*A principal investigator may not implement any changes to an approved study (including to the protocol or informed consent document) without****prior****IRB review and approval, unless the change is necessary to eliminate apparent immediate hazards to the subjects.*

**IRB Amendment**

An IRB Amendment is an online process completed in TCNJ’s iMedris system that provides a description of changes to an approved human subjects study. An amendment can be initiated in iMedris by any study team member listed on the approved application but must be approved and submitted by the PI. A video tutorial for how to submit an amendment through iMedris can be found in the tutorial section of the IRB website.

**AMENDMENT REQUIREMENTS & IRB REVIEW**

For projects that were approved via expedited or full board review, you are required to submit an amendment for IRB approval for any proposed change to the:

* Study team members
* Study protocol or procedures
* Study documentation (e.g., informed consent, recruitment materials, survey instruments)

The amendment's review path (e.g., full board, expedited, administrative) depends on the nature and level of the change.  Substantive changes to a project previously reviewed by the full board most likely will require full board approval also and are subject to the IRB submission deadlines and committee meeting dates.  Minor amendments may be reviewed via an expedited or administrative (i.e., IRB staff) process.  Examples of minor amendments include but are not limited to:

* Addition or deletion of study team members
* Addition of procedures that do not increase risk
* Removal of procedures which would result in reduced risk to subjects
* Addition of non-sensitive survey or interview questions
* Document changes that do not modify the intent of the content (e.g., typographical error corrections, improvements for clarity)
* Addition of, or changes to, recruitment materials or recruitment strategies

For exempt projects amendments are required only for substantive changes that impact or alter the criteria used to make the initial exempt determination.  For example, a request to change a survey project's protocol from the collection of anonymous data (which qualifies for an exempt #2 determination) to the collection of sensitive data linked to personal identifiers would require the submission of an amendment for IRB review.

Once the IRB approves an amendment, the information, protocol, and documentation in the amendment becomes the record of the approved study.