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

Established in 1956 under the joint sponsorship of the Sir Dorabji Tata Trust, the Government of India, and the United Nations, the International Institute for Population Sciences (IIPS) has emerged as a premier institution for teaching, training, and research in Population Studies, serving developing countries across the Asia-Pacific region. Among the regional population centres, IIPS holds a distinctive position as the first institution of its kind and serves a larger population base than any other regional centre. On 19 August 1985, the Ministry of Human Resource Development, Government of India, conferred upon IIPS the status of a "Deemed to be University" under Section 3 of the UGC Act, 1956, enabling the expansion of its academic and research activities. The Institute functions under the administrative control of the Ministry of Health and Family Welfare, Government of India.

In addition to its academic programmes, IIPS conducts extensive research on population dynamics and public health. Its research focuses on the interrelationships among key demographic processes—fertility, mortality, and migration—and their social, economic, environmental, and health determinants. The Institute also undertakes large-scale national surveys, programme evaluations, and policy-relevant studies. Its research activities are supported by the Ministry of Health and Family Welfare, State Governments, international organizations such as the United Nations Population Fund (UNFPA), the World Health Organization (WHO), the International Labour Organization (ILO), the World Bank, and various national and international agencies.

Ethical approval is mandatory for all research projects involving human participants, biological samples, or anonymized data and medical records. Such approval ensures that research is conducted in accordance with established ethical principles and that the rights, dignity, safety, and well-being of participants are protected throughout the research process.

IIPS is firmly committed to maintaining the highest ethical standards in research. The Standard Operating Procedures (SOPs) of the IIPS Institutional Review Board (IIPS-IRB) have been developed in accordance with the ethical guidelines of the Indian Council of Medical Research (ICMR) and the World Health Organisation (WHO). This document is organized into four broad sections.

This document outlines the structure, functions, and key features of the IIPS-IRB; describes the procedures for submission, review, and approval of research proposals; presents guidelines and ethical considerations specific to social science research and details the rules and procedures relating to audits, inspections, and compliance monitoring.

Section – A: Features of Institutional Review Board (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: IRBs are expected to assess proposals on scientific soundness and adherence to ethical principles. IRB aims 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 support the formation and instruction of a research community receptive to regional health care needs.
- To ensure transparency in the research process by reviewing informed consent documents
- To ensure technical rigour of research proposals in a scientifically sound way

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: -

- A Chairperson of eminence, with extensive research experience in fields relevant to the research undertaken by the Institute, high professional repute, demonstrated integrity and strong training in research ethics.
- At least two social scientists or development or behavioural researcher with significant knowledge in behavioural, economic and social sciences or demographic research.
- One or two persons from the basic medical science or public health background.
- One legal expert or retired judge
- One representative of a non-governmental agency and community
- Layperson or community worker
- Convener-cum-Member Secretary- a faculty member from the Institute with an understanding of the Institute's research and administration
- One internal faculty

All members are expected to have training in research ethics.

An observer may be nominated to observe the functioning and modus operandi of the IRB before taking over the responsibilities of the Convener cum-Member Secretary in a future committee.

An IRB Secretariat (or IRB Secretariat Office) is the administrative unit that supports the functioning of the Committee.

Typical responsibilities of the IRB Secretariat include:

- Providing administrative support to the Convener cum-Member Secretary and IRB members.
- Receiving and processing research proposals submitted for ethical review.
- Screening applications for completeness before they are placed before the IRB.
- Coordinating IRB meetings and preparing agendas.
- Maintaining records, minutes, and correspondence related to IRB activities.
- Communicating IRB decisions, queries, and recommendations to investigators.
- Tracking protocol amendments, continuing reviews, adverse event reports, and study closures.
- Ensuring compliance with institutional and regulatory requirements.
- Coordinating training activities for IRB members at periodic intervals

c) Criteria for Selection of Members

- **Chairperson:** The Chairperson must be an 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 1year of prior experience serving on an ethics committee. The Chairperson shall be responsible for decision-making processes. The independent status is critical for the integrity of the IRB's operations. In his/her absence, an alternate member (non- affiliated to IIPS), appointed by the Chairperson may preside over the meeting. He/she will also intervene, when necessary, to communicate the IRB's concerns to the Principal Investigators.
- Social scientists or development or behavioural researcher **:** The scientist/researcher 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.
- **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.
- **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.
- **NGO Representative :** 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.

- **Layperson or community person:** S/he shall represent the interests of patients, participants, and the community by raising ethical, social, and cultural concerns and assessing any societal implications of the research.
- **Convener-cum-Member Secretary:** The Convener-cum-Member Secretary must be from IIPS with expertise in ethics, research, and administrative functions. His/her responsibility is to ensure the researcher's welfare. S/he assisted by the IRB secretariat, must maintain IRB records, schedule meetings, and ensure compliance with the SOP.

d) Tenure and Terms of Appointment

The IIPS IRB committee shall be appointed by the Director of IIPS in consultation with the internal members. New members may be recommended by existing IRB committee, but their appointment must be formalized by the Director. The Director has the authority to approve or reject proposed members based on their qualifications and the needs of the IRB. 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 nine (9) months. 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 regularly (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

- **Training for New Members:** All newly appointed members must participate in an initial discussion before actively participating in IRB meetings. This discussion 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. If a new member lacks a certification in research ethics or GCP, they will be required to obtain this certification within nine months. The IRB Secretariat must document and file the completion of training upon receipt of the certificate from the IRB committee member.
- **Training for Existing Members:** Existing members of the IRB are expected to participate in training sessions at least once every two years to stay updated on the latest developments in research ethics and IRB operations. Members can also receive training whenever there are significant updates to national regulations, international guidelines, or changes to the IRB's SOPs.
- **Documentation of Training:** All training, whether for new or existing members, must be documented upon receipt of the certificate from the IRB committee member. This includes attendance records (wherever applicable), certificate/s, and a brief description of the training content. The IRB secretariat is responsible for maintaining these records.
- **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 can 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-cum-Member Secretary: The Convener-cum-Member Secretary hold a critical operational role in ensuring that the IRB functions smoothly and in compliance with all relevant standards and his/ her duties include:

- **Administrative Responsibilities:** The Convener-cum-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:** S/he 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. Records need to be kept at least 3 years after the completion or termination of the research.
- **Communication with Researchers:** S/he 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-cum-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. S/he must ensure periodic review of ongoing research projects to verify compliance.

- **Ensuring Quorum and Timely Meetings: S/he** 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: S/he** 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-cum-Member Secretary to issue the certificate within two weeks of the IRB final 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 periodic 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 honorarium as per the IIPS-approved rule.

