IRB Reliance Coordinator Mini-Guide

Electronic Submission Tracking and Reporting (ESTR)

December 8, 2023

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Reliance Coordinator Role Overview

A person with the Reliance Coordinator role in ESTR ordinarily coordinates some portions of the review process for projects where Harvard is the Single IRB (sIRB) or Participating Site (pSite).

Involvement in the IRB Review Process

Activities

The Reliance Coordinator is the only person who can complete the following reliance-based activities.

- Can "submit…" reliance-based decisions related to pSites or sIRBs.
- Can create contacts. Permissions will allow those with the IRBD/IRBC role to also complete this task.
  Important! However, currently, it is a Reliance Coordinator responsibility to manage the accurate creation of contacts. This permission will not be given to those with the study team role**.**
- Supports the upkeep of current information for a shared set of Institutional Profiles (IPs). IPs are centrally managed records containing information about the IRBs with which Harvard has a reliance (as a pSite OR sIRB). The base list of IPs in ESTR is built on the list of SmartIRB-participating institutions.

Notifications

The Reliance Coordinator receives notifications at the following steps in the review process:

- If selected as the recipient of a comment notice, and
- When a site is assigned to the Reliance Coordinator (as the IRB Coordinator on the workspace).
- When the Finalize Update activity is completed by a PI/PI Proxy

Note that a Reliance Coordinator will not receive a notice if a site-related RNI or a site modification is submitted. These items must be identified and assigned via the regular new submission assignment process.

Institutional Profile Review Process

At upgrade on December 15 2017, Reliance Coordinators plan to complete individual manual updates to IPs as needed in preparation for or during any per-site review. This includes two required elements: (1) adding at least one contact to any IP that is associated with a current review and (2) adding some information about IRB quality control mechanism in place at this institution.

In the few months following upgrade on December 15 2017, current Reliance Coordinators plan to define a periodic review process that includes:

- Expectations for accuracy of data on IPs (i.e. What is outdated data? Who is responsible for updating the data, and when?)
- Definition of the schedule for updating existing IP review outside of any per-site review based updates
- Identification regarding if individual additions are acceptable or if a "Bulk Update" of institutional profiles is needed
- Cross-team communication expectations

This guide will be updated following the process definition discussion.

Institutional Profile Management

Institutional Profiles (IPs) are set up to manage organizations with which Harvard may enter into a reliance agreement. These Profiles are:

- The source list for study team members to select a "Site",
- Shared between both IRB offices, and
- Should be considered a central resource for IP information.

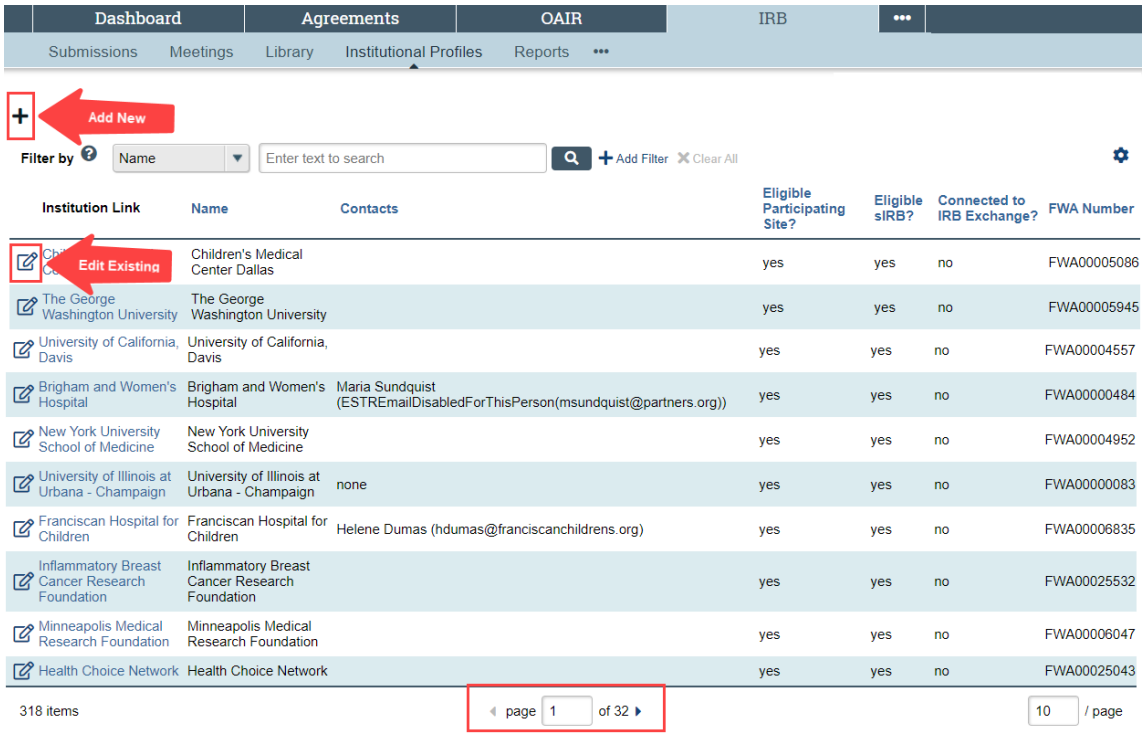
At upgrade, in December 2017, the IPs in ESTR are populated with institutions associated with SmartIRB. Manual updates and management are required for everyday use.

