

# INSIGHT/eIRB SUBMISSION TIPS

## Browser

Insight/eIRB works best when using Internet Explorer 6.0 or 7.0 (PC) or the latest versions of Firefox or Safari (Mac)

## Work-In-Progress

If you start a submission but want to save it for later, it will be saved under the Work-In-Progress tab.

## New Submissions

1. Refer to Protocol Submission Instructions on our webpage (see link below)  
[http://healthcare.partners.org/phsirb/Submission\\_Instructions/New\\_Submission\\_Instructions.03.09.pdf](http://healthcare.partners.org/phsirb/Submission_Instructions/New_Submission_Instructions.03.09.pdf)
2. Adding Study Staff: It is best to search broadly. Search by username (if known) or search by last name and first initial.
3. Investigators with Multiple Appointments: If the person you are adding has an appointment at more than one institution, choose the appropriate institutional affiliation.
4. Study Staff Roles: Choose the role that best describes the person's study-related responsibilities. **Note: Do not choose "Other" simply to avoid requirement for completing Investigator Disclosure Forms.**
5. Certification/Sign off by Study Staff: All study staff with a Partners username receive emails prompting them to login to Insight/eIRB to sign off. Study staff can only sign off once the IRB accepts the submission.
6. Certification/Sign off by Study Staff without Partners Logon: You must have a Partners username and password to login to Insight/eIRB. Therefore, study staff that do not have a Partners username and password must sign off using the PHRC password-protected Word form available on the PHRC website. Once the form is submitted to the PHRC, the form will be scanned and uploaded to the eIRB protocol record.
7. Certification/Sign off by Study Staff Added after Submitted: Study staff added after the protocol is submitted must sign-off using the PHRC password-protected Word form. **Note: When possible, wait to add the person by amendment.**
8. Attachments: You must add all required attachments before clicking on the save button. **Note: If all of the documents aren't ready, you can attach/upload and save the ones that are ready by clicking on the 'hardcopy' button for those that aren't ready.**

## Amendments (Protocol)

1. Complete the eIRB Form and provide rationale for the changes as well as an assessment of any change to risks and potential benefits
2. For sponsor amendments to the protocol, attach the sponsor's amendment document that lists the changes to the protocol (this is usually provided by sponsor for ease of review) and the revised detailed protocol

3. Each document must be given a unique title in the Attachment title text field on Attachments page in order to be saved. For example, if you have two advertisements, both can't be titled "Advertisement." Instead, use Newspaper Advertisement for one and Metro Advertisement for the other or Advertisement 1 and Advertisement 2.
4. When revising documents previously submitted in eIRB, always add a new version of the existing document as follows:
  1. Click on the attachment 'Title,' which opens the version screen
  2. Click the 'add new version' button
  3. Check 'electronic' and browse for the file
  4. Browse and attach the 'marked copy' first
  5. Click the 'Save' button
  6. Next, browse and attach the 'clean copy'
  7. Click the 'Save' button

**Note A:** When attaching consent forms on the Attachments page, enter the attachment 'Title' as what appears on page 1 of the consent form 'Description of the Subject Population' field.

**Note B:** When you add a revised document for the first time you can't version it, so you must attach as a separate document. Because Insight/eIRB will allow only one Protocol Summary and one Detailed Protocol to be attached, you must select the attachment type as 'OTHER' to attach the 'marked/highlighted' version.

## Amendments (Study Staff)

1. Adding Multiple Study Staff: Before the IRB can approve the amendment, ALL of the study staff being added must have completed the human subject protection education requirements and have signed off. Please take this into consideration when adding multiple study staff in one amendment. **Note: Study staff being added will appear in the non-study staff grid of the Active Protocols page until the study staff amendment is approved by the IRB.**
2. Adding Study Staff: It is best to search broadly. Search by username (if known) or search by last name and first initial.
3. Changing/Correcting Institution/Dept/Unit information for study staff: Contact Daniel Connor, [dconnor@partners.org](mailto:dconnor@partners.org)
4. Investigators with Multiple Appointments: If the person you are adding has an appointment at more than one institution, choose the appropriate institutional affiliation.
5. Study Staff Roles: Choose the role that best describes the person's study-related responsibilities. **Note: Do not choose "Other" simply to avoid requirement for completing Investigator Disclosure Forms.**
6. Certification/Sign off by Study Staff without Partners Logon: You must have a Partners username and password to login to Insight/eIRB. Therefore, study staff that don't have a Partners username and password must sign off using the PHRC password-protected Word form found on the PHRC website. Once the form is submitted to the PHRC, the form will be scanned and uploaded to the eIRB protocol record.
7. Certification/Sign off by Study Staff Added after Amendment Submitted: Study staff added after the amendment is submitted must sign-off using the PHRC password-protected Word form. **Note: Once the form is submitted to the PHRC, the form will be scanned and uploaded to the eIRB protocol record.**

