IRB Staff Administration Guide

Electronic Submission Tracking and Reporting (ESTR)

December 8, 2023

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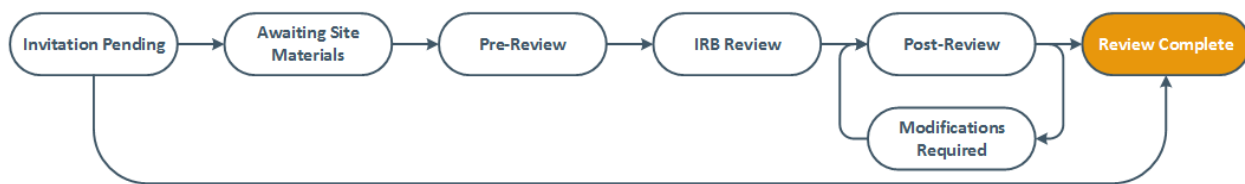
IRB Submission Types

IRB Process Overview

The IRB system treats all types of submissions—studies, sites, and follow-on submissions—very similarly. You perform the similar types of activities and follow the same process for each, with small exceptions. The questions asked are different for each type of submission, but the workflow follows a similar path.

At the highest level, all non-ceded studies and follow-on submissions use the following general IRB process workflow:

At the highest level, all non-ceded sites (participating sites/pSites) use the following general IRB process workflow:

The system shows the appropriate diagram above when you view an individual study and shows the current state of the study in orange.

ESTR accepts the following types of submissions:

- Initial study/main study submissions (new studies)
- Site submissions for both when other engaged institutions or organizations will rely on Harvard review or when associated with an initial External IRB submission.
- Follow-on submissions:
  - Modification/Updates for approved studies (Modification scope includes options to change 'Other parts of the study' and/or 'Study team member information')
  - Continuing Reviews for approved studies
  - Study Closure requests for approved studies
  - New information reports (often called RNI for reportable new information) for approved studies or active research in general
  - Site Modifications to change one or more features of an active site
  - For External IRB projects only, related Study Updates for a modification or update on the status of a study where Harvard relies on the review of another institution

All submission types follow a very similar workflow. Some differences include:

- Each type of follow-on submission has its own set of determinations that differs from the study determinations.

- Studies, modifications, and continuing reviews include optional ancillary reviews that can be conducted concurrently with the IRB's reviews. Site and RNI submissions do not include ancillary review.

- RNI submissions may skip certain states or require committee review after designated review has been completed.

Study Review Process Overview

The basic process for a study—or initial submission—is shown in the following diagram. The exploded view shows what occurs during the IRB review process.
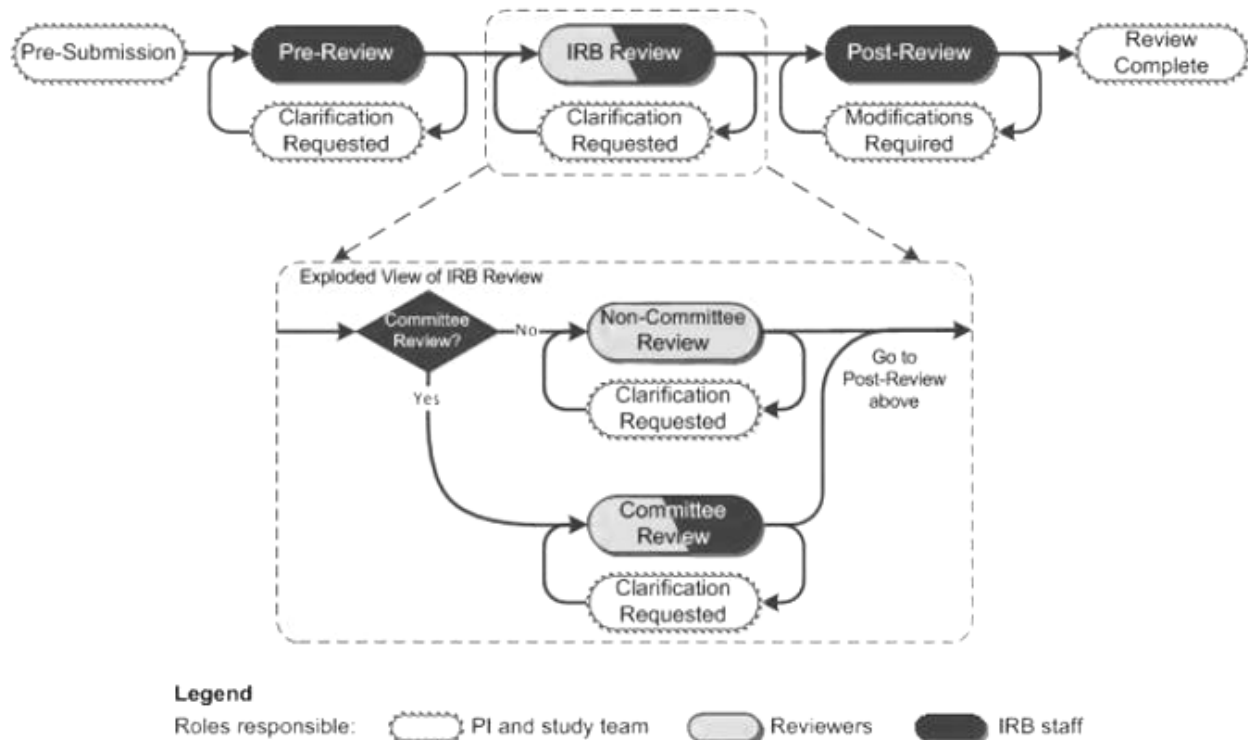
The legend indicates who can take major actions during each state within the process. Keep in mind that the diagram does not show all possible paths that a submission may take. The diagram shows the most likely path through the review process with common options identified.

Studies include:

- Optional ancillary reviews that can be conducted concurrent with the IRB's reviews. For more ancillary review information, see the Ancillary Reviewer Guide section for Ancillary Review Overview.

- The ability to Manage Related Projects, linking a non-follow on record to one or more Agreement or Data Safety records in the suite.

- For collaborative studies where Harvard will be the IRB of record, Sites may be added via activity, with review and consideration of reliance managed on the site workspace. This can be conducted concurrently with IRB review but cannot be completed until initial approval is issued.

Before IRB review activities can begin, the submission must be assigned to an IRB coordinator, as described in [Assigning Ownership of a Study](#).

Tip: If the study is not assigned to the correct IRB, complete the Assign IRB activity to change IRB. After completing the Assign IRB activity, ensure that: 1. the person assigned as coordinator is removed, and 2. the SmartForm is revised to include a responsible department on the Basic Information page that is reviewed under the correct IRB. This will ensure the reassigned IRB remains correct through the life of the study.

Notable information about several states is identified below.

Pre-Review and Clarification Requested: In the Pre-Review state, the IRB coordinator answers questions about oversight agencies, special populations, etc., that apply to the study. Instead of asking the study team to answer the questions, the IRB staff takes responsibility for reviewing the submission information and answering them. Answering these questions before a committee review can save the committee's time if information is found to be missing or inconsistent. The IRB coordinator can send the study back to the study team for clarification if needed, which lets the study team change the study.

The IRB coordinator can also edit the study or perform actions on behalf of the study team. This includes:

- Editing the study when it is in an otherwise editable state (such as clarifications requested); OR
- Completing activities (such as Submit, Submit Response, Add Participating Sites, or Assign PI Proxy).

Important! When determining if this type of submission assistance is appropriate, note that:
- When assigned as IRB Coordinator, if the submission is in an editable state (such as clarifications requested), activities ordinarily available to IRB staff (such as add private comment) may not be visible to this staff member. Visibility will return once the study returns to IRB review, or a determination is made.
- In some circumstances, when assigned as IRB Coordinator on a main study, view of private comments or pre-review activities on already approved follow on submissions may be hidden.
- The assigned IRB Coordinator can take action on the main study and create follow on submissions on behalf of the study team, however, they must be assigned as Coordinator on the main record and the page may need to be refreshed after assignment before necessary options appear.

IRB Study Review Activities: (relevant for Initial, Modification, or Continuing Review/Closure) IRB review is not a single state, but a collection of other states. In addition to requests for clarifications, IRB review includes the following required activity steps:

1. **Submit Pre-Review:** (required step) transitions the submission to the pre-review completed state. Able to be edited on all submission types where it is required. Harvard-tracked items are included in this activity. This includes the determination of whether the study includes Sensitive data, as defined by the Harvard Research Data Security Policy. If a study involves the use of Sensitive data, the IRB Coordinator should inform the researcher of the need to create a submission in the Data Safety application and should instruct the researcher to then link the Safety and IRB submissions together using the Manage Related Projects activity. This request is best completed as part of a

request for clarifications or when modifications are required to secure approval for the submission. When pre-review is submitted, the system confirms that Harvard will review, and locks the External IRB question on the SmartForm.

Note:

- After completing the Pre-Review and proceeding with the review process, the Pre-Review may later be edited via the Edit Pre-Review activity. The ability to edit is no longer available once the Send Letter activity is completed.

- If the Pre-Review is edited after the study has reached the Post-Review state and received a determination of "Modifications Required to Secure Approval," the IRB Coordinator will no longer have the option to "Accept Modifications." Instead, the system will require completion of the Designated or Committee Review activities to proceed with the review.

