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Utah State University - Physical Science Responsible Conduct of Research Course

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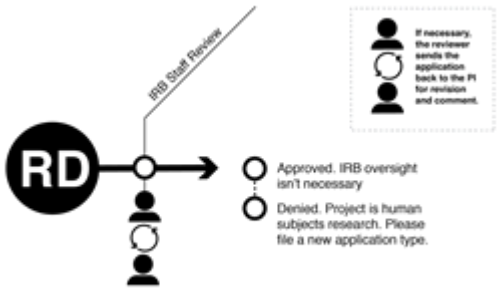
Introduction to Institutional Review Board Structure and Processes

Timelines & Review Types

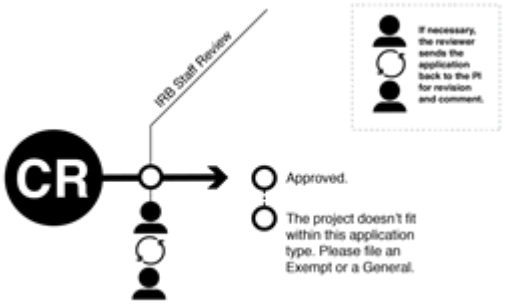
There are five different types of applications and corresponding review types for IRB approval. While you must choose which application type to submit, the IRB Office is responsible for ensuring that your project is reviewed under the correct category.

Request for Determination: Initial review within 1-2 business days



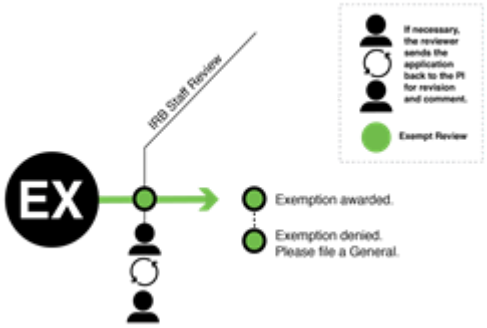
If you are unsure whether your study qualifies as human subjects research and corresponding IRB review, you can submit a request for determination.

Course Research: 2-4 weeks processing time



Most classroom-based activities that mimic research (e.g., purpose, method) do not constitute research according to our policy. As such, the USU IRB can assign formally oversight of methodological and human subjects protections to a Ph.D.-level, CITI certified instructor.

Exempt Application: 1-3 week Process



Under the DHHS regulations, some research is exempt from regulation requirements. Note that **all research** – even research that falls into one of the exempt categories – must be submitted to the IRB prior to the beginning of research activities.

General Application

Expedited: 6-8 Weeks. These types of studies are reviewed by two board members and reported to the remaining board in a monthly report or at its next convened meeting.
Full Board Review: 8 + Weeks. For all studies that do not qualify as exempt or are not eligible for expedited review, protocol review is conducted by the convened IRB at monthly meetings.

Materials to Have Prepared

- Research proposal
- Surveys, questionnaires, data collection instruments, etc.

- Description of vulnerable populations, justification of their inclusion, and steps taken for enhanced protections
- Informed consent documents, including assent documents for work with children
- Recruitment flyers
- Recruitment scripts (for advertisements and in-person)

Staffing

More information about each staff member is available on the **IRB website**.

Institutional official

The Vice President for Research is USU's Institutional Official (IO) and is ultimately responsible for overseeing the protection of human participants involved in USU's human research.

IRB chair

In addition to the responsibilities of IRB membership, the Chair has primary responsibility for conducting IRB meetings and directing the IRB Director and staff to ensure operation of the IRB within all applicable regulatory requirements.

IRB director

The IRB Director, among other tasks, directs and oversees all IRB support functions and operations, serves as a member of the IRB, and develops and implements procedures to effect efficient document flow and maintenance of all IRB records.

IRB Coordinators

IRB Coordinators support the function and operation of the IRB at the direction and under the supervision of the IRB Director. This includes reviewing protocols, attending all IRB meetings, and in some cases serving as an IRB member.

IRB members

IRB members are faculty and community members responsible for ensuring that the rights and welfare of research participants are protected. Members attend IRB meetings on a regular basis, serve as reviewers for research within their areas of expertise, as well as serve as general reviewers on all research discussed at convened meetings.

Institutional Authorization Agreement

If you are collaborating on a project with a colleague at another institution, ask the **IRB staff** about getting an Institutional Authorization Agreement (IAA) or Reliance Agreement in place. IAAs allow one IRB to rely on the review conducted by another IRB. Different institutions have different policies when it comes to IAAs, so be sure to touch base with each IRB to determine necessary steps. Utah State University now uses SMART IRB for its Reliance Agreements, so please **request access** to that system in advance of your need for a Reliance Agreement (you can do it at any time!).

Continuing Review

Continuing Review

It is the responsibility of the PI to assure that IRB approval of a protocol is continuous. All expedited and full board protocols are reviewed at least annually. Chapter 6 of the **IRB Investigator Handbook** outlines the continuing review process in detail.

Amendments (protocol revisions)

Federal regulations require that any proposed change or revision to a currently approved study which affects human participants be reviewed and approved by the IRB **prior** to the implementation of that change.
Non-minor revisions are those that may involve increased risk to participants or that substantially change the structure of the study. Non-minor revisions will require the submission of a new protocol.

Graduate Student Forms

If thesis or dissertation research requires IRB approval, the student must download a copy of the Thesis Approval/Application for Candidacy for a Doctoral Degree Form after it has been signed by all committee members and submit a copy of the document in Protis under the 'Students, Dates, and Funding' tab, where it requests a signed copy of the proposal cover page. The form does not need to be signed by the Graduate School for IRB purposes, just committee members, so students should provide that document in their protocols even though the signature process will still be pending with the IRB Office.

Reportable events

Reportable events include a) deviations from protocols that represent a significant alteration in the approved written protocol and/or affects the safety and welfare of the participant, b) unanticipated problems, and c) pending audits or inquiries from a federal or state department, agency, or sponsor. Chapter 9 of the **Investigator Handbook**

covers each type of reportable event in more detail. Forms for reporting can be found on the **Resources** page of the IRB website.

This module has a quiz.

Return to Gradebook | Take the Quiz