To access and edit IP information:

1. Click the **Institutional Profiles** link in the navigation header.

2. Page through to find the existing IP to **Edit** an IP **OR Add New** if the IP does not yet exist.

Important! When adding a new IP, first contact estrhelp@harvard.edu with the institution's name so it can be added to the ESTR database. After the organization is added to the ESTR database, the remaining steps can be completed.



In the IP pop up (after clicking the open box with pencil icon to edit, or the plus [+] icon to add), add the following required and optional elements.

Pop Up Question/Prompt Details

#	Question/Prompt	Note about anticipated contents
1	Institution (required)*	Contact estrhelp@harvard.edu if the organization name is not available to select.
2	States in which this institution conducts FWA-approved research	Add as applicable/needed.
3	FWA number	Optional but strongly suggested. Is expected to populate into generated documents in the system. Retrieve any FWA or IRBORG details on the OHRP website.
4	FWA expiration date	Add as applicable/needed.
5	FWA information	Add as applicable/needed.
6	IRB registration information	Add as applicable/needed.
7	IORG number	Add as applicable/needed.
8	IRB roster	Add as applicable/needed.
9	Indicate the IRB quality control mechanism in place at this institution (required)	Can be marked as 'none' or 'other' in circumstances where it is unknown but acceptable.
10	Authorization agreements	Add as applicable/needed.
11	Communication plans	Add as applicable/needed.
12	Consent form instructions	Add as applicable/needed.
13	Recruitment material instructions	Add as applicable/needed.
14	Is this institution eligible to be a participating site on a multi-site study? (required)	Ordinarily mark 'yes', unless there is an additional factor to consider. Before marking 'no', please contact the Reliance Coordinator in the partner IRB office to ensure there is no active reliance in place or that any needed additional actions are taken, as needed.
15	Is this institution eligible to be a single IRB of record in a multi-site study? (required)	Ordinarily mark 'yes', unless there is an additional factor to consider. Before marking 'no', please contact the Reliance Coordinator in the partner IRB office to ensure there is no active reliance in place or that any needed additional actions are taken, as needed.
16	Route RNIs to this institution for review when they are the sIRB? (required)	Ordinarily mark 'no' (Harvard manages the RNI reports first), unless there is an additional factor to consider. Before marking 'yes', please contact the Reliance Coordinator in the partner IRB office to ensure there is awareness of an altered process for this institution.
17	Staff members who will serve as points of contact for this institution	Add contacts (see separate instructions) where there are individuals who do not have an HUID, but should receive notices for this organization's IRB.

18	Is this institutional profile active? (required)	Ordinarily mark 'yes', unless there is an additional factor to consider. Before marking 'no', please contact the Reliance Coordinator in the partner IRB office to ensure there is no active reliance in place or that any needed additional actions are taken, as needed.