2. **Manage Ancillary Reviews:** (optional step) available and editable through post-review, and on approved submissions.
   Note: To share a public message with the assigned ancillary reviewer (if the add comment activity is not preferred), the individual assigning the review can: a) add the ancillary review type, b) from the Manage Ancillary Reviews list on the pop up, click update, and then c) partially fill in the activity by marking "no" to question 4 and adding comments/documents for the ancillary reviewer to view when they are completing their review.

3. **Assign Designated Reviewer OR Assign to Committee Review:** (required step) available after pre-review is first submitted and allows for routing to the appropriate type of review.

4. **Determination Entry Activities:**

   - Submit Designated Review: (required step) transitions the submission to post review, Editable through post review and determination. If edited, this activity will update the effective date. If clarifications are requested during this type of review, the SmartForm may be edited as part of the response submitted by the study team.

   - Submit Committee Review: (required step) transitions the submission to post review. Editable through post-review and determination. If edited, this activity will update the effective date. If clarifications are requested during this type of review, the SmartForm will be locked from edits. The submitted response must be within the Submit Response activity completed by the study team.

5. **Post-Review**: The Post-Review state gives the IRB staff the opportunity to complete the following activities:

   1. Finalize Documents: (required step) Mark selected documents attached to a submission as approved to create final copies. Finalize all documents at initial review and finalize only updated documents on modifications. Documents can also be finalized on a Continuing Review, as needed per office-specific policy (CUHS does not finalize documents at the time of Continuing Review; HLC does finalize documents at the time of Continuing Review). Never finalize document that is not included in the approval.

      Note: Non-document type attachments (such as compressed/zip, video, audio, or htm files) may cause a problem when finalizing. It is suggested practice to attached these to the SmartForm as a Supporting Document and categorized as attachment type "other".

   2. Manage Ancillary Approvals: (optional step) Review the status of ancillary approvals on the Reviews tab to make any necessary updates. Complete any needed updates.

3. <u>Prepare Letter</u>: (required step) To inform the study team about the IRB's decision. IRB staff may refer to the local reference regarding specific edits associated with each system-generated template letter.

   Note: The Prepare Letter activity and the letter draft will not appear on the workspace until the send letter activity is completed. To view draft versions of a determination letter before the letter is sent, complete the Prepare Letter activity again.

4. <u>Send Letter</u>: (required step) Notifies the PI, PI Proxy, and Primary Contact that the determination letter is available. Sending the letter also transitions the submission to the state determined by the IRB, such as Modifications Required or Approved.

   If the IRB decided to require modifications to the study before a final determination is issued, the submission moves to the Modifications Required state to allow the study team to respond.

7. **Review Required Modifications**. (required step, for submissions in modifications submitted state)

   The following **must occur when the study team submits the requested modifications**. The IRB coordinator, director, or committee chair can choose to review the modifications using the Review Required Modifications activity. The IRB coordinator and director can also assign the modifications to non-committee or committee review, as appropriate.

   After checking the response from the study team, review required modifications, fill in updated dates, as applicable along with providing a summary of the review for study staff to see on the submission History.

   - Mark "Yes": If Modifications Required to Secure Approval (MRTSA) response fulfills the MRTSA
     - Update the effective date of the approval in this activity.
     - The system will update the IRB determination automatically.
     - If other attributes of the review need to be revised, update the appropriate review activity at this time.
     - Marking "Yes" to the last question on the activity will move the submission to post review (see steps above).

   - Mark "No": If MRTSA response does not fulfill the MRTSA
     - Indicate what actions are needed by the study staff in the text box provided as no letter is issued.
     - If other attributes of the review need to be revised, update the appropriate review activity at this time.
     - Marking "No" to the last question on the activity will notify the study team and return the submission back to the study team for further edits.

   If the changes do not directly relate to the requirements or as needed, the IRB staff member can assign the submission to a designated reviewer (non-committee review) or a meeting (committee review) to complete review of the response.

Other Available Optional Activities

- **Discard and Withdraw:** After pre-submission, Withdraw can be completed at any time before post review, and returns a submission to the pre-submission state for edits and resubmission by the PI/PI Proxy. Discard can be completed when a submission is in an editable state (such as pre-submission or clarifications requested) and will remove the submission from further consideration. If during review, a member of the IRB staff would like to complete the Discard or Withdraw activity on behalf of the study team (in compliance with office procedure), the staff member must first be the assigned IRB Coordinator. If the activity is still not visible after assignment, the IRB staff member can contact estrhelp@harvard.edu for assistance with completion of the activity.

- **Add Reviewer Comments** is available during the IRB review collection of states, the activity as a space to take review notes. Completed activity notes are available to IRB staff and committee members via the History and Reviews tabs in the submission workspace. This information is available until a final determination is issued (not including disapproved, deferred, or modifications required). Once review is completed and when the determination letter with the final determination is sent, the system purges all individual reviewer comments.

- **Revert to Pre-2018 Requirements** This activity is available on the main study workspace of studies that were:

    - submitted before the 2018 requirements became effective and

    - studies that were originally subject to Pre-2018 Requirements, but later changed to 2018 Requirements

    However, the activity is **not** available for studies subject to 2018 Requirements when initially submitted.

    The activity pop up has space for a comment, the addition of supporting documents, and the option to notify the PI/Proxy/Primary Contact (or not).

    Important! This activity will trigger the request for a Continuing Review submission, to revert the study back to pre-2018 common rule requirements. A change in the regulatory authority can only occur on an initial submission or a Continuing Review.

- **Update Expiration Date:** After initial or continuing approval, it may be identified that an end date of approval (or expiration date) is incorrect in the system. If this occurs, an IRB coordinator can execute the Update Expiration Date activity to change the value in the system. Changing a determination value may require additional steps to ensure the update is documented correctly. Specific steps for IRB staff include:
    1. Review the determination letters issued within the last year to identify
        a. If the expiration date has actually changed; and
        b. If the most recent determination letter needs to be re-created and re-sent with the correct date.
    2. If the expiration date on the main study is confirmed as incorrect and:
        a. The study is in the "Approved" state: complete the Update Expiration Date activity on the main study, or
        b. The study is in the "Lapsed" state:
            i. Complete the Move to Approved activity on the main study. Note: No notice will be sent. If a notice is needed, please add a comment.
            ii. Complete the Update Expiration Date activity on the main study.

3. If the most recent determination letter contains an incorrect expiration date, on the workspace with the incorrect letter, execute the Prepare Letter and Send Letter activities.

Participating Site Review Process Overview

As appropriate, the Harvard IRB may review activities taking place at another site, where that site relies on the Harvard IRB review. The review of these participating sites (pSites) and confirmation of reliance is managed in two ways:

Projects created prior to December 15 2017

Confirmation of reliance is considered as recorded as part of the review of the main study (and as part of any subsequent modifications). Information is contained in one of three spaces:
 o Research Locations page of the SmartForm (including site name and location)
  o Last attachment space of the Local Site Documents page of the SmartForm (including any draft or confirmed reliance documentation)
  o Review activities or notes

If a substantive change is to occur on an existing site, or if a new site must be added, the study team can request a modification to "other parts of the study" to change the type of study to collaborative where Harvard will review (questions 8 and 9 on the Basic Information page of the SmartForm) to then allow for the addition of a participating site via the Manage Participating Sites activity.

Projects created after December 15 2017

Only studies indicated as Collaborative (question 8 on the Basic Information page of the SmartForm) AND where Harvard will review for at least one site (question 9 on the Basic Information page of the SmartForm) allow for the inclusion of site review.

Review of a pSite follows an alternate workflow from a study and has some special activities.
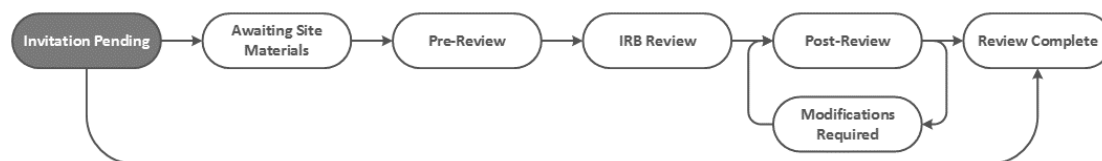
Site review involves the following additional features:
  o Upon completion of the Add/Manage Participating Site activity on the main study workspace, the site submission is created as pending, until pre-review is submitted on the main study. These pending sites can be removed or changed by re-completing the manage participating sites activity. Once a site is pending and pre-review of the main study is completed OR a site is added after pre-review on the main study is completed, the site is:
  o Automatically assigned to the IRB coordinator assigned to the study (if one is assigned), and
  o Immediately available to the IRB for review. So, completion of "Add/Manage Participating Sites" is similar to 'submitting' a participating site.
  o Unlike review of a study, the pSite may be edited until the confirmation of site materials received. Along with other documents, if the study team requires access to the confirmation of reliance, it may be attached to the Local Site Documents page of the SmartForm prior to (or when) confirming site materials as received.

o   Notifications to the PI/Proxy and Primary Contact are from this submission and will occur in addition to any study related review. Consider this when completing site review during the review of an associated study or follow-on.

o   Review cannot be completed on a pSite until the main study review is completed.

o   Best practice indicates that a pSite should only be added (a) during the review of an initial submission or (b) after initial approval, when accompanied with a modification submission.

o   Review of the associated main study cannot be completed unless required elements of the pSite Institution are added to the Institutional Profile. Note that the system will show an error message when attempting to complete the Send Letter activity.

pSite Review Activities: (relevant for Initial, Modification, or Continuing Review/Closure) IRB review is not a single state, but a collection of other states. In addition to requests for clarifications, IRB review includes the following required activity steps:

1.   **Submit Invitation Decision:** (required step) allows for the recording if it is acceptable to proceed with considering the request. If question 1 on this activity is marked:

     o   Yes: it transitions the submission to awaiting site materials. Able to be edited on all submission types where it is.

     o   No: it transitions the submission to inactive. The study team can complete the Record Response activity for additional consideration of Harvard Review of the site.

