How to.... In e-IRB

Emory University
Institutional Review Board
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How to access e-IRB

1. Login to your account at https://eresearch.emory.edu/Emory/. Remember to use the same information you use for other Emory applications such as People Soft or Outlook.

2. Once logged in, you will notice certain areas in your e-IRB account. First, under “My roles”, you will see your activities with the IRB. For most investigators, you will just have a “Study Staff” option. In this example this investigator is also a member of the IRB committee. As such, this investigator has another role option reading “IRB Committee Member”. In order to access your studies, the “Study Staff” option should be highlighted. People have that have a role as Department Approvers, will also see that option. If you are signing in to approve a study for your department, be sure to have that option in **Bold**. To select one role over the other, just click on the role.
3. When working or approving IRB submissions (new studies, amendments, continuing reviews, protocol deviations and close outs), your “to-do” list will be located at the “My Inbox” tab. In this case, this investigator does not have any pending activities, but in case of anything pending, this person would have to just click on the study under “My Inbox” to access it and approve it.

4. If you want to see your current approved studies, click on the “IRB” tab.
5. You will see all the studies you are participating in at the moment. If you want to access one, just click on the study, so it will open. You will notice how many studies you have and the current status of them. Let’s click on one to check the status and work done before.

6. Once open, you will see all the communications with the IRB regarding the study and if they are any pending activities. In this example we can see the study has been approved because there is a date after “Expiration date” and there is a view of the letter of approval. You can also see under “My activities” all the things you could use to communicate with the IRB. In this case, because this investigator is an IRB member, he can send a private comment to the IRB but that is not the case for regular research staff. Let’s click on the current amendment workspace ( ) to see how it is progressing.
7. In this case, the amendment was just submitted so the IRB has not reviewed it yet. Once approved, we will be able to see an approval letter and expiration date. This amendment just has the date of submission. To come back to the previous window, just click on the study name under the home tab.

In addition, when coming back to the main study page you could access the current approved documents by clicking on “View Study” or “Printer Version”. In addition, the tab called “Documents” has your current approved consent forms.
How to create a new study in e-IRB

1. After logging into the system, you will find a column with options at your left hand side. Go to the end of the column “New IRB Study”.

2. After clicking on the button, a new window will appear with different questions. Use the Smartform to guide you through the process. According to the answers provided, the system will determine which other information the IRB needs to make a determination. Next we will point out some important parts of the forms to guide you further. In this window, you will provide your study information as well as the study team. Be sure to place people in their correct function. For study team members that are not part of Emory, they should be included under Non-Emory Study Staff.
3. The next window will ask information about study sites. Indicate the places where the study will take place and information will be stored.

4. Another important information to provide if the source of study funding, if any. The IRB needs the current copy of the contract with the sponsor (or the draft if still in negotiation) to match it with the consent documents. In case of questions regarding the contract part of your study, please contact the Office of Clinical Research and the Office of Sponsored Programs.
5. When providing information about the study sponsor and clicking on “Add”, a new window will pop out asking for additional information.

6. For any study submitted, we require a lay summary and a protocol. For information of how format these documents, please go to the following link for more information. Look under “Lay summary guidance” and “Protocol format”:

http://www.irb.emory.edu/researchers/formstools/formstools.cfm#oth
7. The following are important questions to answer in order to understand if your study is a prospective or retrospective research. Depending on the answers, the system will take you to different parts of the application and skip others.

8. If answered “Yes” to question one and “No” to question 2, the system will take you to the Biomedical Research window.
9. If the first question is answered “No” and the second is answered “Yes”, the system will take you to the Social Behavioral Research Window. It is possible that your study has both components, so be aware that you might need to answer both groups of questions.

10. We also required detail information about the study population. Please, remember that we considered “enrolled” the amount of patients consented in the study, even if they are screen failures or if they withdraw from the study.
11. Another important area is the HIPAA determination. This will help us know if your study is under the “Covered Entity” as described in the form.

HIPAA Determination

The "RWHSC" is comprised of the School of Medicine (SOM), School of Nursing (SON), School of Public Health (SPH), Yerkes Primate Center (YPC), Student Health Services (SHS), Psychologic Counseling Center.

For a list of PHI identifiers, go to http://www.irb.emory.edu/researchers/formstools/docs/other/ph_ids_identifiers.pdf

1.0 * Will you be receiving or disclosing any information about a person's health, healthcare or payment for healthcare that has any associated identifiers?
   ☑ Yes ☐ No ☑ Clear

2.0 * Is there any person on the study (Study Staff) that is part of the "RWHSC Covered Entity"?
   ☑ Yes ☐ No ☑ Clear

3.0 * Will any protected health information (PHI) be provided by any component of the "RWHSC Covered Entity"?
   ☑ Yes ☐ No ☑ Clear

