Institutional Review Board (IRB): Structure and Guidelines

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About the IRB

DA-IICT has established the Institutional Review Board (IRB) for research involving human participants. The main tasks of the IRB are as follows:

- The IRB must review and approve all proposed research involving human subjects before participant recruitment and data collection can start.
- The primary concern of the IRB is to minimize any risk for subjects arising out of the study while allowing the researcher to collect the necessary information.
    - Privacy and confidentiality of the participants are sought to be protected within the research setting.

IRB Members

- **Internal**

  Prof. Aditya Tatu, DA-IICT (Chair)
  Prof. Bakul Gohel, DA-IICT
  Prof. P S Kalyan Sasidhar, DA-IICT
  Prof. Bharani Kollipara, DA-IICT
  Prof. Arpit Rana, DA-IICT
  Prof. Rachit Chhaya, DA-IICT

- **External**

  - Prof. Dileep Mavalankar
    Former Director, IIPH Gandhinagar
    Honorary Distinguished Professor, IIPHG

Policy

What needs IRB Approval?

All Human Subjects Research must be approved by the IRB. Therefore, if your research meets the definitions of BOTH RESEARCH AND HUMAN SUBJECTS, you must complete the IRB process.

Definitions

- **Research**: Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102)

  Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. On the other hand, surveys sent out by departments with the objective of garnering feedback to improve services provided, are not looking to add to generalizable knowledge, and therefore would not constitute research.

- **Human Subject**: A human subject is a living individual about whom an investigator conducting research obtains
  - Data through intervention or interaction with the individual, or
  - Identifiable private information (45 CFR 46.102)

- **Interaction**: Interaction includes communication or interpersonal contact between an investigator and subject (45 CFR 46.102)

- **Intervention**: Intervention includes both physical procedures by which data are gathered and manipulations of the subject or subject's environment that are performed for research purposes (45 CFR 46.102)

- **Minimal Risk**: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily

encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102)

Who needs to apply for IRB approval?

Any researcher/investigator including faculty (regular/visiting), UG/ PG student, PhD student, research associate, research scholar, academic associate, staff member conducting research using human subjects with the intention of developing or contributing to generalizable knowledge (which includes but is not limited to publishing in academic outlets) at DA-IICT needs to submit their research protocol to the IRB for approval.

Secondary data:

Researchers need not apply for IRB approval if their data is:

- Research that utilizes secondary (existing) data sets does not meet the definitional criteria for "human subjects" research and, therefore, typically does not require IRB approval, for example, data that is publicly available (e.g., through a public website or publication or by subscription).

Researchers must apply for IRB approval if their data is:

- Not publicly available OR
- Not de-identified so that it is possible to link a record to a particular individual OR coded so that it would be possible to link a record to a particular individual.

Classroom Research at DA-IICT:

The IRB has determined that research conducted in the classroom using DA-IICT students or analysis of preexisting data of the students in the class for research purposes will require IRB approval (before the course – class activity) begins. *Detailed guidelines will be provided in the next version of this document.*

Process

The IRB process at DA-IICT has the following steps:

1. If you are unsure whether your project/research qualifies for "human subjects" research; please write to irb@daiict.ac.in . You can also fill in the IRB form and submit your research proposal. Any waivers will be communicated to you or you will be instructed to apply for IRB approval. (If you are instructed to apply for approval, then, go to step 2).
2. Download the IRB application from, "IRB Application" form (updated link will be copied here); attach all supplements and required information.
3. Mail your completed IRB Application and attachments as per requirement to irb@daiict.ac.in
4. Your application will be reviewed to determine if it is complete. You will be asked to furnish additional information if required.
5. Completed applications will be evaluated by the IRB chair and the IRB members and the investigator will be informed of the approval/denial/pending decision.
6. You will hear back from the IRB within **two to four weeks**. This could either be an approval, a rejection, or a request for more information.
7. No research can be conducted until the investigator has received confirmation from the IRB Chair that the application is **either exempt or approved**, or in the case of renewals and modifications, until they are approved.
8. Work on a project **cannot be modified** from the approved protocol. Please note that the IRB should be notified in case of any **Reportable new information**.
    a. **Reportable new information:** Work done outside of the approved protocol, participant problems and adverse events.

