Release Notes 1.20.0

As part of the October 16-October 19 upgrades, new functionality and enhancements are introduced throughout the system, affecting those who use ESTR in different ways. **Overall system use and navigation remains the same**. Changes to the system do not alter any IRB policies or the human subjects research application requirements. For full instruction on using ESTR and any new features, visit the Job Aids section of the ESTR Support Site.

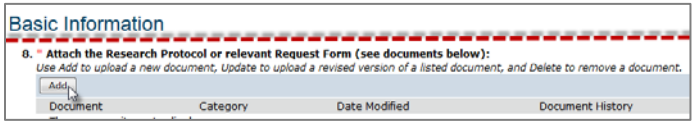
Click to jump to:

Highlights for Principal Investigators and Study Staff

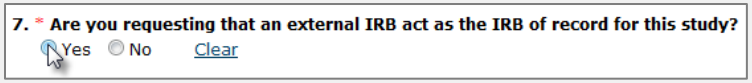
Revised SmartForm Pages

Additional instructional text appears on every page, without extra clicks

Document attachments and other prompts appear on different pages of the form than before. This allows for better document management and "smarter" form branching.



Abbreviated form for External IRB requests, where a Harvard IRB relies on the IRB review of another institution.



What hasn't changed about the SmartForm? The same materials are required for review of IRB submissions.

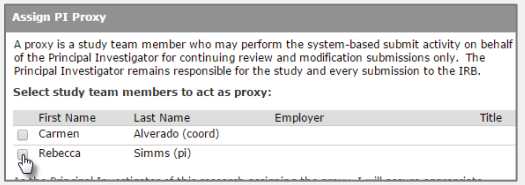
Updated Authority to Submit

Initial submissions can only be sent to the IRB by the Principal Investigator (PI).

After initial approval, the PI can select from members of the approved study team to "Assign PI Proxy". The proxy can submit follow-on submissions (modifications and continuing reviews) on behalf of the PI.

Assigned PI proxies (see above):

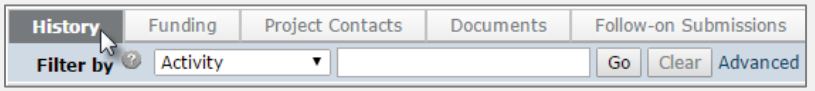
- Can submit modifications and continuing reviews on behalf of the PI
- Receive copies of all study notifications
- Can be changed by the PI any time after initial approval



What hasn't changed about permissions? Study team members can still create and edit follow on submissions and "submit changes" when clarificaitons are requested by the IRB. Additionally, Primary Contacts still receive copies of all study notifications.

Submission Workspace Improvements

Items filled in on the electronic SmartForm, can be viewed at-a-glance via workspace tabs.

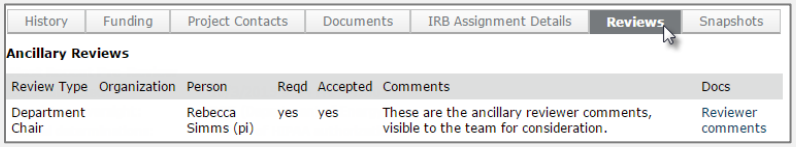


The Documents tab includes a link to the history for each document associated with the study.

What hasn't changed about workspaces? Final versions of study documents remain accessible via the Documents tab. All IRB determination letters can be accessed quickly from the Follow-on Submissions tab.

New Review and Communication Features

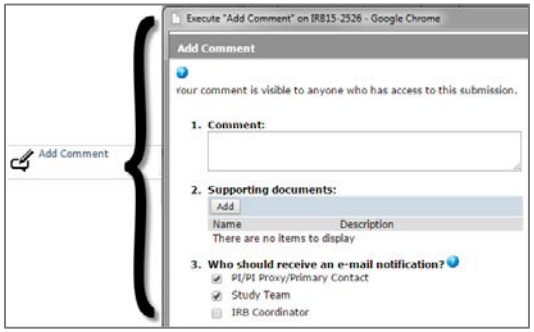
Faculty Sponsor and other non-IRB reviews are completed and recorded via the "Ancillary Review" process. To help reduce review timelines, this process occurs in parallel to IRB review.



