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Institutional Review Board (IRB) Policy Manual & Forms

About DAI Research & Advisory Services (DAI)

DAI Research & Advisory Services Pvt. Ltd. (DAI) is a social-science research organization committed to advancing data-driven, evidence-based insights that inform inclusive and equitable development.

DAI's Institutional Review Board (IRB) upholds the highest ethical standards for all research involving human participants, guided by the principles of the **Belmont Report**, the **U.S. 45 CFR 46 (Common Rule)**, and the **Indian Council of Medical Research (ICMR) National Ethical Guidelines (2017)**.

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*(This section provides the **official definitions and key terms** used by the DAI IRB. It clarifies essential concepts related to research involving human subjects—such as "research," "human subject," "minimal risk," "exempt status," and "protected health information"—to ensure consistent interpretation and application of ethical and regulatory standards in human subject research)*

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*(This section outlines the **guidelines** of DAI IRB, detailing the policies, procedures, and ethical standards governing research involving human subjects. It defines the review and approval process, criteria for ethical compliance, informed consent requirements, ongoing monitoring, reporting obligations, and record-keeping responsibilities to ensure that all human subject research is conducted with integrity, safety, and regulatory compliance.)*

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IRB Protocol for Application Review

Step 1: Submission of the application: The principal investigator is responsible for submitting completed application, with any necessary attachments, to the attention of IRB Chairperson via email to irb@daiadvisory.in

Step 2: Preliminary review by administration: The administrative staff will review the application for completeness within three working days after its receipt. If the application is incomplete, it will be returned to the principal investigator for completion. If the application is complete, it will be forwarded to the Chairperson of the IRB.

Step 3: Preliminary review by the Chairperson: The Chairperson will review the application to decide whether it merits expedited review or not. If it merits expedited review, the Chairperson will assign it to one member of the IRB for review, or to him or herself. If expedited review has not been requested, the Chairperson will notify the full Board of a date for a review, which may take place telephonically, and forward the materials to the Board members.

Step 4: Review

- **Expedited review**: The Board member assigned to undertake expedited review may exercise the full powers of the Board and reach any decision except for disapproval. If the assigned Board member feels disapproval is in order, he or she must take the application before the full Board.

- **Full Board Review**: Full Board review may take place telephonically. At least 3 members of the Board must be present, and meetings may take place telephonically when necessary. Minutes shall be taken that show attendance at the meetings, actions taken, votes taken, the reasons for requiring changes or disapproving research, and a written summary of any controverted issues and their resolution. If requested by the Board, a staff member of DAI Research & Advisory Services may attend meetings and draft these minutes.

- **Standards for review**: The Board, or its delegate in the case of an expedited review, must consider whether the proposed research meets the following standards.
    - The study uses procedures that are consistent with sound research design.
    - Proposed research activities minimize the potential risk to the human subjects.
    - Risks to subjects are reasonable, in relation to anticipated benefits to subjects (if any), and to the importance of the knowledge that may reasonably be expected to result.
    - Selection of subjects is equitable.

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  - Informed consent will be sought and appropriately documented when necessary, or waiver is requested.
  - The research plan makes adequate provision (when appropriate) for:
    - monitoring data to ensure the safety of subjects
    - protecting the privacy of subjects
    - maintaining the confidentiality of data
  - When subjects are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, mentally disabled persons) additional safeguards are included.
- **Informed Consent:** The minimum requirements for informed consent are that the subjects are provided with the following information:
  - (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
  - (2) A description of any reasonably foreseeable risks or discomforts to the subject.
  - (3) A description of any benefits to the subject or to others which may reasonably be expected from the research.
  - (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
  - (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
  - (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
  - (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
  - (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

- **Waiver of Informed Consent:** When a request has been made to waive the requirement of informed consent, or to alter some of the required features of informed consent, if the Board or its delegate (in the case of an expedited review) finds that
  - (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or

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procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
    - (2) The research could not practicably be carried out without the waiver or alteration.