9. The IRB should be **notified before a change** is made to the approved protocol. Things that require IRB review and modification approval:
    a. Change in funding
    b. Change in Investigators
    c. Change in approved consent document
10. Approved applications **will be valid for a period of one year.** Work on a project cannot extend beyond the date approved by the IRB.
11. A mail will be sent to the Principal Investigators **60 days prior to the expiration** of the approval date.
12. The Principal investigators are required to submit their current status of the project/research study to the IRB by furnishing all information in the form "**Progress Repor**t". If the project requires extended approval, then all required information for the "**Continuing IRB review**" should be submitted. If the project is closed, then a "**Final report**" has to be submitted indicating the closure of the project/study. In any case, the IRB should be intimated about the status of the project before the approval expires.
13. Failure to receive the approval for continuing review before the expiration date means that the project/research must stop immediately.
14. Continuing Review is periodic review of research activities necessary to evaluate the progress of the study and to determine whether the risk/benefit ratio has changed, whether there are unanticipated findings involving risks to participants or others, and whether any new information regarding the risks and benefits should be disclosed to participants.
15. The IRB conducts the continuing review at intervals appropriate to the degree of risk, but not less than once per year (45 CFR 46.109(e) and 21 CFR 56.109(f)). Although the IRB usually adheres to the scheduled date for a protocol's continuing review, depending upon the risk, the IRB can determine that a protocol must have a continuing review at any time.

Categories of IRB Review

Depending on the risk, a research proposal will fall into one of the three categories of review:

- Exempt Review
- Expedited Review
- Full Board Review

Exempt Review

A research activity /project may be categorized as "Exempt" if it is considered less than minimal risk.

Projects will not be given Exempt status if they include any degree of deception, involve more than minimal risk to participants, involve sensitive information, or include or vulnerable populations. Exempt review recommends that the involvement of human subjects is restricted to the categories mentioned in 45 CFR 46.101(b).

Research/Projects that qualify under the exempt status are reviewed by the IRB Administrator and the IRB Chair. Exempt review research does not require further review after the initial approval unless the investigator/researcher decides to change the protocol/research design.

Note: The IRB determines whether the research/project is to be given an Exempt status. An investigator has to submit the IRB application and wait for the approval to begin his research activity.

Expedited Review

Research activities/projects may be categorized as "Expedited" if they are considered no more than minimal risk to human subjects. Research under expedited category does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate informed consent procedures. Categories of research under expedited review are mentioned in 45 CFR 46.110.

Research/Projects that qualify under the expedited status are reviewed by the IRB Administrator and the IRB Chair. Expedited review may also be used when minor changes/modifications are proposed to an approved research project during the period for which approval is authorized. Research projects with Expedited review status have to undergo the annual review process (required to submit a progress on the current status annually) and have to be renewed annually.

Note: Expedited review does not mean quick review. It means that the research project will be reviewed by the IRB Chair and IRB Administrator. The IRB determines whether a research project requires expedited or full board review. Alternatively, if a research project does not meet the criteria for exempt research will undergo the expedited review process.

Full Board Review

Research activities/projects that are greater than minimal risk are categorized as "Full Board Review". Research projects that do not qualify under "Exempt and Expedited review" fall under the category of "Full board review". If the research project involves protected populations such as children, prisoners, or disabled individuals, and/or intentional deception of the subjects or projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal) then it qualifies for a full board review.

Research projects with full board review status are reviewed and approved by the convened IRB. Research projects with such status have to undergo the annual review process and have to be renewed annually. Any new changes/modifications to the project after the initial approval must be reviewed and approved before they are implemented.

Note: The IRB determines whether the research project qualifies for a full board review.

Risk Categories

RISK: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

Physical Risk: Physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research.

Psychological Risk: May be experienced during the research situation and/or later, as a result of participating. Includes anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, altered behavior.

Social/Economic Risk: Alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, labeling with negative consequences, or diminishing the subject's opportunities and status in relation to others. Economic risks include payment by subjects for procedures, loss of wages or income, and damage to employability.

Legal Risk: Risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally or civilly liable.

