

FAQ on Submitting a Project to Western IRB

Is my project eligible to be reviewed by Western IRB (WIRB)?

Projects eligible for submission to Western Institutional Review Board must meet the following criteria:

- Adult
- Phase I, II or III
- Industry sponsored
- Multi-site

Can I transfer my existing UA project to WIRB?

No. The contract between The University of Arizona (UA) and WIRB does not allow existing UA projects to be transferred to WIRB.

What is the University of Arizona's role when a project is being submitted to WIRB?

In accordance with the Office of Human Research Protections (OHRP), investigators at the University of Arizona are obligated to submit research through the UA IRB. The UA and WIRB have a contract that allows the UA to turn over its IRB responsibilities to WIRB for a subset of projects (see section "Is my project eligible to be reviewed by Western IRB?"). The UA's role is to perform a local context review that ensures that the project is in compliance with all state and local laws and that UA Policy and Procedures are followed. Finally, the local context review evaluates whether the project is appropriate to be conducted at this institution. Part of the local context review is to ensure that all necessary approvals are in place (see UA HSPP Policies and Procedures Section I.B.3.a.i.)

"All other approvals" includes:

- Institutional Review Committee – (Conflict of Interest) – a Conflict of Interest Disclosure form must be on file with the Vice President of Research Office.
- Scientific Review Committee – for all projects conducted at the Arizona Cancer Center
- Medical Radiation Safety Committee – for any project using radiation, MRI, or lasers, regardless of clinical indication
- Institutional Biosafety Committee – for projects that involve gene therapy, recombinant DNA, or use of agents from the CDC/DHHS Select Toxins list
- UMC Clinical Biomedical Engineering – for projects using an electrical device at UMC on UMC patients that is not currently overseen by UMC.

Please note that any applicable approvals from the above entities must be secured and submitted prior to initiation of the research study.

What needs to be submitted to the UA HSPP office for a new project requesting review by WIRB?

- Application – WIRB Local Context Review
- WIRB Application Form
- \$1,000 review fee paid at the time of submission

How do I submit my request to the UA HSPP office?

1. Submit the Project Approval Form for Submission to Western IRB (WIRB), WIRB application, and IDB to the HSPP office. In accordance with FSO requirements, the original signed IDB must be submitted to the HSPP office to obtain the appropriate original signatures. The Project Approval Form for Submission to WIRB may be scanned and sent electronically to irb@email.arizona.edu.
2. This document will be forwarded to Wendy Tate for processing.
3. A letter allowing review by WIRB is issued to the PI.
4. The PI submits the project and the UA letter to WIRB for review.
5. WIRB notifies the PI and the HSPP office of the project approval.
6. Upon receipt, the HSPP office will request complete project documentation for further review. Documents may be sent electronically to irb@email.arizona.edu. Use clear email names and document names to help facilitate review of the project.

What are the PI's responsibilities for a project to be overseen by WIRB?

As the HSPP office will not be seeing the project in its entirety until after WIRB approval, the PI is responsible for ensuring that all local policies and procedures are properly executed in the WIRB submission. While requirements will vary depending on the type of project, the following represent major items that the PI will need to address.

The number of subjects to be enrolled locally must be included in the consent form.

Contact information for The University of Arizona Human Subjects Protection Program must be included in the consent document as subjects may want to talk to a neutral, local party.

Entities that have access to study information, including The University of Arizona Human Subjects Protection Program and other local applicable entities (e.g. Cancer Center, University Medical Center, University Physicians Healthcare, etc.) must be listed in the consent form and PHI Authorization Form (if applicable) has having access.

In accordance with the operating procedures of the biomedical IRB Committees at The University of Arizona, the PI must ensure that the local site will not allow unspecified future research to be conducted on samples collected under the proposed research project. Research will be limited to the anatomical system, class of diseases, or drug/device being studied. Arrangements must be made with WIRB and the sponsor to ensure this requirement is met.

In accordance with Federal regulations and UA HSPP Policies and Procedures, the consent form must not contain and exculpatory language. The UA has set that exculpatory language includes any language regarding lack of compensation for research-related injury due to the subject failing to follow instructions.

In accordance with the UA HSPP Policies and Procedures, all study staff must maintain active human subjects training (CITI) approval throughout the life of the project. UA CITI training must be renewed every two years.

In accordance with AAHRPP accreditation requirements, the PI must ensure that they have identified all units that need to be prepared for their involvement in the research project and the

mechanism used to facilitate communication with those units. This includes services rendered by University Medical Center (pharmacy, nursing, radiology, phlebotomy, laboratory services, etc.).

