Renewal of Human Research

**Guidance**

All non-exempt Human Research must receive IRB review and approval at intervals appropriate to the degree of risk, but not less often than once a year (45 CFR 46.109(e)). 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.

**Requirements**

Investigators must receive IRB approval prior to the expiration of the study. To obtain continued approval for the study, investigators must:

- Complete the [F212: Renewal Progress Report](#).
- Submit renewal paper between **30 and 45 days prior** to the expiration of the study.

**NOTE:**

Email reminders are sent to investigators 60 days prior to expiration. Reminders are sent to the PI and contact person listed on the IRB application.

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 days prior** to the expiration date will be reviewed and granted new expiration dates.

Materials received less than 30 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.

- 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, submit those amendments separate from the annual renewal by using the [F213: Amendment of Approved Human Research](#). Remember that 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.
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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.

*Expansion of continuing review requirements*

The University of Arizona has adopted flexible procedures for projects that are not federally funded, supported, or otherwise subject to the federal rules. Projects that meet the requirements of the Flexible Policy may be eligible for a two-year renewal instead of the federally required no greater than one year renewal policy.

These projects will be processed under expedited review according to 45 CFR 46.110 but approval will be valid for two years, rather than one year as required in 45 CFR 46.109(e). Studies limited to data analysis *may* qualify for exempt 8.

*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 revisions 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 requirements for reapproval, 45 CFR 46.111, have been met.
2. Minor changes to the protocol do not need to be incorporated into the protocol document each time. However, 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.
3. The IRB may require, at its discretion, more frequent updates to the protocol if the changes to the protocol are extensive.