**At upgrade on December 15 2017, basic auto-created IPs contain a set of information for SmartIRB participating institutions. These basic IPs include data for above items: 1, 3, 14, 15, 16, and 18.*

3. Click **OK** to close the pop up and save the changes.

Request a Contact

In ESTR, a Contact is a person who:

- Has a limited profile in the system,
- Can receive notifications, and
- Does not have permissions to log in (and likely never will).

If a person needs access to a submission or will have some affiliation with Harvard, ensure that the person obtains an HUID through regular affiliation or the Harvard Sponsored Role process.

To request a contact be added to the system, email estrhelp@harvard.edu with the following information:

1. First and last name
2. Employer/Affiliation
3. Business phone (if appropriate)
4. E-mail address

External IRB Project Review

To Create an External IRB Submission (in brief)

For a study team to propose that Harvard rely on the review of another institution, the study team (or a member of the IRB office, on their behalf) must follow these steps in ESTR (Note: for expectations regarding the content of the submissions, please see local policy and the Study Submission Guide):

1. Create a new study.
2. On the Basic Information Page, mark 'yes' to number 5 (indicating that an external IRB will act as the IRB of record for this study).
3. Fill in the reminder of the "External IRB" SmartForm.
4. Submit the request for Harvard review.

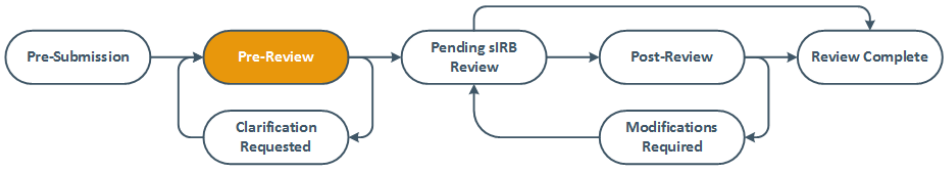
Important! Between December 15, 2017 and April 2019, request for review by an External IRB created two workspaces and submission numbers for projects. With the April 2019 upgrade, these two workspaces were merged. As part of the merge, the following record updates occurred:

- All previously split submission data was merged into a main project workspace with the corresponding Site numbering (even if the submission type is Initial Study).
- Any corresponding External IRB workspace was marked as 'discarded'.
- The merge activity is recorded on the History tab of both the Site and External IRB workspaces.

Prior to this merge, there were special steps to complete for the assignment and management of both the External IRB and corresponding Site workspaces. Special practices are no longer necessary and regular unassigned queue management steps can be used to identify and assign new requests for External IRB review or associated study updates/site modifications.

External IRB Review States

The submission workspace will contain the content of IRB review and ultimately, the confirmation of reliance. This workspace will function similarly to others, where the study team can only edit the SmartForm when in Pre-Submission, Clarifications Requested, or Modifications Required.



- For multi-site or collaborative projects, the SmartForm will have extended content and when Harvard review is completed, these projects will transition to the Active state with the submission type label IRB Site.

- For single site projects the SmartForm will have focused site content and when Harvard review is completed, these projects will transition to the External IRB state with the submission type label Initial Study.

While the final review state for the submission will depend on the selection of multi-site/collaborative or single-site, the following instruction refers to any type of submission where there is a request for Harvard to rely on the review of another IRB as an "External IRB" submission.

To Review an External IRB Submission:

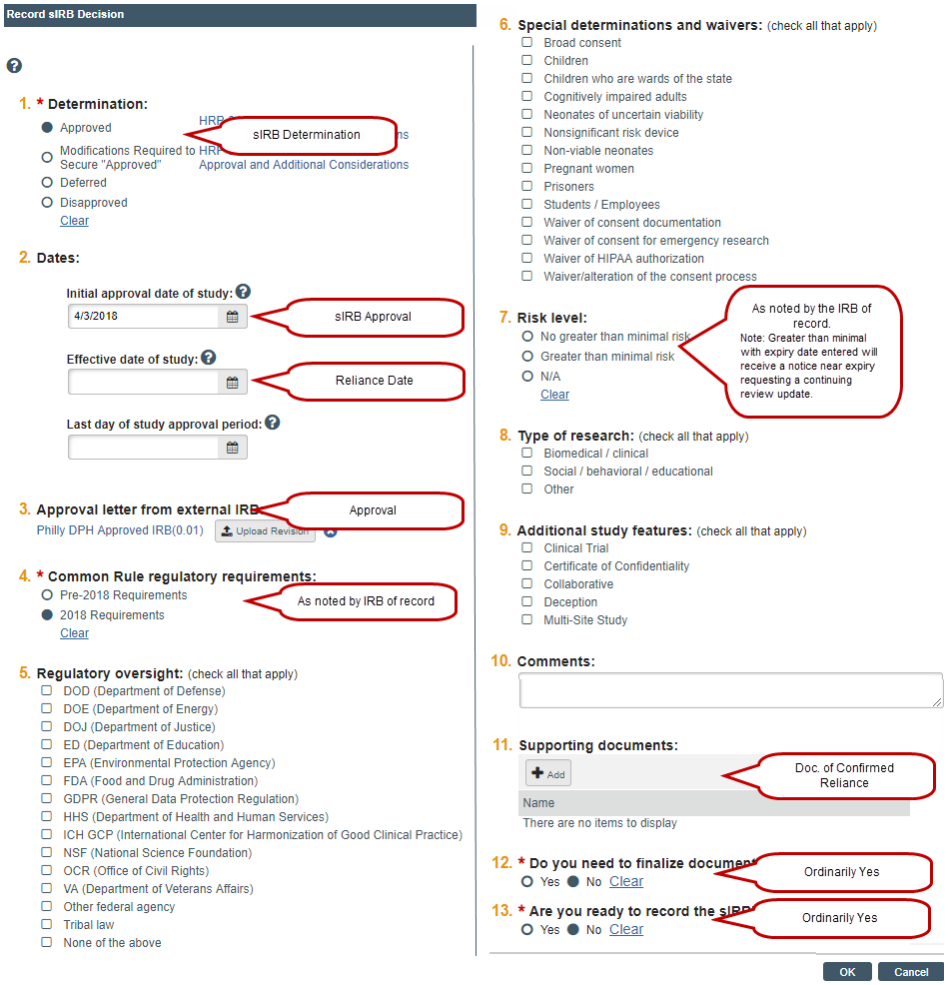
1. **Request Clarifications:** (optional activity) To request changes to the submission SmartForm or request clarification.

2. **Correspond with sIRB**: (optional activity) To send an email to the contact on the associated IP or any person on the study (including the PI, Primary Contact, or study team members). This activity is public on the submission history, independent of who is named as a correspondence recipient. This activity can be executed many times and at any point during and after review is completed.

   Note: To help with information sharing, summary SmartForm and activity information is combined to a single view on the Reviews tab of the workspace. This view is only available for reliance requests during review.

3. **Confirm Reliance:** (required activity) To indicate that reliance will be sought and documented via a later activity, and to indicate regulatory elements of the project as needed**.** A document attached to this activity will appear on the submission history only.
   Important!
   - Completion of this activity indicates that the request for External IRB review can proceed. Once this activity is completed, questions 4 and 5 on the Basic Information page of the SmartForm can no longer be edited. Additionally, the submission type label will be confirmed based on the selection of multisite/collaborative or single-site.
   - This activity cannot be edited after it is completed unless the site is withdrawn and resubmitted.

4. **Record sIRB Decision:** (required activity) Upon receipt of a copy of the approval letter from the IRB of record AND confirmation of reliance (for example; via email, SmartIRB, or executed IAA), complete this activity to indicate completion of Harvard review. This can be edited after completion and until the letter is sent, via the Edit sIRB Decision activity.
    - Until this activity is completed, the study team and assigned coordinator can edit the submission.
    - Use the comment space of this activity to indicate if the reliance is also managed in SMART IRB, with the number by indicating "SMART IRB: ####".
    - After question 13 in the activity pop up, the reliance coordinator has the option to include Harvard tracking elements (such as the option to edit data security level and flag relevant reporting items).
    - On the submission workspace, the approval document attached via this activity will appear on the documents tab and supporting documents will appear on the reviews tab.