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

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

- When a regular member completes his/her tenure.
- A regular member who fails to attend three (3) consecutive IRB meetings may be subject to removal, as decided by the Director of IIPS in consultation with internal members. If a regular member resigns or drops out before the tenure is completed.

- If the volume of proposals and frequency of review demands the appointment of new members.

- **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.
- **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 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 nine (9) 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 Convener-cum-Member Secretary.

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. If the quorum is not met, the meeting cannot proceed, and any decisions made will be invalid. The IRB Secretariat 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 his/her absence, an alternate member (non-affiliated to IIPS), appointed by the Chairperson may preside. The acting Chairperson must ensure that all decisions are made in accordance with ethical and procedural standards.

Procedure for Resignation, Replacement, or Removal of Members

- **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.

- **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/ Convener-cum-Member Secretary, 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.
- **Disqualification:** A member may be disqualified if they fail to attend three consecutive IRB meetings or are involved in misconduct, a breach of confidentiality, or conflicts of interest that undermine the functioning of the committee. Relocation, prolonged inability to perform assigned duties due to health or other circumstances, inadequate handling or undue delay in responding to online IRB-related activities, or any other situation that affects a member's ability to discharge their responsibilities effectively may result in a request for the member to resign from the IRB. In cases of serious misconduct, the Committee may recommend suspension or removal of the member, as appropriate.

The Institute Director/Vice Chancellor may replace a member under the above circumstances, in consultation with and with the consent of the Chair, convener cum-Member Secretary and/ or the internal members of the IRB.

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 verbally or in writing before 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 or convener or the senior-most member 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 prove evidence 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.

Conflict of Interest between PI/Researcher and IRB Member: If the Principal Investigator (PI) or any member of the research team has an actual, potential, or any other conflict of interest with an IRB member, the concerned PI shall document and disclose the conflict and request the Chair or Convener to recuse the IRB member from the review, discussion, and decision-making process related to the proposal. The recusal shall be documented in the meeting minutes.

i) Functions of IIPS IRB

The Institutional Review Board (IRB) generally convenes once every quarter or earlier, depending on the receipt of at least two applications requiring Full committee ethical review. The primary purpose of these meetings is to assess research proposals involving human participants and to ensure that appropriate measures for the protection of human subjects are incorporated into the study design.

Projects submitted for ethical review may be funded by the Institute or by external funding agencies and organizations. Eligibility for review includes projects in which a faculty member of the Institute is involved as a Principal Investigator (PI), Co-Principal Investigator (Co-PI), Consultant, or Collaborator. Research proposals originating from Population Research Centres (PRCs) may also be submitted for review by the 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.
- **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 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.

k) Risks and Benefits in research

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.

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

Risks in social- behavioural science and population-based health studies:

Type of Risk	Definition/Description with Social Science Examples
Less than minimal risk	The probability of harm or discomfort anticipated in the research is nil or not expected. Examples include research using fully anonymized or non-identifiable secondary data, publicly available datasets, aggregate administrative data, systematic reviews/meta-analyses, analysis of census data, and research based solely on publicly available documents or records.
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 the general population. In social science research, examples include routine surveys or interviews on non-sensitive topics, collection of demographic and socioeconomic information, observational studies in public settings where individuals are not identified, routine educational or workplace assessments, and interviews involving general health, family, migration, employment, or living conditions where disclosure is unlikely to result in harm.

Type of Risk	Definition/Description with Social Science Examples
Minor increase over minimal risk or Low risk	The increment in the probability of harm or discomfort is only slightly greater than the minimal-risk threshold. In social science research, this may include research involving sensitive or potentially stigmatizing topics, such as sexual and reproductive health, gender-based experiences, domestic violence, substance use, mental health, HIV status, experiences of discrimination, or illegal/legally sensitive behaviour; research involving children, adolescents, persons with impaired decision-making capacity, or other potentially vulnerable groups; collection of identifiable or potentially re-identifiable personal information; interviews that may cause temporary emotional distress; research on traumatic or highly personal experiences; and research where disclosure of information could result in social, psychological, reputational, familial, educational, or employment-related consequences. Appropriate safeguards for privacy, confidentiality, voluntary participation, and referral/support mechanisms should be considered.
More than minimal risk or High risk	The probability or magnitude of harm or discomfort anticipated in the research is substantially greater than that ordinarily encountered in daily life and may involve significant physical, psychological, social, legal, economic, or reputational risks. In social science research, examples may include research involving highly sensitive populations or circumstances where participation or disclosure could result in serious harm, such as studies of survivors of severe violence or trafficking where disclosure may create immediate safety concerns; research involving undocumented or otherwise legally vulnerable populations where disclosure could have serious legal consequences; research involving coercive or highly sensitive interventions; experimental manipulation likely to cause significant psychological distress; research requiring disclosure of highly sensitive information that could lead to serious social, familial, legal, or employment consequences; or studies involving substantial deception or concealment that could reasonably cause significant distress or harm. Such research requires enhanced risk-mitigation measures and careful IRB review.

m) Review Process for Research Involving Vulnerable Populations

- 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:
- 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.

- **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.
- **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.

- **Privacy and Confidentiality:** The Principal Investigator 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. Sharing raw data, including audio-visual material, should protect the confidentiality of the individual and research setting by sufficiently processing the data to mask identifiers before sharing.

- **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.

- **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 the nature of the research, the level of risk to participants, the characteristics of the study population, the procedures involved, and the sensitivity of the information collected, a research proposal may be considered under one of the following review categories: (A) Exemption from Review, (B) Expedited Review, or (C) Full Committee Review. The final determination of the appropriate review pathway shall be made by the IRB and shall not be based solely on the investigator's self-assessment.

1. Exemption from Review

Proposals that present less than minimal risk to participants and fall within categories specified by the IRB may be considered for exemption from review. Exemption is generally applicable to research where there is little or no possibility that participation or disclosure of information could result in physical, psychological, social, legal, economic, or reputational harm to individuals or communities.

Examples of situations in which exemption from review may be considered include:

- Research involving publicly available data, records, reports, census tables, published datasets, or other information where individuals cannot reasonably be identified.
- Research involving fully anonymized or irreversibly de-identified secondary data, where the investigator does not have access to identifiers or reasonable means of re-identification.
- Systematic reviews, meta-analyses, bibliometric studies, or analyses of published literature that do not involve interaction with human participants or access to identifiable private information.