2.   **Confirm Site Materials Received:** (required step) to mark that all relevant site-specific materials have been received for review.

3.   **Correspond with Site:** (optional step) without the option for clarifications requested, this is a method to request information/changes or to communicate with individuals associated with the site (including the site IRB contact), and:

     o   Send a notice to any person associated with the study or site, including the other IRB office contact.

     o   Include the text in the activity within the email sent to the recipient(s), and

     o   While not preferred, if a person chooses to reply to this notice: you will receive replies to this notice in your email inbox, rather than posted on the submission workspace.

4.   **Assign Designated Reviewer OR Assign to Committee Review:** (required step) available after pre-review is first submitted and allows for routing to the appropriate type of review.

5.   **Determination Entry Activities:** Can only be completed after approval of the associated study. Attach relevant confirmation of reliance (such as an executed IAA) to the appropriate space in this activity. However, if the study team requires access to the confirmation of reliance, it may be attached to the Local Site Documents page of the SmartForm via a Site Modification, after approval.

     •   Submit Designated Review: (required step) transitions the submission to post review, Editable through post review and determination. If edited, this activity will update the effective date. If clarifications are requested during this type of review, the SmartForm may be edited as part of the response submitted by the study team. When Harvard reviews for the site, any Harvard-relevant determinations (including data security level) are recorded on the main study.

     •   Submit Committee Review: (required step) transitions the submission to post review. Editable through post-review and determination. If edited, this activity will update the

effective date. If clarifications are requested during this type of review, the SmartForm will be locked from edits. The submitted response must be within the Submit Response activity completed by the study team. When Harvard reviews for the site, any Harvard-relevant determinations (including data security level) are recorded on the main study.

6. **Post-Review:** The Post-Review state gives the IRB staff the opportunity to complete the following activities:

    1. Finalize Documents: (required step) Mark selected documents attached to a submission as approved to create final copies. Finalize all documents at initial review and finalize only updated documents on modifications. Documents can also be finalized on a Continuing Review, as needed per office-specific policy. Ordinarily, while the activity is available, we do not finalize unchanged documents at the time of Continuing Review. Never finalize document that is not included in the approval.
    Note: Non-document type attachments (such as compressed/zip, video, audio, or htm files) will not finalize unless they are attached as a Supporting Document and categorized as attachment type "other".

    2. Prepare Letter: (required step) To inform the study team about the IRB's decision for the site. IRB staff may refer to the local reference regarding specific edits associated with each system-generated template letter.
    Note: The Prepare Letter activity and the letter draft will not appear on the workspace until the send letter activity is completed. To view draft versions of a determination letter before the letter is sent, complete the Prepare Letter activity again.

    3. Send Letter: (required step) Notifies the PI, PI Proxy, and Primary Contact that the determination letter is available. Sending the letter also transitions the submission to the state determined by the IRB, such as Modifications Required or Approved.

        If the IRB decided to require modifications to the study before a final determination is issued, the submission moves to the Modifications Required state to allow the study team to respond. In order to issue a final determination for the site, the Review of Required Modifications activity must be completed following response from the study team.

Modifying and Closing Sites

If the site needs to be revised while the study is active, study staff may propose a modification to the site via a site modification. A site modification only affects the site from which it is proposed. Review of a modification proceeds along the above-described site review steps. Once the site modification is approved, all approved elements will update the main site workspace.

If the site must be closed or made inactive during the larger project, the study team may provide an update about study in ESTR in one of two ways:

1. Complete the Report Continuing Review Data activity (only the PI can complete this activity) in the site workspace to provide an update and request closure in the comment activity, OR

2. Complete the Add Comment activity to communicate an update in site status with IRB staff.

Following receipt of a continuing review or update information for the site, IRB staff may take the following actions:

1. Administratively close the site via the Close Site activity. OR

2. Complete the Update Site Status activity to move the submission to the appropriate status.

   Note: Any status except "Terminated" may be chosen when awaiting additional information and the Site may be returned to active status by re-completing this activity. Choosing the Terminated status will end review of the site and render it no longer active. Once a site is terminated, it cannot be re-activated or re-added.

If the larger study needs to be closed, all related pSites must be closed as well before ESTR will allow for closure of the main study. Upon closure, a notification will be sent to the pSite contacts as listed on the Institutional Profile.

Ancillary Review Management

Ancillary reviews allow individuals, departments, offices, and other additional reviewers to give feedback, approval, and/or provide documentation on the submission in parallel with the IRB review. During IRB review, staff of the IRB office will manually select the reviewer or reviewing organization/department each time a review is needed or required. IRB staff can add ancillary reviewers to a study, modification, or continuing review. See the Ancillary Review Guide for an Ancillary Review Overview and Ancillary Review Types.

To initiate an ancillary review, IRB staff must manually select the reviewer or reviewing organization/department from the Manage Ancillary Review activity each time a review is needed or required. IRB staff can add ancillary reviewers to a study, study modification, or continuing review as follows. Complete the Manage Ancillary Reviews activity, and:

1. Add ancillary reviewers after the application has been submitted for IRB review.

2. Add individuals or organizations/departments as reviewers (Organizations will be available in the system from a pre-defined list. If the organization is missing, indicate an individual named reviewer in the "Person" space and contact the ESTR Help Desk to request adding the organization/department).

3. Indicate if the review is required or suggested. When making this selection, note that:

   A required ancillary reviewer receives the submission in the Dashboard, where it remains until the reviewer accepts the submission while an optional reviewer does not see the submission in the Dashboard.

   Both required and optional reviewers

   - Receive a system notification when they have been sent a request for ancillary review. Reviewers can use the Submit Ancillary Review activity to provide feedback.

   - Will only see a submission in the Dashboard (as applicable) after the submission has been sent to the IRB office for review.

4. Write in the comment space on the assignment pop-up to share a public message with the assigned ancillary reviewer. There is no character limit on the note and the comment will appear on the Reviews tab, for reference with the ancillary review assignment details.

Once the review is assigned, the original pop up will display the added review type.

4. To withhold a notice from the system (to the reviewer) because documentation may already be received or is otherwise in progress, IRB staff may either:

    - Assign yourself in Question 1 when adding the ancillary review. Remember to select the correct type of review and complete the steps to also "accept" the review.
    - Immediately after step 3, without closing the Manage Ancillary Reviews pop up (and all in the same set of actions):
      1. Click "Update" beside the newly added review type
      2. On the pop up:
          Question 4 Mark "Yes" (*This is OK – this is standard wording but based on the History and the attachment it is known that you are completing this on behalf of the reviewer.*)

          Question 5 Fill in a note, if one is available.

          Question 6 Attach an electronic version of the emailed approval/confirmation documentation.

      3. Click OK, the additional pop up will close.
      4. See the update to the item displayed on the table in the pop up.
      5. Click OK.

    Important! When completing these steps, note that **your entries on this activity are** recorded on the History and Reviews tab and are **visible to everyone** who can access the submission (PI, study team, IRB staff, etc.).

Add ancillary reviewers at any time. Ancillary review can be submitted by the assigned ancillary review when a submission is in review and after the review has been completed. While Ancillary Review may be submitted by the assigned reviewer in any state, if documentation of a non-required Ancillary Review happens to be received via comment or email after a final determination is issued, on approved submissions, IRB staff may include it via the Manage Ancillary Reviews activity which is available in all states, except Pre-Submission.

Modification, Continuing Review and Study Closure Process Overview

The basic process for either a modification or continuing review is shown in the following diagram. The exploded view shows what occurs during the IRB review process.
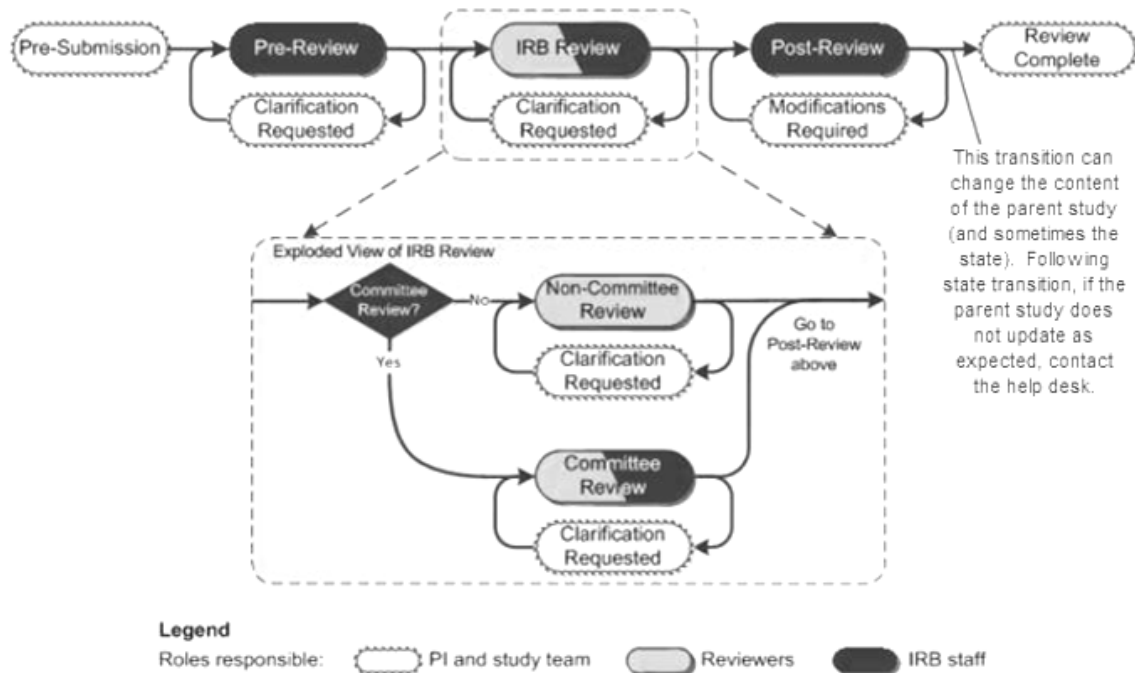
The legend indicates who can take major actions during each state within the process. Keep in mind that the diagram does not show all possible paths that a submission may take. The diagram shows the most likely path through the review process with common options identified.