5. **Finalize Documents:** (required activity) To finalize non-study team documents attached to the Site SmartForm

6. **Prepare Letter:** (required activity) To create an External IRB letter confirming reliance for the study team/funding organization. Note that it is important to view the contents of the SmartForm in advance. When creating the letter, the funding source will only populate with Harvard funding. If there is funding not processed through Harvard, it will be marked on the Local Funding page of the

SmartForm and should be written in to the letter, beside the funding sources prompt. Indicate external funding as "funding name (external funding, not processed through Harvard)".

7. **Send Letter:** (required activity) To notify the PI/Proxy, Primary Contact, and IP contact that Harvard reliance is confirmed. The submission will transition to Active or External IRB as appropriate to the study type.

   If review elements must be updated after Send Letter is completed but a Study Update or Site Modification is not appropriate, the Return to Post Review activity can be completed so that steps 4 to 7 above can be re-completed.

Participating Site Review

To Create a Participating Site Submission (pSite, in brief)

Important! Sites added before Pre-Review is submitted will appear in a pending state and will not have a workspace. You cannot proceed with these review steps until pre-review is completed. This is to allow for edits to the Main study SmartForm before site workspaces are created. Once Pre-Review is submitted, sites created in error must be transitioned to "inactive" and cannot be removed (see sub-section *Reverting a pSite In-Review to Inactive*)

For a study team to propose that Harvard review for another institution, the study team (or a member of the IRB office, on their behalf) must follow these steps in ESTR (Note: for expectations regarding the content of the submissions, please see local policy and the Study Submission Guide):

1. Visit a main study workspace (in any state), where it is indicated on the Basic Information page of the SmartForm that BOTH:
    a. This is a collaborative or multisite study ('collaborative' is marked for number eight), AND
    b. Harvard will act as the IRB of record for any project ('yes' is marked for number nine).

2. In the main study workspace, complete the Manage Participating Sites activity, and on the activity pop up:
    a. Indicate the institution: by selecting from a list populated by the Institutional Profiles created and managed by a Reliance Coordinator.
    b. Indicate the site Principal Investigator: by selecting from individuals with an HUID or contacts managed by a Reliance Coordinator. Note: It is advised that study teams indicate the Harvard PI in this space when the site PI name is not readily available.
    c. If Pre-Review is not yet completed on the main study, re-complete the Manage Participating Sites activity to modify the site list at any time.

3. Click OK on the pop up.

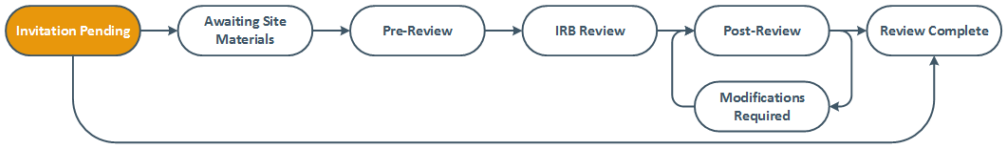
4. After Submit Pre-Review is completed on the Main study, visit the Site workspace to include additional site-specific content on the Site SmartForm, as needed, by clicking Edit Site.

    Important! Any added Sites are automatically created in an IRB-review state. Note that in order for IRB review to begin, the additional completion of a 'submit' activity is not required. The added Site will automatically be assigned to the IRB coordinator on the main study (if there is one assigned) and will appear as in review in that IRB Coordinator's InBox. The automatically assigned IRB Coordinator must assign this to the Reliance Coordinator to proceed with review steps, as appropriate.

