Arizona State University

IRB FAQs

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General Inquiries

How do I know if my proposed project requires ASU IRB approval?

IRB review is required if the study meets the definition of involving human subjects and the definition of research.

- A human subject is defined as "a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information."
- Research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

This includes conducting research using online surveys, analyzing human subject data that have been previously collected, analysis of coursework, interviews, etc.

If you are unsure if IRB review is required, please contact ASUIRB@asu.edu.

Are there any special requirements if ASU is serving as a study site?

If ASU is serving as a study site and no ASU students, faculty, staff, or employees will be members of the research team (or will be collaborating with external research team outside ASU besides being subjects of the research/research participants), then formal review by the ASU IRB is not required. Note that the ASU IRB cannot provide access to the study sample. You may be required to contact the appropriate department/unit for approvals. For studies involving data collection from ASU students outside ASU PI's academic unit, additional approvals may be required from the Provost Committee.

What is ERA and how do I access the portal?

ASU's Enterprise Research Administration system (ERA) provides an integrated platform for the administration of research and sponsored projects at ASU. ASU Researchers use this portal to submit IRB application materials for review. To access the portal, click here.

I am trying to login to ERA, but I am receiving an error message. Who should I contact for assistance?

You must reach out to RTSHelp@asu.edu and ensure to include "Assign to ERA Dev" in the subject line. In addition, copy the ASUIRB@asu.edu inbox for awareness.

Who can serve as the Principal Investigator (PI) on an IRB submission?

Only full-time faculty/staff (i.e., not students or postdocs) can serve as the PI on the IRB submission. See policy regarding PI eligibility.

What resources are available to review Federal regulations and ASU policies?

Investigators can review Federal regulations, Federal guidance documents, ethical codes, and ASU and ABOR policies and procedures related to Human Subjects Research here.

CITI Training

Who is required to complete human subjects research training and how can I access it?

All researchers and study team members engaged in human subjects research at ASU must complete training before being approved to work on a project (whether they are currently affiliated with ASU or as an external collaborator). We define "engagement" as being involved in any of the following activities:

- obtaining informed consent of a human subject for research
- data collection (unless they are collecting data as part of their normal job and are not involved with the research project beyond their 'job' for example, a hired phlebotomist or professional transcription service)
- data storage or access to study data
- data analysis (even if the data is de-identified)

ASU provides IRB training through a third-party called CITI Program, which can be accessed at the link here. If you have questions about whether someone is engaged in research or about CITI, you may contact ASUIRB@asu.edu.

Does my CITI training expire?

CITI Program training is valid for 48 months. You are required to complete the refresher course once your training expires.

I am transferring from another university. Does ASU accept certificates from other institutions?

ASU may accept IRB training that was previously completed through another institution (either CITI training or an alternative). Please upload a copy of your certificate of completion with other study materials when you submit your IRB study. The IRB can let you know if this is appropriate.

How do I login to CITI and start my IRB training?

For instructions on how to do so, you can click here, scroll down to the bottom of the webpage, and review the appropriate process:

- Instructions to login into CITI training with your ASURITE
- Instructions to login into CITI training as an external affiliate/collaborator
- Instructions to ASU as an affiliation if you have already completed CITI training at another institution

Application Process

My sponsor requires IRB approval before my grant can be accepted. What documentation can I provide since my study plans are not finalized yet?

Occasionally, a sponsor will require IRB approval or pending approval before a grant will be accepted. A 118 letter (named from Federal Regulation 45CFR46.118) is for just-in-time situations where the funding agency needs documentation from the IRB, but the IRB doesn't have anything to review. It is notification that the IRB is aware of the study and that approval will be obtained once materials have been developed. The 118 letter doesn't let you conduct any

research with human subjects (actual approval is still required), but does let you develop the materials to conduct that research.

To request a 118 letter:

1. Log into ERA IRB module: https://era.oked.asu.edu
2. Create a new study.
3. Fill out the basic IRB study information.
4. Under “Attach a protocol" section, fill out/upload the JIT 118 letter template with your specific project information, available here:

5. Under "Study Funding Sources", include: the funding source (typically the direct sponsor unless there is a primary/originating sponsor), Grants Office ID (FP000XXXXX), and the fully funded proposal.
6. Finish the application and return to the main IRB submission page.
7. Click "submit response".

