PHRC INSIGHT/eIRB
FAQS AND TROUBLESHOOTING

1. **Can Insight/eIRB be accessed from outside the Partners computer network?**

   Answer: Yes, Insight can be accessed remotely by using the secure web address https://insight.partners.org.

2. **Will Insight/eIRB work using a PC browser other than Internet Explorer?**

   Answer: Insight/eIRB has only been tested using Internet Explorer 6.0 or higher. Users have experienced problems when using Firefox; therefore we recommend using Internet Explorer.

3. **Will Insight/eIRB work using a MAC?**

   Answer: Yes, the Insight application works with MACS. Supported browsers are Safari and Firefox.

4. **Is the user name and password required for Insight the same as my Partners user name and password? What happens when my Partners password changes?**

   Answer: Yes, Insight uses Partners user name and password. If you change your Partners password, your new password will immediately take effect in the Insight application.

5. **Why do the names of study staff being added by amendment appear in the non-staff grid on some of the Staff & Access pages?**

   Answer: The names of study staff being added appear only in the Staff & Access study staff list of the pending amendment to add them. The names appear in the non-study staff access list of all other Staff & Access pages until the amendment to add them is approved. Then they appear in the Staff & Access page of the Active Protocol.

6. **How do people sign off in Insight/eIRB?**

   Answer: When you get an email letting you know that you have an Activity, click on the link in the email. This will take you directly to Insight. Once you login to Insight, you will be taken directly to the Activity. Follow these steps:
   - Review Submission by clicking on View Application or View Full Application
   - Click on the Action Required, for example, 'Principal Investigator Review'
   - Read the applicable certifications and check all checkboxes
   - Enter your Partners user name and password
   - Click Authenticate
   - Click Accept or, if applicable, Decline

NOTE: You do not necessarily need the email to complete the action. You can manually navigate to the activity by clicking the Humans>Activity List tabs.

7. **How will external (non-Partners) study staff certify/sign off?**

   Answer: Because you must have a Partners user name and password to access Insight, external (non-Partners) study staff must complete the Word password-protected Co-Investigator/ Study Staff Certification form available on the PHRC website. You can scan the completed and signed form and email it to your protocol administrator or you can fax the form to 617-424-4199. We will upload the scanned form or scan and upload the form to the Staff & Access page. **Note: If the external person is submitting an application to their own IRB for approval, do not list them on the Partners application. List only study staff covered by the Partners IRB approval. If you have any questions, contact Maria Sundquist, 617-424-4101.**

8. **What is the difference between the permissions of 'Edit' and 'Manage'?**

   Answer: Someone with 'Edit' permissions can create and make changes to a new protocol or create and make changes to a new submission for an existing protocol. Someone with 'Manage' permissions has 'Edit' permission and can change ('Manage') the permissions of others.

9. **How do I give someone who is not part of the study staff access to the protocol?**

   Answer: Anyone with 'Edit' or 'Manage' permission to the protocol can add someone to the non-study staff access list by selecting the protocol from the Active Protocol tab, going to the Staff & Access page, and clicking on the 'add users for access' button. Remember to indicate if the person being added is a contact person (check box) and their permissions (View, Edit, or Manage) before saving.

10. **How do I go back to add a form to my submission?**

    Answer: On the Forms page of the submission, click the 'add/delete forms' button at the bottom of the page. You can then add or remove a form as needed.

11. **I am the submitter and the PI. Do I have to sign off?**

    Answer: Yes. Once you click the submit button, you should receive an activity with a direct link to the sign off activity. You can also manually navigate to the activity by clicking the Humans>Activity List tabs.

12. **I am the PI. While reviewing the submission, I notice some edits that I would like to make. Can I?**

    Answer: Yes. Until the PI signs off, the submission is considered a draft and is unlocked. If you would like to make changes when you are reviewing the required activity (PI sign off), click the appropriate tab (Forms, Staff & Access, or Attachments) on the Action Required page.

Note: For amendments, only those tabs relevant to the submission will be available for editing.

The **FORMS** tab displays all the forms completed.
The **STAFF & ACCESS** tab displays the names of the study staff and their role.
The **ATTACHMENTS** tab displays study related documents.