5. The unassigned site that is created may be:
    - Assigned by the IRB Coordinator indicated on the main study.
      OR
    - Assigned from the list of records listed in the 'Unassigned' tab on the Submissions page.

pSite States

The Site workspace will contain the content of IRB review *for that Site* and ultimately, the confirmation of reliance. This workspace is for informational purposes and the SmartForm can be edited at any time until post-review.



pSite Review – Additional Considerations

- **Before main study approval:** If the Site is created during Harvard IRB review of the main study, the Site review cannot be completed until IRB review of the main study is complete.
- **After main study approval:** If Harvard IRB review of the main study is complete, best practice indicates that the Site review be accompanied by a modification request. The system will allow for independent review of a Site (without a modification). However, the site reviewer must ensure that an additional modification review is initiated.

To Review pSite Submission:

ON THE SITE WORKSPACE:

1. **Assign Coordinator:** (required activity) Per practices of your IRB, assign the coordinator managing the site review in the site workspace. It is a good idea to also share a private comment (with notice) indicating the status of the site materials/review (relative to the main study) for the newly assigned coordinator to pick up review activities from there.
2. **Submit Invitation Decision:** (required activity) Once it is clear whether reliance makes sense/will occur, record the decision via this activity. A notice is sent to the PI and Primary Contact when this activity is completed.
   - Mark 'yes' for item one: to move forward with negotiating a reliance request changes to the site submission or request revision to the External IRB submission.
   - Mark 'no' for item one: to move the site submission to "Inactive". Note that if 'no' is marked in error, the Record Response activity can be completed to re-initiate Harvard IRB review.
3. **Correspond with sIRB**: (optional activity) To send an email to the contact on the associated Institutional Profile or any person on the study (including the PI, Primary Contact, or study team members). This activity is public on the submission history, independent of who is named as a correspondence recipient. This activity can be executed many times and at any point during and after review is completed.

   Important! Since there is no 'clarifications requested' process on a pSite, this activity can be used to request updates/edits to the information including the SmartForm. Be sure to coordinate any additional notices or requests with the IRB Coordinator assigned to the study or modification review, to ensure streamlined communications with the study team.
4. Complete the **Site Materials Received** activity**:** (required activity) To indicate all materials needed to accept review have been received.

5. **Assign Designated Reviewer OR Assign to Meeting**: (required activity) To move the review of the Site forward such that it corresponds and is appropriate, considering with the mode of review of the main study.

   Important! The SmartForm is able to be edited in every state until the next activity (#6) is completed. So, before moving on: determine if you want to attach any executed agreements to the Site SmartForm. You must do this before moving to the next activity. If you do not, you will only be able to edit the SmartForm if: (a) modifications are required to secure approval or (b) a Site Modification is created after approval.

6. **Submit Site Designated OR Committee Review**: (required activity) To indicate the approval associated with the Site. On the activity pop up:

   - Include a brief note about the scope of work in the notes space provided. This is to assist with managing any modifications or continuing review associated with the main study.
   - If not attached/planned for attachment to the Site SmartForm, attach any executed agreements to the supporting documents section.

   Important! Determination information can be recorded and saved on this activity but it cannot be submitted until review of the main study is complete. At this time, the system will not separately notify the IRB Coordinator on the Site (or any Reliance Coordinators) of main study approval. This needs to be additionally monitored/communicated between IRB staff members.

7. **Finalize Documents:** (required activity) To finalize non-study team documents attached to the Site SmartForm.

8. **Prepare Letter:** (required activity) To create a letter confirming reliance or to add a copy of the main study approval letter, as deemed appropriate by IRB best practices.

9. **Send Letter:** (required activity) To notify the study team and IP contact that reliance is confirmed.

Reverting a pSite In-Review to Inactive

It is sometimes necessary to render a site inactive after step 1 above. This can only be done AFTER issuing approval (i.e. completing steps 3-8 to the approved state). After approval, complete the **Update Site Status** (for an inactive state that can be returned to active, if ever needed) or **Close Site** activity (for a closed state, that will permanently close the site).

Site Follow-on Review and Closure

Harvard-Reviewed pSites

For sites where Harvard is the IRB of record, it is expected that reviews of modification or continuing review are incorporated in the process associated with review of the project, and are not additionally described here, specifically for the Reliance Coordinator. Please see the IRB Staff Administration and Study Submission Guides for information about pSite follow-on review, until closure.