Modifications and continuing reviews include optional ancillary reviews that can be conducted concurrently with the IRB's reviews. For more ancillary review information, see Ancillary Review Overview in the Ancillary Review Guide.

Modifications and continuing reviews must be created, submitted and reviewed as separate submissions, even if they are created and processed at near the same time.

A study closure can only be requested via the continuing review form. When prompted for the submission type, the study team must select continuing review to proceed and provide the needed information for the IRB to consider study closure.

Modifications

When a study is approved, the system copies the approved study to create a draft study. When a modification is created, the draft study is updated with the proposed changes, while the approved study remains unchanged. When the modification is approved, the changes are published into the approved study.

A modification can apply to the study team membership, to the other parts of the study, or to both. The system allows only one modification at a time to each part of the study. For example, you cannot open a

modification of study team membership if the study already has an open modification applying to study team membership or to the entire study.

Note: When reviewing a modification that may change the status of a study from Not Human Subjects Research or Human Research, Not Engaged to an Approval (by full committee, on an Expedited basis, or by way of an Exemption determination), consider copying the study to review the changes on a new record. Changing review type from Not Human Subjects Research or Human Research, Not Engaged to Approved can sometimes disrupt anticipated activities/views on the main study workspace.

Pre-Review for Modifications and Continuing Reviews

Pre-review information populates with the last form entries for all items except the Harvard tracking items (data security level and reporting elements) and is able to be edited with each submission type. Entries to pre-review activity fields on a modification or continuing review will update the study's pre-review information once the modification or continuing review is approved.

Since the pre-review entries may be altered with these types of submissions, in post-review, IRB staff are provided with different determination letter templates depending on the type of review and type of submission.

Tip
- If creating a continuing review or modification on behalf of the study team, the IRB staff member can create the submission but will be unable to make edits at first. Save the initial page, exit and assign the IRB Coordinator. Only the assigned IRB Coordinator can make edits to a submission on behalf of the study team.
- Making changes to the study team members page on behalf of the study team can sometimes result in display errors. If you encounter an error (such as "you do not have permission to view this page") and you are assigned as IRB coordinator on the modification, contact estrhelp@harvard.edu for assistance with the changes.

Study Closure through Continuing Review

When a continuing review form indicates that the top four research milestones listed on the form have been met (study is permanently closed to enrollment/never open for enrollment, all subjects have completed all study-related interventions, collection of private identifiable information is complete, and analysis of private identifiable information is complete), the parent study is closed automatically when the Continuing Review submission is approved. The top milestones indicate that all enrollment, interventions, and handling of subjects' private identifiable information is complete.

During review of the Continuing Review, if other elements of the submission indicate that the study team would like to keep the submission open for IRB review when it otherwise qualifies for closure (AND the first four research milestones are marked), IRB staff may request clarifications or (depending on the state of the submission) determine "modifications required to secure approval" on the Submit Designated Review activity to allow for a milestone to be de-selected. This will allow for regular continuing review to proceed. For any changes such as this, it is recommended that the special continued review request be explained in the progress report attached to the continuing review SmartForm.

To close a study during the regular continuing review process:
- Check to ensure that there are no other follow-on submissions in mid-review (such as a Modification, Site, or RNI in mid-review). If any are in review, complete the Discard activity on

those submissions. If these are not discarded, the system will automatically discard them upon closure.

- Complete the Designated Review form indicating that the submission is Approved Expedited under category "Other". Additionally, on the Designated Review Form, indicate the approval, effective as the same day of determination and let the last day of approval auto-populate.

In the Post-Review state for a study being closed, the study closure letter template is presented instead of the approval template. Upon completion of the Send Letter activity, an e-mail notification is sent to inform the PI that review of the submission is complete.

Administrative Closure Process

Based on IRB policies and procedures, a study may be administratively closed by IRB staff.

To administratively close a study:

1. Navigate to the study, see [Accessing a Submission](#).

2. In the main study workspace select "Close Study (Admin)" from the 'Next Steps' section on the left side of the screen.

   Ⓞ Close Study (Admin)

   Note that this option will not appear on a main study that is still in review or which received a "Human Research, Not Engaged" or "Not Human Subjects Research" determination.

3. A pop up will appear that asks if you want to permanently close the study. Additionally, the pop up will provide a list of modification and continuing review submissions that are pending on the study. This will prompt you to review any pending items before you administratively close the study. If you close the study, any open Modifications and Continuing Reviews will automatically be discarded. RNI submissions or Sites will not be discarded automatically.

4. If you wish to proceed with an administrative closure, add any comments you like to the Comment box and then click "OK."

   The study will transition to a Closed state and an automatic notification is sent to the PI, PI Proxy and Primary Contact.

Closing a study with related pSites

If a researcher has requested closure for a multi-site study, all pSites must be closed before ESTR will allow for closure of the main study.

See the section of this guide on [Modifying and Closing pSites](#) for additional information.

RNI Process Overview

The basic process for reportable new information (RNI) is shown in the following diagram. The exploded view shows what occurs during the IRB review process.
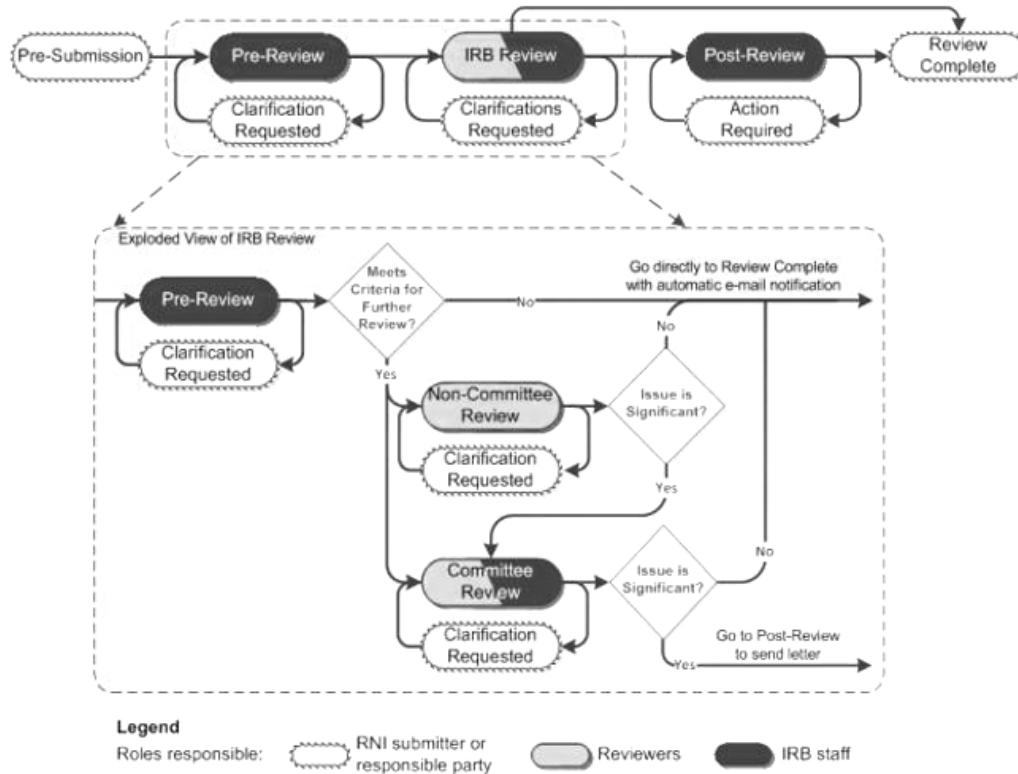
The legend indicates who can take major actions during each state within the process. Keep in mind that the diagram does not show all possible paths that a submission may take. The diagram shows the most likely path through the review process with common options identified.

Unlike all other submission types, an RNI submission:

- Does not include ancillary review.
- Can be reviewed and acknowledged by an IRB coordinator if not deemed to be serious.
- Transitions from completion of designated review to committee review if deemed to be serious.
- Can be assigned to a responsible party for follow-up action.
- Is visible to IRB staff at all times, independent of which IRB is assigned to review.

Any person with access to ESTR can create and submit new information. However, when linking a study to the RNI, they can only associate submissions to which they have access.

Tip: If the RNI is not assigned to the correct IRB, complete the Assign IRB activity to change IRB.