- Analysis of publicly available demographic information, such as population size, age-sex distribution, fertility, mortality, migration, urbanization, or other aggregate indicators at the district, state, national, or international level.
- Observation of public behaviour where information is recorded without linked identifiers and disclosure of the information would not reasonably harm the interests, privacy, dignity, or welfare of the persons observed.
- Analysis of publicly available election, administrative, census, economic, environmental, or other aggregate statistics where individual participants are not identifiable.
- Quality-control and quality-assurance audits conducted within the institution where the primary purpose is institutional improvement and the activity does not involve research use of identifiable private information.
- Comparison of instructional techniques, curricula, classroom management methods, or other educational practices where the activity is undertaken as part of routine educational improvement and does not involve collection of sensitive identifiable information.
- Consumer acceptance studies related to taste, food quality, or similar non-sensitive characteristics where participation involves no more than ordinary daily-life activities and no sensitive personal information is collected.
- Secondary analysis of aggregate demographic or health indicators available through government reports, public statistical systems, or other openly accessible sources.

Exemption should not ordinarily be applied to research involving identifiable private information, sensitive personal information, interaction on highly sensitive topics, or procedures that may reasonably result in psychological, social, legal, economic, or reputational harm.

For studies seeking exemption, the investigator shall submit an exemption application rather than the full detailed application required for expedited or Full Committee Review. The application should provide sufficient information for the IRB to determine whether the study meets the criteria for exemption.

The submission should include:

- An exemption application/request letter.
- A brief study protocol or research proposal describing the objectives, design, data source, study population, and proposed analysis.
- Data collection tools, questionnaires, interview guides, or observation schedules, where applicable.
- A description of the source and nature of the data and whether any identifiers are available.
- A description of measures for maintaining confidentiality and data security, where applicable.
- Any other documents considered necessary by the IRB.

The IRB certificate for proposals determined to be exempt from review may be issued by the IRB Secretariat within 20 days of submission, following scrutiny by the Chairperson and the Convener-cum-Member Secretary. Where the Convener-cum-Member Secretary has a conflict of interest, the Chairperson shall consult the senior-most appropriate member of the Committee or an internal member and issue necessary directions to the IRB Secretariat to ensure timely processing.

An exemption determination does not exempt the investigator from complying with applicable requirements relating to confidentiality, privacy, data protection, responsible conduct of research, or institutional policies.

2. Expedited Review

Research proposals involving no more than minimal risk to participants may be considered for expedited review. Expedited review is intended for research in which the potential risks to participants are limited and do not exceed those ordinarily encountered in daily life or routine activities, or for minor changes to research that has already received IRB approval.

Once a complete application has been submitted for expedited review, the proposal should ordinarily be reviewed within 15 days.

The Chairperson, Convener-cum-Member Secretary, or member(s) of the IRB specifically designated by the Chairperson may undertake expedited review if full board meeting is not possible in a short notice.

Examples of research that may be considered for expedited review include:

- Routine social and demographic surveys involving non-sensitive information such as age, sex, education, occupation, household composition, migration history, fertility history, housing conditions, or access to public services.
- Interviews or questionnaires concerning general health, ageing, family structure, employment, education, migration, fertility, mortality, or living conditions where the anticipated risk is no more than minimal.
- Research involving routine collection of information on household socioeconomic characteristics, provided that appropriate safeguards for privacy and confidentiality are in place.
- Minor amendments to an approved research protocol that do not increase the risk to participants or materially change the objectives or methodology.
- Minor deviations from an originally approved protocol during the approved period, where such deviations do not affect participant safety, rights, welfare, or the scientific validity of the research.
- Continuing review of an approved proposal where there is no additional risk to participants or where the remaining activity is limited to data analysis.
- Revised proposals previously approved through Full Committee Review where the proposed revisions do not increase the level of risk.
- Minor amendments to questionnaires, interview schedules, recruitment materials, participant information sheets, or consent documents where such changes do not materially alter the risk-benefit assessment.
- Secondary analysis of identifiable data that has already been collected for research or non-research purposes, where the proposed analysis presents no more than minimal risk and adequate confidentiality safeguards are in place.
- Research involving data, documents, records, or specimens originally collected for non-research purposes, provided that the proposed use involves no more than minimal risk and appropriate privacy and confidentiality protections are maintained.
- Research involving non-invasive or routine procedures where the likelihood of significant adverse effects is negligible.
- Social or demographic research involving children, adolescents, older persons, or other potentially vulnerable groups may be considered for expedited review when the study presents no more than minimal risk and appropriate additional safeguards are in place. Vulnerability alone should not automatically require Full Committee Review.

Expedited review should not be used merely to shorten the review period for a proposal that otherwise requires Full Committee Review. If the reviewer(s) determine during expedited review that the research involves greater than minimal risk, substantial ethical concerns, significant vulnerability, or other issues requiring broader deliberation, the proposal shall be referred to the Full Committee.

In the event of a serious outbreak, disaster, or other public health emergency where urgent research is required and a convened Full Committee meeting cannot reasonably be constituted within the required timeframe, an expedited or emergency review mechanism may be used, subject to applicable institutional and regulatory requirements. Wherever feasible, prior written approval of the IRB shall be obtained before initiation of an intervention. Such research shall subsequently be presented to the Full Committee for review or ratification, as applicable.

For predictable emergencies or disasters, research protocols may be reviewed and approved in advance for implementation when the emergency or disaster occurs, provided that the protocol

clearly specifies the circumstances, procedures, participant safeguards, and conditions under which the research will be initiated.

If the Convener-cum-Member Secretary, Chairperson, or designated reviewer has a conflict of interest in a proposal, the concerned member shall not participate in its review or decision-making. The Chairperson shall issue appropriate directions to the IRB Secretariat to ensure that an alternative qualified reviewer is assigned and that the review is completed without unnecessary delay.

3. Full Committee Review

All research proposals involving more than minimal risk, or proposals that do not qualify for exemption or expedited review, shall be submitted for Full Committee Review.

Full Committee Review shall normally involve circulation of the proposal and relevant documents to the members of the IRB, presentation of the proposal before the Committee, detailed discussion of the ethical, scientific, social, and participant-related issues, and a documented decision of the Committee. The Committee may seek clarification or additional information from the investigator before arriving at its decision.