External IRB Projects

For multi-site or collaborative projects that are in the Active state, study revisions and updates that are reviewed by the IRB of record can be recorded by either:

a) Updating Study Details to provide an update to Harvard about general status or study content and provide a copy of the approval letter from the IRB of record. The scope of the changes are specific to:
   - Basic Study Information (such as PI or PI fCOI reporting)
   - External IRB Details (such as an updated determination)
   - Study Funding (including changes to a related GMAS project)
   - Study Scope (regarding the involvement of drugs or devices)
   - Study-Related Documents

OR

b) Creating Site Modification to provide information about revisions to Harvard-site information or activities and provide a copy of the approval letter from the IRB of record. This option only shows for multi-site or collaborative projects. The scope of the changes are specific to:
   - Study team and research location
     - Harvard Study Team (such as new or removed team members)
     - Harvard Research Locations
   - Other parts of the site
     - Harvard Site Information (such as Harvard PI or Harvard PI fCOI)
     - Additional Local Funding Sources (funding that is non-sponsored and not listed in GMAS)
     - Harvard-Specific Documents

For single site projects that are in the External IRB state, study revisions and updates that are reviewed by the IRB of record can be recorded by Updating Study Details (Create Site Modification will not display) to provide an update to Harvard about general status or study content and provide a copy of the approval letter from the IRB of record.

Update Study Details

- A member of the study team or IRB staff can click the "Update Study Details" button on the submission workspace, a SmartForm will open.
- When edits are complete, IRB staff or the PI or PI Proxy may click Finalize Updates (on the left side of the submission workspace) to complete the updates. The main study workspace will update with the changes and the Harvard IRB assigned coordinator will be notified that an update has occurred.

Important! If you do not see the option to Finalize Updates, contact ESTRhelp@harvard.edu for assistance.

Site Modification (in brief)

For a study team to propose a modification to a site where Harvard relies on the review of another institution, the study team (or a member of the IRB office, on their behalf) must follow these steps in ESTR (Note: for expectations regarding the content of the submissions, please see local policy and the Study Submission Guide):

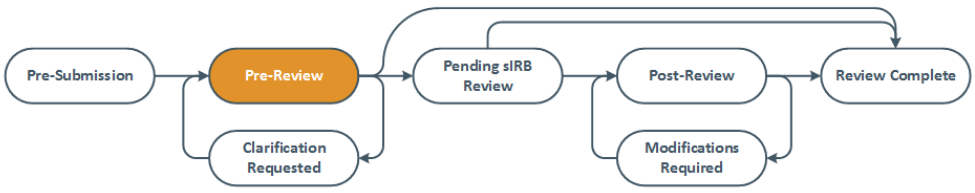
1. Visit the study workspace
2. Click Create Site Modification / Modify Site
   Note: If the Create Site Modification button is not visible, make sure that there is (1) a primary contact assigned – this can be assigned to be the PI if no other person is appropriate and (2) if IRB staff want to assist, an IRB coordinator should be assigned.
3. Follow SmartForm steps to indicate the modification scope, description, and revised elements of the approved Site.
4. Once the SmartForm revisions are complete, Submit the modification for Harvard IRB review.
5. The unassigned site modification that is submitted may be assigned from the record listed in the 'Unassigned' tab on the Submissions page.

Important! If the standard options to Modify Study or Create Continuing Review are available on a workspace that represents reliance, please check the Basic Information page of the SmartForm. Records created before October 2015 may have incorrect information on the SmartForm which limit the ability to review any follow-on submissions. To proceed with a modification to one of these old records:

- [**preferred option**] Copy the record to propose changes on the new submission and re-confirm reliance. With this option, the legacy record should also be closed.
  OR
- Contact ESTRhelp@harvard.edu to change the value to the "External IRB involved" question on the Basic Information of the SmartForm before a modification is created. With this option, there is some risk to carrying forward an older, and possibly incomplete record.

Site Modification States

The Site modification workspace will contain the content of IRB review and ultimately, the confirmation of revisions to the reliance. This workspace will function similarly to others, where the study team can only edit the SmartForm when in Pre-Submission, Clarifications Requested, or Modifications Required.



