

MAKING CHANGES/AMENDMENTS TO APPROVED RESEARCH PROTOCOLS

Once the IRB has approved a project, it must be carried out exactly as planned. Any changes, including (but not limited to) subject population, recruitment plans, research procedures, study design, study instruments, study sites, or research personnel, must be approved by the IRB prior to implementation.

Researchers planning a change should submit the following to the IRB office:

1. The amendment request form, available in the forms section of the website.
2. Copies of any correspondence from sponsor regarding the change/amendment (if applicable).
3. One copy of the revised corporate protocol (if applicable).
4. One marked copy of the revised IRB application (with all changes underlined or highlighted) and one clean copy. **The amended IRB application must be signed by the PI. Department Chair/Dean's signature is not required.**

If the change to the protocol makes it necessary to change the consent document, the following should also be submitted:

- **One marked and one clean copy of the revised IRB application (part A, part B, schematic diagram) and consent document**

Minor protocol/consent changes may be approved by expedited review. These would be changes that do not adversely alter the overall risk: benefit profile of the study; would not affect the willingness of current subjects to remain in the study; and do not alter the scientific validity of the study design. Changes to study design, which may increase risk to subjects, may require full board review. Changes that are perceived to significantly affect the risk/benefit ratio for subjects must be reviewed by the full Board.

Implementation of any change must not occur prior to IRB approval unless the change is required to eliminate an immediate hazard to the subjects. In this case, the IRB should be notified as soon as possible of the change.

Changing the Principal Investigator

If a Principal Investigator is on sabbatical leave from the University, an interim PI must be appointed. The IRB should be informed of this person's qualifications. If a researcher leaves the University permanently, the IRB should be notified of any interim investigators and of the final replacement. Such changes require prior review and approval by the IRB. **An amended (page 1) of the IRB application should be submitted with the signature section completed (new PI and Department Chair/Dean's signatures are required).**