Amendments for Registration and Exempt Projects

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, nothing further is required, but a note-to-file can be filed within your project-related documentation if desired. If an amendment is submitted to the IRB and the proposed revisions qualify as administrative or minor only, the amendment will be returned with instructions for withdrawal. Please note, the IRB Office recognizes that federally-funded exempt projects may have Sponsor-related requirements for IRB review of changes and will honor these requests.

A *substantial revision* is defined as a change to the project that impacts design, procedures, or population in some manner or otherwise requires revisions to the IRB application due to an institutional requirement. This guidance aims to provide examples of substantial revisions that would require an amendment to an Exempt or FLEX/Registration project as well as real examples that have been assessed to date.

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 ancillary approval or requiring new ancillary approval

Any changes that impact review by an ancillary committee should adhere to the institutional requirements for those committees.

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 subjects

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, additional project sites, and/or 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.

Examples seen by the Minimal Risk Research Team to date:

Category of change	Recommended to file an amendment	Indicated an amendment is not required
Identified data storage location	The data storage location was revised to another external location.	The data storage location was revised from one MCW-supported platform to another MCW-supported platform.
Consent form revision	The Sponsor requires an IRB approval letter with a consent form's new version date	Updating version date on the bottom of the form
Revising eligibility criteria for record review project	Adding a new disease/disorder type or making major timeframe revisions (this is considered a change in subject population)	Minor revisions that clarify laboratory values within the same overall population