IRB Protocol Amendments

The IRB reviews and approves submitted protocol amendments based on the nature of the amendment and its effect on the protocol risk level.

Minor Amendments:

Minor amendments include items such as personnel additions or minor changes to survey instruments. These amendments can be submitted using a simple memorandum to the IRB with all required documentation attached.

Personnel Additions: Please be sure to include the following.

- Contact information for the new person.
- Page 12 of the IRB Protocol Form initialed and signed by the new person.
- A copy of the training certificate confirming completion of the <u>Social and Behavioral</u> <u>Researchers</u> online training course for the new person.

Changes to Survey Instruments:

- Provide a justification in your memo for the changes made to the survey instrument.
- Provide a complete copy of the proposed new survey instrument.

Major Amendments:

Major amendments include items such as adding a whole new population or data collection process to the protocol. For major amendments, the entire IRB Protocol Form should be revised by adding the new population or procedures. To assist the IRB in reviewing the amendment, please note the changed text on the Protocol Form in **bold** letters or by some other identifying characteristic.

Major amendments that elevate the risk level of the protocol will require re-review of the complete protocol. For example, if you amend your protocol to include surveying children, your risk level may increase and therefore the amended protocol may require Full Board review at a convened meeting.

All amendments vary so please contact the Office of Research Compliance at 936-261-1553 when planning your amendment for additional assistance.