Examples of research that may require Full Committee Review include:

- Research involving more than minimal physical, psychological, social, legal, economic, or reputational risk.
- Research involving a minor increase over minimal risk where the nature of the research or potential consequences warrant consideration by the Full Committee.
- Research involving sensitive social or demographic issues where participation or disclosure may reasonably result in significant harm.
- Studies on experiences of domestic or gender-based violence, trafficking, severe discrimination, exploitation, or other traumatic experiences where participation may cause substantial psychological or social distress or create safety concerns.
- Research involving undocumented, stateless, trafficked, incarcerated, or otherwise legally vulnerable populations where disclosure of information could have serious legal or social consequences.
- Research involving highly sensitive information relating to sexual behaviour, reproductive health, HIV status, substance use, mental health, criminal or legally sensitive behaviour, or other information where disclosure could result in significant stigma, discrimination, family conflict, legal consequences, or loss of employment or social standing.
- Research involving substantial deception or concealment where the deception may materially affect participants' autonomy, psychological well-being, or ability to make an informed decision.
- Research involving interventions or procedures that present greater than minimal risk.
- Research involving significant manipulation of participants' behaviour or circumstances that may result in psychological or social harm.
- Research involving vulnerable populations where the nature, magnitude, or context of the risk requires Full Committee consideration. Vulnerability by itself should not automatically determine the review category.
- Research involving major amendments, major protocol deviations, or violations that may affect participant safety, rights, welfare, or the validity of the research.
- Research in which new information, serious adverse events, complaints, or other developments substantially alter the anticipated risk-benefit assessment.
- Research where the IRB determines that the proposal raises complex ethical, social, cultural, legal, or community-level concerns requiring consideration by the full membership of the Committee.

- Research involving emergency or disaster situations where the nature or urgency of the research requires Full Committee consideration, either through a scheduled or specially convened meeting.

Research involving vulnerable populations should not automatically be classified as requiring Full Committee Review solely because of the characteristics of the participants. For example, a routine, low-risk demographic survey among older persons or adolescents may qualify for expedited review where appropriate safeguards are in place. Conversely, a study involving adults from the general population may require Full Committee Review if it involves highly sensitive information or substantial potential for social, psychological, legal, or reputational harm.

o) Review of Amendments, Deviations and New Information

Any significant amendment to an approved protocol, including changes in study objectives, methodology, participant population, recruitment procedures, data collection methods, consent procedures, or risk profile, shall be submitted to the IRB for review before implementation, except where an immediate change is necessary to eliminate an apparent immediate hazard to participants.

Minor amendments that do not increase the level of risk may be considered through expedited review. Major amendments that alter the risk-benefit assessment or introduce significant new procedures or risks shall be referred to the Full Committee.

Major protocol deviations or violations, serious adverse events, participant complaints, or new information that may materially affect the safety, rights, or welfare of participants shall be reviewed by the IRB. Based on the revised risk-benefit assessment, the Committee may require modification of the protocol, additional safeguards, suspension, or termination of the research.

p) Authority to Determine the Appropriate Review Category

The determination of whether a proposal qualifies for exemption, expedited review, or Full Committee Review shall rest with the IRB or its duly authorized members in accordance with this SOP. Investigators may indicate the review category they believe is applicable at the time of submission, but the final determination shall be made by the IRB.

A proposal initially submitted for exemption or expedited review may be transferred to a higher level of review if the IRB determines that the nature or level of risk, the sensitivity of the information, the characteristics of the study population, or any other ethical consideration warrants such review.

Similarly, the level of review for continuing applications or amendments may be changed where new information or changes in the research alter the risk-benefit assessment.

Where required under institutional policy, decisions made through expedited or subcommittee review may be placed before the Full Committee for information or ratification. The Full Committee shall retain the authority to review, modify, suspend, or reverse such decisions where there are substantive concerns relating to the rights, safety, dignity, or welfare of research participants.

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 once every quarter or upon receipt of an adequate number of applications for reviewing project proposals (at least 2), 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 45 days ahead of the meeting schedule.

IIPS ethics committee evaluates a research proposal by assessing its scientific validity, participant welfare, and post-study integrity. They ensure the study design is methodologically sound and that the social benefits outweigh any physical, psychological, or social risks. Committees scrutinize the informed consent process for clarity and voluntariness, check for equitable participant selection, and review strict protocols for data privacy and confidentiality. They examine safeguards for vulnerable populations and any potential conflicts of interest to ensure the entire lifecycle of the project is transparent and accountable.

Process and Timeline for Review of Research Proposals

a) **Initial Administrative Screening**

The IRB Secretariat shall conduct an initial screening of the application within **two (2) weeks** of receipt to assess completeness of documentation and adherence to submission requirements.

b) **Technical Screening**

Following successful administrative screening, a detailed technical review shall be undertaken by designated internal members of the Committee within **one (1) week**.

c) **Assignment of Review**

Based on the nature and risk category of the proposal, the application shall be assigned for exempt, expedited, or full Committee review within **four (4) weeks** of receipt of a complete application.

d) **Full Committee Review**

Proposals requiring full Committee review shall be placed on the agenda of the next scheduled IRB meeting. The IRB shall ordinarily convene **three to four times annually**, or more frequently if required.

e) **Communication of Decision**

The IRB Secretariat shall communicate the Committee's decision, comments, or requests for modification to the Principal Investigator within **3 weeks for full committee review**.

f) **Revision and Resubmission of Proposals**

Principal Investigators (PIs) shall revise the proposal and associated documents in response to the comments provided by the IRB and submit a point-by-point response or rebuttal letter indicating the revisions made and the rationale for accepting or not accepting specific recommendations. Submission of a revised proposal does not automatically guarantee IRB approval. The revised proposal shall be re-evaluated by the full Committee. Ethical clearance and issuance of an approval certificate shall be granted only after the IRB is satisfied that all ethical concerns have been adequately addressed and the proposal receives the requisite approval of the Committee in accordance with quorum requirements. Any attempt to improperly influence the review process or the decisions of IRB members shall be reported to the Committee and dealt with in accordance with institutional policies and applicable regulations.

g) **Confidentiality of Proceedings and Communication of Decisions**

The minutes of all IRB meetings shall remain confidential and shall be maintained for official use only. To ensure transparency while preserving confidentiality, a brief summary of the meeting outcomes, will be uploaded to the IRB webpage. The Principal Investigator shall be informed of the Committee's decision and provided with anonymized reviewer comments and recommendations through official communication, ordinarily within two (2) weeks of the meeting.

h) **Issuance of Approval Certificate**

Upon approval of a proposal by the IRB, the Convener shall initiate the process for issuance of the ethical clearance certificate. The certificate shall be signed by the Chairperson or an authorized signatory designated by the Committee. The Convener shall also prepare and submit a status report of proposals reviewed and approved for updating the IRB webpage and institutional records. Once the IRB is satisfied that the study is in no way harmful to the subjects under study, IRB Convener cum Member Secretary provides Ethical Clearance Certificate, valid for the period of study specified, signed by the chairperson.