  Any approved waivers must be indicated on the response form.

- **Waiver of Documentation of Informed Consent:** When a request has been made to waive the requirement of documentation of informed consent, the Board or its delegate must find that
    - (1) The only record linking the subject and the research would be the consent document and that the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each subject should be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern, or
    - (2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

  Any approved waivers must be indicated on the response form.

Step 5: Request for further information or modification: At the discretion of the Board or its delegate, rather than disapproving an application, the Board may ask for further information from the Principal Investigator for reasonable modification of the protocols. Any agreed-upon modification should be stipulated in the response of the Board.

Step 6: Response to Principal Investigator and Record Keeping: The sheet attached to this document must be completed for each project reviewed, and three copies should be filed. The Chairperson should keep one copy, should forward one copy to the Principal Investigator, and the other copy must be sent to the DAI Research & Advisory Services office.

Step 7: Yearly Renewal: Applicants must renew their application, generally one year after the date of approval.

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Response of Institutional Review Board (IRB)

Principal Investigator: _____

Title of Study: _____

Date of Decision: _____

[ ] Approved

[ ] Approved with stipulations/modifications (*explain*)
_____
_____
_____
_____
_____
_____

Does the Board find that risks to subjects are reasonable, in relation to anticipated benefits to subjects (if any), and to the importance of the knowledge that may reasonably be expected to result, and justify the use of the experimental framework?
_____
_____
_____

[ ] Disapproved (*explain*)
_____
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Other remarks:
_____
_____
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IRB Definitions

- *"Research"* US Federal guidelines (45 CFR 46) define "research" as: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Research includes formal interviews, responses to questionnaires, and related activities that may be quantified as part of study data. Research does not include interviews used to provide quotes or illustrative statements – used in journalism or related projects.

- *"Human Subject"* US federal guidelines (45 CFR 46) define "human subject" as: "A living individual about whom an investigator (whether professional or student) conducting research obtains:

    1. data through intervention or interaction with the individual, or
    2. Identifiable private information."

  The DAI IRB does not consider research to involve "human subjects" where the research uses only coded private data, provided the data were not collected specifically for the proposed research by an intervention with a living individual, and provided the researcher cannot identify the individual(s) from whom the data, specimens or cells were obtained (for example because the key to decipher the code has been destroyed or an agreement exists prohibiting the release of the key to the investigators).

- "Intervention" includes both physical procedures by which data are gathered (for example, drawing blood) and manipulations of the subject or the subject's environment that are performed for research purposes.

- "Interaction" includes communication or interpersonal contact between investigator and subject.

- "*Projects involving* DAI Research & Advisory Services *personnel or funding"* The DAI IRB is responsible for reviewing research performed as research projects which involve DAI Research & Advisory Services personnel as primary researchers, as well as research involving any form of DAI Research & Advisory Services support, such as funding, personnel, facilities, academic credit or access to experimental subjects. Such research is included wherever it is performed.

- *"Minimal risk"* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations and tests.

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- *"Exempt status"* Exempt status may be granted for research activities in which the only involvement of human subjects will be in one or more of the following categories:

    1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

    2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

    3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

    4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

    5. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Determination of exempt status rests with DAI IRB.

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- *"Full Board review"* Full Board review is a review of an application for research involving human subjects which is carried out by the entire DAI IRB on an as-needed basis.

- *"Expedited review"* Expedited review is a review of an application for research involving human subjects that is carried out by the Chairperson of the IRB or an IRB member designated by the Chairperson, of programs involving minimal risk or entailing minor changes to a previously approved protocol. In carrying out this review, the reviewer(s) may exercise all the authority of the Board, except that they may not disapprove the research. Such disapproval may only be made by the full Board.

