Amendment Vs Note to File Tip Sheet

The MCW IRB does NOT need or want every administrative or minor revision as an amendment for projects determined to meet criteria for Exempt or Registered/FLEX review. Amendments for Exempt and Registered/FLEX projects should be submitted only when the proposed changes qualify as *substantial revisions*. If changes do not qualify as substantial revisions, a note-to-file for minor revisions can be filed within your project-related documentation. If an amendment is submitted to the IRB that where the proposed revisions qualify as administrative or minor only, the amendment will be returned with instructions for withdrawal.

A substantial revision is defined as a change to the project that impacts design, procedures, or population in some manner. The following substantial revisions, changes that do impact risk or design, to your Exempt or FLEX Registration study would require you to submit an amendment:

Updates to the consent process

This includes adding a new consent process, such as requesting a waiver of consent or linking to a bank where consent has already been addressed.

Changes impacting existing MRI approval or requiring new MRI approval

Any changes to the MRI process should be described in a new amendment. Please reach out to the MRI safety committee for more information.

Substantial revisions to the recruitment procedures

This includes the addition of a new recruitment procedure, the addition of new recruitment material, or substantial revisions to existing recruitment procedures and/or material.

Requesting review of a new consent form

This includes performing substantial revisions to a consenting document or adding a consenting document, such as an informational letter or full informed consent form.

Adding sensitive questions to a survey or interview process

This includes the addition of questions asking about mental health, self-disclosure of PHI, or if any disclosure of responses place subjects at risk for criminal or civil legal actions, or cause them to be at risk for damage to their financial standing, employability, or reputation.

Adding procedures that could affect risks to participants

This includes but is not limited to the addition of non-invasive biospecimen collection, including blood draws, urine, and saliva, or the addition of collection of data through non-invasive procedures such as EEGs, ECGs, moderate exercise, etc.

Adding procedures which require review under a different regulatory pathway

This includes but is not limited to the addition of audio/visual recordings, and secondary biospecimen review as the addition of these activities may require review under a different regulatory pathway.

Adding new subject populations to the project

This includes but is not limited to the addition of minors, non-English speaking subjects, or individuals with decreased decisional ability.

Changing the Principal Investigator or project funding

Changing the Principal Investigator requires the completion of the Agreement of Investigator Responsibilities form, which should be uploaded within a new amendment. The addition of funding such as federal or For-Profit funding requires additional IRB review.

Note-To-File Requirements

A Note-To-File should be completed prior to implementing any changes to the study. The Note-To-File should contain the following elements when applicable and should be saved with project documentation.

1. Institutional or departmental letterhead

2. PRO # of the Study, Study Title as displayed in eBridge, Principal Investigator of Study, and Name/Role of person completing Note-To-File

3. Today's Date and Date change will be implemented

4. A thorough description of the change including what the change entails (from what to what) and what section on the SmartForm or in the protocol the change will be made.

5. Justification and rationale for the change including why the change doesn't increase or decrease risks to subjects