

IRB Basics

What is the IRB?

A committee of faculty, staff and community members, supported by a group of IRB staff, that reviews human subjects research projects to meet two primary goals:

1. Protection of the **rights and welfare of human subjects** who voluntarily give their time, energy, and often very private, personal information to better society through research;
2. Maintain **institutional compliance** with federal requirements.

What does the IRB consider during review?

Non-exempt projects must meet ALL of the following criteria to be approved:

1. **Risks to subjects must be *minimized*** – sound scientific design, no unnecessary procedures, adequate plans to prevent harm (when possible), researchers are qualified, etc.
2. **Risks must be reasonable in relation to anticipated benefits** of the research – in other words, there must be adequate scientific justification for exposing research participants to any risks associated with the study.
3. **Subject selection must be equitable** – participant selection should be justified by the research question(s); not solely due to ease of access (particularly if they may be vulnerable).
4. Adequate provisions to protect the **privacy of subjects** and to **maintain confidentiality of the data collected** – the IRB considers both privacy and confidentiality at all parts of the study (recruitment, during data collection, security of the data, sharing of results, etc.).
5. **Informed consent will be obtained** from each participant *prior to their inclusion* in the study, unless waived by the IRB.¹
6. **Informed consent will be documented** (by handwritten or electronic signature), unless this requirement is waived by the IRB. If the documentation requirement is waived, the IRB may require written information to be provided to research participants.
7. When appropriate, **additional safeguards** are in place to protect the rights and welfare of subjects who may be **vulnerable to coercion or undue influence (children, educationally or economically disadvantaged, individuals with impaired decision-making capacity, prisoners, students or employees—in some cases)**.
8. When appropriate (i.e., clinical trials, high risk research, etc.), the research plan includes **adequate provisions for monitoring the data collected to ensure the safety of subjects**.

¹ Consent is not required prior to screening/assessing eligibility when the procedures are limited to obtaining information through oral or written communication from subjects (e.g., screening interviews or surveys), or obtaining data from records or stored bio-specimens.

Does the entire committee review all IRB applications?

No. Review is handled differently depending on a variety of factors, including regulatory requirements, risk to subjects and ethical considerations, ISU policies, etc. There are different types of review that vary in terms of regulatory requirement and who conducts the review. Review types are as follows:

Exempt Review

Certain types of projects are deemed “exempt” from most regulatory requirements governing human subjects research. However, these projects still require review by IRB Administrative staff to assess whether they eligible for exemption. In some cases, a process called “limited IRB review” is required.

Exemption is allowable only when *all of the following conditions* are met:

- A. Research presents little to no risk of harm to participants; AND
- B. All research procedures fit into one or more of the regulatory exemptions; AND
- C. Confidentiality of participants will be protected when results are disseminated (no deductive disclosure concerns); AND
- D. The research does not include prisoners. Research with prisoners reviewed under the 2018 Common Rule may be exempt if the research is intended to involve a broader population, and only incidentally includes prisoners.

Common examples of exempt research include:

- Anonymous surveys of adults;
- Interviews/focus groups with adults where the topics are not sensitive or overly personal (would not present any risk if accidentally disclosed);
- Research in established/accepted educational settings involving only normal educational practices;
- Secondary research using de-identified data or records (e.g., de-identified student record data) or information that is publicly available (public blog posts, public meeting minutes, etc.);
- Some research involving benign behavioral interventions that are brief in duration, harmless and painless, and not physically invasive, such as solving puzzles under various noise conditions, or playing an online game. Participants must prospectively agree, and data can be obtained only through verbal or written responses from participants or audiovisual recording.
- Taste tests of food products that involve only wholesome foods without additives, or where additives/ingredients are at levels deemed safe by the FDA or USDA.

Note: Surveys and interviews with children are not eligible for exempt review.

Although there are fewer regulatory requirements for exempt research, **researchers are expected to honor basic ethical considerations, such as voluntary informed consent, protecting confidentiality, etc.**

Non-Exempt Review

The IRB is responsible for ensuring that all non-exempt research meets regulatory requirements governing human subjects research. Non-exempt research is reviewed in one of two ways:

1. **Review and approval by an IRB Chair** (including the Co-Chair or Vice Chair) on behalf of the IRB. This is also known as “Expedited” review, and is allowable under the following conditions:
 - A. The research presents minimal risk – risk commensurate with routine physical/psychological exams or daily life; AND
 - B. All research procedures fit into one or more regulatory categories (including minor changes to research previously approved by the full-board); AND
 - C. Confidentiality of participants will be protected when results are disseminated (no deductive disclosure concerns); AND
 - D. The Chair(s) have the appropriate disciplinary expertise to evaluate the research.

Common examples of research eligible for Chair/Expedited review include:

- Many social/behavioral research methods (that do not involve thorny ethical issues, such as deception, coercion concerns, or inclusion of vulnerable populations, or collection of highly sensitive information);
- Secondary use of private and identifiable existing data
- Use of non-invasive, FDA cleared sensors (EEG, EKG, etc.), or noninvasive specimen collection (hair clippings, skin cells, saliva samples, etc.);
- Mild to moderate exercise, height/weight measures;
- Blood draws (under certain amounts and for certain populations).

2. **Review by the convened board during a meeting** – also known as “full-board review”. The full-board reviews:
 - A. Research projects not eligible for exempt or IRB Chair (“expedited”) review;
 - B. Research projects that the Chair(s), at their discretion, refer for board review;
 - C. Adverse events, unanticipated problems, cases of noncompliance, and similar issues;
 - D. IRB policies

Common examples of research requiring full-board review

- Research involving vulnerable populations (prisoners, children in some cases, subjects with cognitive impairment, employees/students in some cases);
- Collection of highly sensitive or personal information (detailed health/mental health, sexual practices, illegal behavior, drug/alcohol use, etc.);
- Invasive or strenuous procedures, x-rays or DXA scans, some blood draws;
- Research on drugs, food additives/products, dietary supplements, or medical devices

How do I seek IRB approval of a new human subjects research project?

