THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

Renewal of Human Research

Guidance

Any project that requires a renewal, must submit renewal paperwork to renew the project for another year. Investigators must receive IRB approval prior to the expiration of the study. The IRB decides the frequency of renewal for each human research project to ensure the continued protection of the rights and welfare of research subjects. The IRB may designate a review that is more frequent than annually.

Investigators with projects approved prior to the 2018 human subject rules are grandfathered under the old rules. This means that any existing project must continue submission of renewal requirements for the life of the project, unless the project transitions to the new rules. Projects will be sent instructions for transitioning to the new rules at the time of continuing review.

Research projects under the new 2018 human subject rules removed the requirement for renewals except for projects that are greater than minimal risk (e.g., full committee projects). The University of Arizona, however, has determined that some minimal risk projects should still have a renewal requirement as identified below.

Exempt Research

Human Research projects that are deemed exempt do not have a renewal requirement. This includes exempt research that received a limited IRB review. However, exempt research will be given a five (5) year expiration date so that the Human Subject Protection Program can update its records. Projects that are not federally funded or supported, or FDA regulated, and would normally qualify for an exemption if they were funded, will also receive a five (5) year expiration date.

Minimal Risk Research

The 2018 human subject rules eliminated the requirement to submit renewal paperwork at least annually for minimal risk research (note, this does not apply to FDA regulated research). This research will be given either a three (3) or five (5) year expiration date so that the Human Subject Protection Program can update its records.

In addition, the University of Arizona has determined that some projects may require more routine monitoring and has identified the following types of projects or instances when a renewal may be required:

- Projects involving Native Americans;
- Principal Investigator (PI) or Co-PI that have received serious or continuing non-compliance determinations in the past two (2) years;
- Projects that involve deception but do not receive the subject's prior authorization to be deceived before engaging in the deception;
- FDA regulated research eligible for expedited review under expedite category 1 on approved drugs or devices; or
- As determined by the IRB on a project basis depending on the risks in the research project.

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Greater than Minimal Risk Research

Projects deemed greater than minimal risk will have a renewal required at a period determined by the IRB. This renewal will usually be annually; however, it may be more frequent depending on the type of project, risks of the research (e.g., phase 1 studies), or for investigators with a history of serious or continuing non-compliance.

Renewal Process

To obtain continued approval for the study, investigators must:

- Complete the 'Renewal/Closure for Human Subjects'
- Submit renewal paper between **30 and 45 calendar days prior** to the expiration of the study.

NOTE: Email reminders are sent as a courtesy to investigators 60 calendar days prior to expiration. Reminders are sent to the PI and contact person listed on the IRB application. Ultimately it is the responsibility of the PI to track the expiration date and ensure appropriate documents are submitted within the required timeline so that the project can receive approval prior to expiration.

The Office for Human Research Protections requires that the review of the project should be as close as possible to the expiration of the study to maintain an accurate representation of the human research project. Therefore, projects submitted more than 45 calendar days prior to the expiration date will be reviewed and granted new expiration dates.

Materials received less than 30 calendar days from expiration may not have enough time to be reviewed prior to the study expiring. If the study expires before reapproval is granted by the IRB, all project activities must stop. The project will be administratively closed by the HSPP and a new application for approval is required.

The administrative closure of a project will not be reversed due to a PI not receiving or reading the renewal reminder notice.

Maintain copies of all information submitted to the IRB in case revisions are required.

When there are potential delays in submitting materials to the HSPP, please contact the office so that, if possible, arrangements can be made.

Do not submit amendments to previously approved research as part of the renewal. If the renewal involves amendments to previously approved research, those amendments must be submitted separate from the annual renewal by using the Amendment to Approved Human Research form. The HSPP can only process one submission at a time. Once the renewal is approved, the amendment may be submitted. If there are outstanding circumstances, please contact the HSPP. For studies overseen by outside IRBs, forward a copy of the IRB renewal to the HSPP department email (VPR-IRB@email.arizona.edu) for record-keeping.

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Updated Protocols

The IRB is required to review the protocol, in its entirety, to continue to determine that the elements for approval are met. The protocol should be updated regularly so that a current protocol document exists. For sponsored research, a separate protocol is usually updated and supplied by the sponsor of the research throughout the course of the research. Frequently for Social and Behavioral Researchers or for Investigator Initiated studies, the IRB application may be the actual protocol document that is used by researchers to conduct the study.

The IRB understands the logistics of continually updating protocols for each and every change made. Therefore, the IRB has instituted the following requirements for making revision to protocols during the course of the research activity:

1. The IRB will use submitted amendments during the course of the approval period, and the last updated protocol submitted, to determine if the approval requirements in 45 CFR 46.111 have been met.
2. The IRB will require that at least every five (5) years, the protocol (which may be the IRB application, or may be a separate protocol document) be updated to reflect all changes made over the course of the five years, IF an updated protocol has not already been submitted in that time period via an amendment.