- *"Protected Health Information"* Protected Health Information under the HIPAA Privacy Rule means any health information that might directly or indirectly identify an individual, and that is maintained or transmitted in any form or any medium. Protected Health Information includes :

    - Names
    - Addresses
    - Names of relative(s)
    - Names of employer(s)
    - Dates
    - Social security numbers
    - Medical record numbers
    - Health Plan or account numbers
    - Telephone or fax numbers
    - E-mail addresses
    - Vehicle or device serial numbers
    - Certificate or license numbers
    - Internet Protocol addresses
    - Web URLs
    - Biometric identifiers, including finger and voice prints
    - Photographs (full face)
    - Any other unique identifying number, characteristic or code

  Protected Health Information excludes education or employment records.

- *"Authorization for Release of Protected Health Information"* An Authorization for the Release of Protected Health Information is a written document a research subject must sign at the time of executing an informed consent document that specifically authorizes the researcher to disclose the subject's protected health information. The Authorization must be written in plain language and specify: What information will be disclosed:

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- The names the persons or organizations authorized to disclose the information
- The names of the person or organization authorized to receive the information
- Why the disclosure is being made
- The date the authorization will expire
- That the subject may revoke the authorization at any time
- That the subject cannot participate in the research if they do not sign the Authorization

- *"Waiver of Authorization"* A Waiver of Authorization is the permission granted to a researcher by the IRB to use or disclose a subject's protected health information without the subject's prior authorization. The IRB will grant a Waiver if the following criteria are met:
  - Use or disclosure of the protected information involves no more than a minimal risk to the privacy of individuals based on:
    - A plan to protect identifiers from improper use and disclosure
    - A plan to destroy identifiers from improper use and disclosure
    - Written assurances the health information will not be reused or disclosed to others
  - The research cannot be conducted without the waiver
  - The research cannot be conducted without access to and use of the protected health information

- *"De-identified Data"* Health information that has been de-identified is no longer subject to the HIPAA Privacy Rule. To meet the standard for de-identification the information must **not** include any of the following:
  - Names
  - All geographical subdivisions smaller than a state
  - All elements of dates directly related to an individual (except year)
  - Telephone numbers
  - Fax numbers
  - E-mail addresses
  - Social security numbers
  - Medical record numbers
  - Health plan beneficiary numbers
  - Account numbers
  - Certificate or license numbers
  - Vehicle identifiers and serial numbers
  - Device identifiers and serial numbers
  - Web URLs
  - Internet Protocol address numbers
  - Biometric identifiers including finger and voice prints
  - Full face photos
  - Any other unique identifying number, characteristic or code

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- *"Limited Data Set"* A limited data set is de-identified health information that eliminates all personal identifiers but allows for the inclusion of dates and geographic information to the level of city or zip code. A limited data set can only be used or disclosed if the researcher has completed a formal data use agreement with the IRB governing the disclosure of the information.

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IRB Guidelines

Summary

DAI Research & Advisory Services policy is to ensure that all research projects involving its personnel or funding and involving human subjects are reviewed and approved by its Institutional Review Board (DAI IRB). The purpose of DAI IRB is to review social and economic experimental evaluations. Experimental evaluations protocol involving drugs, medical procedures, or other biological agents must also seek approval from the appropriate ethical review body, and approval of this Board alone is not sufficient.

DAI IRB approval must be obtained prior to the beginning of any human studies. Those studies underway prior to the formation of this Board should submit applications within 2 months for review. For research involving minimal risk, approval is granted for one year and must be renewed annually. For research involving more than minimal risk, renewal frequency will be determined by the Board upon approval. The DAI IRB meets on an as-needed basis to review proposals according to the framework laid out below.

Review and Approval of Studies

Before conducting research involving human subjects, investigators must obtain, complete, and submit an application for DAI IRB Approval of the study. These applications will be available on DAI Research & Advisory Services website or by writing to irb@daiadvisory.in

For most studies, a full application for approval to use humans as experimental subjects (standard form) must be submitted.

