ISB IRB FREQUENTLY ASKED QUESTIONS (FAQs)

- **What is the IRB?**
  IRB is the acronym for the Institutional Review Board. The IRB deals with the review of behavioral research involving human participants. The IRB approves and monitors ALL studies involving human participants to ensure that the experiments or surveys are designed to meet legal and ethical concerns and do not involve unnecessary risks for the participants.

- **When am I required to submit a proposal regarding research with human participants?**
  All research projects that will involve human participants must be submitted for IRB review and approval before participant recruitment and data collection; this includes advertising the study or any other subject recruitment procedures.

- **If I am just doing a simple survey, do I need to submit my proposal to the IRB**?
  Yes. If a study involves human participants, then approval from the IRB must be in place before any interventions or interaction with human participants.

- **If I am not collecting any identifying information in my human participant research project, do I need to submit my proposal to the IRB committee?**
  Yes. All research involving intervention and interaction with human participants, regardless of whether or not any identifying information is collected, must be submitted to the IRB for review. However, if your research project involves use of existing information collected from human participants (*e.g.*, secondary databases and existing biological samples), but there are no identifiers linking individuals to data/samples, then the IRB may approve your project with "Exempt status". Please contact IRBassist@isb.edu for any questions or more information.

- **Does research at a pilot or feasibility study stage need IRB approval?**
  Pilot studies and feasibility studies, including those involving only one human participant, require the same scrutiny as full-scale research projects. Pilot studies should be identified as such in the IRB application. It must be explained to the participants in the consent process that this is a pilot study. When the pilot study becomes the main study, the Principal Investigator must submit his or her revised protocol for review.

- **Do research projects conducted by ISB students need IRB approval?**
  Yes. Research projects undertaken by ISB students must be submitted for IRB review. This includes Faculty Initiated Research Projects (FIRP) or independent studies involving human-participant research. If the result of the project is to be used exclusively in a classroom setting for teaching, then the project may not be considered research. However, this means that at no point after the closure or conclusion of the course can the results or data be used for presentation, publications, or research purpose. Students should discuss this with their

instructors or faculty advisor and contact IRBassist@isb.edu to determine if their project requires IRB review.

- **If I will be coordinating with another institution, do I need to submit my proposal to the ISB IRB and to the other institution as well?**
  If you are a faculty member at ISB and you are the Principal Investigator/Co Investigator you must obtain ISB IRB approval regardless of where the research takes place. Principal Investigators must contact the IRB at their respective institutions whenever a collaborative research project is taking place.

- **If my research will be done in another country, do I need to obtain ISB IRB review and approval?**
  Yes. Principal Investigators must obtain ISB IRB approval regardless of where the research takes place. You should also be aware that you may require local IRB approval in addition to ISB IRB approval.

- **If my coauthor is from another institution, are they required to obtain IRB approval from their institution?**
  If your coauthor will not be involved in the data collection, and will only be involved with analysis of de-identified data and or/ writing the results, then they do not have to submit IRB approval from their institute. In this case they cannot use the study instruments approved by ISB IRB to collect data elsewhere. If your coauthor will be involved in the data collection process then they are required to submit IRB approval from their institute.

- **If my study involves deception, what additional precautions do I need to take for my proposal to the IRB?**
  The use of deception in research should be considered carefully. Deliberate deception of participants may occur only in cases when information about the study is withheld in order to ensure valid results. Deliberate deception should never get participants to do something that they would otherwise not do if they were fully informed of the situation and were not being deceived.

  Investigators considering deception should provide justification for the deceptive techniques they will use and should also document that there are no equally effective non-deceptive techniques available. They should describe the method, rationale, and their process of informing participants about the purpose of the research in the form of a debriefing statement, before or immediately after the conclusion of data collection.

- **If I am doing qualitative research studies, do I need to submit my proposal to the IRB?**
  Yes. Qualitative research including observation, depth interviews, focus groups and any other methodology involving interaction with human participants are required to be submitted for IRB approval.

- **Do students undertaking class projects need to obtain IRB approval?**
  Research activities such as class projects developed to provide research experience to students do not add to generalizable knowledge and do not need IRB approval.