RNI Review Workflow

The RNI workflow uses similar states to a study, but the IRB review process routes the submission differently depending on the significance of the determinations selected. This reduces the IRB's time spent handling insignificant issues. The rules are:

- When an RNI submission is **not** considered a serious* issue, the submission transitions directly to the Acknowledged state and sends an e-mail notification indicating that the review is complete.

- Any RNI submission that represents a serious* issue must eventually go through committee review to determine any follow-up actions. After committee review, serious* submissions go to the Post-Review state so the coordinator can prepare and send a letter.

* Serious: For an RNI submission to be considered a serious issue, the determinations selected must include an unanticipated problem involving risks, serious or continuing non-compliance, or suspension or termination of IRB approval. If none of these are selected, the workflow routing handles the RNI as less significant.

Activities to complete review occur in the following general order:

1. **RNI Pre-Review:** The review process starts with a pre-review that enables the coordinator to make the final determinations regarding any RNI submission that is not considered serious.

   If the RNI submission is **not** considered a serious issue and is **not** marked as "Additional review required," the submission transitions directly to Acknowledged and a notice is sent to the PI, RNI Reporter and Primary Contact.

   Otherwise, the coordinator can assign the submission to a designated reviewer or to committee review.

   Important! For RNI submissions related to VA studies, a designated reviewer or committee must always review the submission. The coordinator should select the determination "Additional review required" and then assign the submission for further review.

   If the related studies are added to the RNI, the forms for Submit RNI Pre-Review and Submit RNI Designated Review display text to alert the reviewer that the submission is associated with a VA study.

2. **If further review is needed:**

   - **RNI Designated Review:** The RNI designated reviewer starts from the determinations selected in pre-review and can modify them as needed.

     If the RNI submission is **not** considered a serious issue, the submission transitions directly to Acknowledged and a notice is sent to the PI, RNI Reporter and Primary Contact. Otherwise, the submission transitions to Committee Review so it can be assigned to a meeting.

     OR

   - **RNI Committee Review:** The committee review starts from the determinations selected in the previous review and can modify them as needed.

     If clarifications are requested in Committee Review, only an IRB staff member with the "IRBD" role can Submit Response back for review to proceed

     If the RNI submission is **not** considered a serious issue, the submission transitions directly to Acknowledged and a notice is sent to the PI, RNI Reporter and Primary Contact. Otherwise, the submission transitions to Post-Review so a letter can be prepared and sent. The committee can also require follow-up actions to resolve the issue, as described below.

     Note: When assigning an RNI to Committee Review, complete the Track Harvard Determinations activity on the workspace (even if all items are blank or N/A). This helps to generate the

meeting agenda.

3. **Prepare Letter and Send Letter:** If action is required (see below) or a determination letter must be issued. When the Send Letter activity is completed, a notice is sent to the PI, RNI Reporter and Primary Contact.

Action Required Workflow

For issues considered serious based on the selected determinations, the committee can indicate that follow-up action is required to resolve the reported issue, specify an action plan, and assign a responsible party for carrying out the plan. In Post-Review, the generated letter includes the action plan and is sent to the responsible party in addition to the other involved individuals.

If action is required, the submission transitions from Post-Review to Action Required when the letter is sent. Only the assigned responsible party can respond using the Submit Action Response activity when the action has been completed. Then the completed action can be reviewed and verified in the Action Submitted state by the coordinator, director, committee administrator, or committee chair. Alternatively, the submission can be assigned to a designated reviewer or to committee review to verify the completed action.

If the assigned responsible party is unable to complete the Submit Action Response activity, IRB staff can reassign the responsible party by completing the Assign Responsible Party activity.

To assist reviewers, the Action Plan tab displays the latest action plan and all activity history that may have specified or changed the action plan, reviewed the completed actions, or changed the responsible party.

Tip: If you assign a submission to committee to review the required actions, follow these steps to capture the correct information to be shown in the meeting minutes:

1. Make sure you use Assign to Meeting to get the submission on a meeting agenda.

2. Use the Review Required Actions activity to verify completion of the action. Whether actions were completed or more action is required, do not make changes to the existing action plan or other action-related questions, only add information to what is currently noted.

3. If the actions were completed as required, from the Post-Review state, use Submit RNI Committee Review as follows:

   a) If the action was completed correctly, leave "Is further action required" set to Yes. Don't make changes to the action plan or other action-related questions.

   b) Add text to the additional information and notes to say that the action was verified as completed.

   c) Record the votes and other details from the meeting that should display in the meeting minutes.

   d) Review the generated minutes document and update it if necessary to ensure that all the appropriate information for this review is included.

   The Committee Review will retain the final decision, visible on the "Reviews" tab of the workspace. View activity details to see each recorded action at the meeting and after.

Related Studies and Modifications

An RNI submission can be associated with one or more studies where review was already completed, or with no study at all. For example, a research coordinator might allege that an investigator is conducting research that was never submitted to the IRB for review. It would not make sense to associate this RNI submission with a study within the system. An RNI submission cannot be associated with a study that is currently in review. Additional considerations when relating studies and modifications:

- An RNI submission can also be associated with a modification to a study, such as a modification that is created in response to the reported information. When adding a related modification, the study that is being modified must be added first.

- There are a few methods for associating an RNI submission with related submissions:

  - When the RNI is created from a study's workspace, that study is added to the RNI's list of related submissions.

  - When creating the RNI, one of the questions enables the submitter to add related studies and modifications.

  - After creation of the RNI, the Add Related Submissions activity can be used activity to add related studies and modifications. The activity is available to the submitter, coordinator, director, committee chair or administrator, responsible party, and the PI or PI proxy of any study that is already related.

- The PIs, PI proxies, primary contacts, and study team members of all related studies are given read access to the RNI submission. All of these parties except the study team members receive the same e-mail notifications as the RNI submitter throughout the workflow.

For additional tips, see the Help for the specific question or form where you are adding the related submission.

External IRB Process Overview

See the separate Reliance Coordinator Mini-Guide for information about review of studies (and sites) where Harvard IRB cedes authority over a study to an external IRB of record.

Document Change Process Overview

As a result of IRB reviews or changes to research, the study team may need to make changes to a study's documents.

Use of Word "Track Changes" functionality is recommended so that changes may be easily identified for reviewers. When the documents are finalized, IRB system software will automatically accept the changes and remove any comments in the final versions. Refer to local IRB guidance regarding any requirements associated with including and reviewing documents with "Track Changes" enabled. The following are suggested practices based on system capabilities.

Process	Suggested steps for using tracked changes
Study staff updates the original study documents.	Retrieve the Word version of documents from draft column of the Documents tab for the study. Edit the original documents with change tracking enabled and then within the appropriate SmartForm page, click "update" beside the originals and upload the revision with the tracked-changes. IRB staff assigned as coordinator are ordinarily able to assist with these steps, as applicable. However, IRB staff cannot update documents on Modifications.
IRB reviewers review the study.	Use the review features in Word to toggle between showing the original and final versions of the document. No changes are made to the documents; documents remain in tracked-changes format.
IRB coordinator or director approves the documents using the Finalize Documents activity.	Finalizing the documents accepts the tracked changes and removes any comments to create a final version of the document. The draft version will still have the tracked changes. The draft and final documents appear on the Documents tab for the study. Study team member documents that are attached to the Study Team Members page of the SmartForm and appear on the Project Contacts tab of the submission workspace are not in the set of documents to finalize (nor do they appear on the Documents tab of the submission workspace). However, they will be listed with reviewed documents on the determination letter, as appropriate.

Note: Use of drag and drop to upload revisions of existing documents ordinarily records an update to the system version number and may not trigger an entry in the view differences version of the SmartForm. If you expect that a document was changed and it does not display in view differences mode, use the document history view link to confirm if a document change has been recorded in the system.

Basic Administration Tasks

IRB staff members play a key role in preparing for reviews, moving a submission through the stages of review, and communicating the results to the study team. Here are a few keys to the process:

Assigning each submission to an IRB coordinator is a crucial step to allowing further actions to be taken on the submission. Any IRB staff member can assign a coordinator, as described in Assigning Ownership of a Study.

Your inbox provides a helpful list of items that need your attention. For details, see the IRB Reviewer Guide section on Locating Your To-Do List and (this) IRB Staff Guide section on Understanding the Dashboard.

One of the more complex IRB processes is running a committee meeting. For a checklist to help you through the process, see Committee Meeting Management.

During all states of review, IRB staff can post a private comment in the submission workspace.

💬 Add Private Comment

This helps to note any issues that arise during the review which must remain on the permanent record for the submission or study. As part of posting a private comment, you will have the option to select recipients. When completing the private comment activity, note:

- Sending a notice by selecting recipients is not required to save the comment to the workspace.
- Private comments are only visible to IRB staff and committee members.
- Based on the current set up for the Harvard IRBs, if "IRB Director" is selected, all members of the IRB office will receive a notice.
- Do not use the private comment activity to add or attach items that should be reviewed as part of the submission SmartForm.
- If you are the assigned IRB Coordinator, you will not have access to the Add Private Comment activity when a submission is in editable states (such as Clarifications Requested).

