

Changes to IRB Funding Review Process

IRB approval of new research projects with for-profit funding will no longer be held until the clinical trial agreement (CTA) and budget have been executed.

Background: The IRB reviews the executed CTA and budget and compares it to the consent form to confirm consistency between what costs are covered by the research project, what costs research subjects will be responsible for, what happens in case of research related injury, and who pays for the cost of medical care in the event of a research related injury.

The current process: Final IRB approval is held until the CTA and budget are executed and finalized in eBridge. The CTA documents are compared with the PRO Smartform (IRB application) and the consent form submitted to the IRB to confirm consistency with the proposed consent form language cost and injury sections. After this review and reconciliation of language, final IRB approval is granted.

The new process as of October 12, 2024: Final IRB approval will NOT be held until the CTA and budget are executed and finalized. IRB review will occur as usual and final IRB approval will be granted even if the CTA and budget are NOT yet executed and finalized. The funding review will be deferred until the CTA and budget are executed and finalized.

When the CTA and budget are executed and finalized, the IRB Office will be notified through the eBridge system automatically, and the funding review will occur. If the funding review identifies errors in the consent form or PRO SmartForm (IRB application) that disagree with the information in the executed CTA and budget, an amendment will need to be submitted to the IRB within 30 days to correct the errors and any subjects consented with an incorrect consent form will need to be re-consented with a revised IRB approved consent form.

What is NOT changing: The process and content of the funding review by the IRB will not change, only the timing of the review is changing to allow flexibility in achieving final IRB approval before this review is complete.

If the CTA and budget are executed and finalized during the IRB review process, the funding review will NOT be deferred and be done in conjunction with IRB review, as it is today.

Institutional process and reviews outside of IRB review have not changed and will still need to be completed in the same way prior to opening a research project to accrual.