference, organization chart) in print form in the IRB office
5. Availability of latest signed SOPs in print and/or electronic form in the IRB office
6. Review SOPs and note any omissions or deviations with reasons
7. Availability of all national and international ethics guidelines and regulations in print and/or electronic form
8. Review ongoing and completed research study files for signed documents, noting any missing/incomplete documents and actions taken
9. Ensure availability of documents regarding list of members, tenure, appointment details, CVs, and training of IRB members
10. Ensure documents regarding staff appointments, CVs, and training of IRB members are available
11. Ensure security measures for the electronic database and office records are in place
12. Confirm proper maintenance, retrieval, storage, archival, and tracking of study files per SOPs
13. Confirm proper labelling and indexing of study files and storage cabinets
14. Designate members to communicate with auditors/inspectors, be available for audit, prepare action plan, and conduct follow-up audit (if applicable)
15. Report audit findings and inspection report at the full board IRB-IS meeting
16. Arrange for meeting venue, catering, accommodation, and travel for the visit if necessary