Step 1: Take [Human Subjects Protection Training](#) – training is also required for all personnel on the project.

Step 2: Develop and finalize your research plan, including the logistics of how it will be carried out, and the materials you will use for recruitment, consent and data collection – you will need this information to complete the IRB application.

Step 3: Check the [PI Eligibility Policy](#) – if you are a student, post-doc, or are otherwise not eligible to serve individually as PI, identify someone to serve as “Supervising Investigator.”

Step 4: Complete an IRB application in [IRBManager](#).

If you have questions, feel free to contact [IRB staff](#) or your Supervising Investigator (for student projects).

Step 5: Obtain required signatures – allow time for review by those signing

Applications must be reviewed and signed by the **PI, Supervising Investigator** (when applicable), and PI’s **Department Chair/Supervisor**. **IRBManager will notify parties by email when an application has been routed to them for signature.** Keep in mind that some departments have an internal review process required prior to Department Chair review.

NOTE: The PI, Supervising Investigator, and all faculty and P&S staff members of the research team also complete a brief Conflict of Interest (COI) check before an initial application for a study is routed to the department chair for review. These study personnel will receive a COI notification from IRBManager after the PI (or Supervising Investigator, when relevant) has approved the application.

Step 6: Once all parties have signed the application, it will be automatically routed to IRB staff.

What happens next?

- 1. Initial Screening** -- IRB Administrators screen incoming applications for completeness and to determine level of review (exempt, full-board, Chair review).
 - Incomplete applications – those that are missing key information or necessary materials – are sent back to the PI.
 - Complete applications – placed in queue for review.
- 2. Pre-Review** -- an IRB Administrator works with you to prepare applications for final review by the full-board or IRB Chair(s). The Administrator may grant exemption for eligible projects.
- 3. Full-Board or Chair Review** – a careful review of the protocol to assess whether the criteria for approval are met. Possible outcomes include:
 - Approval as proposed
 - Approval with specific contingencies or stipulations
 - “Defer” or “Table” review because additional information is needed
 - Disapproval (only the full-board can disapprove projects; disapproval is very, very rare)

4. **Post-Review follow-up** – you will be informed about the outcome of review and any stipulations for approval or additional information needed.
5. **Approval!** Once you receive notification of approval (it will be sent via email by IRBManager), you may proceed with the project! No recruitment of subjects or data collection can begin until you receive the notification of approval.
 - For studies which require formal continuing review, approval is granted for a specific period of time, established during IRB review, based on risk to participants and regulatory/policy requirements (see [Continuing Review guidance](#) for more information).

What are my responsibilities after IRB approval is obtained?

1. **Strictly following the approved protocol**
2. **Seeking prior IRB approval of Changes/Modifications to the approved protocol**
 - Required for **ANY change to non-exempt research**
 - Required for [SOME changes to exempt research](#)
3. **Promptly reporting any [adverse events or unanticipated problems](#)** (e.g., a subject is harmed, confidentiality breaches, laptop containing data is stolen, complaints, etc.).
4. **Promptly reporting to the IRB any noncompliance or protocol deviations** (if you realize that you have not been following the approved protocol).
5. For some non-exempt research, **renewing IRB approval ([continuing review](#)) prior to expiration.**
6. Formally **“closing” the project** to IRB oversight once the research is complete or no longer requires oversight. In general, IRB oversight is no longer required when:
 - All enrollment, data collection, and follow-up with human subjects is complete; and
 - All data have been completely de-identified, including destruction of any “keys” linking ID codes with subjects’ identities.See the IRB Guidance on [Study Closure](#) for specific details.
7. **If you leave ISU, and your research is ongoing**, consider the following options:
 - a. If you will continue to collaborate with ISU researchers, the ISU IRB may be able to continue oversight; an ISU faculty member must agree to assume the role of PI on the project.
 - b. Check with your new institution about their requirements; a formal agreement allowing their IRB to rely on ISU’s IRB for review may be needed.
 - i. If you will no longer collaborate with anyone at ISU, you should transfer IRB oversight to your new institution and formally close the project to oversight at ISU.

When does the IRB Meet?

The IRB (full-board) normally meets twice monthly, on the first and third Tuesdays.

Schedules can change during summer, breaks, and holidays. Check the IRB website for the [IRB meeting schedule!](#)

Are there any deadlines for submission of IRB applications?

For research that is **reviewed by the IRB Chair(s)** or is **eligible for exempt review**, there are **no submission deadlines**; applications are placed in a queue and reviewed in the order they are received.

For research that requires **review by the full-board**, the **submission deadline is two weeks prior to a scheduled meeting**. This timeframe is to allow adequate time for IRB staff to prepare the application and ensure IRB members have sufficient time for a careful review.

Normally, applications received by the deadline are placed on the agenda for the next IRB meeting. However, this may not occur if:

- The application is incomplete or requires significant revision to address issues related to lack of clarity, missing materials, inconsistencies, etc.
- The research requires input from a member or consultant with specific expertise, and that individual is unavailable or needs additional time for adequate review.
- There is unusually high volume, and the agenda for the upcoming meeting is already “full.” In this case, the application will be placed on the agenda for the first available meeting.

Submission deadlines may change around holidays, breaks, or during the summer due to member availability. Check the IRB website for [submission deadlines](#).

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