- **Does my teaching study require IRB approval?**
  The answer is **yes**, if:
  1. You will be using the data in your dissertation or thesis.
  2. The data will be published.
  3. The data will be used to create a presentation that will be given at a peer-reviewed or professional conference.

  The answer is **no**, if you will be collecting the data only to improve your teaching skills.

- **When may I begin data collection for my study?**
  You must receive approval from the IRB before beginning participant recruitment, data collection, or data analysis. A confirmation via e-mail will be sent to you when your project has gained IRB approval.

- **How long will it take for me to obtain approval to do my study?**
  The IRB typically takes about 2 weeks to review an application. It may take the IRB up to 4 weeks to revert on more complex applications, such as research involving vulnerable populations (including minors), external organizations or sensitive issues.

- **Who can I talk to if I have a question about my project involving human participants?**
  Please write to IRBassist@isb.edu.

- **Are there sample protocol submissions available for a researcher to view?**
  A sample protocol would not be useful as there would be important modifications appropriate for each specific application. The application form is straightforward, and the policy and FAQs are detailed. Additionally, the IRBassist is available to answer questions from investigators about the review process, and to help investigators in preparing their protocols.

- **What does the IRB look for in an application? Are there standard evaluation criteria for evaluation?**
  The IRB considers whether risks and benefits of a study are acceptable and managed properly, and whether the individuals asked to participate in the study have adequate information about the study and its risks and benefits. The IRB's role is to review the study and to ensure that the proper precautions are taken to protect individuals when they agree participate in the study. The IRB also ensures that research participation is completely voluntary and there is no coercion involved. Please note this is particularly critical when participation is sought from students enrolled in an ISB course by the concerned teaching faculty.

- **What does informed consent mean?**
  Informing participants of the risks, benefits, and procedures involved in the study is a standard requirement in research with human participants. Consent is not considered to be "informed" unless the investigator discloses all the facts, risks, and discomforts that might be expected to influence the individual's willingness to participate in the study. This applies to all surveys, research methods, experiments, interviews, and observations in which participants are identified.

- **Do I have to always obtain informed consent?**
  Yes, the IRB requires obtaining the informed consent from participants.

- **Do I always have to obtain written permission from parents if children participate?**
  The IRB requires obtaining permission from the children's parents or guardians when children (less than 18 years) participate in research studies.

- **If I am not collecting any identifying information, do I still need to have informed consent from participants?**
  Yes. All the elements of the consent must be collected from the participants when they agree to participate in the research, even if the study is truly anonymous and is not coded for identifiers.
  - **Personally Identifiable Information (PII)** – also referred to as sensitive personal information is information that can be used on its own or with other information to identify, contact, or locate a single person, or to identify an individual in context. Under the US Health Insurance Portability and Accountability Act (HIPAA), there are 18 identifiers that are considered personally identifiable information
  - Personal Identifiers :
  - Name
  - Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
  - All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
  - Telephone numbers
  - Fax number
  - Email address
  - Social Security Number
  - Medical record number
  - Health plan beneficiary number
  - Account number
  - Certificate or license number
  - Any vehicle or other device serial number
  - Web URL
  - Internet Protocol (IP) Address

- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual.
- There are also additional standards and criteria to protect individual's privacy from re-identification. Any code used to replace the identifiers in datasets such that the information would still be considered identifiable if there was a way to identify the individual even though all of the 18 identifiers were removed.

- **Private Information** - includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (**45 CFR 46.102**) In general, private information is considered to be individually identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person could ascertain the identities of the individuals

- **Protected Health Information (PHI)** – includes under US law, any information about health status that is created or collected by a "Covered Entity" (or Business Associated of a Covered Entity) and can be linked to a specific individual. When personally identifiable information is used in conjunction with one's physical or mental health or condition, health care, or one's payment for that health care, it becomes Protected Health Information (PHI).

- **How is consent obtained for online research?**
  Participants still must be presented with the consent information in a separate document online before the research begins even if the actual research does not record the participants' information. Please write to the IRBassist@isb.edu for more information and refer to the sample online consent form.

- **How is consent obtained for research with illiterate participants?**
  Participants who cannot read or write must be verbally presented with the consent information in a manner that they understand and a thumb impression should be obtained. Please write to IRBassist@isb.edu for more information.