Average Timelines for Review and Approval

The timelines indicated below are approximate and may vary depending on the completeness of submissions, responsiveness of the Principal Investigator (PI), availability of reviewers, and scheduling of Committee meetings.

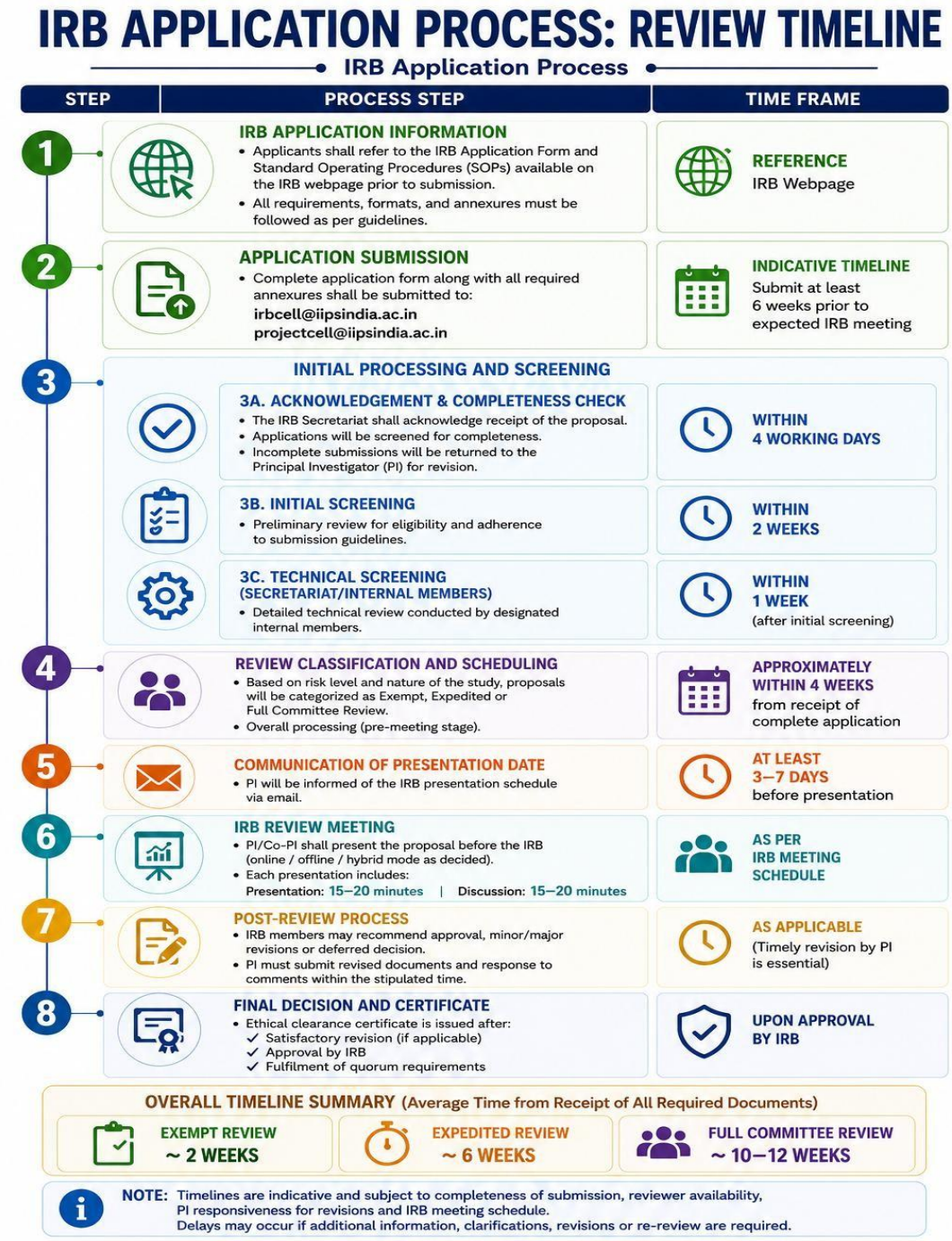
a) **Exempt Review:** The average time for processing and issuance of an exemption certificate is **approximately two (2) weeks** from the date of receipt of all required documents and determination of eligibility for exemption.
b) **Expedited Review:** The average time for expedited review is **approximately six (6) weeks** from the date of receipt of all required documents, subject to the availability of designated reviewers, timely submission of revisions by the PI (if required), and completion of all review requirements necessary for issuance of the approval certificate.
c) **Full Committee Review:** The average time for full Committee review is **approximately ten (10) to twelve (12) weeks** from the date of receipt of all required documents, subject to scheduling of the IRB meeting, review by the full Committee, timely submission of revisions by the PI (if required), fulfillment of quorum requirements, and approval by the Committee for issuance of the ethical clearance certificate.

The above timelines are indicative and do not constitute a guarantee of approval. Delays may occur if additional information, clarifications, revisions, or re-review are required.

IRB Review Timeline

Stage	Activity	Timeline
1	Submission of proposal and supporting documents	Day 0
2	Administrative screening by IRB Secretariat for completeness and adherence to submission guidelines	Within 2 weeks of submission
3	Technical screening by designated internal members	Within 1 week after administrative screening
4	Determination of review category (Exempt, Expedited, or Full Committee Review)	Within 4 weeks of receipt of the complete application
5A	Exempt Review	Average 2 weeks from receipt of all required documents
5B	Expedited Review	Average 6 weeks from receipt of all required documents, subject to availability of committee members and timely response from PI
5C	Full Committee Review	Average 10–12 weeks from receipt of all required documents, subject to meeting schedule, and timely response from PI
6	Communication of comments/decision to PI	Within 2–3 weeks of the review/Committee meeting
7	Submission of revisions and response letter by PI (if required)	As early as possible by PI
8	Review of revised submission	Depends on extent of revisions required
9	Issuance of Exemption/Approval Certificate	Upon fulfilment of review requirements, quorum requirements, and approval by the Committee
10	Upload of status report and update of IRB records/webpage	Within 1 week of certificate issuance

Note: The above timelines are indicative and assume submission of complete documentation. Delays may occur due to incomplete applications, requests for clarification, extensive revisions, reviewer availability, scheduling of Committee meetings, or other administrative requirements. Approval is not guaranteed and is contingent upon satisfactory ethical review and compliance with IRB requirements.



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 review type format (pdf), Proposal (pdf), Coordinator/s CV (pdf), Consent form, and Tools (pdf) to the Member Secretary, IIPS- IRB. All the documents to be compiled into a single consolidated PDF document as per annexure with index and page number in a specified sequence. 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 in participant selection, consent and data

Participant Selection: Describe the criteria for selecting participants and their right to withdraw from the study.

