



IRB Human Subject Research Process for Faculty, Staff, and Administrators

This document outlines the procedures for all human subject research conducted by Fresno Pacific University faculty, staff, and administration. The following process must be completed **before** research is conducted.

1. The faculty, staff, or administration member serving as the primary investigator must submit the **IRB Proposal Form** with the following documents (if applicable):
 - a. Consent form(s), assent form(s), and/or information sheet(s);
 - b. Instruments or questionnaires that will be used as part of the research;
 - c. Documented approval from the organization or institution where the research will be conducted.
2. Please submit all IRB application materials to IRB@fresno.edu. Failure to include all required application materials including the **IRB Proposal Form** may result in an application processing delay. Applications are processed in the order received.
3. Data collection may begin upon email notification of IRB approval. A copy of the approval letter will be emailed to the primary investigator.
4. If the primary investigator decides to make any changes to the study (e.g., methodology, investigator, consent form, questionnaire), he or she must submit those changes to the IRB within three (3) working days and wait for approval by the IRB before implementation.
5. The primary investigator must notify the IRB within three (3) working days of any new information that may impact the risk-benefit ratio and then wait for approval by the IRB before continuing with the study.
6. The primary investigator must notify the IRB within twenty-four (24) hours of any serious or unexpected adverse events that occur during the study. Less serious adverse events must be reported to the IRB within three (3) working days.
7. IRB approval expires one year from the date of approval unless indicated otherwise in the approval letter. For research that takes more than one year to complete, the primary investigator must submit a **Research Project Continuation Form** to IRB@fresno.edu.
8. The **IRB Proposal Form** and **Research Project Continuation Form** are available on the FPU website.
9. Specific questions about the IRB application process should be addressed to

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