12. The consent process needs to be detailed in the next group of questions.

Informed Consent Process

1.4 * Indicate the type of Consent and/or Assent requested:
   ☑ Written signed consent by the subject
   ☑ Written signed consent by a legally authorized representative (for an adult)
   ☑ Verbal consent for an adult
   ☑ Written signed consent for a minor 15-17
   ☑ Verbal assent for a minor 15-17
   ☑ Parental consent
   ☑ Waiver of Assent
   ☑ Waiver of parental consent
   ☑ Parental written signed consent (i.e., information sheet, telephone consent, verbal ophthalmic consent)
   ☑ Verbal assent for Cognitively Impaired outside

2.8 * Provide the number of CONSENTS contained in this submission (do not include Stand-alone or separate HIPAA authorization)
   1

3.8 * Provide the number of ASSENTs contained in this submission (do not include Stand-alone or separate HIPAA authorization)
   0

4.8 * How will consent be obtained?
   ☑ Information obtained by having the patient sign the consent form document. However, if patient informed consent is ongoing, interactive
   ☑ Information obtained by having the patient sign the consent form document. However, if patient informed consent is ongoing, interactive

5.8 * Where will consent be obtained? (Office, Hospital, home, phone)
   The initial informed consent discussion will occur in the oncology clinic.

13. At the end of this page, you will have to upload your study and HIPAA consent forms. For guidelines and information about these forms, please go to:
   http://www.irb.emory.edu/researchers/formstools/formstools.cfm#consent
14. The protocol should always include a Data Safety and Monitoring Plan. For other studies with increased risk, a Data Safety and Monitoring Board, Local Board or Monitor might be necessary.

15. Under “Miscellaneous Documents” please include only document that do not have another appropriate place to be uploaded. In addition, include all current CITI certifications for the study staff.
16. Complete the Conflict of Interest (COI) Section. For more information, please read the Emory COI policy and contact the Office of COI. You can find their information at http://www.coi.emory.edu

17. The final page will indicate the next steps. It is important to remember that after finishing with the form, the submission needs to be sign off by the Principal Investigator and Department Approval. If any Co-Investigators were included, they also need to accept their role as part of the study team before the PI can submit the form. The IRB office will not see the submission after all these steps are fulfilled.
FINAL PAGE

Please select "Final" in status and exit the application. The application will still be available until it is submitted to the Principal Investigator. "Final" will NOT submit the application for review.

Please note that a submission may only be resubmitted by reviewers through the Principal Investigator. To do this, the Principal Investigator must select "Submit" in the study workspace.

You cannot submit an application if you are not logged into the study workspace. Please log in to contact the IRB Office (e-IRB@emory.edu or 404-727-3758) or http://www.emory.edu/IRB with any questions or concerns.

Things to remember:
- If you already entered Community Advisory Board (or other committees) information, you must apply to those committees separately using the process in place for those committees. You must also note (if on the "Required Review" section)
- If you need to enter OHRP-Studies Only information, you must also apply to the IRB equally using the process in place for the OHRP. You must also note (if on the "Required Review" section)
- You must submit your study to the appropriate IRB, and/or Institutional Review Board (IRB) and/or Institutional Review Board (IRB) as appropriate. For more information on OHRP, contact Emory University OHRP office.
- If your study is IRB-approved, you must ensure the sponsor has completed its work and that all changes have been reviewed. You must then contact your IRB office.
How to Submit a Continuing Review in e-IRB

1. After logging into the system, and clicking on the study (under the inbox tab), please select “New Continuing Review” under “My Activities”.

2. The Smartform will guide you through the process and ask you relevant questions about the study status, patients enrolled and any problems you might encountered in the past year.
3. Please, check our guidelines at http://www.irb.emory.edu/documents/NC%20UP%20Guidance.doc when referring to Unanticipated Problems and Protocol Deviations. For participant deaths, the IRB needs to know at continuing review for subjects that died for a reason other to the study participation.

4. The IRB also need to know how many patients were enrolled in the study. Be aware that if you are close to the enrollment approved number, you should considered submitting an amendment increasing the number. Surpassing the approved number is considered Non-Compliance.
5. It is important to upload any information you might have about the study at this point. We also need to obtain information regarding new research finding from other studies, if any.

6. The IRB requires submitting any report from audits conducted from the FDA, OHRP or study monitor. Please, also submit a document explaining if any of those findings were reportable per our guidelines and if they were when they were reported to our office. You have 10 calendar days to report any unanticipated problem or protocol deviation that fulfill our requirements.
7. In addition, any reports given from the sponsor or DSMB need to be uploaded. Please remember to include a document explain the findings and if they are reportable to the IRB.

8. The last page will review your answers before submission. Please remember that clicking finish will not submit the form; it will just send it to the PI’s inbox so he can submit the form to the IRB.
1. After logging into the system, and clicking on the study (under the inbox tab), please select “New Amendment” under “My Activities”.

2. Follow the Smartform to indicate the areas of your original submission you would like to change. According to our answers, the form will request additional information per changed item.
3. Once all questions have been answered, the last page will indicate a link to go to the approved submission form. Once you click on that link, the next window will take you to the form. Please make all the needed changes, click submit and exit and the form will take you back to this same page.

4. As with any other form, once the “finish” button is clicked, the form will be sent to the PI for approval. The form will not be received by the IRB office once the PI submits the form.