Access to Studies by Role

Access to a study is personalized based on role in the system and the role one plays in relation to the particular study. The following table summarizes the policies controlling the visibility of submissions (both studies and follow-on submissions):

User role	Information visibility
Study staff	Access to submissions that include you on the study team, as the primary contact, or on the guest list. You cannot view the assigned reviewers or committee members, or gain access to the reviewers' comments. You can view the date and time of any meeting to which the submission is assigned. Current members of the study team manage this access by completing the Assign Primary Contact or Manage Guest list activities or by adding/removing names from the Study Team Members page of the SmartForm.
IRB staff, IRB committee members	Access to all submissions. For studies that include you on the study team, you cannot gain access to the IRB reviewers' comments, private comments or certain review activities. IRB staff and the site manager manage this access. Following official request sent to the estrhelp@harvard.edu, the site manager adds a system role to the individual person profile, then IRB staff complete

User role	Information visibility
	activities on the Committee workspace to change Committee membership.
Ancillary reviewers, other reviewers who are not IRB committee members	Full access to submissions assigned to you for review, except site workspaces. Site additions can be viewed on the main study workspace. IRB staff and the site manager manage this access. Either IRB staff identify the reviewer by name when assigning ancillary review; granting access OR following official request sent to the estrhelp@harvard.edu, the site manager adds reviewers to the appropriate department.
Administrative office viewers, those with read-only access to all submissions reviewed by the IRB or which are associated with a particular department	Read only access to all submissions associated with the IRB or department. IRB staff and the site manager manage this access. Following official request sent to the estrhelp@harvard.edu, the site manager adds viewers to the appropriate department within the organization profile or Administrative office via settings.
Site manager	Full access to all submissions. Current site manager manages this access on the person profile.

IRB Review Activity Visibility Summary

The following table summarizes the visibility of review activity details on the submission workspace history or review tabs.

Visibility *(including user-entered notes)*	User Roles
Add Comment	IRB Staff, Committee Members, Everyone else with Submission Access
Add Private Comment	IRB Staff, Committee Members
Correspond with Site/pSite (site)	IRB Staff, Committee Members, Everyone else with Submission Access
Assign Coordinator	IRB Staff, Committee Members, Everyone else with Submission Access
Submit or Edit Pre-Review	IRB Staff, Committee Members
Invitation Decision Submitted (site)	IRB Staff, Committee Members, Everyone else with Submission Access
Request Clarifications (Non-Committee or Committee Review)	IRB Staff, Committee Members, Everyone else with Submission Access
Harvard Determinations (tracked in pre-review or edit p-rereview)	IRB Staff, Committee Members, Everyone else with Submission Access
Manage / Submit Ancillary Review	IRB Staff, Committee Members, Everyone else with Submission Access

Manage Ancillary Review	IRB Staff, Committee Members, Everyone else with Submission Access
Add Review Comments	IRB Staff, Committee Members
Site Materials Received	IRB Staff, Committee Members, Everyone else with Submission Access
Submit Non-Committee or Committee Review (study or site)	IRB Staff, Committee Members
Finalize Documents	IRB Staff, Committee Members, Everyone else with Submission Access
Prepare Letter	IRB Staff, Committee Members
Send Letter	IRB Staff, Committee Members, Everyone else with Submission Access
Create Printable Attachments	IRB Staff, Committee Members
Review of Required Modifications	IRB Staff, Committee Members, Everyone else with Submission Access
Update Expiration Date	IRB Staff, Committee Members, Everyone else with Submission Access
Close Study (Admin)/Close Site	IRB Staff, Committee Members, Everyone else with Submission Access
Related Projects	IRB Staff, Committee Members, Everyone else with Submission Access

Dashboard Overview

The Dashboard is composed of two tabs: My Inbox and My Reviews. **My Inbox** contains all studies or other submissions that require you (or your team members) to take action. See the examples below to understand what you should and should not expect to appear in My Inbox. **My Reviews** contains only studies for which you are an Ancillary or Designated IRB Reviewer.

Tip: Look at the State column in My Inbox and see the explanation for that state in the table below.

Your role	In My Inbox		Not in My Inbox
	State	Explanation	
Research team			
Study team member or study's primary contact **Note:** Any team member can make changes to the study, and submit changes. Only the PI can initially submit. The PI may assign a proxy to submit follow on submissions after initial approval.	Pre-Submission	Complete the study forms. The PI must submit it to the IRB to let the review begin.	Studies the IRB is reviewing
	Clarification Requested	Change the study to clarify as needed, and provide summary notes to the IRB when submitting the changes. **Note:** If the clarification was requested from Committee Review, you can only provide notes. You are not allowed to change the study.	Approved studies
	Modifications Required	Modify the study to meet IRB requirements and submit it with changes.	Closed studies

Your role	In My Inbox		Not in My Inbox
	State	**Explanation**	
Reviewers and committee members			
IRB committee member or occasional reviewer	Non-Committee Review	You have been designated as the reviewer for this not human subjects research, exempt or expedited study. You must submit your final review before the IRB decision can be communicated to the study team. If you request clarifications, the study comes back to you to finish the review after the clarifications are made.	Studies assigned to other reviewers
	Committee Review	You may be part of the committee that will review this study. If so, review the study details in advance. You can request clarifications. Record your notes and recommendations in the system before the meeting as described in the online help.	Studies assigned to other committees
Ancillary reviewer	One of several	You have been selected as a reviewer (either by name or representing a specific organization). The IRB can begin its review before you submit your review. The IRB may or may not wait for your input before completing its review of the study.	Studies not yet submitted for review
IRB administrative staff			
Assigned IRB coordinator (IRBC)	Pre-Review	Newly submitted studies appear in the Unassigned tab of the Submissions page. Once assigned to an IRB coordinator, items will appear in that person's Inbox. The assigned coordinator must submit a pre-review and assign the study to designated review or a committee.	Studies not yet sent to a mode of review
	Post-Review	The IRB decision has been made. You must prepare correspondence and send it to notify the investigator of the decision. You can also finalize study documents to create a permanent record.	Studies being reviewed by individual reviewers
	Committee Review	You can assign the study to a particular meeting, remove it from a meeting agenda and reassign it to another, and assign specific reviewers. The IRB director, IRB chair, or you must submit the committee's review decision.	Studies assigned to other IRBCs
	Site-Review States (Invitation Pending, Awaiting Site Materials, Pending sIRB Review)	Participating Sites associated with studies where Harvard is the IRB of record will be automatically assigned to the IRB coordinator assigned on the main study. Sites associated with the request is for Harvard to rely on another IRB, will appear in the Unassigned tab of the Submissions page. Once assigned to an IRB coordinator, items will appear in that person's Inbox.	Sites assigned to other IRBCs, where reliance is confirmed, or the site is inactive.
Committee chair	Committee Review	The study has been assigned to your meeting. The IRB director, IRB coordinator, or you must submit the committee's review decision.	Studies assigned to other committees

Assigning Ownership of a Submission

Before an IRB reviewer can take action on a study, the study must be assigned to them. Any IRB staff user with coordinator permissions or higher can take ownership of the study or assign it to another IRB staff member. The study can be reassigned at any point, as needed.

When a study is first submitted to the IRB, it will appear on the Unassigned tab on the Submissions page and in all IRB staff Inboxes (see Accessing a Submission for information about navigating the Submissions page). After a coordinator is assigned, only this assigned reviewer sees the study in My Inbox and on the Submissions page, on the My Work List tab. The submission will move to and from the coordinator in box and work list tabs as the IRB needs to take action in the review process. Note that the Unassigned and My Work List tabs are only visible to IRB staff.

To assign a coordinator:

1. From the Unassigned list (on the Submissions page)

    a. Click the **My Actions** link on right side of the listing

    b. Choose the **Assign Coordinator** option

    c. Select yourself or another IRB staff member

    d. Click **OK**

    - OR -

2. From the Submission workspace

    a. Open the study

    b. Click **Assign Coordinator** on the left

    c. Select yourself or another IRB staff member

    d. Click **OK**.

The reviewer gains access to activities that are reserved for the assigned reviewer and can move the study through the IRB review process.

Tip: If creating a continuing review or modification on behalf of the study team, the IRB staff member can create the submission but will be unable to make edits at first. Save the initial page, exit and assign the IRB Coordinator. Only the assigned IRB Coordinator can make edits to a submission on behalf of the study team.

Submission Navigation

Once you open a submission, you see the webpage for this submission; also referred to as a "workspace". The workspace is your access point for:

- Viewing the submission contents and details, including all actions performed on it
- Performing actions on the submission

The figure below identifies the key workspace elements that help you find your way around the IRB system and perform actions on the submission.

Workspace Regions
Image displays the Initial/Main study workspace for reference.

