THE UNIVERSITY OF ARIZONA Research & Partnerships

Continuing Review of Human Research

Guidance

Any project that requires a Continuing Review must submit a Continuing Review in eIRB to renew the project for another year. Investigators must receive IRB approval prior to the expiration of the study. The Institutional Review Board (IRB) decides the frequency of Continuing Review 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 Continuing Review requirements for the life of the project unless the project transitions to the new rules.

Research projects under the new 2018 human subject rules removed the requirement for Continuing Review except for projects that are greater than minimal risk (e.g., full committee projects) or U.S. Food & Drug Administration (FDA) regulated. The University of Arizona, however, has determined that some minimal risk projects should still have a Continuing Review requirement as identified below.

Institutional Continuing Review Requirements

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 Continuing Review may be required:

- Projects involving Native Americans;
- Principal Investigator (PI) has received serious or continuing non-compliance determinations in the past two (2) years;
- Externally-funded projects that involve deception but do not receive the subject's prior authorization to be deceived before engaging in the deception;
- A Conflict of Interest Management Plan exists;
- FDA regulated research eligible for expedited review under Expedite Category 1 on approved drugs or devices;
- Projects deemed Expedited Category 9; or
- As determined by the IRB on a project basis depending on the risks in the research project.

Greater than Minimal Risk Research

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

Continuing Review Process

If a Continuing Review is required, investigators must submit a Continuing Review in eIRB at least 30 days prior to the expiration of the study to obtain continued approval for the study. All submissions will receive a new expiration date at time of Continuing Review. Submit a combined Modification and Continuing Review if study materials need to be updated at time of Continuing Review.

eIRB notifications are sent as a courtesy to investigators prior to expiration. Notifications are sent to the PI, Primary Contact, and PI Proxy listed in eIRB. 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. If the study expires before reapproval is granted by the IRB, all project activities must stop. The project will enter a Lapsed state if a Continuing Review is not submitted before the expiration date. Refer to *Concluding Human Research* guidance.

When there are potential delays in submitting materials to the IRB, please contact the Human Subjects Protection Program office so that, if possible, arrangements can be made.

Migrated Protocols

Protocols migrated to eIRB will maintain their assigned expiration date and Continuing Review requirement. At time of Continuing Review, the IRB will assess if the project is eligible for elimination of Continuing Review all together, as outlined in the regulations and per institutional policy.

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 PI should ALWAYS maintain a copy of the protocol, including all modifications, that is current and complete. This helps prevent non-compliance.

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 revisions to protocols during the course of the research:

1. The IRB will use submitted Modifications during 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 may 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 a Modification.