What is the Wizard Tool and how do I know if my study is eligible?

ASU IRB has implemented a Wizard tool to streamline IRB review process for studies that fall under one or more exempt categories. ASU researchers can gather more information about the Wizard tool by clicking here.

My study is not eligible for the Wizard Tool. How does the ASU IRB review applications?

Submit your study directly to ERA. If you have questions about your study’s determination, you can contact ASUIRB@asu.edu for clarification.

ASU’s review process is designed to efficiently assess the risk of a study to human subjects. Studies involving higher risk undergo greater scrutiny while low risk studies can be reviewed and approved more quickly.Studies proposed with protected/vulnerable populations like prisoners, pregnant women, fetus involving risks to these populationscan take longer to approve. Also, studies that are proposed with Tribes require cultural review in addition to IRB review.

In general, there are three review categories:

	Expires	Requires Modifications	Requires Reporting of Adverse Events (RNIs)	Requires Yearly Continuing Review (CRs/MODCRs) or study closure
Exempt	No	*Some	Yes	No
Expedited	Yes	Yes	Yes	IRB makes the determination
Full Board	Yes	Yes	Yes	**Yes

* Changes to exempt studies do not need review unless change would make the study non-exempt, a change in the approved procedures, and/or changes to study team members. Contact ASUIRB@asu.edu to determine if a modification is required.

** Must be done by a convened full board. The board review schedule can be found here.

For additional details, you can review additional resources on this topic by clicking here.

I would like to submit my study for IRB review. What materials do I need to prepare before submitting my application to ERA?

You can view details on protocol submission here.

In general, the following items are required:

1. Identification of an eligible PI; see policy: https://researchadmin.asu.edu/pi-eligibility
2. Protocol template: fill out every section of the form according to the guidance provided within it. If a section does not apply, provide a brief explanation as to why. Every submission must include one of the two protocol templates, which can be found here.
3. Recruitment materials: you must submit any recruitment materials to be used for review and approval. You may create your own or use one of the following templates for guidance.
4. Consent form: almost every study will require a consent form to be developed and attached to the submission. Use the appropriate form for guidance. If your research involves minors, an assent, and parental permission form may be required. Medical release or data repository consent form templates are also available.
5. Identification of study team and completed CITI training.
6. Fully funded proposal documentation (if your study is externally funded outside of ASU). You will also need Grant Office ID (FP000XXXXX) and to notate the direct sponsor (or prime/originating sponsor) within the Study Funding Sources in ERA.
7. Site permissions (if applicable): we prefer having the letter on the external organization's letterhead that has all the contact information for the authorized signatory official. As far as content is concerned, you must include the following:
    A. A statement that they are aware of ASU researchers conducting the project.
    B. A few details about the purpose of the project, target participants and proposed data collection procedures, and any other resources that the site is willing to offer (such as conference room, staff etc.).
8. Review of special circumstances (further discussed below)

As I am gathering my application materials, what are some examples of special circumstances I should consider?

Below are some examples of special circumstances that may be applicable to your study. If you have any questions, you may email ASUIRB@asu.edu. To review the special considerations listed below in greater detail (as well as other examples), you may access the link here.

A. Data Use Agreements (DUAs)

A Data Use Agreement (DUA) may be required whenever certain types of human subject data are being sent or received between ASU and an Outside Party. If there is a need to

put a DUA into place per data provider's request or a signature is needed on a current DUA, please reach out to proposalandnegotiation@asu.edu. DUAs typically have institutional terms and conditions; therefore, they should not be signed by an Investigator/student/post doc.

B. Research Subject Compensation

Arizona State University (ASU) is responsible for maintaining various levels of confidentiality with respect to information obtained from or about individuals participating in research. At the same time, ASU must comply with the record keeping requirements of the State of Arizona, sponsoring agencies, and the Internal Revenue Service. Consistent with FIN 421-05 ("Human Subject Payments"), payments to individuals participating in research studies must be recorded as a form of compensation. When considering payments to individuals participating in research studies, researchers are strongly advised to review FIN 421-05 ("Human Subject Payments") as well as FIN 401-03 ("Prohibited Transactions") carefully and consult with their unit's business operations team during research study planning.