- For studies that qualify for exempt status, an abbreviated application for approval to use humans as experimental subjects (exempt status form) may be submitted.

Applications are reviewed within one month of the receipt of the application. However, at the discretion of the Chairperson, where there exists no more than minimal risk to subjects, an expedited review may be performed.

After reviewing the application, DAI IRB reports its decision to the responsible investigator.

- Protocols may be approved as submitted. For research involving minimal risk approval is for one year. For research involving more than minimal risk the DAI IRB will determine the duration of the approval, which maybe for less than one year.
- If a protocol does not meet DAI IRB stated criteria for acceptance, or if an application is incomplete, DAI IRB may inform the investigator of suggested modifications and request revision and re-submission.

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- If an investigator fails to respond within 60 days to a written request from DAI IRB for information or protocol changes then the application will be withdrawn. The investigator will be informed of this decision in writing. To continue the research the investigator will have to resubmit an application to DAI IRB.

Where the research involves collaboration with another institution(s), then DAI IRB requires that the principal investigator and his collaborating researcher(s) obtain approval from that institution(s) institutional review board, if any, and forward copies of the approval to DAI IRB.

Approval is subject to continuing review. Approval must be renewed (usually annually).

Criteria for Review

For a study involving human subjects to be approved by the DAI IRB, it must satisfy the following criteria.

- The study uses procedures that are consistent with sound research design.
- Proposed research activities minimize the potential risk to the human subjects.
- Risks to subjects are reasonable, in relation to anticipated benefits to subjects (if any), and to the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable.
- Informed consent will be sought and appropriately documented when necessary, or a waiver is requested (see below).
- The research plan makes adequate provision (when appropriate) for:
    - monitoring data to ensure the safety of subjects
    - Protecting the privacy of subjects
    - Maintaining the confidentiality of data
- When subjects are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, mentally disabled persons) additional safeguards are included.

Waiver of Documentation of Informed Consent

When a request has been made to waive the requirement of documentation of informed consent, the application should document that either:

- (1) The only record linking the subject and the research would be the consent document and that the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each subject should be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern, or

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- (2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Ongoing Monitoring and Reporting

After receiving approval to conduct a study, investigators must inform DAI IRB if there are changes in the protocol that impact human subjects, or if adverse reaction risks are noted.

- *Changes in Protocol:* If protocol is modified after a study has been approved by DAI IRB, investigators must obtain DAI IRB approval for any changes that may affect the rights of human subjects. These include, but are not limited to, changes that may impact discomfort or risks associated with study procedures, change in study personnel, the amount of time required by subjects, confidentiality of data, the privacy of subjects, or other rights. Investigators are not required to contact DAI IRB if changes in protocol are restricted to methods of data analysis or other points that do not alter requirements of or interactions with human subjects.
- *Adverse reactions, injuries, or unanticipated risks:* All serious or unexpected adverse reactions or injuries, including those that result in a subject dropping out of an experiment or requiring medical attention, must be reported to DAI IRB, orally or by e-mail, within 48 hours. All other adverse events should be reported within 10 working days of occurrence. DAI IRB must also be informed if, during the conduct of a study, any unanticipated risks to subjects are noted. Again, approval of the DAI IRB is not sufficient for experiments involving medical or biological agents.

Continuing Review

All studies approved by the DAI IRB require continuing review. Approximately 60 days before approval expires, the DAI IRB will notify the Principal Investigator that a Continuing Review Questionnaire (CRQ) must be completed. This form must be completed and returned to the DAI IRB before the expiration date. After the completed CRQ is received and reviewed by the DAI IRB a renewal letter will be sent to the Principal Investigator extending the approval (usually for one year). No further research with human subjects can be conducted under this protocol without DAI IRB approval. If deemed necessary, the DAI IRB will use sources other than the investigator to verify that no material changes, other than those reported, have occurred to studies since the previous DAI IRB review.