The Department Head and/or Dean of the unit overseeing this project must be notified of the intent to perform this project. They must concur with the submission of this project. Concurrence does not need to be documented.

In accordance with The University of Arizona Policy, the original signed consent forms must be stored in the official departmental location as designated by the Department Head. This is to ensure access by auditing entities at any time.

In accordance with UA HSPP Policies and Procedures, any recruitment or research procedures that will be done outside of the PI's home department/clinic will be done after obtaining written site authorization from a member of that unit with authoritative power to grant access.

No study procedures will take place at the Southern Arizona VA Health Care System (SAVAHCS) in accordance with national VA regulations.

Can I use the WIRB approved consent form template?

Yes. WIRB has their consent form template with our required language integrated into it. If WIRB is creating the final consent forms for the project, they will add our required language (e.g. contacts, number of local subjects to be enrolled and research-related injury language).

Can I use the sponsor's consent form template?

Yes; however, if there is language that is against University of Arizona policies and procedures, the PI should revise this language to be in accordance with local policy.

What will I receive from the UA HSPP office?

When a request to submit to WIRB is granted, the PI (and listed coordinator or Co-PI) will get a "facilitated review" form. This correspondence form will state the materials that were received and the project is allowed to be reviewed by the WIRB.

What happens after WIRB approves the protocol?

When the HSPP office receives notice that WIRB has approved the project, the HSPP office will contact the PI and request the following documents:

- Other UA Committee approvals (if applicable)
- Consenting instruments (this can be on the UA consent template, the WIRB consent template, or the sponsor's model consent)
- Recruitment materials
- Questionnaires, surveys, interview questions
- Case report forms
- Research protocol
- Investigator's Brochure

Changes in Conflict of Interest

1. Any revision to the investigator's conflict of interest information must be reported to the Vice President of Research Office. This form can be found at <http://vpr.arizona.edu/conflict-of-interest>.

Changes in Radiation/MRI/lasers

1. Any revision to the quantity, type, or frequency of radiation/MRI/lasers must be submitted to the Radiation Control office prior to implementation of the change. Their contact number is 626-6850.

Changes in Select Agents, Recombinant DNA, or Gene Therapy

1. Any revision to the select agents, recombinant DNA, or gene therapy must be reported to the Institutional Biosafety Committee. Their forms can be found at <http://ibc.arizona.edu/forms>.

Amendments

1. Changes to the project are submitted directly to WIRB for review.
2. After WIRB approval, the UA HSPP office will be notified by WIRB.
3. The HSPP office will ask the PI to forward an electronic copy of all necessary documents (protocols, IB, etc. not connected to the approval) to UA HSPP office for file completion. No UA Request for Amendment Form is necessary.
4. UA HSPP office will review the documents to ensure the project still follows UA policies and procedures. If there are any issues, the HSPP office will contact the local PI. Study procedures may proceed unless notified otherwise.

Unanticipated Problems, Protocol Deviations/Violations, Adverse Event Reporting

1. Unanticipated problems involving risks to subjects or others, protocol deviations/violations, and adverse events are submitted directly to WIRB in accordance with their policy.
2. If the event is *local*, an electronic copy of the WIRB paperwork is also sent to the UA HSPP office. No UA Study Related Problems Form is necessary.
3. If any documentation is issued by WIRB regarding the event(s), then a copy will be sent to the UA HSPP office.
4. UA HSPP office will review the documents and if there are any issues, the HSPP office will contact the local PI. Study procedures may proceed unless notified otherwise.

Continuing Review

1. Continuing review paperwork is submitted directly to WIRB for review.
2. After WIRB approval, the UA HSPP office will be notified by WIRB.
3. The HSPP office will ask the PI to forward an electronic copy of all necessary documents (protocols, IB, etc. not connected to the approval) to UA HSPP office for file completion. No UA Request for Amendment Form is necessary.
4. UA HSPP office will review the documents to ensure the project still follows UA policies and procedures. If there are any issues, the HSPP office will contact the local PI. Study procedures may proceed unless notified otherwise.

Who is my UA contact for WIRB projects?

For any questions or comments regarding the WIRB process at The University of Arizona, please contact:

Wendy R. Tate, PSM, CIP
Co-Director, Operations
Human Subjects Protection Program
Phone: (520) 626-2979
Email: wrtate@email.arizona.edu