Didn't mean to create a submission at all? Use the Discard activity to completely remove a submission from IRB consideration.

Want to make changes to a study mid-review, but it has already been submitted? Use the Withdraw activity to return a submission back for further edits and then complete the Submit activity again to send it back into IRB review.

On a submission, add a comment to post a note on the workspace or to send notice the study team or the IRB Contact (or both!).



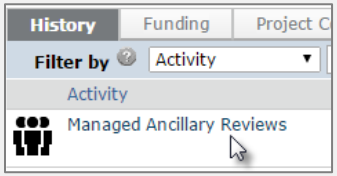
With regard to these elements, what hasn't changed about review?

- *If the IRB identifies that an ancillary review is required, it will be recorded on the submission History and Reviews tabs, or otherwise communicated to the study team during the review. Ancillary review types and documentation requirements are not changed with this upgrade.*
- *Required elements of the proposed project or project changes must be attached within the electronic SmartForm. Any attachments to comments, withdrawals, or other activities are considered notes for the record or reference, and are not part of the study materials.*

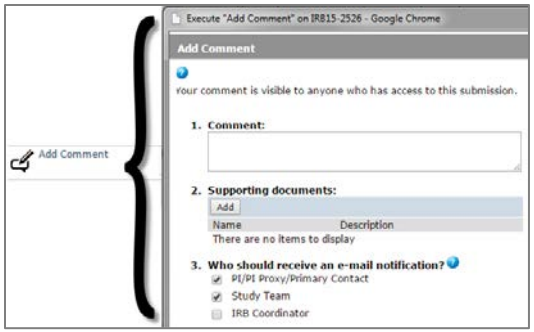
Highlights for Faculty Sponsors of Non-Faculty Principal Investigators, Department Reviewers, and reviewers in other Harvard offices

New Ancillary Review and Communication Features

Based on elements of the submitted project, when an ancillary reviewer is identified, IRB staff will send a notice to the reviewer. Ancillary review occurs in parallel with IRB review and does not hold up the IRB review process.



On a submission, add a comment to post a note on the workspace or to send notice the study team or the IRB Contact (or both!).



As required, record review by completing the Submit Ancillary Review activity. As needed, attach review-related documentation to the activity form so that it can be stored in ESTR and referenced from the submission.

Faculty sponsors no longer receive copies of all study notifications by default. Faculty sponsors may be added as PI proxy to additionally receive study notices.

What hasn't changed about ancillary review? Documentation of a particular ancillary review may be required before IRB approval can be issued. If a notice of ancillary review is received, please complete the requested review as soon as possible to reduce any unnecessary delays in IRB determination.

Highlights for IRB Staff and Committee Members

In addition to the changes for study teams and ancillary reviewers; IRB staff and Committee members will see the following changes.

New Review Steps

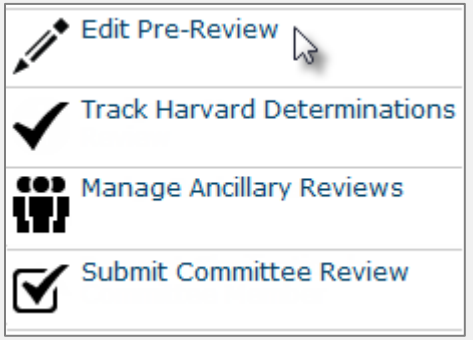
Regulatory and Harvard determinations must be recorded via the following activities:

- Pre-Review
- Track Harvard Determinations
- Manage Ancillary Approvals*
- Designated or Committee Review

View details about what was marked on previous activity forms:

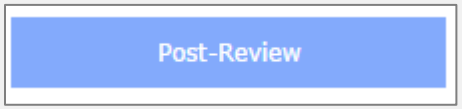
- Click the item in the history, on the submission
- View the determination letter on the submission
- View the Reviews tab (does not include Harvard Determinations)

*In addition to a new space for the ancillary reviewer to record the determination, IRB staff must trigger all non-IRB reviews.