Record Keeping

The DAI IRB will keep records of all applications and decisions at the DAI Research & Advisory Services office. Principal Investigators are required to maintain a research file

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for all DAI IRB approved studies. This file will act as the investigator's documentation of proper performance of the study. This file should include :

- All correspondence with the DAI IRB and the research sponsor (if applicable)
- Documentation of subject eligibility
- Copies of the signed consent forms obtained from all subjects participating in the study regardless of whether or not the subjects completed the study
- Any data derived from the study
- Copies of all documentation relating to the privacy of a subject's protected health information

In accordance with federal regulations the research file must be kept in a secure location by the principal researcher for at least 3 years after completion of the research. DAI IRB encourages researchers to maintain the file for longer periods, if practicable. The conditions for maintaining confidentiality of the subjects and the research records are however, required for the life of the data.

The research file may be reviewed by the DAI IRB, federal, state or local authorities, sponsors, and other authorized individuals to ensure proper performance of the study. These rules also apply to student researchers.

Collaborating Institutions

If a researcher conducts human subjects research in collaboration with another institution, then the DAI IRB will approve the research with the stipulation that the research cannot commence until the DAI IRB receives written notification of approval from the collaborating institution's IRB. There may, however, be circumstances that warrant aspects of the research commencing before a collaborating institution has formally approved the study and the DAI IRB will consider these on a case-by-case basis.

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IRB Principles Under DPDP Act, 2023

Purpose

This section outlines DAI Research & Advisory Services' commitment to ensuring full compliance with India's Digital Personal Data Protection (DPDP) Act, 2023 in all research activities involving personal or sensitive data. It applies to all research proposals, data collection, analysis, and storage processes overseen by the Institutional Review Board (IRB).

Scope

The policy applies to all researchers, staff, contractors, and partners engaged in studies that collect, process, or store digital or physical personal data of research participants. It covers data obtained directly from individuals or indirectly through secondary datasets.

Key Principles of Compliance

DAI IRB mandates adherence to the following principles under the DPDP Act, 2023:

1. **Lawful and Purpose-Specific Processing:**

   Personal data shall be collected and processed only for legitimate, specific, and explicitly stated research purposes that have been reviewed and approved by the IRB.

2. **Consent and Notice:**

   Informed consent must include a clear data-use notice describing:

   - What personal data will be collected and why;
   - How the data will be stored and protected;
   - Whether it will be shared, transferred, or anonymized; and
   - The participant's right to withdraw consent at any stage.

3. **Data Minimization and Storage Limitation:**

   Only the minimum necessary personal data shall be collected. Data will be retained only as long as required for the approved research purpose and securely destroyed thereafter.

4. **Data Security and Safeguards:**

   Researchers must implement appropriate technical and organizational safeguards, including encryption, password protection, access controls, and secure storage (digital and physical).

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5. **Data Subject Rights:**

   All research participants retain the right to:

   - Access their personal data collected for research;
   - Request correction or deletion of inaccurate information;
   - Withdraw consent for future data use; and
   - File grievances with DAI's Data Protection Officer.

6. **Cross-Border Data Transfer:**

   Any transfer of personal data outside India must comply with DPDP Act requirements and occur only with IRB approval and explicit participant consent.

7. **Anonymization and De-Identification:**

   Personal identifiers must be removed or coded wherever possible. Only de-identified or limited datasets may be shared for analysis, ensuring participants cannot be reasonably re-identified.

8. **Data Breach Notification:**

   In the event of a data breach, the Principal Investigator must report the incident within **72 hours** to both the DAI IRB and the designated Data Protection Officer, including a summary of affected data and remedial measures undertaken.

Institutional Responsibilities

- **IRB Oversight:** The IRB shall verify DPDP compliance during application review and ensure that consent and privacy protections are clearly described.
- **Data Protection Officer (DPO):** DAI shall designate a DPO responsible for compliance with the DPDP Act, managing grievances, and coordinating with the IRB on data incidents.
- **Training:** All investigators and staff handling personal data must complete annual training on data protection and privacy under DPDP guidelines.

