TEXAS A&M UNIVERSITY- San Antonio

IRB Minor and Major Amendments.

This is a reference document to be used to guide submissions for submitting amendments to protocols via CAYUSE.

All amendments to approved protocols need to be submitted for IRB review. Please follow the guidelines provided below for exempt, expedited and full board studies.

Amendments to Exempt studies:

Examples of **minor** amendments to exempt protocols:

- Addition or removal of study personnel other than the principal investigator.
- Minor revisions to recruitment materials and method, such as a change to the phone number or the addition of a newspaper ad when using language similar to an already approved flyer.
- Minor revisions to surveys, interviews, or focus group instruments that do not fall outside the scope of the original approved instruments such as wordsmithing and the addition of clarifying or similar questions to those previously approved, or deletion of questions.

Examples of **major** amendments to exempt protocols:

- Change in principal investigator.
- Change in funding source.
- Change to study purpose or procedures such as adding a survey on a different topic than previously approved or collection of data falling outside the parameters of the data collection previously approved.
- Changes to study population targeted for recruitment such as adding a new population or substantively revising the inclusion/exclusion criteria for the current population.
- Changes to the identifiability of the research data you will receive or record. For example, your exempt application states that you will not collect names with the surveys, but you now want to, or you now want to record identifiable data from an existing dataset.
- Changes to the risks involved in the study.

If you are submitting a major amendment to exempt protocol, you need to submit a new application via the CAYUSE system.

Amendments to Expedited and Full-board studies:

Minor amendments to previously approved protocols are reviewed using the expedited review procedure. To be considered a minor amendment, ***all*** the following criteria must be met:

- The proposed change does not significantly alter the risk-to-benefit ratio.
- The proposed change does not significantly affect the safety of subjects.
- The proposed change does not involve the addition of invasive procedures (procedures not otherwise eligible for expedited review).
- The proposed change does not involve the addition of procedures, interactions, or inventions that add significant physical, social, or psychological risks.
- The proposed change does not involve the addition of a vulnerable population in research initially reviewed by the full board and,
- The proposed change does not significantly alter the hypotheses or research design in research initially reviewed by the full board.

Examples of **minor** amendments:

- Title change
- Clarification of issues
- Addition of risks to the informed consent and other study documents at the IRB's request
- Increase in the amount of blood drawn
- Increase in medication dose
- Requested changes by the Radiation Safety Office
- Extended accrual period
- Addition of non-invasive test (e.g. urine pregnancy test)
- Addition of audio recording
- Addition of video recording

Major amendments to previously approved expedited and full board review protocols receive the same level of review as the original project. A major change in research protocol may involve increased risk or discomfort or decrease the potential benefit to the subjects.

Examples of **major** amendments requiring review:

- Change in principal investigator
- Increase in the amount of blood drawn
- Safety issues
- Extension of the study duration
- Multiple changes in the study design
- New software in devices
    - the original performance and effectiveness or the safety or the intended use of the SaMD (Software as Medical Device). These changes may include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.
- Additional arm added to the study
    - Arm: A group or subgroup of participants in a clinical trial that receives a specific intervention/treatment, or no intervention, according to the trial's protocol.
    - Arm type: A general description of the clinical trial arm. It identifies the role of the intervention that participants receive. Types of arms include experimental arm, active comparator arm, placebo comparator arm, sham comparator arm, and no intervention arm.
- Additional population added to the study (including vulnerable populations)
- Increase of medication dose
- Increase in infusion rate
- Increase in radiation exposure

If you are submitting a major amendment to expedited or full board protocol, you need to submit a new application via the CAYUSE system.

These examples are not exclusive. Please contact Dr. Rani Muthukrishnan rmuthukrish@tamusa.edu or the IRB Office irb@tamusa.edu for guidance if you have any questions.