Justify why a specific group is chosen and how fairness is ensured in selection.
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.

- **No identifying information**, such as the respondent's name or address, should be recorded on the consent form, except for the respondent's signature, if they voluntarily choose to provide it. A respondent must not be coerced or compelled to sign the consent form if they do not wish to do so. However, every consent form must include a signed statement from the interviewer confirming that the contents of the consent form were explained to the respondent and that the respondent voluntarily agreed to participate in the interview.
- **Witness to the Consent Process:** A witness is not required for the informed consent process. PIs must not indicate that a witness will be present to observe the consent process or sign a statement confirming that they witnessed the consent process.

- **Consent for Re-approach:** If the study involves contacting or approaching the respondent again at a later stage, such as in a longitudinal study, consent for future re-approach must be explicitly obtained as part of the original consent process.
- **Audio/Video Recording:** If audio or video recording of the interview or other research activities is proposed, specific and explicit consent for such recording must be obtained from the respondent.
- **Research Involving Minors:** For studies involving minors, informed consent must be obtained from the parent or legal guardian, and assent must be obtained from the minor. Even where the parent or guardian has provided consent, the interview or research procedure must not proceed if the minor does not provide assent.

Data Security and Confidentiality: Outline how you will ensure data security, privacy, and confidentiality throughout the research process. Sharing raw data, including audio-visual material, should protect the confidentiality of the individual and research setting by sufficiently processing the data to mask identifiers before sharing

- **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: irbcell@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.
- The cover letter must include a clear and explicit statement affirming that data collection has not yet commenced.
- Include documents mentioned in the checklist should be submitted.
- All pages should be numbered.
- Proofread your application carefully before submission.

Don'ts:

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

c. Attachments: Checklist for attached documents:

- Cover letter
- Forwarding letter by the competent authority for Non-IIPS proposals
- Copy of filled-in and duly signed IRB Form
- Project proposal
- Brief description of the proposal
- Curriculum Vitae of Investigators in prescribed format
- In case of collaborative research, attach the MOU with the collaborating organization
- Format of review type
- Participant information sheet-cum-Informed Consent form, (if multiple respondents, consent should be taken from each respondent)
- Informed Assent form (If applicable)
- Investigator self-declaration form
- 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 of 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:

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

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

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

- 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.

- 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.

- The projects are to be presented before the IRB Committee, with the time equally divided between the presentation and the question-and-answer session.

- 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 behavior 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 behavior 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 behaviors may be discovered or observed. While researchers are not required to interrupt such behaviors to determine the truth. They must document these in the research findings and responsibly disseminate the findings for the larger social good.
- **Reporting Harmful Behavior:** researchers have duty to report patterns of harmful behaviors (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 behavioral 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 behavioral 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. Verbal consent is sufficient. However, for large surveys and sensitive studies, written consent of local authorities or state government is a must. 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. How long data will be kept **and what will happen to it afterward.** Sharing raw data, including audio-visual material, should protect the confidentiality of the individual and research setting by sufficiently processing the data to mask identifiers before sharing.

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.

- Informed consent is very often dynamic in nature and negotiable. When written consent may not be possible, other means could be used and documented.
- The IIPS-IRB may look at issues that pertain to the design involving researcher– participant relationships, informed consent process and conduct of the research.
- 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.

- On some occasions/in some observational research the IRB may approve waiver of consent, provided mechanisms for maintaining privacy and confidentiality are justified.
- 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.
- Sharing raw data and notes with repositories, researchers, peer communities, institutions, and funders is increasingly becoming a requirement for transparency in research.
- 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.
- 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) In-house Audit

The IIPS-IRB may conduct periodic in-house audits of its activities, records, and approved research studies to ensure continued compliance with applicable ethical guidelines, institutional policies, and the approved Standard Operating Procedures (SOPs).

- The IRB may periodically review the progress of approved studies until their completion through study progress reports, review of study files, or other appropriate monitoring mechanisms.
- The Convener-cum-Member Secretary, in consultation with the Chairperson, may identify studies, records, or IRB processes for internal audit based on the nature and risk of the research, compliance requirements, or any concerns identified during routine review.
- The audit shall include verification of relevant IRB records, including applications, review documents, minutes, correspondence, approval letters, continuing review reports, amendments, deviations, adverse event reports, and study closure reports, as applicable.
- The Chairperson shall designate the Convener-cum-Member Secretary and/or other IRB members to undertake the audit. The IRB Secretariat and Project Cell shall provide the necessary assistance and documentation.
- The audit findings shall be documented, and any deficiencies identified shall be communicated to the concerned person(s) or unit(s). Corrective and preventive actions (CAPA), along with a timeline for completion, shall be documented and monitored by the IRB.
- Where necessary, the Chairperson may direct a follow-up audit to assess whether the corrective actions have been effectively implemented.
- A comprehensive record of the audit, including the audit checklist, findings, corrective actions, and follow-up reports, shall be maintained by the IRB Secretariat in a dedicated audit file.
- An in-house audit shall ordinarily be conducted annually , if considered necessary by the Chairperson or the IRB.

b) Audit/Inspection by External Agency

An audit or inspection may be conducted by an authorized external agency or regulatory/government authority to assess the functioning of the IIPS-IRB and its compliance with applicable ethical, regulatory, and institutional requirements.

- External auditors/inspectors may review IRB documents, facilities, records, approved research studies, and other resources considered relevant to the audit or inspection.
- Auditors/inspectors shall ordinarily be representatives of the concerned government or regulatory institution/body with appropriate knowledge of applicable ICMR guidelines and other relevant ethical and regulatory requirements. A maximum of two auditors may be notified prior to finalization of the audit/inspection date, where applicable.

c) Notification and Preparation

- Upon receiving written or electronic communication regarding an external audit or inspection, the Convener-cum-Member Secretary shall promptly inform the Chairperson, relevant IRB members, and, where applicable, the Head of the Institution, indicating the proposed date, purpose, and scope of the audit/inspection.
- The Chairperson shall designate the Convener-cum-Member Secretary and/or other IRB members to coordinate the audit/inspection, with assistance from the IRB Secretariat and Project Cell.
- All relevant documents shall be reviewed, organized, and made readily accessible in accordance with the requirements communicated by the auditing/inspecting authority.
- Any incomplete or missing documentation identified during preparation shall be addressed appropriately, and the corrective action taken shall be documented.