NOTE: Department Research Administrator and Business Officer staff are critical partners in assisting faculty members to determine an appropriate mechanism for research subject payments. Business office resources regarding research subject pay can be found here.

C. Collaborating with Other Institutions

When work involves researchers from multiple institutions under the purview of different IRBs, you may proceed one of two ways:

1. Have each IRB review the submission independently. Your initial submission should only include ASU researchers and describe the scope of the project as ASU will be involved. Other researchers can then be added via a modification as their IRBs review and approve their role in the project.
2. Have one IRB serve as the IRB of record. This means that one IRB gives up oversight of the research activity to another IRB via an affiliation agreement. These agreements are designed to reduce duplication and increase efficiency by designating a single IRB review when more than one site is involved in a research project. The research team will need to contact each IRB to confirm that they are willing to defer review to a single IRB of record before submitting. Institutional officials at each IRB will then sign an affiliation agreement that you will need to submit according to their policies and procedures. Details on affiliation agreements can be found here.

When another IRB is designated as the IRB of record, then the ASU IRB will rely on the review, approval and continuing oversight by the responsible IRB. After the external IRB has agreed to serve as the IRB of record, ASU will conduct a local context review. A local context review is required when ASU researcher(s) are engaged in human subjects research (through consenting, collecting data or analyzing data even if it is de-identified).

When submitting a local context review via ERA for review, ensure the following documents are included:

1. External IRB Documents:
    a. IRB approval letter
    b. Approved IRB protocol application
    c. All approved document (consent forms, recruitment scripts, data collection tools, etc.)
2. Local context review form
3. For any external collaborators:
    a. CITI training completion certificates
    b. A word document with a list of external study team members describing their roles
4. If there are funds coming to ASU (Study Funding Sources):
    a. Funding Source (XXX)
    b. Grants Office ID (FP000XXXXX)
    c. Attachments (fully funded proposal)
5. IRB reliance agreement/Institutional Affiliation Agreement (which may be executed before ASU PI submits to the IRB or during the IRB review at ASU via email or SMART IRB portal)

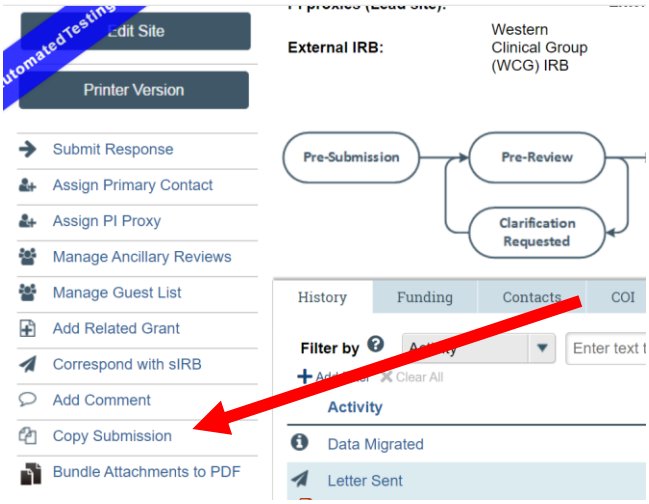
I have all my materials ready to go. How do I submit my study through ERA?
To submit your study to ERA for IRB review, please click here to watch videos on the submission process.

Study Closure

Our team has completed all human subjects research activities. We are now in the process of publishing our results. Do I need to submit a Continuing Review?
If all human subjects research activities are complete, including data analysis (even if the data is de-identified), then you may close the study.

The activities for this project are complete. How do I close my study in ERA?
Instructions for closing an IRB study can be found here.

If my study is closed, am I able to reopen my study for additional project scope?
Though you are not able to reopen a study that has been closed, you can create a new submission by selecting “Copy Submission” within the study record:


Edit Site
Printer Version
Submit Response
Assign Primary Contact
Assign PI Proxy
Manage Ancillary Reviews
Manage Guest List
Add Related Grant
Correspond with sIRB
Add Comment
Copy Submission
Bundle Attachments to PDF
External IRB:
Western Clinical Group (WCG) IRB
Pre-Submission
Pre-Review
Clarification Requested
History
Funding
Contacts
COI
Filter by
Clear All
Activity
Data Migrated
Letter Sent