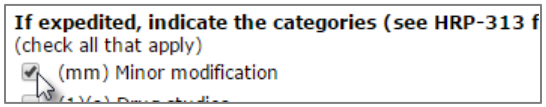
Add *temporary* review comments during non-committee or committee review. Review comments are "deleted" from view following determination.

Forgot to mark a determination element? There's no need to contact the help desk! All review activities are available to edit through Post-Review (for some, even after the letter is sent). Note that if a designated or committee review is re-completed, it will update the effective date.

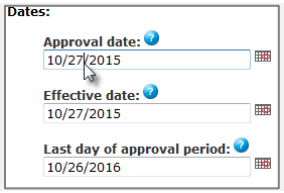


The designated review activity form allows for alternate review types. As appropriate:

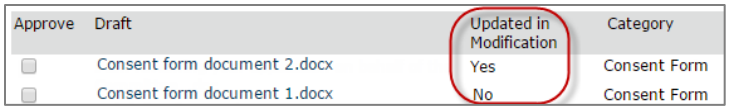
- Expedited: "(mm) Minor modifications" should be select for items which meet the criteria for review under 46.110(b)(2)
- Exempt: "Other" should be selected for items that meet 46.118 or NHSR Mod criteria.



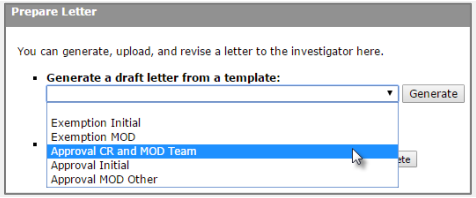
Account for approval anniversary dates or approval for less than one year within the non-committee and committee activity forms by writing in dates.



Finalize documents activity requires a check for each reviewed document, displays items changed in the modification, and "accepts all changes" in tracked Word documents.



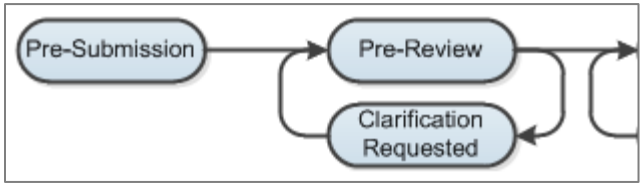
Generate letter for submissions approved by the Full Committee or by Expedited procedures now have additional options. The option "Approval CR and MOD Team" will display elements of the parent study on the letter, while "Approval MOD Other" will display elements of the draft/revised study under review.



Submission contents and review of the following submission types has been revised:

- Request for the Harvard IRB to rely on an External IRB
- Request for study closure
- Report of New Information

Review the submission guide for new/changed steps in completing these reviews.



What hasn't changed about review? Along with a few more elements which can be recorded within activities, the same materials and ancillary reviews are required for review of IRB submissions.

Security Permissions and Views

IRB Coordinator may be assigned while items are in pre-submission to help with submissions, as-needed. Rules regarding when items appear in any person's InBox only start to work after the IRB Coordinator is assigned.

Submissions are locked from further edits when assigned to a committee meeting. When requesting clarifications in Committee review, ONLY reference information can be provided via the Submit Response activity. To make SmartForm edits after assignment to a meeting:

- The submission can be removed from the agenda,
- The submission can be withdrawn to be re-submitted, or
- A determination of modifications required to secure approval can be issued.

IRB Staff can assist with any activity that study staff or ancillary reviewers are able to complete. This includes assigning a PI proxy, submitting studies or follow on submissions, and submitting changes. Use with caution: Completing study staff activities on behalf of the study team may affect visibility into private or reviewer comments.

What hasn't changed about views? Edit and view permissions.