Region	Information in this region
1	**Status** Visible in all workspaces, the status region will show: • The status of the submission once it is created and through the review process, • Information about when a submission was sent to the IRB and updated, and • Initial/Main study workspaces also display the initial and approval end (expiration) dates for reference, as applicable.
2	**Next Steps** Visible in all workspaces, this set of blue buttons allows for: • Editing or viewing the current submission SmartForm, • Displaying a printer version, • Viewing changes over time, and • On Initial/Main study workspaces only: Creating new Continuing Review, Modification, or Reportable New Information submissions for the study.
3	**Activities** Visible on all workspaces, activity buttons display depending on the type of submission, the status of the submission, and your role on the study. Mostly, activities displayed take action on the submission only. However, Assign PI Proxy, Assign Primary Contact, Manage Related Projects, and Manage Guest List are only visible on the Initial/Main study workspace.
4	**Submission Overview** This section displays the following submission-specific items for reference: • Number and name of the submission/workspace being viewed • PI, submission type, primary contact, PI Proxy/ies (if assigned), and IRB office and coordinator (if one is assigned)

		• IRB determination letter (labeled "Letter"), if a determination has been made • Regulatory Oversight to indicate if a submission is/was subject to review under pre-2018 Common Rule or 2018 Common Rule • Image of the state of review for the submission. Note that when viewing an Initial/Main study workspace the image may indicate "review complete" while an associated submission (such as a Continuing Review or Modification" is under review).
5		**Notification Area** When the record has not yet been submitted for review, a reminder to complete the submit activity displays in this space.
6		**Submission Tabs** On a submission, the Initial/Main study workspace shows all current approved details (including documents and study team members) while all follow on submission workspaces display information that was proposed at the time of review and determination. Click on tabs to view: • <u>History</u> Information about each action taken on a submission and in-brief view of comments. • <u>Funding</u> List of all funding listed on the SmartForm, with a link to GMAS, if applicable. • <u>Contacts</u> List of study team members listed on the SmartForm. The tab also includes their current Human Subjects Training information on file and their training expiry date. If no training is listed, they do not have current active training. Each team member is listed with a Date Modified, intended to show when any additions or revisions occur during review or modification. • <u>Documents</u> Draft and finalized documents submitted for review, with versioning information for each document • <u>Sites</u> Links to associated Site workspaces for a study (only visible on the *main study workspace* of collaborative projects where Harvard is the IRB of record for at least one site) • <u>Follow-on Submissions</u> Links to Continuing Review, Modification/update, or Reportable New Information workspaces for a study (only visible on the *main study workspace*) with quick access to all determination letters • <u>Reviews</u> View additional details about the review, including ancillary review details, data security level determinations, and completed checklists. • <u>Snapshots</u> View of the application at each change in state (for example, the appearance of the SmartForm between pre-review and changes submitted) • <u>Related Projects</u> Information about Agreements, Data Safety, and other IRB submissions which have been associated with the study via the Manage Related Projects activity (only visible on the main study workspace) including the current state of the related submission and a link to the related project workspace.

Once a determination is made on an initial submission, two things change about the initial submission workspace, also referred to as the "main study workspace":

• The main study workspace is the webpage where all current information about the study is located, including the most current approved study documents and the current expiration date, as applicable.

• Additional submissions that follow initial determination may be created from the main study workspace. These modifications/updates, continuing reviews, sites or reportable new information are referred to in the system as "follow-on submissions". Follow-on submissions which are associated with a study can also be accessed from the initial submission/main study workspace.

Viewing Submission Details

Depending on your role or the actions required, you may need to view detailed information provided as part of the submission.

To view the details of a submission:

1. From the Dashboard, click the name of the submission to open it.

    Note: If the submission does not appear, see the IRB Reviewer Guide on [Accessing a Submission](#).

    For an initial submission, click **View Study**

    For a continuing review or modification, click **View Submission**

    For a site review, click **View Site**

    For a new information report, click **View RNI**

2. Use the Continue and Back buttons to view all of the pages and attachments.

    Clicking Continue from the Supporting Documents page (the last page of the form) exits the study.

For a quick view, complete the Create Printable Attachments activity to view a single document containing all attachments via links on the submission **History tab**. Use the Printer Version link on the left to view or print the submission SmartForm pages.
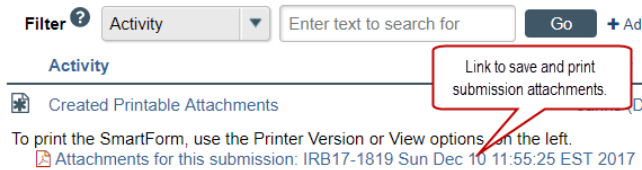
To view the documents included as part of the submission, you have these options:

While viewing the details of the study (as instructed above), click the name of each document when you encounter it on the various forms. Documents are listed in tables throughout the forms.

When you have opened the study workspace (as in step 1 above), you can view a list of all the attached documents in one place by clicking the Documents tab.
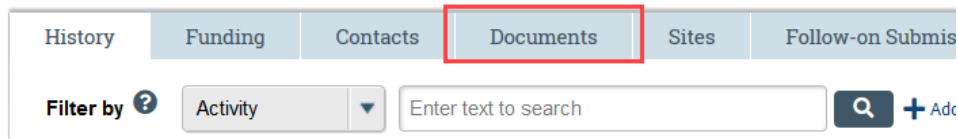
If the study team updated the documents, they may contain tracked changes. You can use the review features in Word to toggle between showing the original and final versions of the document. When the IRB approves the documents, all tracked changes will be accepted and comments removed in the final versions.

Note: On modifications, the documents tab will include a column to indicate if the document has been updated as part of the submission. This column is sorted with "yes" at the top.

To view the information entered for pre-review, non/committee review, ancillary or tracked Harvard determinations (including data security level):

1. Open the study as instructed in step 1 above.

2. Click the **Reviews** tab.

If the information entered on this tab is inaccurate, contact the study's IRB coordinator to request a change. The coordinator can change the pre-review, non/committee review, ancillary and Harvard determinations information until the determination letter is sent to the study team.

Person Profile Management

When reviewing a submission, some elements of a person profile may require update, such as Human Subjects Training or if the PI is or is not restricted.

Only IRB Staff have permissions to view and edit certain details. For instructions to view and edit a person profile to update Human Subjects Training or Restriction status, IRB staff can reference separate guidance or contact estrhelp@harvard.edu.

To edit contact information in ESTR, the individual requiring the change must follow instructions provided at: https://harvard.service-now.com/ithelp?id=kb_article&sys_id=840d9ad80f70fe802dfe5bd692050e42 to update information associated with their central profile.

Committee Meeting Management

The checklists below identify the major steps for preparing for, conducting, and completing a committee meeting. The checklists assume you have already created the committee and the meeting.

Steps are performed by a member of the IRB office per office standard procedures.

Preparing for Each Meeting

Well in advance of the meeting:

1. Assign studies (including Modifications, Continuing Reviews, and Reports of New Information) to the meeting (from the submission workspace).

2. Add any non-study related agenda items or documents, as needed by completing the Update Other Agenda Items or Update Documents activities in the meeting workspace. Note that items related to the review of a submission should be associated with that submission and not added via these activities. Note that while any added Other Agenda Items appear with the list of submissions, any documents added via the Update Documents activity will only appear on the Supporting Documents tab.

3. Assign reviewers to the submissions assigned to the meeting. Reviewers can be changed at any time by completing this activity. However, assign from the meeting workspace all in one activity, for notifications to be sent to assigned reviewers.

4. Prepare the agenda. To simplify member navigation, download the prepared and formatted agenda, convert it to pdf, and upload the pdf as a revision before completing step 5.

5. Send the agenda to committee members and any additional recipients.

Tip: If you change the official agenda for any reason, such as a) for internal purposes (for example, to create a notes document based on the agenda) or b) to revise items after you have sent it out: make sure you **verify and upload the final version of the meeting agenda to the meeting workspace** before the meeting and as needed use the Send Agenda action to inform members of the change.

Just before the meeting:

1. Edit the meeting attendance if you know who is planning to attend.

2. Remove any studies in the Clarification Requested (Committee Review) state from the agenda if the missing clarifications warrant delaying a committee decision. Reassign the submissions to a later meeting.

    Studies in the Clarification Requested (Committee Review) state that remain on the agenda will transition back to the Committee Review state when the meeting is convened.

Conducting the Meeting

We recommend dedicating one person to fill out the Submit Committee Review forms and record the non-submission information such as meeting start and end times.

During the meeting, it may be helpful to display study information and committee member review comments in the course of discussion. See tips for navigating to study information.

Meeting administration:

1. Record meeting times, attendance, and other non-submission items. **Note:** You may wish to record this information using the meeting minutes template. To do so, prepare the meeting minutes, save the generated document to your computer, and then use it to record the information. When you prepare the final minutes (as instructed below), copy and paste the items recorded during the meeting into the final version of the minutes.

2. If you have not already, send the agenda. With this activity, you can select recipients of the notification that the agenda and materials are ready for review prior to the meeting.

3. Convene the meeting. **Note:** Convene Meeting returns agenda items in the Clarification Requested (Committee Review) state to the Committee Review state, even if no response was sent from the study team. This allows for a determination to be recorded on all submissions associated with the agenda.

4. (Optional) Under "Previous meetings with minutes for approval," click a previous meeting to go to its workspace. Then you can display its minutes, approve them, and return to the current meeting.

5. Click the **Expedited Submissions Approved** link to display the report. **Note:** To keep a permanent record of the approved expedited submissions reviewed during the meeting, export the report to Excel and save it to your computer. Later, copy and paste the information from the report into the minutes.

Tips for navigating to submission information:

From the meeting workspace:

To show more information, click the name of a submission or item in the agenda items list.

From the submission workspace:

- To show study details in the forms, use Review/View Study (or View Submission/View RNI).
- To show attached documents, use the Documents tab.
- To show information recorded during pre-review and comments from individual committee members, use the Reviews tab.

Recording decisions, events, and notes:

1. From the individual reviewer checklists, reviewer comments, and committee discussion, fill out all relevant checklists to reflect the final committee opinion and reasoning. These files should be attached in the Submit Committee Review activity.

2. Perform **Submit Committee Review** (or **Submit RNI Committee Review** for an RNI) to record decisions and information for each submission reviewed. Attach the relevant checklists. **Note:** The IRB coordinator assigned to the study can also submit the committee review.

    If there is not enough time to completely fill out the committee review form during the meeting, finish it as soon as possible after the meeting. You can complete some of the form and select "No" to the question "Are you ready to submit this review?" The system will save what you have entered so you can update and submit it later.

    Important! Don't miss the Submit Committee Review or Submit RNI Committee Review step. Correspondence cannot be prepared and sent to the investigator for a study until this step has been completed.