A research study will involve minimal risk, if

1. The participant experiences no pain or physical danger
2. The participant experiences no emotional arousal or psychological stress beyond the levels normally to be expected in everyday life.
3. The project neither induces nor attempts to induce long-term significant change in the participant's behaviors (including attitudes toward self and others)
4. The data would not embarrass or socially disadvantage the participant, were confidentiality to be violated

Privacy: Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

Loss of Confidentiality: Confidentiality is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks include invasion of privacy, as well as the social, economic and legal risks outlined above

Principal Investigator Responsibilities:

The Principal Investigator at DA-IICT

- Completes the appropriate human subject protection training programme / CITI certification, and will oversee the ethical conduct of research of his team of researchers. **At this stage, CITI certification is not mandatory.**
- Ensures that all researchers assisting in the conduct of the study/ any external marketing research agency recruited for data collection are informed of their obligations for following the DA-IICT-IRB approved protocol.
- Ensures that they will perform the research as per the approval granted and must also ensure to follow the terms as per the grant, contract, or funding agency, if any.
- Ensures that the researchers will not make changes /modifications to the approved informed consent process until approved by the IRB, except where necessary to eliminate apparent immediate hazards to participants, and will inform the IRB (and sponsor as applicable) of any such changes.
- Obtains continuing review and approval of ongoing non-exempt research at the interval determined by the IRB to avoid expiration of IRB approval.
- Monitors the on-going research activity and will report any adverse events to the IRB.
- Provides a final study report to the IRB and any other required reports to sponsors or funding/regulatory agencies, as applicable, when all research activities have ended.

- Must retain research-related records (e.g., the study protocol, consent forms, IRB correspondence, etc.) for audit or inspection for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements). Primary research data will be retained for a minimum of five years after final project closeout.
- If a Principal Investigator leaves the School or is unavailable to personally conduct or supervise ongoing research (e.g., on sabbatical or extended leave), he/she must make arrangements to amend (including a change in PI) or terminate the research, as appropriate.

DA-IICT- IRB Member Roles and Responsibilities

- **IRB Member Responsibilities:**

  IRB members (Primary) are responsible for:

  1. Completing human subjects research training (IRB member)
  2. Attending IRB meetings
  3. Reviewing research applications by Expedited procedures(when required)
  4. Reviewing research applications by Full board review procedures(when required)
  5. Working with investigators to resolve IRB-related issues
  6. Reporting any attempts of undue influence to the Institutional Official
  7. Maintaining knowledge of current regulations and DA-IICT-IRB policy

- **IRB Chair:**

  1. Completing human subjects research training (IRB Chair)
  2. Providing leadership and guidance to the IRB
  3. Conducting convened IRB meetings
  4. Reviewing research applications, monitor divisions(of both regular and expedited procedures)

5. Ensuring that IRB members with a conflict of interest do not review research where he/she has a conflict
6. Conducting review of IRB minutes/annual report
7. Selecting new IRB members
8. Reviewing and signing DA-IICT-IRB related correspondence
9. Reviewing the IRB budget.
10. To nominate an alternate chair during his absence or when he/she has a conflict of interest

- **Alternate IRB Chair:**

  Assumes the responsibilities of the IRB Chair when the IRB Chair is not available or has a conflict of interest.

- **Alternate Members:** Alternate members are to be nominated to serve as substitute for primary IRB members in case of absence of primary member, conflict of interest, need of specific expertise. The IRB minutes will document when an alternate member substitutes for a regular member. Any alternate member is to be nominated by the committee chair in consultation with the committee and the Director.

References:

The document is adapted from various sources and similar such boards

1. Institutional Review Board (IRB) (isb.edu)
2. IRB (iiit.ac.in)
3. Penn IRB | Survey & Interview Research - Penn IRB (upenn.edu)
4. Policies and Procedures | Human Research Protection Office (HRPO) | University of Pittsburgh
5. 45 CFR 46 | HHS.gov

INSTITUTIONAL REVIEW BOARD APPLICATION FORM TEMPLATE

Note: Researchers applying for IRB approval should prepare a document containing the information asked for in the below format. Not all information asked for in the form may be relevant to a particular project, in which case, the principal investigator may skip certain form heads; however, he/she must make sure to be as thorough as possible in details.

The duly filled and signed application should then be sent for approval to the IRB.