Retention and Disposal

Research data containing personal information shall be securely maintained for a minimum of three years after project completion or as mandated by donor or regulatory requirements. All personal data shall be permanently destroyed (digitally wiped or physically shredded) after the retention period unless extended retention is justified and approved by the IRB.

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Grievance Redressal

Participants may submit complaints or inquiries related to their data rights or privacy breaches to:

Data Protection Officer (DPO)

DAI Research & Advisory Services Pvt. Ltd.

ECO Centre, 16th Floor, Eastern Metropolitan Bypass, EM Block, Sector V, Bidhannagar, Kolkata – 700091, West Bengal, India

✉ dpo@daiadvisory.org | ☎ +91 933 127 8800

IRB Summary Memo

Purpose

This memo provides a concise overview of DAI's Institutional Review Board (IRB) / Human Subjects Committee (IRB) structure, responsibilities, and processes. It serves as a quick-reference guide for investigators, partners, and staff engaged in human-subjects research.

1. Institutional Commitment

DAI Research & Advisory Services is committed to protecting the rights, dignity, and welfare of all individuals participating in research. The IRB operates under IORG0010769 and IRB00012768, complying with: - The **Belmont Report** principles of Respect for Persons, Beneficence, and Justice. - The **U.S. 45 CFR 46 (Common Rule)**. - The **ICMR National Ethical Guidelines (2017)**.

2. Scope of Oversight

The IRB reviews all projects that: - Involve human participants or identifiable private information. - Are conducted, funded, or supported by DAI or its affiliates. - Utilize DAI resources, personnel, or data.

Collaborative studies must also obtain approval from partner institutions' ethics Boards.

3. Review Process Summary

Step	Activity	Responsible	Timeline
1	Submission of Application & Checklist	Principal Investigator	≥30 days before research start
2	Completeness Screening	IRB Secretariat	5 working days
3	Assignment of Review Type	IRB Chair	Within 7 days
4	Board Review & Decision	IRB Members	Within 30 days
5	Communication of Decision	IRB Secretariat	5 working days post-review
6	Continuing Review / Renewal	Principal Investigator	Annually or as specified

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4. Responsibilities of Investigators

- Do not begin research before IRB approval.
- Use approved consent templates and translate them into local languages.
- Report serious adverse events within 48 hours.
- Submit renewal applications 60 days before expiry.
- Retain data securely for at least five years after project completion.

5. Ethical Standards

- Voluntary informed consent.
- Equitable participant recruitment.
- Risk minimization and benefit justification.
- Protection of privacy and confidentiality.
- Safeguards for vulnerable populations.
- Transparency and accountability in conduct.

6. Contact Information

DAI Institutional Review Board (IRB) Secretariat
ECO Centre, 16th Floor, Eastern Metropolitan Bypass,
EM Block, Sector V, Bidhannagar, Kolkata, West Bengal – 700091, India
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7. Policy Review

The IRB reviews and updates its policies every three years or sooner if necessary.

IRB Application

Please answer every question, and mark N/A if not applicable. Please submit this form plus a completed checklist for application along with copies of questionnaires and consent forms.

I. BASIC INFORMATION

1. **Title of Study**	
2. **Principal Investigator**	
Name :	Address :
Title :	
Affiliation :	
Phone number :	Email :
3 . **Associated Investigators**	
Name :	Address :
Title :	
Affiliation :	
Phone number :	Email :
Name :	Address :
Title :	
Affiliation :	
Phone number :	Email :
Name :	Address :
Title :	
Affiliation :	
Phone number :	Email :
Name :	Address :
Title :	
Affiliation :	
Phone number :	Email :
4. **Collaborating Institutions** *(If you are collaborating with other institutions you must also obtain approval from any IRB or Ethics Board in those institutions and forward documentation of this approval to the DAI IRB*	
5. **Location of Research**	
6. **Funding** *(If your research is or will be funded by outside institutions, please enclose one copy of the proposal or the draft proposal.)*	
7. **Anticipated dates of research** *(Applications to the DAI IRB must be submitted prior to the beginning of the research project.)*	
Start Date:	End Date:

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II. STUDY INFORMATION

1. **Purpose of Study** *(Please provide a concise explanation of the research project you are undertaking, including background, nature, and reason for the study, in non-technical language which can be understood by non-economists.)*
2. **Study Protocol** *(Please provide a detailed description of the study protocol, including selection and sampling criteria, data collection techniques, and the nature of any intervention. Provide sufficient information and detail in non-technical language such that the protocol can be understood by non-economists. Define any abbreviations, and do not exceed 2 pages. If questionnaires, interviews, standardized tests, biomedical tests, or any other data collection techniques are to be used please attach a copy of the protocol and questionnaire to the application.)*
3. **Investigational Drugs and Medical Devices, Special Diets and Radioactive Materials** *(This Board does not constitute sufficient review for the use of non-FDA approved drugs and medical devices. If you are using non-FDA approved drugs or medical devices, please contact the DAI IRB.)*
Does this project include the use of investigational (non-FDA approved) drugs or medical devices, special diets, or radioactive material? [ ] YES [ ] NO

III. HUMAN SUBJECTS

1. **Subjects**	
A. Estimated Number:	B. Ages(s):
2. **Criteria for inclusion or exclusion**	
A. What are the criteria for inclusion or exclusion?	
B. Are any of these criteria based on race or ethnic origin, age, or gender? If so pleas explain and justify.	
3. **Vulnerable Groups**. *Please explain the inclusion of any vulnerable population (children, cognitively impaired persons, prisoners or others) and why that population is being studied.*	
4. **Subject recruitment**. *Identification of subjects must be ethically and legally free acceptable and free of coercion. Please describe what methods will be used to recruit subjects.*	
5. **Subject Compensation**. *Payment must be reasonable in relation to the time and trouble associated with participating in the study. It cannot constitute an undue inducement to participate.*	
A. Describe any plans to pay subjects in either cash or kind (i.e. gifts).	

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B. Describe any plans to reimburse subjects for travel or other expenses.
6. **Potential Risks**. *A risk is a potential harm that a reasonable person would consider important in deciding whether or not to participate in research. Risks can be physical, psychological, sociological, economic, or legal, and include pain, stress, and invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible, for example by using appropriate safety devices, monitoring, and withdrawal of a subject if there is evidence of a specific adverse event.*
A. What are the risks or discomforts associated with each intervention or procedure in the study?
B. What procedures will be in place to minimize or prevent these risks and discomforts?
7. **Potential Benefits**.
A. What potential benefits might the subjects receive from participating in the study?
B. What potential benefits can society expect from the study?
8. **Data collection, storage, and confidentiality**
A. How will data be collected?
B. Is there audio or videotaping? [ ] YES [ ] NO *If yes explain the procedures you will follow.*
C. Will the data be associated with personal identifiers or will it be coded? [ ] Personal Identifiers [ ] Coded *Explain the procedure you will follow.*
D. Where will the data be stored and how will it be secured?
E. What will happen to the data when the study is completed?
F. Could the data collected in the study affect a subject's relationships with other people (family relationships, employer/employee relationships, …)
7. **Deception**. *Investigators may not exclude information from a subject that a reasonable person would want to know in deciding whether to participate in a study.*
Will information about research purpose and design be withheld from subjects? [ ] YES [ ] NO *If yes, explain and justify.*

