

Completing the eProst/IRB7 application for External IRB studies

If an investigator wishes to use an external IRB for the review/oversight of a particular study, a written request must be sent to the HSRO for consideration. The below work instructions only apply to those studies for which an external IRB is providing IRB oversight. UM will have already agreed to cede IRB oversight to a central IRB (NCI-CIRB, WIRB, Massachusetts General Hospital for NeuroNext, U of Cincinnati for StrokeNet, etc.) or to another external IRB (FL-DOH, etc.). An IRB of Record will not otherwise be available for selection in the application unless it has already been approved for inclusion.

- In the Basic Information page of the Study SmartForm, ensure all required fields are properly completed
 - Q1-Q4: ensure consistency with uploaded documents
 - Q5: if 'Yes', needs a management plan from the UCOIC which may include disclosure language in the ICF
 - Q6: should indicate 'Yes' and select the appropriate external IRB in the follow-up question
- On the External IRB page of the Study SmartForm,
 - 1: Ensure appropriate external IRB is selected
 - 2: No need to upload the IRB authorization agreement; these are kept on file at the HSRO
 - 3: Appropriate approval letter from the External IRB must be uploaded
 - 4: Appropriate approval date should be entered; confirm by reviewing the approval letter
 - 5: Appropriate expiration date should be entered; confirm by reviewing the approval letter
 - 6: Supporting documents approved by the external IRB (Protocol, or correspondence, etc.), as applicable, must be uploaded
(NOTE: ICFs and other documents intended for the subjects should be uploaded via the Update Study Information activity so they can later be moved to the Finalized documents set.)
- The system will prompt you to execute the **Update Study Information** activity; this must be done prior to submission. This activity is required only for new External IRB studies.
 - Click on the "Update Study Information" activity and complete the information required
 - 1: Upload study protocol
 - 2: Select funding source; if you cannot find the name of the funding organization, please send an email to the ORIM team so it can be added
 - 3: Add all study personnel
 - 4: If a drug/biologic study, select/add drugs to be used in the study
 - a: If study will be conducted under an IND, select Yes
 - b: Enter IND information

- c: Upload appropriate document for IND (FDA letter or other communication with FDA, etc.)
- 5: If a device study, select/add devices to be used in the study
 - a: Make appropriate selection
 - b: Enter IDE/HDE information, if applicable
 - c: Upload appropriate document for IDE/HDE (FDA letter or other communication with FDA, etc.)
- 6: Upload consent forms approved by the external IRB
- 7: Make appropriate selection (Note: This used to identify the study as a clinical trial. This determines whether or not the study will automatically be set up in Velos and will be monitored for billing compliance. It's important that the right selection is made.)
- 8: Answer if applicable
- 9-18: Ensure answers to ancillary committee questions are consistent with the description of the study in the protocol document
 - If any ancillary reviews are required, make sure that you uploaded the appropriate supplemental forms at Q19
 - If Pathology, must have Pathology questionnaire
 - If JHS, must have JHS CTO form
 - If UMH, must have UMH form
 - If CRC, must have CRC Service Request Form
- 19: Upload supporting documents (HIPAA forms, assessments/questionnaires, etc.). If the study uses Velos, upload anything that needs to be displayed in the D-Link here. **Please do NOT upload these in the External IRB page of the SmartForm.**
- If all information is complete/accurate, click "OK"
 - PI must execute the 'Submit' activity
 - Upon submission by the PI, the system will notify all applicable ancillary committees that the study requires their review.
- Once all applicable ancillary committee approvals and departmental/division approval have been received, and all COI disclosures have been made (and any potential conflicts addressed by the IRB or COIC), the HSRO will execute the **Confirm External IRB** activity which changes the state to External IRB.
- If the study has an external IRB approval date and expiration date, the study team is responsible for entering these into eProst (and keeping them updated throughout the life of the study) by executing the **Update External IRB** activity.
- For any future updates to the study (including study team members, external IRB-approved documents, etc.), the study team must:
 - Use the **Update Study Information** activity to update information
 - Send email to Evelyne Bital notifying the HSRO so any required documents may be finalized

External IRB: Investigator Guide

Dated: 4/23/2014

- For future updates to the study's expiration date, correspondence with the external IRB, or to close the study, the study team must use the Update External IRB activity to make the appropriate updates.