Wrapping Up After the Meeting

1. If you haven't yet submitted the final committee review for each study, do this before proceeding to the next steps. **Note:** From the meeting workspace, look at the Record Decision column for the agenda items. The column will indicate Submit Committee Review or Submit RNI Committee Review if the action has not yet been completed.

2. Prepare the minutes. The minutes will contain the committee decisions for each study. If there is a problem when attempting to generate the minutes, check each submission assigned to the meeting to ensure that the Track Harvard Determinations activity was completed (even if no values were entered on the activity form).

3. Open and save the minutes on your computer. Add the meeting times, attendance, and any other non-submission items to the minutes. **Note:** If you used the minutes template to record information during the meeting, simply cut and paste the information from that document into the minutes.

4. Perform **Prepare Minutes** again to upload the revised minutes.

5. Follow your internal processes to obtain the appropriate approvals of the meeting minutes.

6. Inform the IRB coordinator(s) that they can send correspondence to the investigators. For each study, the assigned coordinators:

    a. Review pre-review selections, including Harvard determinations, and the status of ancillary approvals on the Reviews tab to make any necessary updates. Complete any needed updates.

    b. Finalize the study documents to create an approved copy, in certain cases adding a watermark.

    c. Prepare a letter which includes the IRB decisions.

    d. Send the letter.

7. Send the minutes to the committee members.

8. Close the meeting.

After the period for receiving comments from committee members has passed, perform **Approve Meeting Minutes**. Until you perform this action, the minutes are listed in the next meeting's workspace
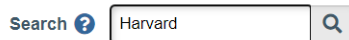
with the approve activity available there as well. If Minutes require further revision after approval, complete the Prepare Minutes activity in the appropriate meeting's workspace again to save the revision and then re-complete the Approve Minutes activity to complete the process.
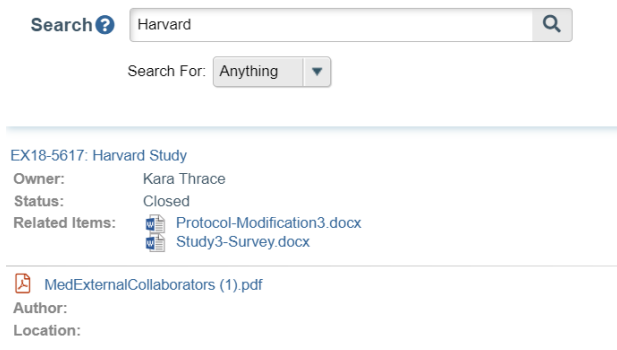
Using Site Search

Reviewers can see the option to conduct a keyword search of information on submission records and within record attachments.

To search:

1. Log in to irb.harvard.edu

2. Click **IRB** in the top navigator.

4. In the search bar (at the right, just above the tabbed area), type the keyword(s) then click the **magnifying glass** icon. A pop up will appear and results may take a moment to display.

Search ❓ [Harvard   ] [🔍]

5. In the pop up of results, identify the items of interest and click to those items, as needed.
    - Results may be records, records and attachments to the SmartForm, or records and attachments on activities. Attachments are listed as Related Items and do not represent all the attachments on that record.
    - If a result displays without an author or record, it means the document was removed from a record but still exists in the system database.

Search ❓ [Harvard   ] [🔍]

Search For: [Anything   ▼]

EX18-5617: Harvard Study
Owner: Kara Thrace
Status: Closed
Related Items: 📄 Protocol-Modification3.docx
                📄 Study3-Survey.docx

📄 MedExternalCollaborators (1).pdf
Author:
Location:

Generating Standard Reports

The IRB system includes many standard reports regarding studies and reportable new information (RNI) to help you find relevant submissions and understand the overall operation of the IRB. In addition, Harvard custom reports are available in via the Custom tab of the Reports page.

The reports provide links to the individual submissions, as well as sorting and filtering options.

Any user has access to reports, but the data in the reports is limited to the studies visible to the individual. For example, a Studies Involving Children report generated by a PI will include only the studies that person can see elsewhere in the system--studies for which the person is included on the

study team or guest list. IRB coordinators, directors, and committee members generally have access to all report data.

To generate a standard report:

3. Log in to irb.harvard.edu

4. Click **IRB** in the top navigator.

6. Click **Reports** in the IRB sub-menu.

   The list of standard reports appears. To find a custom report, click the **Harvard Custom Reports** tab.

7. Identify the report to generate and click the link. The report appears, listing the relevant submissions.

   Tips
   - Try filtering the list by status. Next to Filter by, select **Status**. Then type the state to view, such as **Approved** for a study report or **Acknowledged** for an RNI report and click **Go**.
   - If you or members of your office **require special access** to multiple studies or reports for a department or school, please contact your IRB office or estrhelp@harvard.edu for special access.

To generate a report listing you as the Principal Investigator (PI) and/or Study Team Member:

1. Log in to irb.harvard.edu

2. Click **IRB** in the top navigator.

3. Click **Reports** in the IRB sub-menu.
   The list of standard reports appears; click the **Harvard Custom Reports** tab.

4. Locate the **Study Team Member Report** on the list and click the hyperlink.

5. A report will appear listing all submissions where you are either listed as the PI or listed as an approved Study Team Member.

6. Report results can be exported to Excel from the results pop up window in one of two ways

   1. Click the **Actions** option to choose **Export to CSV.** The option will change to the words "please wait" until the export is prepared and (depending on your browser settings) it will save the file to your default folder or a pop up will appear for you to choose the location to save the file.
      OR
   2. Click the **gear icon** to choose **Export to CSV** at the bottom of the panel. The option will change to the words "please wait" until the export is prepared and (depending on your browser settings) it will save the file to your default folder or a pop up will appear for you to choose the location to save the file.

   Note: Exporting a file may take time. If the file is large, you will see a status value display or the message "Please wait…". It is important to wait for the process to run, rather than re-trying the export.

Producing the AAHRPP Annual Report

The IRB system can complete a large portion of the AAHRPP annual report for you, while letting you fill in the information that is not stored in the IRB system.

Note: Site manager permissions are required to perform the initial setup step. IRB director permissions are required to generate the report. To configure the form output or update the Annual Report Form, contact estrhelp@harvard.edu.

To update contact information to include in the report:

1. Log in to irb.harvard.edu with site manager permissions.
2. Update the IRB Settings area with appropriate organization and contact names to be included in the report.
3. Log off.

To generate the AAHRPP report:

1. Log in to irb.harvard.edu with IRB director permissions.
2. Click **IRB** in the top navigator.
3. Click **Reports** on the left.
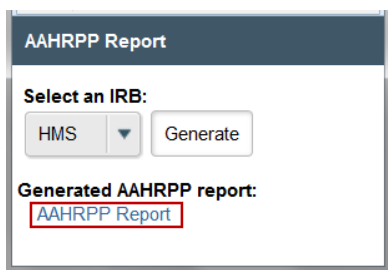4. Click **Generate AAHRPP Report** on the left.

Next Steps

Generate AAHRPP Report
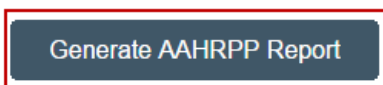
A new window opens.

5. Select the IRB office to include in the report.
6. Click **Generate**. Note: This process can take a few minutes.

   After a few minutes, a link to the generated report appears in the same window.

AAHRPP Report

Select an IRB:

HMS ▼ Generate

Generated AAHRPP report:
AAHRPP Report

7. Click the link and choose to save the report as a Microsoft® Word file.

Important! The report is not stored in the IRB system, so save the file in an appropriate location for later retrieval if you need to keep a permanent copy.

8. Click **Close** to dismiss the window.

To complete the generated report:

1. Open the saved file.

2. Review the answers that are filled in and adjust the answers as necessary if the IRB system does not contain complete data (or add the information to the IRB system and regenerate the report).

3. Answer the questions that are blank, saving the file often.

    To mark a check box in the document:

    a) Right-click the box and select **Properties**.

    b) Under Default value, select **Checked**.

4. Scroll through every page, being sure to answer each question.

5. Follow the checklist located at the end of the document, verifying the report contents and creating a PDF file to send to AAHRPP.

Finding More Information

Resource	Description	How to Access It
Help for a field or page	More information about a question or form.	Click the question mark icon ❓ next to the question or at the top of the form.
Help system	The full online help system, with search and table of contents. The online help contains procedures and information for all users.	Click the **Help Center** sub-menu link at the top of the screen.
IRB Study Submission Guide	Instructions for submitting a study for review.	Click the **Help Center** sub-menu link at the top of the screen. On the Guides tab, click the name of the guide to open it.
IRB Study Reviewer's Guide	Instructions for reviewing an IRB submission.	
IRB Staff Administration Guide	An overview of the IRB review and administration process.	
IRB Library	Document templates, checklists, and forms.	Click the **Library** sub-menu link at the top of the screen.
ESTR Support	External website with additional information about using ESTR	estrsupport.fss.harvard.edu
ESTR Help Desk	Contact for help with ESTR access and use	estrhelp@harvard.edu
IRB Websites	Information about the IRB review process and requirements	▪ HMS, HSDM, and HSPH (Studies in Longwood Area only) at hsph.harvard.edu/orarc/irb ▪ FAS, GSE, HKS, HBS, SEAS, HLS, GSD, HDS, and Radcliffe Institute (Studies in University Area only) at cuhs.harvard.edu

This guide was created and edited by Harvard University based on materials originally produced by Huron Technologies, Inc.