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8. **Adverse Effects**. *Serious or unexpected adverse events or injuries must be reported to the DAI IRB within 48 hours. Other adverse events should be reported within 10 working days.*
What follow-up efforts will be made to detect any harm, and how will you inform the Board of any adverse events?
9. **Informed Consent**. *Documented informed consent is a requirement for all participants in all studies. You can find templates for informed consent available on the website. Draft informed consent documents must be submitted along with this application. Informed consent sheets must be translated into the language relevant to the study area if relevant. Under certain circumstances the Board may waive the requirement for informed consent.*
Attach informed consent forms or explain why the Board should consider waiving the requirement for informed consent.
10. **Health Information Privacy Laws**. If the release of this information is part of your study protocol, please contact the Board for additional information. Identifiable health information means health information that can be linked to the identity of a subject.
Do you plan to use or disclose identifiable health information outside of the participating research organizations? [ ] YES [ ] NO *If yes please contact the Board for additional information.*

IV. INVESTIGATOR'S ASSURANCE

I certify that the information provided in this application is correct and complete.

I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Board.

I agree to comply with DAI Research & Advisory Services policies as well as Indian, United States, and local laws on the protection of human subjects including:

- Performing the study according to the approved protocol
- Not implementing any changes to the protocol without Board approval
- Obtaining informed consent from all subjects using the approved consent form (unless requirement is waived by the Board)
- Protecting identifiable information, especially health information
- Promptly reporting significant and unexpected adverse events.

Signature of Principal Investigator

_____ Date._____

Print full name and title

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IRB Application Checklist

Instructions

Use this checklist to verify completeness of all documents before submitting your application to the DAI Institutional Review Board (IRB). Attach this checklist to the front of your submission packet.

I. Administrative Information

Item	Description	Attached (☑)	Comments
1	Completed DAI Human Subjects Application Form	☐	
2	Study Title Clearly Stated	☐	
3	Principal Investigator (PI) CV and Qualifications	☐	
4	Co-Investigators Listed	☐	
5	Institutional / Partner Approvals (if applicable)	☐	
6	Funding Source and Sponsor Details	☐	

II. Study Protocol and Materials

Item	Description	Attached (☑)	Comments
1	Detailed Study Protocol	☐	
2	Research Instruments / Questionnaires	☐	
3	Sampling Plan / Recruitment Strategy	☐	
4	Data Collection Procedures	☐	
5	Adverse Event Management Plan	☐	

III. Informed Consent

Item	Description	Attached (☑)	Comments
1	Consent Form (English)	☐	
2	Consent Form (Local Language)	☐	
3	Parental / Guardian Consent (if applicable)	☐	
4	Assent Form (for minors)	☐	
5	Waiver / Alteration Request (if applicable)	☐	

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IV. Data Protection and Privacy

Item	Description	Attached (☑)	Comments
1	Data Anonymization / Coding Plan	☐	
2	Secure Storage and Access Control Description	☐	
3	Data Retention Schedule	☐	
4	Compliance with DPDP Act, 2023	☐	
5	Data Sharing / Transfer Plan	☐	

V. Risk and Safety

Item	Description	Attached (☑)	Comments
1	Risk Assessment Summary	☐	
2	Mitigation Measures	☐	
3	Safety Monitoring Plan	☐	
4	Emergency Response Protocol (if applicable)	☐	

VI. Ethical Compliance

Item	Description	Attached (☑)	Comments
1	Statement of Compliance with Belmont Principles	☐	
2	Conflict of Interest Declaration	☐	
3	Training Certificates (e.g., CITI / NIH)	☐	
4	Previous IRB Approvals (if any)	☐	

VII. Submission Verification

Item	Description	Completed (☑)	Comments
1	All Sections of Application Completed	☐	
2	All Attachments Labeled and Organized	☐	
3	Electronic Copy Sent to irb@daiadvisory.org	☐	
4	Hard Copy (if required) Submitted	☐	

Applicant Certification:
I certify that the information provided in this submission is accurate and complete to the best of my knowledge.

PI Signature : _____ **Date :** ___

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