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 8.0. 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. The 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 the Accept or Decline radio button
   - Read the applicable certifications and check all checkboxes if you Accept, or enter Decline comments if you decline
   - Enter your Partners user name and password
   - Click the Submit button

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 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 make changes to new protocol or existing protocol submission. Someone with 'Manage' permissions has 'Edit' permission and can submit submissions and 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: No. Once the submission is submitted it locks. You would need to decline the submission for it to unlock. Once the submission is unlocked, you can make your changes and resubmit from the Submission tab. The activity will then be regenerated in your Activity List.

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 and the staff being added have signed off. 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 if the staff being added have a row indicating they have approved. If a row does not appear with the staff name, they most likely have not signed off yet. The Human Research Office will not receive a staff amendment until the PI and all staff being added have signed 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: If you are the PI or a contact person, the decline notes should be in the email alerting you to the decline. If you did not receive an email, the comment should also be on the 'Workflow History' page. To go there, click the 'Pending Applications' page, search for the transaction then click the 'Workflow History' icon on the far right of the row listing the transaction. When the page opens, locate the row with the rejection/decline and the comment should be in the last column. If there is no comment, contact your protocol administrator.

17. How do I change the Principal Investigator (PI) of a protocol?

Answer: Initiate a new amendment in eIRB and answer 'yes' to the questions about adding or removing staff and changing the PI. After saving the form, click the Staff & Access tab to indicate the new PI. If the new PI is already listed on the study, you need to remove the name with the old role and search and add the name back and indicate the new role. Do the same if the old PI will be still part of the study but under a different role. Remove the names first before clicking the 'add study staff' button at the bottom of the staff grid to search and add.

Once submitted, the old PI will receive an email and activity to sign off. When they do, an email and activity is sent to the new PI. If the study involves an intervention and/or interaction with human subjects the new PIs department/unit chief/chair will receive an email and activity to sign off after the new PI signs off. Once complete, it comes to the Human Research Office for review.

18. How can I submit a continuing review (CR) if my protocol has expired?

Answer: If the protocol has expired, it will be listed under the 'Inactive Protocols' tab. Click on the protocol title to open and select 'Continuing Review' from the 'Create New Process' dropdown and complete the form. Since the protocol expired, you will also need to complete the Minor Deviation/Violation log and attach under the Attachments tab of the continuing review application before submitting.

19. 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.'

-On the Attachments page to add a revised document: click the 'Add Version' hyperlink on the document row you want to update.
-Click Electronic
-Click the Browse button to locate and select the file
-Click the Save button

NOTE: If you are submitting an updated version of a document you will need to attach two copies. One 'revised/marked' version and one 'clean/unmarked' version. If the document is protected you will not be able to use the Tracked Changes function in Word, use Bold/Underline/Strikethrough to indicate what words you are deleting and what words you are adding. Always attach the marked version first and then the clean.

20. 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.’

21. 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.

22. **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.

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

Answer: The staff person will be able to change their own **institution and/or department / unit** designation if they have access to the Admin module in Insight.

Once they change their information, this new information will appear in all new submissions. If the application has already been submitted, or they do not have the Admin module, contact the PHS Insight Help Desk at 617-424-4175.