8. Changing Contact Person: You may change study staff contact person(s) at any time without submitting an amendment to the IRB. This can be performed on the Active Protocol>>Staff & Access pages.
9. Changing PI: You must delete the current PI and add the new PI. You must obtain approval of the appropriate Department Chair. Currently Dept. Chair approval must be documented using the PHRC password-protected Word form on the PHRC website because eIRB workflow does not include electronic submission of changes in PI to Dept. Chair for electronic sign-off. **Note: There can only be one PI per site (e.g., BWH, MGH).**
10. Non-Study Staff Grid: You may add individuals who do not have a study related role, but assist the PI with protocol submission paperwork. Non-staff can be added /removed at any time by anyone with 'manage' permission without submitting an amendment.

## Other Events – Revised Investigator’s Drug Brochure (IDB)

1. Complete the eIRB Form and address the following:
  - Whether, based on the new information in the IDB, any changes to the protocol and/or consent form are warranted
  - Whether, based on the new information in the IDB, subjects are placed at increased risk of harm than was previously known
2. Attach IDB
  - If there is no IDB already attached in the record:
    - Click ‘add a row’ on the Attachments page
    - Check ‘electronic’ and browse for the file
    - Click the ‘Save’ button
  - If there is a IDB already attached add a new version of the current IDB
    - Click on the attachment ‘Title,’ which opens the version screen
    - Click the ‘add new version’ button
    - Check ‘electronic’ and browse for the file
    - Click the ‘Save’ button
3. Attach the sponsor’s list of changes to the IDB in addition to the revised IDB
  - Attach the sponsor’s list of changes to the IDB

## Continuing Review

1. Refer to Continuing Review Instructions on our webpage (see link below)  
[http://healthcare.partners.org/phsirb/Submission\\_Instructions/Continuing\\_Review\\_Submission\\_Instructions.03.09.pdf](http://healthcare.partners.org/phsirb/Submission_Instructions/Continuing_Review_Submission_Instructions.03.09.pdf)
2. Check Study Staff & Access to make sure that the staff list is correct. **Note: You must look at the Staff & Access page under Active Protocols to review the current list. If changes are needed, submit an amendment in eIRB.**  
  
Attaching Consent Forms [studies that were not created originally in eIRB]: When attaching consent forms on the Attachments page, enter the attachment ‘Title’ as what appears on page 1 of the consent form ‘Description of the Subject Population’ field.
3. Submitting Amendments, Violations, etc, at Continuing Review: Create a separate new submission (process) for the amendment (Amendment) and/or protocol violation (Other Event), or other event. If amendments are submitted at the same time as the continuing review, the revised documents should be attached to the amendment, and the amendment will be reviewed with the continuing review. Indicate in the Continuing Review form that an amendment has been submitted for review with the continuing review. **Note: Amendments to the Protocol Summary, Detailed Protocol, or Consent Form submitted after the continuing review has**

been reviewed or distributed to IRB members for review at a convened meeting will not be reviewed until continuing review has been completed.

## Responses

1. Complete Response form responding point-by-point to each of the committee's questions/issues. When complete, attach the form on the Attachments page of the submission.

[http://healthcare.partners.org/phsirb/Submission\\_Instructions/Response\\_to\\_Review.1.09.doc](http://healthcare.partners.org/phsirb/Submission_Instructions/Response_to_Review.1.09.doc)

**Note:** The Principal Investigator no longer needs to sign the response form. When the response is attached and the submission is re-submitted they will receive an informational email.

2. When revising documents previously submitted in eIRB, always add a new version of the existing document as follows:
  1. Click on the attachment 'Title,' which opens the version screen
  2. Click the 'add new version' button
  3. Check 'electronic' and browse for the 'marked copy' first
  4. Click the 'Save' button
  5. Next browse for the "clean copy"
  6. Click the 'Save' button
  7. Resubmit by clicking on the Submission tab, click the 'run application review' button and then the 'submit' button.

**Note:** Limit your response to the changes required by the IRB upon review of the submission. Do not view this as an opportunity to make additional changes and/or bypass the amendment process.