

## **IRB POLICY**

Research at the Indian School of Business conducted using human participants is under the purview of the Institutional Review Board (ISB-IRB). The purpose of IRB is to facilitate human subjects' research and to ensure that the rights and welfare of these subjects are protected during their participation. The IRB approves and monitors all studies involving human participants to ensure that the experiment or survey is designed to meet legal and ethical concerns and does not involve unnecessary risks for the participants. The IRB comprises of faculty and staff members of ISB.

The IRB at ISB strives to hold the highest standards of ethics in conduct of human research, and to create a culture of respect for human participants. The ISB-IRB works towards creating awareness and protects the rights and welfare of human participants and researchers.

### **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

1. Data through intervention or interaction with the individual, or
2. 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 (resident/visiting), FPM student, PGP 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 the Indian School of Business 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.

### **CLASS ROOM RESEARCH AT ISB:**

The IRB has determined that research conducted in the classroom using ISB 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.

#### **Important: Please note the following rules with respect to research conducted on students enrolled in classes at ISB (all programs).**

1. Research conducted in class may NOT be linked to course grades and this should be explicitly stated in the consent form and announced in class.

2. Research participation may be solicited in lieu of extra course credit in the class, up to a maximum of 3%, provided an alternate assignment of equivalent time requirement is provided.
  - This needs to be explicitly stated in the course outline BEFORE commencement of Session 1.
  - It should be clearly mentioned that extra credit can only lead to a higher grade, however not participating in research for extra credit will not lead to obtaining a lower grade.

***Sample acceptable language to be included in the course outline (edited as necessary):***

***Extra Credit (max 3%):***

There will be opportunity to earn extra credit, up to a maximum of 3%, by participating in research studies run by the **ISB Behavioral Lab**. There will be a maximum of three such opportunities and you would get 1-1.5% extra credit (added to your total grade) for participation in each, up to a maximum of 3%. Students will be notified about availability of a research study participation opportunity via email from the ISB Behavioral Lab, which would contain a link to the study. Participation in research studies is completely optional. Those who do not wish to participate in research studies, but want to earn extra credit, have the option of writing a 3-page paper discussing practical managerial applications of any topic of their choice covered in the consumer behavior class.

***Final Grades:***

Grades from all components except for extra credit will be added, and grades for all students would be assigned according to a curve. Following this, points earned as extra credit will be added. Please note that extra credit can potentially move you up the curve, but you cannot get a lower grade because you did not earn extra credit.

3. In-class research solicitation should not be done by the instructor of the course (to avoid potential coercion in participation).
4. If the instructor is a co-investigator in the research, his or her name may not appear on the consent form.
5. If the research/survey is to be sent out as an email link, it is recommended that the email goes from the account of the ISB Behavioral Lab Manager.

## The IRB Process:

The IRB Process has the following steps:

1. If you are unsure whether your project/research qualifies for “human subjects” research; please write to [IRBassist@isb.edu](mailto:IRBassist@isb.edu) . 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” from ([updated link will be copied here](#)); attach all supplements and required information.
3. Mail your completed IRB Application and attachments as per requirement to [IRBassist@isb.edu](mailto:IRBassist@isb.edu)
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**.
9. **Reportable new information**: Work done outside of the approved protocol, participant problems and adverse events.
10. The IRB should be notified **before** a change is made to the approved protocol. Things that require **IRB review and modification approval**:
  - Change in funding
  - Change in Investigators
  - Change in approved consent document
11. Approved applications will be **valid for a period of one year**. Work on a project **cannot** extend beyond the date approved by the IRB.
12. A mail will be sent to the Principal Investigators **60 days prior to the expiration** of the approval date.
13. 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 Report**”. 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.

14. Failure to receive the approval for continuing review before the expiration date means that the project/research must stop immediately.
15. **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.
16. 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.

### **TYPES 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 subject is restricted to the categories mentioned in [45 CFR 46.101\(b\)](#).

Research/Projects that qualify under the exempt status are reviewed by 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 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 ISB**

- Completes the appropriate human subject protection training programme / CITI certification, and will oversee the ethical conduct of research of his team of researchers.
- 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 ISB-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.

## **ISB- IRB MEMBER ROLES AND RESPONSIBILITIES**

### **IRB Member Responsibilities:**

#### **IRB members (Primary & Alternate) 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 ISB-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 ISB-IRB related correspondence
9. Reviewing the IRB budget.

**Alternate IRB Chair:**

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

**Alternate members:**

1. Alternate members are appointed to serve as a substitute for a regular/primary IRB member and to ensure that the IRB has appropriate expertise to review research.
2. The IRB roster indicates which primary member for which the alternate can substitute.
3. The alternate member steps in when there is a conflict of interest to the primary IRB member reviewing the research study.
4. When an alternate member substitutes for a primary member, the alternate receives and reviews same materials as the primary members.
5. The IRB minutes will document when and alternate member substitutes for a regular member.