I. Basic Details about the Investigator/s

1. **TITLE**
2. **PRINCIPAL INVESTIGATOR**
3. **CO-PRINCIPAL INVESTIGATOR (S)**
4. **ADDRESS**
5. **PHONE**
6. **EMAIL**
7. **DESIGNATION OF THE PRINCIPAL INVESTIGATOR**

II. Basic Details about the Project

1. **A BRIEF DESCRIPTION OF THE RESEARCH**
2. **DURATION**
3. **REVIEW CATEGORY: 1) EXEMPTED; 2) EXPEDITED; 3) FULL**

III. Complete Details of Research Methodology Adopted.

1. **ALL RELEVANT DETAILS ABOUT THE HUMAN SUBJECTS INVOLVED IN RESEARCH**

   (For example, age, sex, demography, education, nationality, disability status, employment, financial status, etc, as applicable)

   NOTE: The Board may solicit more information or clarification if necessary.

2. **DESCRIBE THE DATA COLLECTION PROTOCOL NORMS AND PROCEDURES AS APPLICABLE TO PARTICIPANTS**

   (For example, participant recruitment & compensation details, consent acquisition, confidentiality norms, information provided to the subjects)

   If the research requires that written consent be obtained from the participants, please use the consent form appended.

3. **RESEARCH GOALS & METHODOLOGY**

   a. **Write briefly about the PURPOSE and SCOPE of the research.**

   b. **Data collection methods:(fieldwork, ethnography, participant observation, internet-based research, questionnaires, audio/video recordings, participant observation etc)**

4. **ENUMERATE THE ADDITIONAL RISKS INVOLVED, IF ANY.**

5. **MEASURES UNDERTAKEN TO MITIGATE RISKS AND THEIR FALLOUT**

6. **FUNDING INFORMATION**

   (Details about the funding agency, amount, duration etc)

7. PRINCIPAL INVESTIGATOR'S ASSURANCE

I hereby certify that the information provided here is accurate and complete to the best of my knowledge. I will abide by the review committee's recommendations. I further assure that the participants' rights will be protected from any harm or risk or loss of confidentiality. All changes done to research subsequent to this application are further liable to be approved by the board.

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

Any participant should sign only after ascertaining that the details mentioned below are explained to him satisfactorily. *For online studies, the specified details must be included in the privacy policy of the online platform before the study starts.*

Title of the Study:

Principal Investigator:

You can contact the study investigator if you have any questions about the study, concerns or complaints. Contact Principal Investigator

Funding Source:

Information to the Participant:

- Explain the rationale and purpose of the research.
- Indicate why the potential participant is being asked to participate.
- Give a step-by-step guide to the procedures followed.
- Indicate the expected length of the subject's participation.
- Explain reimbursement procedures

Potential Risks & Benefits

- Explain risks, if any, that could potentially cause damage or discomfort to the participants. For. example:
    - Data collected in this study may be stored and shared for future research in a de-identified fashion. It would not be possible for future researchers to identify you. This can be done without again seeking your consent in the future, as permitted by law.

- You must be at least 18 years old to participate. If you are not 18 or older, please inform the researcher and do not complete the survey.
- Explain preventive and safety measures taken to protect the confidentiality and privacy rights of the participants.
- Indicate the benefits to the participants, if any, for taking part in this study

Confidentiality and Privacy

- Specify briefly the procedures (e.g., coding of research data, storage of linkage code information in separate locked files, firewalls) that will be used to protect the confidentiality of the research subjects.
- Specify the procedures followed to make the participants identity anonymous.
- Address the concerns, if any, about the potential risks to participants once the results are shared with professional and non-professional fora like conferences, classrooms, news media etc.

Withdrawal from Participation

- Information to be shared with the participant regarding his/her withdrawal from the study.

  (*You can withdraw from this study at any time. Any identifiable data obtained as part of this study prior to the date that you withdrew your consent will continue to be used by the investigators for their research purposes. If you want to withdraw, notify the study team. Your decision to withdraw will have no effect on your current or future relationship with DA-IICT)*

Participant Rights

Explain the rights the participant has. (*This is purely a voluntary activity. The participant is free to decline to take part in any activity that he/she deems inappropriate for him/her. In case of any ill treatment or misdemeanor or any untoward behavior during the research activity, the participant can inform the principal investigator through email or in person.*)

Consent to Participate

(This may be customized if necessary)

This research has been reviewed by the Institutional Review Board (IRB). The above information has been explained to me to my satisfaction. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. By signing this form, I consent to participate in this research study _____; and indicate that I have understood what this study is about.

A copy of this consent form will be given to me.

Name of the Participant

_____

Signature of Participant