After you have made your changes, go back to the Activity List>Action Required page and complete the action required/electronic sign off.

13. I submitted a study staff AME several weeks ago, but it hasn't been approved yet?

Answer: Check the Workflow History to see if the PI has signed off and the Human Research Office has received the submission. From the Pending Applications page, click the 'Workflow History' icon in the last column of the submission row. Look at the Workflow History Description column (fourth column) and find the row for the PI sign off activity. Look at the Output column (second column). If the Output column indicates 'approved,' the PI has signed off. If the column indicates 'rejected,' the PI has rejected the amendment. If the Output column is blank, the PI hasn't signed off. If the PI has signed off, check to see whether the Human Research Office has received the amendment by finding the row for the Human Research Office sign off activity.

If the PI has signed off and the Human Research Office has received the amendment, check the amendment submission Staff & Access page to see if all of the study staff have completed CITI and/or have signed off, and follow-up with study staff, as needed. If they have signed off, there will be a pdf icon in the column labeled 'Staff Certification.' Contact your protocol administrator if the CITI information does not appear to be correct in eIRB/Insight, or the study staff is having trouble signing off.

14. I submitted a new protocol for review. Where is it?

Answer: You can check the progress of any submission from the Pending Applications page. Search for the submission and click the 'Workflow History' icon in the last column of the submission row. You can then check the Workflow History to see who has signed off. The PI and, if applicable, the dept/unit chief/chair need to sign off before the submission will go to the Human Research Office. Look at the Workflow History Description column (fourth column) and find the row for the sign off activity. Look at the Output column (second column). If the Output column indicates 'approved,' it has been signed off. If the column indicates 'rejected,' the activity has been returned to the submitter. If the Output column is blank, it is still awaiting sign off.

15. **My submission was declined by the Human Research Office because it was a duplicate. How do I delete it?**

Answer: Click the 'Pending Applications' tab, open the submission and click the 'delete application' button at the bottom of the 'Forms' page. You must have 'Edit' or 'Manage' permission to delete a submission.

16. **Why was my submission declined by the Human Research Office?**

    Answer: When the Human Research Office declines a submission, they add a comment in the Workflow History. To view the Workflow History, click the 'Pending Applications' tab, find the appropriate submission, then click on the icon in the 'Workflow History' column (last column) of that row. When the Workflow History page opens, locate the row in the Output column (second column) that indicates the submission was 'rejected.' The comment entered by the Human Research Office should appear in the Comment column (last column) of that row. If there is no comment, contact your protocol administrator.

17. **How do I submit an amendment to change the Principal Investigator (PI) of a protocol?**

    Answer: Initiate a new amendment in eIRB but answer 'no' to question about adding or removing staff. In the text field that asks you to describe the change, enter the name of the new PI and indicate whether the current PI should be removed or will remain a co-investigator.

    If the study involves an intervention/interaction with human subjects, complete and sign/date the Principal Investigator and Dept/Unit Chief/Chair Certification form. If the study is limited to health/medical records, excess human material, secondary use of data/samples, or data repository, complete and sign/date the paper 'Principal Investigator Certification' form located on the PHRC website. When you have the required signatures you can scan and attach in the Attachment page of the submission in Insight. You will need to answer 'yes' to the question about adding study related documents. This will unlock the Attachment tab for you to attach. If you can not scan, submit the amendment and fax the form to your protocol administrator at 617-424-4199.

18. **IRB approval of my protocol has expired and I am trying to create a continuing review, but I can't create one.**

    Answer: Contact your protocol administrator. Currently eIRB does not allow for submissions to be created on expired protocols. The protocol administrator will add a continuing review to our Rex database so it appears that the CR has been received. This will change the overall status of the protocol to Hold-Lapsed. The next day, after the nightly data feed runs, the protocol will appear under the Active Protocols tab. You can then create and submit the continuing review.

19. **I am trying to submit a new document as part of my response to the IRB, but I can't see the 'add row' button on the Attachments page.**

    Answer: Check to make sure the submission is unlocked. Click the Pending Applications tab. The lock icon is located in the Lock Status column (3rd from the last column) on the Pending Applications page. If the icon displays as locked, contact your protocol administrator to unlock. Once they do, you will need to log out/in of Insight for the page to refresh and the submission to appear unlocked.

