PARTNERS HUMAN RESEARCH COMMITTEE
CONTINUING REVIEW SUBMISSION INSTRUCTIONS
Insight/eIRB

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 Help Desk if you do not have access to Insight/eIRB.

REQUIREMENT FOR CONTINUING REVIEW: Continuing review is required to obtain re-approval of ongoing research OR to report study completion or closure. Submissions must be complete and must include all protocol documents material to continuing review and re-approval of the research.

Note: The Protocol Summary/Detailed Protocol must be up-to-date and reflect all changes approved by the PHRC to date.

DEADLINE FOR CONTINUING REVIEW: Continuing review submissions must be submitted at least **45 days prior to the IRB approval expiration date** to allow sufficient time for review.

eIRB FORMS: Continuing review forms must be completed online by creating a continuing review submission in eIRB. The application will select the continuing review form based on the form submitted previously. See the Continuing Review Quick Reference Guide for more information.

Note: The continuing review form may be changed if needed by using the Add/Delete Forms functionality.

Continuing Review Amendments: Submit changes proposed with the continuing review as an amendment. Indicate on the amendment form that the amendment is to be reviewed with the continuing review submission. The amendment should include a brief description of the proposed changes and the updated documents with the proposed changes highlighted.

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 CITI training is up-to-date. To make changes to the study staff listing, submit an amendment to add/delete study staff, as appropriate.

Note: The Insight/eIRB application will validate that all study staff are in compliance with CITI training requirements (completion of CITI course within 3 years) before the application can be submitted. If a study staff's CITI completion has expired or will expire in the next month that person should complete the refresher course or an amendment must be approved to remove that study staff before submitting the continuing review.

eIRB ATTACHMENTS (PROTOCOL-RELATED DOCUMENTS FOR REVIEW):

eIRB continuing review submissions must include the documents material to review and re-approve the research. This includes current versions of the documents you submitted to obtain approval of the research initially.

Note: The PHRC may decline a continuing review submission when the submission does not include the information needed for continuing review or discrepancies are noted in the submission.

- **INTERVENTION/INTERACTION**

  On the Attachments page of the submission, check the box 'Include with Submission' next to the following documents:

  - ✓ Protocol Summary, current dated version (must reflect all changes approved by the PHRC)
  - ✓ Detailed Protocol, current dated version (must reflect all changes approved by the PHRC)
  - ✓ Research Consent Forms for re-approval when enrolling subjects (without approval footer)
  - ✓ Recruitment Materials (letters, postcards, posting, advertisements, telephone scripts, etc.) when applicable and recruiting subjects
  - ✓ Instruments and Questionnaires, when applicable

- ✓ Investigator Brochure, when applicable (for drug or device studies)
- ✓ Package Inserts, when applicable (for drug studies)
- ✓ DSMB/DMC Report, when applicable
- ✓ Coordinating/Statistical Center Report, when applicable
- ✓ Monitoring Group Report, when applicable
- ✓ Adverse Event Tracking Log (for investigator-monitored studies only)
- ✓ Minor Deviation Tracking Log, when applicable
- ✓ IND/IDE Annual Report (for investigator-sponsor IND/IDE only)
- ✓ FDA Form 483 received since last review, when applicable

Note: The Insight/eIRB application will <u>not</u> allow you to version documents on the Attachments page. Submit an amendment to make changes to any of the previously approved documents. Add a new row to attach documents required at continuing review, e.g., safety monitoring reports, minor deviation log, IND/IDE annual reports.

❖ **DATA OR TISSUE REPOSITORY**
- ✓ Data or Tissue Repository Standard Operating Policies and Procedures
- ✓ Any other documents submitted initially to obtain approval

❖ **HEALTH/MEDICAL RECORDS**
- ✓ Data Collection Form, when applicable
- ✓ Any other documents submitted initially to obtain approval

❖ **EXCESS HUMAN MATERIALS**
- ✓ Data Collection Form, when applicable
- ✓ Consent Form(s), when applicable
- ✓ Any other documents submitted initially to obtain approval

❖ **SECONDARY USE DATA/SAMPLES**
- ✓ Consent Form(s) for source studies
- ✓ Any other documents submitted initially to obtain approval

❖ **COORDINATING CENTER / CORE LAB**
- ✓ Clinical/Detailed Protocol, when applicable
- ✓ Statement of Work, when applicable
- ✓ Model Consent Form, when applicable
- ✓ Manual of operations, when applicable