d) Conduct of the Audit/Inspection

- The Chairperson, Convener-cum-Member Secretary, or designated IRB member(s) shall receive and accompany the auditors/inspectors to the designated meeting room. Relevant members and staff shall be available as required.
- At the beginning of the visit, the auditors/inspectors shall explain the purpose, scope, and requirements of the audit/inspection.
- The Chairperson, Convener-cum-Member Secretary, designated IRB members, and Secretariat staff shall respond to questions accurately, clearly, courteously, and transparently.
- Documents and information requested by the auditors/inspectors shall be provided promptly through the IRB Secretariat, subject to applicable confidentiality and institutional requirements.
- The Convener-cum-Member Secretary or designated IRB member shall document the observations, comments, recommendations, and deficiencies identified during the audit/inspection.

e) Corrective and Preventive Action

- Upon receipt of the formal audit/inspection report, the Convener-cum-Member Secretary and designated IRB members shall review the findings and recommendations and place them before the Chairperson for appropriate action.
- Where deficiencies are identified, a corrective and preventive action (CAPA) plan shall be prepared, specifying the corrective measures, responsible person(s), and timelines for completion.
- The action plan shall be communicated to the concerned auditing/inspecting authority, where required, after approval by the Chairperson.

- Where necessary, the Chairperson may direct an internal follow-up audit to assess the implementation and effectiveness of the corrective actions.
- The outcome of the follow-up audit shall be documented and reported to the Chairperson and, where applicable, communicated to the external auditing/inspecting authority.

f) Documentation and Record Keeping

- The IRB Secretariat shall maintain a dedicated audit/inspection file containing the notification, correspondence, audit/inspection agenda and checklist, documents submitted, observations, formal reports, corrective and preventive action plans, and follow-up reports.
- All records relating to external audits/inspections shall be maintained confidentially and retained in accordance with the IRB's record-retention requirements and applicable regulations.

g) Audit Schedule and Honorarium

- An external audit may be conducted annually or at such other intervals as required by the competent government or regulatory authority, or as approved by the Director/competent institutional authority.
- Where external auditors are appointed by the Institute, any honorarium or related expenses shall be paid in accordance with applicable Government of India and institutional rules.

h) Resolution of Legal Matters and Disputes

All legal matters and disputes arising out of or in connection with the functioning of the IIPS-IRB shall, in the first instance, be referred to the IIPS Institutional Review Board for appropriate consideration and resolution. If the matter remains unresolved within three months of receipt of the grievance, it shall be subject to the exclusive jurisdiction of the competent courts in Mumbai.

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

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

International Institute for Population Sciences

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IIPS-IRB Application Form

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 ☐ Revise ☐

SECTION A: ADMINISTRATIVE INFORMATION				
Project Investigators	**Name, Qualifications and Designation**	**Department and Organization Address and Contact Details**	**Roles and Responsibilities**	**Signature**
PI:				
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 the 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
Type of Study: (Tick √ / X)

Socio-Behavioural Science ☐ Clinical Single center ☐ Clinical Multi- centric ☐ Epidemiological and Public health ☐ Basic science ☐ Biological sample ☐	Retrospective ☐ Prospective ☐ Quantitative ☐ Qualitative ☐ Mixed method ☐	Cross sectional ☐ Longitudinal/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 ☐ Vaccines ☐

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? **If yes,** IND No:	Yes	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)	☐

vii.	Special group subjects	Yes ☐	No ☐

If yes in special subject group, tick the appropriate boxes

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

6. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐

Indirect Identifiers/coded ☐

Completely anonymized/ delinked ☐

ii. Confidential handling of data by staff	Yes	No	NA
7. Use of biological/ hazardous materials i. Use of fetal tissue or aborts	Yes	No	NA
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 ionizing radiation/radioisotopes	Yes	No	NA
If yes, has Bhabha 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 ☐

Note: If Oral/Verbal consent is proposed; the investigator shall indicate the justification for using verbal/oral consent and shall follow the approval and documentation requirements specified by the IIPS-IRB/EC.

In case of a minor children:

Verbal assent from of minor (7-12 yrs.) along with parental consent ☐

Written assent from of 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	☐	e.g. 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
If 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:

i. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No

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 analysed 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. iii. Is there a plan for interim analysis of data?	Yes	No

iv. 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 ☐ by any other company ☐	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**
Any other information:			

Date:

Place: **Principal Investigator**

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IIPS-IRB

CV Format for Investigators

Format Curriculum Vitae for Investigators

Name:	
Present affiliation *(Job title, department, and organization):*	
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.

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IIPS-IRB

Expedited Review

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:

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

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IIPS-IRB

Exemption from Review

Title of study:

Principal Investigator (Name, Designation, and Affiliation):

1. Choose reasons why exemption from ethics review is requested[1,2]?

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

Signature of PI:

Comments of Project Cell:

Signature of Convener:

i. *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*

ii. *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*

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.

No identifying information, such as the respondent's name, address, or other personal details, should be recorded on the consent form, except for the respondent's signature if they voluntarily choose to provide it. Respondents must not be coerced or compelled to sign the consent form if they do not wish to do so. However, every consent form must include a signed statement by the interviewer confirming that the contents of the consent form were explained to the respondent and that the respondent voluntarily agreed to participate in the interview.

Obtaining Informed Assent from Children or Minors Parents, legal guardians, or a legally authorized official must agree/ sign consent forms permitting children or minors to participate in research projects. In addition, children and minors are required to sign an Assent Form if they wish to. Where verbal/oral assent is obtained in younger children or in age-appropriate circumstances, the process should be documented in accordance with the approved procedure, and the parent/legal guardian's confirmation or counter signature should be obtained, wherever applicable. 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.

If the study involves re-approaching or contacting the respondent at a later stage, such as in a longitudinal study, the respondent's consent to be re-approached must be obtained explicitly as part of the original consent process.
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:

- **Yes,** I agree to take part in this study**.** ☐
- **No,** I do not want to take part in this study**.** ☐

Signature: Thumb Impression of Child/Adolescent (if applicable):
Date: / /

Note: Where written assent is not appropriate and verbal/oral assent is used, the same shall be obtained only in accordance with the approved procedure, after obtaining consent from the parent/legal guardian, and shall be documented by the person obtaining assent.