If the submission is unlocked, check your permission on the Staff & Access page. You must have 'Edit' or 'Manage' permission to make changes to a submission. If your permission is 'View,' ask someone with 'Manage' permission to change your permission to 'Edit.'

If the submission is unlocked and you have 'Edit' or 'Manage' permission, check your browser. Users have experienced problems when using Firefox on a PC. Switch to Internet Explorer (IE).

20. I can't version or attach a document in the Attachments page.

Answer: Check to make sure the submission is unlocked. Click the Humans>Pending Applications tab. The lock icon is located in the Lock Status column (3rd from the last column) on the Pending Applications page. If the icon displays as locked, contact your protocol administrator to unlock. Once they do, you will need to log out/in of Insight for the page to refresh and the submission to appear unlocked.

If the submission is unlocked, check your permission on the Staff & Access page. You must have 'Edit' or 'Manage' permission to make changes to a submission. If your permission is 'View,' ask someone with 'Manage' permission to change your permission to 'Edit.'

Check to see if the document title is a hyperlink. If the document title on the Attachments page is underlined, the document has turned into a hyperlink. If it hasn't turned into a hyperlink, delete the attached document by clicking on the checkbox in the row under Mark for Deletion column. Then, re-add the document by clicking the 'add a row' button at the bottom of the Attachments page and attach the document. If you have to add a marked and a clean version of the documents, attach the clean as the correct 'Attachment Type' and attach the marked with the 'Attachment Type' as 'Other.'

21. Why can't I delete a submission?

Answer: The submission may be locked. Click the 'Pending Applications' tab. The lock icon is located in the Lock Status column (3rd from the last column) on the Pending Applications page. If the icon displays as locked, the submission has already been accepted by the PHRC. If the submission was already accepted by the PHRC, the submission must be formally withdrawn.

If the submission is unlocked, check your permission on the Staff & Access page. You must have 'Edit' or 'Manage' permission to make changes to a submission. If your permission is 'View,' ask someone with 'Manage' permission to change your permission to 'Edit.'

If the submission is unlocked and you have 'Edit' or 'Manage' permission, check your browser. Users have experienced problems when using Firefox on a PC. Switch to Internet Explorer (IE). If you are still unable to delete, contact the PHS Insight Help Desk at 617-424-4175.

22. I can't add someone to the non-study staff grid.

Answer: You may not have permission to make changes to the protocol. Check your permission on the Staff & Access page. You must have 'Edit' or 'Manage' permission to make changes to a submission. If your permission is 'View,' ask someone with 'Manage' permission to change your permission to 'Edit.'

23. I am trying to create an amendment, but I don't see the 'create new process' drop down menu,

Answer: You may not have permission to make changes to the protocol. Check your permissions on the Staff & Access page. You must have 'Edit' or 'Manage' permission to create an amendment. If you only have view, anyone that has Manage access can change this for you or contact the Insight Help Desk. If you have no user name next to your name on the Staff & Access page this could also cause a problem. If so, contact the PHS Insight Help Desk at 617-424-4175.

24. **I saved a new submission but when I log back in to Insight I can't find it.**

Answer: Prior to submission, the protocol is listed in the 'Work in Progress' tab. Click the 'Work in Progress' tab and search by PI Name, or if PI has not been assigned yet, by Title. You can also sort by PI by clicking on the column heading to find protocols without a PI.

25. The institution and/or department / unit designation for one or more of the study staff is incorrect. How do I get this corrected?

Answer: Contact the PHS Insight Help Desk at 617-424-4175.

26. I want to amend my 'exempt' or 'not human subject' protocol, but I can't create an amendment.

Answer: You can not create an amendment for a protocol that has been determined to be 'exempt' from the requirements of 45 CFR 46 or has been determined 'not human research.' You must discuss any proposed changes in the research activity (not changes to study staff) with the Human Research Office (IRB) to determine if the proposed changes are within the parameters of the exemption or determination of 'not human research.'