ESTR FAQ

Investigators and Study Staff

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How do I access the ESTR?

1. Go to https://irb.harvard.edu/
2. Log in to the system using HUID and PIN.
3. You will see your personal page.

How do I get an HUID and PIN?

Please see information about HUID and ESTR.

How to I maintain access to ESTR during a session?

1. Ensure you have a stable internet connection.
2. If accessing the system on a Harvard campus, it is suggested that you either:
    a. Obtain a hardwired connection, or
    b. Access the "Harvard University" wireless network (this may require computer registration at first access, but will not require registration for subsequent sessions).
3. Interact with the system at least once every 30 minutes.
4. For security reasons, the system will time-out after an idle 30 minutes and may or may not save any previously unsaved information.

For more information: Please also see the desktop standards available on the support site.

How do I find and get to a study?
Please see information about finding a submission.

How do I view an application (or SmartForm)?

1. Click the "Submissions" link on the left side of the screen.
2. From the "All Submissions" tab, go to the desired study workspace by clicking on the blue text under the "Name" label.
3. View the SmartForm and attachments in one of two ways:
    a. Select "View Study" to view each individual page of the SmartForm and attachments per SmartForm page.
    b. Select "Printer Version" to view a continuous view of all SmartForm pages and links to attachments.

How do I work with a "migrated" application?
Please see information about working with a study that was active as we transitioned to using ESTR, also called a "migrated study".

What does the study number mean?
A study has a number that contains a "type" acronym:

- IRB means you are viewing the parent record for a study or an initial application.
- CR means you are viewing a Continuing Review
- MOD means you are viewing a Modification
- RNI means you are viewing Reportable New Information
- No Acronym (just a five digit number) means you are viewing a parent record for a migrated study.

How can I get access to a study?

- You must first have an HUID. If you do not have an HUID, please follow the steps outlined in the section "*How do I get an HUID and PIN?*"
- Contact the Principal Investigator on the study or a member of the approved study team to complete the appropriate activity for access to the study workspace:
    1. Complete the "Manage Guest List" activity. This is read-only access.
    2. Complete the "Assign Primary Contact" activity. This is read/edit access to the study. The person named in this space also receives all automatic study notifications.
    3. Complete the "Create Modification/CR" activity to add you as personnel on the study. As approved personnel, you will have read/edit access to the study.
        - **Note:** This is not immediate. You will only have access after the modification is approved.
    4. Completing the "Edit Email List" activity will allow selected approved study staff members to receive all automatic study notifications.

More information about access and who can submit information to the IRB is available on our Support Site.

Why does a study appear in the "Inbox" of my personal page?
Items will appear in your in-box when action is required. Action is required when a study is in the following states:

- Pre-Submission: The study must be submitted.
- Submitted (but PI Attestation has not yet been submitted): The PI must log in and submit attestation.
- Clarifications Requested (Pre-review or Non-Committee review): The clarifications requested by the IRB must be submitted.
- Modifications Required to Secure Approval: Response to Committee concerns must be submitted.
- Deferred: Response to Committee concerns must be submitted.

Items requiring action will also appear in the "All Submissions" tab of your personal page. Clicking on this tab will allow you to view all projects to which you have access and will show all items in their various states.

How can I access or request a report?
Please see information about working with reports.

Why is the link to a workspace not working?
A link to a study workspace is associated with the submission in a particular state. If any activity which transitions a study to a different state is completed (such as, the application is submitted) after you capture the web address, the link will no longer work. To navigate back to the study in its new state:

1. Select the "Submissions" link on the left side of the screen.
2. The "All Submissions" tab displays. The "All Submissions" tab captures all items to which you have access in their various states.
   This tab will display all items to which you have access, including those projects that are approved, those that require your action (i.e. you have not yet submitted the item or the item is pending your response following the IRB's request for clarifications) and those projects that are currently under review by the IRB.

How can I get additional access and user rights (such as a department viewer or Committee member)?

1. Send the names of individuals to ESTRhelp@harvard.edu.
2. The request will be logged and reviewed
3. Once access is granted, you will receive an email.

Who receives study notifications?

- By Default (these individuals cannot opt out of notifications): the Principal Investigator, Primary Contact and Faculty Sponsor (if there is one) when action is required on a protocol (such as: the study is due for renewal, assurance or revision is required, or a determination has been made).

- A member of the approved study team can also complete the "edit email list" activity to add any approved study team members as recipients of these notices.
  NOTE: you must already have access to a study (by being a guest or approved study team member) in order to be successfully added to the email list and receive notices.
- Please see information about working with notifications for more details.

When is Department Review required?
Please see the Longwood Medical Area IRB website for department review requirements. This requirement is not in place for materials submitted to the University Area IRB.

How do I add personnel to an approved study?
Please see information on changing study personnel.

Why am I receiving reminders if I already submitted a continuing review application?
ESTR will send automatic email notifications of study expiry until the study is re-approved. If you visit the CR workspace and it indicates that the application has been submitted, you can disregard the notices. However, if you receive a notification of lapsed approval and you have already submitted a continuing review, please contact the IRB office for an update on the status of review.

Who can submit an application?
Please see information about access and who can submit information to the IRB.

How do I fix my continuing review so that it includes a modification?
Applications for continuing review are separate from modification requests. Therefore, you can proceed with the continuing review submission (submit and respond to requests from the IRB), and at the same time create a modification.
Please see information about how to create a modification or continuing review.

How do I withdraw an application?
The option to withdraw is only available when a determination has not been issued by the IRB office.

1. Log in to ESTR.
2. Go to the workspace for the ***specific*** submission (i.e. initial application, continuing review, modification, etc.) you wish to withdraw.
3. Select the "Withdraw" activity from the study workspace.

Note: Withdrawing a modification, reportable new information, or continuing review submission will not affect the status of the main study. However, if an initial application is withdrawn; the whole study is withdrawn from further review.

When can a submitted application be edited?

1. A SmartForm is opened for edits or changes to attachments in the following states:
    - Pre-submission (i.e. the application has not yet been submitted for IRB review)
    - Clarifications requested (a notification is sent to the PI and primary contact when an application is changed to this state)
    - Modifications Required (a notification is sent to the PI and primary contact when an application is changed to this state)
2. Study staff (including PI) or IRB staff may make edits during these states by selecting "edit study" in the submission workspace.

Note: When a submission is under IRB review and the IRB reviewer makes a request for clarifications, the requested changes can be made by any person listed as approved study staff; however, one of these individuals **must select "submit changes" in order to return the submission back to the IRB reviewer**. Please note that making changes to an application and submitting changes back to the IRB are separate actions within the system.

How do I close a study?

Please see information on how to close a study.