- **What are the requirements for consent for phone based research?**
  For protocols involving oral consent, the following information is required to be communicated to the participants:
  1. The purpose of the study and the procedures involved.

2. What the participant will be asked to do and the time spent by the participant.
3. The expected compensation that will be awarded during or after participation.
4. The voluntary nature of participation in the study.
5. That the participant is free to withdraw at any time.
6. That the information will remain confidential.
7. The contact information of the researcher and of the IRB.

- **Are there any sample consent templates available for review?**
  Yes. Click *here* for sample consent forms.

- **What are the requirements for research conducted with an external organization that involves data sharing?**
  The IRB would require a letter of consent for the specific research by the appropriate authority in the external organization. Please consult with the legal team at ISB, to clarify whether a NDA would be appropriate in your case. In case an external data collection agency (example, a market research agency) is used, a declaration from the agency is required stating that all ISB IRB protocols would be followed and the consent form would be administered.

- **What are the IRB requirements for training?**
  Investigators and researchers must have the training and expertise to ensure that the rights, welfare, and safety of participants are protected and must apply all relevant professional standards to research.

  At ISB, all researchers are required to successfully complete the CITI Program training and ethical conduct of research with human participants.

- **Who is required to complete human participants training?**
  All faculty, researchers, staff, and students at ISB who intend to conduct research with human participants must complete human participants training and obtain a CITI certification. Approvals for including human participation in research will not be granted until this training has been completed.

- **How can I take training?**
  Write to the ISB IRB at IRBassist@isb.edu for instructions and guidelines on CITI training.

- **Does the IRB provide any other training to investigators?**
  Yes. The IRB strives to provide information and assistance to researchers and investigators. The IRB holds formal training sessions to help educate the research community about different IRB and human participant research topics. Arrangements can be made to present IRB topics to a small group of people to meet their specific needs or to more general groups.

- **Where can I access the IRB application form?**
  Download the IRB application from the Atrium; attach all supplements and required information. Atrium: *click here*

- **When should a modification to an already approved research study be submitted?**
  Any and all major changes (collection of new outcome variables, identifying or sensitive information, or use of different stimuli materials as approved in the original protocol) to an approved research study must be submitted to the IRB before implementing the changes in the research study.

- **What do I have to do if I need to modify a research project?**
  Investigators and researchers with approved projects must submit a modification application to the IRB at IRBassist@isb.edu if there are any changes in the research protocol, funding, study design, informed consent procedure, or Principal Investigator team.

- **How long is the IRB approval on my protocol valid?**
  At the Indian School of Business our IRB approval on the originally submitted materials is valid for one year. During this time any modifications in the research protocol need to be submitted for review.

- **Does an approval of modification extend the original approval date?**
  No. The original date of the approved application will not change when approval for modification is obtained.

- **If my protocol is approaching the expiration date, what do I do?**
  It is the responsibility of the Principal Investigator to submit a progress report on the current status of the project and to seek continued approval for his or her human participation research. Approximately two months before the approval expiration date, the IRB office will send a reminder to the Principal Investigator or faculty advisor. If approval is allowed to expire, all research on the study must cease until renewed approval is granted.
  The **progress report** can be accessed *here.*

- **Can the IRB temporarily or permanently discontinue a research project as a result of unanticipated problem involving risks to participants or others**?
  Yes. If an unanticipated problem poses risk to participants or others, the IRB may temporarily discontinue a research project and conduct a thorough investigation. If required, the ISB legal team may get involved to seek appropriate legal help.

  Serious adverse events must be reported to the IRB immediately in a written report by the Principal Investigator. Prompt reporting is required, as serious unanticipated problems may require modification of the research protocol, design, or informed consent procedure.

- **Can the IRB request revisions to an approved research study and informed consent procedure in case of an unanticipated problem?**
  Yes. As a result of an investigation of an unanticipated problem, the IRB may request modification of the research protocol, design, or informed consent procedure

- **Do I need to inform the participant if I am audio recording or video recording the interview (online interview or in person interview)?**
  Yes, this information must be provided to the participant in the consent form and only after the consent is taken, the researcher should start recording the interview.