THE UNIVERSITY OF ARIZONA Research & Partnerships

Modifying Approved Research

Requirements

The Institutional Review Board (IRB) must review and approve all changes to previously approved research prior to implementing the change. Modifications to human research include **any change** from what was previously approved, including but not limited to: title, key personnel, study procedures, recruitment text or locations, data collection measures, security and storage of data, or eligibility.

The only exception to this policy is when a change is needed to eliminate apparent immediate hazards to human subjects. If a change occurs to eliminate immediate risk, the IRB must be notified within **five (5) days** as outlined in the Human Subjects Protection Program (HSPP) Guidance, *Reporting Local Information*.

Level of Review and Modification Requirements

Full Committee Review: Modifications that do not meet the regulatory criteria for expedited review must be reviewed by the Full Committee at a convened meeting. Researchers should allow approximately one month for a Full Committee review and approval of a major modification as described below.

Expedited Review: Modifications that meet the criteria for expedited review will be reviewed by an IRB Chair or Chair designee according to the expedited review procedures. Researchers should allow at least one week for an expedited review and approval of a minor modification reviewed by the expedited process.

Exempt or Minimal Risk Review: For projects that were initially deemed exempt or minimal risk, follow the HSPP Guidance, *Exempt Minimal Risk Research*.

Protocols initially approved by Expedited Review that may be reviewed as Expedited	Protocols initially reviewed by Full Committee that may be reviewed as Expedited
• The modification continues to pose no more than minimal risk to subjects. • The modifications do not involve any procedures that do not meet Expedited categories 1 through 7.	• Modifications do not pose an increased risk to subjects, AND the modification constitutes a minor change. • Any added procedures that fall within Expedited categories 1 through 7.

Modifications that do not fulfill the above criteria may require Full Committee review. At the discretion of the IRB Chair or Chair Designee, any modification may be forwarded to the Full Committee for review. In addition, any expedited modification that the IRB Chair or Chair Designee disapproves of will be forwarded to the fully convened IRB Committee for a final determination.

Examples of **Minor Changes** (generally reviewed via Expedited Review) and **Major Changes** (generally reviewed by Full Committee):

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Minor Changes	Major Changes
• Typographical, format, and grammatical changes to previously IRB-approved documents (NOTE: These changes cannot change the meaning or intent of the previously approved language) • Updates to contact information • New recruitment tools • Translations to documents where the English version is IRB approved • Adding site authorization for research site • Minor Changes to study documents such as surveys, questionnaires, or brochures • New study documents to be distributed or seen by subjects that are similar in substance to those previously approved • Changes in payment to subjects or the amount subjects are paid or compensated that do not affect the risk/benefit ratio • Decrease in the number and volume of sample collections as long as they do not affect the risk/benefit ratio • Addition/changes to study personnel	• Changes that adversely affect the risk/benefit ratio of the study or specifically increases risk to subjects (submit promptly within 30 days) • Changes in inclusion/exclusion criteria that impact the risk/benefit ratio • Significant changes in study design, such as the addition of a new population or elimination of a study arm • New risk information that is substantial or adversely affects the risk/benefit ratio • Significant changes to study documents to be distributed or seen by subjects • New study documents to be distributed to or seen by study subjects that includes new information or substantially different information from materials already approved • New or revised financial conflict of interest management plans

Investigator Responsibilities

An investigator must submit to the IRB the requested change, justification for the change, and all revised documents for review. Modifications may not be implemented until **after** IRB approval is received, unless to eliminate immediate or apparent hazard to subjects which must be reported to the IRB within **five (5) days**.

More than one Modification at a time per project may be submitted to the IRB for review and approval. However, eIRB only allows for one type of Modification to be created and submitted at a time. For example, only one "Study team member information" Modification can be submitted at a time. Please review the eIRB User Guides for more information.

Emergency Deviation from an Approved IRB Protocol

If a deviation is required to eliminate an apparent immediate hazard to a research subject or group of subjects, then the researcher should make whatever changes are needed to protect the safety and welfare of the subjects and may do so without prior IRB review. However, a Reportable New Information (RNI) must be submitted in eIRB within **five (5) days** of the change.

Anticipated Deviation from the Approved Protocol — Single Subject Exceptions

If an investigator anticipates the need to deviate from the previously approved protocol for a single subject, the investigator should submit a Modification to the IRB for approval of the deviation.

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Two examples of the most common sorts of these requests are to change the schedule of the procedures or to waive an inclusion or exclusion criteria for one subject. The following information will be requested when the Modification is reviewed by the IRB:

- Whether the sponsor has approved the request for a protocol exception for this subject, and to provide any documentation from the sponsor of their approval
- A description of the protocol criteria for which the PI is seeking exception, and an explanation why the requested exception is appropriate or necessary
- Whether the exception increases the risk or lowers the potential benefits for the subject
- Whether a Modification will be submitted to reflect the protocol exception for future subjects
- Whether the current informed consent document adequately covers the exception, and if not, a revised consent form is requested

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 Protocol for Human Research* 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 Modifications 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 Protocol for Human Research* or 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.
3. The IRB may require, at its discretion, more frequent updates to the protocol if the changes to the protocol are extensive.