To Review an External IRB Project and Site Modification Submission:

ON THE SITE WORKSPACE:

1. **Request Clarifications:** (optional activity) To request changes to the Site Modification submission or request revision to the External IRB submission. As part of requested clarifications, the assigned IRB Coordinator can request updates to the External IRB submission SmartForm.

2. **Correspond with sIRB**: (optional activity) To send an email to the contact on the associated Institutional Profile or any person on the study (including the PI, Primary Contact, or study team members). This activity is public on the submission history, independent of who is named as a correspondence recipient. This activity can be executed many times and at any point during and after review is completed.

3. **Accept Site Updates:** (required activity) To indicate that a reliance update will be sought and documented via a later activity**.**

   Important! This activity cannot be edited after it is completed unless the Site Modification is withdrawn and resubmitted.

4. **Record sIRB Decision:** (required activity) Upon receipt of a copy of the modification approval letter from the IRB of record, and confirmation of continued reliance (as applicable), complete this activity to indicate completion of review. When completing this activity, note that:

   - If item we on this activity form is marked "no", a notice is sent, and the submission will move to the approved state. All proposed changes will copy to the main study workspace, as the current approved version of the study. A letter may still be prepared and sent if "no" is marked in error.
   - If item 12 on this activity is marked "yes", no notice is sent, and the ordinary post review activities (i.e. finalize, prepare letter, and send letter) will need to be completed to move the submission to the approved state and for all proposed changes to copy to the main study workspace, as the current approved version of the Site.

To Report Continuing Review or Close an External IRB Site (in brief)

For a study team (or a member of the IRB office, on their behalf) to indicate continuing review information or closure when Harvard relies on the review of another institution:

1. Visit the Site workspace
2. Complete the Report Continuing Review Data activity. Once the activity is completed, the site PI and the assigned IRB Coordinator receive a notice.

Important! To request closure: In the comment space provided on the activity, indicate that closure is appropriate (and why), and attach the IRB of record closure to the activity, if available.

Upon notification of reported continuing review data, the IRB Coordinator may update the status of the site by completing the:

- Return to Post Review activity and re-recording a determination
  OR
- Close Site / Close Study Activity, as appropriate. Close Site will appear on submission type: IRB Site, and Close Study will appear on submission type: Initial Study. Closing the study via this activity may not notify the PI/Proxy and Primary Contact. Complete the Add Comment activity to also send a notice to the PI/Proxies, Primary Contact and/or Study Team.

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 Medical Area only) at hsph.harvard.edu/ohra ▪ 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.

Appendix I: External IRB Numbering Overview

The following is a summary of the expected features 'going forward'. Projects created before April 2019 may have different statuses and ID prefixes. State and prefix noted as "old" below are references to the legacy statuses and ID prefixes.

Initial/Main Submission

Created via the "Create Study" option, where Harvard is reviewing or relying.

Single or Multi-Site?	IRB of Record?	Is Harvard sIRB for other pSites?	Activities Required to Complete Review	Anticipated Review Complete State	ID Prefix
Single *Initial study type record*	External	N/A	Confirm Reliance Record sIRB Decision	External IRB	IRB-
Multi *Site type record*	External	N/A	Confirm Reliance Record sIRB Decision	Active *(Old: External IRB)*	IRB- *(Old: SITE)*
Multi *Initial study type record*	Harvard	Yes	Add Participating Sites	Approved	IRB-
Single OR Multi *Initial study type record*	Harvard	No	Standard committee/designated review activities	Approved	IRB-

Participating Site Submission

Created via the "Add Participating Site" activity for a multi-site study, where Harvard is the single IRB of record for other participating sites.

Single or Multi-Site?	IRB of Record?	Is Harvard sIRB for other pSites?	Activities Required to Complete Review	Anticipated Review Complete State	ID Prefix
Participating Site of Multi-site study *Site type record*	Harvard	N/A	Submit Invitation Decision Submit Site Materials Site-specific committee/designated review activities	Active	SITE-