[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:* ___/ ___/ ___

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. No identifying information, such as the respondent's name, address, or other personal details, should be recorded on the consent form, except for the respondent's signature if they voluntarily choose to provide it.
5. Respondents must not be coerced or compelled to sign the consent form if they do not wish to do so. However, every consent form must include a signed statement by the interviewer confirming that the contents of the consent form were explained to the respondent and that the respondent voluntarily agreed to participate in the interview.
6. If the study involves re-approaching or contacting the respondent at a later stage, such as in a longitudinal study, the respondent's consent to be re-approached must be obtained explicitly as part of the original consent process.
7. Verbal/oral consent may be used with prior approval of the IIPS-IRB/EC. In such cases, the participant must still be provided with all essential information relating to the study, including its purpose, procedures, risks, benefits, confidentiality protections, and the voluntary nature of participation. Where verbal/oral consent is approved, the process shall be documented appropriately, including the date and time of consent, and signature of the interviewer. Verbal/oral consent shall not be adopted as a routine substitute for written informed consent.
8. There are 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.
9. The informed consent form should be submitted in English as well as in local language(s).
10. 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.
11. Informed consent is a continuous process involving three main components:
    providing relevant information to potential participants, ensuring the competence of the individual, ensuring the information is easily comprehended by the participants, and ensuring voluntariness.

Part - A

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IIPS-IRB

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 minutes 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 refi1se 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 given with signature. ☐
2. Consent given with thumb impression. ☐
3. Verbal/oral consent given . ☐
4. Consent refused. ☐

(Respondent's declaration)

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 b nm e 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 or verbally agreeing to participate in this study. I understand that I can withdraw at any time without giving a reason and without any loss of benefit.

[Interviewer'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 and signature:

Date: -----/-------/- -

If you have any questions about the study, please contact:

Contact Information:

Principal Investigator (Pl):
Name: _____Designation: _____
Institution: _____Phone: _____
Email: _____

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IIPS-IRB

IIPS-IRB: Informed Consent Form

Parent/Guardian Consent Form for Participation of a Minor in Research

(Sample)
Title of the Study: _____
Name of Principal Investigator: _____
Institution: _____
Study Identification No.: _____

1. Purpose of the Study
I have been informed about the purpose and objectives of the above-mentioned research study. The researcher has explained to me why my child is being invited to participate and what the study involves.

2. Procedures Involved
I understand the procedures that my child will be asked to undertake, including interviews, measurements, collection of information or biological samples, if applicable. I have been given an opportunity to ask questions and have received satisfactory answers.

3. Voluntary Participation
I understand that my child's participation is voluntary. I understand that I may refuse permission for my child to participate or withdraw my permission at any time, without giving a reason and without any penalty or loss of benefits to which my child is otherwise entitled.
I also understand that **my consent does not override my child's willingness to participate**. If my child does not wish to participate or does not provide assent, the research procedures involving my child will not be undertaken, except where specifically permitted by applicable ethical guidelines.

4. Risks and Benefits
The researcher has explained the possible risks, discomforts, and benefits associated with participation. I understand that reasonable measures will be taken to minimize any risks or discomfort to my child.

5. Confidentiality
I understand that information collected about my child will be kept confidential and will be used only for the purposes explained to me. Identifying information will not be disclosed in reports, publications, or presentations unless required by law or specifically authorized.

6. Audio/Video Recording
If applicable, I have been informed about the proposed audio/video recording of the research

activities. I understand the purpose of the recording and how it will be stored and used.

I give permission for audio/video recording:

☐ Yes ☐ No

7. **Future Contact/Re-approach**

If applicable, I have been informed that the researcher may need to contact my child again for follow-up or future stages of the study.

I give permission for my child to be re-approached for this study:

☐ Yes ☐ No

8. Questions and Concerns

I have been informed whom to contact if I have questions, concerns, or complaints regarding the study or my child's participation.

Name/Designation of Contact Person: _____

Contact Details: _____

9. Consent Statement

I confirm that:

- I have read, or the contents of this consent form have been explained to me in a language that I understand.
- I have had sufficient opportunity to ask questions and have received satisfactory answers.
- I understand the purpose, procedures, possible risks and benefits, and voluntary nature of the study.
- I understand that I may withdraw my permission for my child's participation at any time without penalty.
- I understand that my child will also be asked to provide **assent** in an age-appropriate manner before participating.
- I understand that if my child does not agree to participate or withdraws assent, the research procedure will not proceed, even if I have provided parental/guardian consent.

I voluntarily give permission for my child to participate in this research study.

Relationship to Child: _____

Signature/Thumb Impression/verbal agreement of Parent/Guardian: _____

Date: _____ **Place:** _____

10. Statement by the Researcher/Interviewer

I confirm that I have explained the purpose, procedures, potential risks and benefits, voluntary nature of participation, confidentiality provisions, and other relevant information regarding the study to the parent/legal guardian in a language that they understand. I have answered all questions to the best of my ability and confirm that the parent/legal guardian has voluntarily provided consent for the child's participation.

Name of Researcher/Interviewer: _____

Signature: _____ Date: _____

11. Child Assent

I confirm that the child has been provided with age-appropriate information about the study and has been given an opportunity to ask questions and express their willingness or unwillingness to participate. **Parent/guardian consent alone shall not be considered sufficient where the child does not provide assent, as required by the approved study protocol and applicable ethical requirements.**

Name of Researcher/Interviewer: _____

Signature: _____ Date: _____

Form Part – A

International Institute for Population Sciences

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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. If the study involves re-approaching or contacting the respondent at a later stage, such as in a longitudinal study, the respondent's consent to be re-approached must be obtained explicitly as part of the original consent process.
6. I will terminate the study at any stage, if 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)
Department _____

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 • Transportation charges • Hospitalization	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)

No.
Date:

Institutional Review Board
(IRB00013212)

Project title:

_____

Name & Address of Institution:

_____

Principal Investigator:
Name: _____
Address: _____
Contact Number: _____
Email ID: _____

Name of Co-PI:
_____

Collaborators' Name:
_____

Sponsor:
_____

Address: _____
Contact No.: _____
Email: _____

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
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.**

Chairperson
IRB Committee

Convener
IRB Committee

International Institute for Population Sciences

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Deonar, Mumbai, Maharashtra 400088
https://www.iipsindia.ac.in/

IIPS-IRB

Audit and Inspection Checklist

Audit and Inspection Checklist

1)	Date of letter of communication regarding audit/ inspection
2)	Date(s) agreed upon for the audit/inspection
3)	Ensure IRE-IS members and staff have been informed about the date(s) and time
4)	Ensure availability of IRB-1S related information (mandate, terms of reference, organization chart) in print form in the IRE 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, CYs, and training of IRB members
10)	Ensure documents regarding staff appointments, CVs, and training of IRE 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 IRE-IS meeting
16)	Arrange for meeting venue, catering, accommodation, and travel for the visit if necessary

SOP approved by:

IRB Members & Director, IIPS (IIPS/DIR/IRB/0443/2026)
Date: 28 August 2026