

PARTNERS HUMAN RESEARCH COMMITTEE CONTINUING REVIEW SUBMISSION INSTRUCTIONS Insight/eIRB

NOTE: CONTINUING REVIEW IS REQUIRED TO: (1) OBTAIN RE-APPROVAL OF THE PHRC OF HUMAN-SUBJECTS RESEARCH THAT IS ONGOING, OR (2) INFORM THE PHRC OF COMPLETION OF THE STUDY OR CLOSURE OF THE STUDY PRIOR TO COMPLETION.

About Insight/eIRB: The eIRB application is part of the Insight Humans Module. The Insight Humans Module enables the user to prepare, submit, and track IRB submissions online. Note: You must have a Partners username and password to access Insight and use eIRB. Contact the PHS Insight HelpDesk if you do not have access to Insight/eIRB.

For continuing review of protocols received prior to March 1, 2009, the continuing review form must be completed online using eIRB and the current versions of the approved protocol documents will need to be attached to the Insight/eIRB record for re-approval. **Note: Complete and submit continuing review submissions at least 45 days prior to the IRB approval expiration date to ensure sufficient time for review.**

Once the eIRB continuing review form, staff list, and attachments have been completed, the submission may be submitted to the PI for signature. After the PI signs off, the submission will be submitted to the IRB (PHRC) to accept for review. Note: The PHRC may decline a submission when a review of documents identifies discrepancies in the submission or additional information is needed for review.

Note: An amendment must be submitted separately to request approval of any changes you propose to the approved protocol.

eIRB FORMS: Continuing review forms must be completed online by creating a continuing review submission in eIRB. Select the continuing review form that corresponds to the human research activities involved in your study.

eIRB STUDY STAFF: Review the study staff list on the Active Protocols>Staff & Access page in Insight/eIRB to ensure that the study staff listing is correct and up-to-date. To make changes to the study staff listing, submit an amendment to add/delete study staff, as appropriate. Note: Submission of an amendment is required to make changes to the study staff. **The names of study staff submitted via amendment for IRB approval appear in the non-study staff grid until the amendment is approved.**

eIRB ATTACHMENTS (PROTOCOL-RELATED DOCUMENTS FOR REVIEW): eIRB submissions for studies involving an intervention or interaction with subjects must include the following documents, when applicable:

- Protocol Summary, current dated version, incorporating all changes approved by the PHRC since last review
- Detailed Protocol: current dated version, incorporating all changes approved by the PHRC since last review
- List of Questionnaires and Instruments, when applicable
- DSMB/DMC Report, when applicable
- Coordinating/Statistical Center Report, when applicable
- Monitoring Group Report, when applicable
- Investigator Adverse Event Report (**for investigator-monitored studies only**)
- Minor Violation Report, if there have been any minor violations since last review
- NIH Grant: Non-competing renewal (Type 5) or Competing Renewal (Type 2), when applicable

- IND/IDE Annual Report (**for investigator-sponsor IND/IDE only**)
- FDA Form 483 received since last review, when applicable

In addition, the following documents are needed when the study is open to enrollment and subjects are being recruited:

- Research Consent Forms for re-approval (copies without approval footer)
- Recruitment Materials (letters, postcards, posting, advertisements, telephone scripts, etc.), when applicable

Documents that are available electronically should be uploaded to the Attachments page in Insight/eIRB submission. Hardcopy documents should be faxed or mailed to the IRB accompanied by the eIRB Coversheet, which can be generated from the Attachments page.

FOR STUDIES THAT HAVE BEEN COMPLETED OR ARE BEING CLOSED PRIOR TO COMPLETION:

Complete the appropriate Continuing Review Form to inform the PHRC of completion of the study or study closure prior to completion. In such cases, submission of the Protocol Summary and Detailed Protocol is not required. **NOTE: Continuing review is required to close out the study file.**

HELPFUL SUGGESTIONS

- **Make sure the study staff list is correct and up-to-date.**
- **Make sure the Protocol Summary has been updated to reflect all changes approved by the PHRC since the last review and is consistent with the currently approved protocol.**
- **Make sure the Detailed Protocol has been updated to reflect all changes approved by the PHRC since the last review.**
- **Make sure the Research Consent Form submitted for re-approval is consistent with the currently approved Research Consent Form.**
- **Check to be sure that you have included all required documents with your submission.**