

PROTECT 10.5.7 Upgrade Release

Communications Plan & Release Notes

Release Date: Oct 31, 2024

1. **IRB | NEW: sIRB Sites will now have a Discard activity**

A “Discard” activity will be available for initial single IRB of record (sIRB) sites, which was not previously available for these types of submissions. This will be useful if a pSite was created by mistake, it can now be discarded up until the point in the workflow just prior to approval.

2. **IRB | NEW: IRB Staff will now have an ability to Discard submissions as well.**

IRB Staff will now be able to Discard IRB submissions. This will be useful when the submission has been with the study team awaiting clarifications for an extended period of time.

3. **IRB | NEW: PI proxy will be able to Report Continuing Review Data (on Sites and External Studies)**

Fixed an issue where a PI proxy was not able to Report Continuing Review Data on sites and external studies. Previously, the PI proxy (or for sites at single IRBs of record, the PI proxy of the multi-site study) was not able to run the “Report Continuing Review Data” activity. This has been fixed so that the PI proxy can Report Continuing Review Data on sites and external studies, and so can the multi-site study PI proxy for sites at single IRBs of record.

4. **IRB | NEW: New “Scope” column on the Follow-On Submissions tab**

A new "Scope" column has been added to the "Follow-on Submissions" tab for both initial studies and sites. This column now displays the type of modification, which for Initial studies will read either, "Other parts of the study" or "Study team member information" in cases where there is a Modification or a Mod/CR. For Sites, it will read as either blank or “Other parts of the site”.

5. **IRB | NEW: In-Review tab now has an “Expiration Date” column**

On the IRB tab > In-Review tab, there is now a column called “Expiration Date”. It displays the initial study expiration date, when applicable.

6. **IRB | NEW: Improved Help Text and Application Questions**

The leaders in our IRB and Compliance offices have coordinated an effort to review and improve some of the IRB SmartForm Application questions and the system’s “help text” (the question mark icon bubble text) to be easier for users to understand and to gain more complete responses on the forms.

NIH PROTECT system users can look forward these improvements in the following IRB Submission Type forms: Initial Study Application, Modification/Update Application, Continuing Review/Study Closure Application, Reportable New Information Application.

NOTE: We made sure in our optimizations to be sure not to change the meaning of any questions, nor did we add any new questions.

7. **IRB | FIX: Study updates for External Site Studies synced to Initial Submission**
Previously, there was an issue where study updates were not being synced in the initial submission for external single site studies. When the sIRB review was updated during a study update for an external single site study, the changes were not updated on the parent study once the update was completed. This has been fixed.
 8. **IRB | FIX: pSite notification recipients**
Previously, the pSite contacts were not being notified when the pSite modification was approved. Now the pSite PI, PI proxy, and primary contact are being notified along with the NIH Staff.
 9. **RNI | NEW: New report “New Information Reports by Category” RNI**
Under *IRB tab > Reports tab > Standard Reports tab*, there is a new report called “New Information Reports by Category”. It displays the RNIs the user has access to see, and their category (major protocol deviation, non-compliance, new information, etc.).
NOTE: The category that is displayed in the report is the category the user selects on the form when submitting the report, not the IRB determination of the event.
 10. **RNI | NEW: PIs and Proxies can edit and submit RNIs created on their related submission(s).**
Previously, only the creator of an RNI could edit or submit the RNI form. Now, the PI and Proxies on a related submission can both edit and submit an RNI form that was created by a different person. For this feature to work, there has to be a related submission added to the RNI form.
 11. **RNI | NEW: New activity on RNI (Manage Editors)**
There is a new activity on the RNI workspace that allows IRB Specialist, IRB Director, and RNI Creator to select users from the system to be additional RNI editors on that submission form.
 12. **RNI | FIX: Expanded the ability to edit RNIs in the Action Required state**
Previously, users could not edit RNIs in an Action Required state. This has been revised so that the RNI creator, responsible parties, and additional editors are able to edit RNIs in this state.
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Section 2
IRB STAFF-ONLY RELEASE NOTES

1. **IRB | NEW: Can filter by “Institution” on Institutional Profiles list**
Previously, the "Institution" filter didn't exist in the "Filter by" drop-down list for Institutional Profiles. Now, the filter has been added, along with a new column labeled "Institution," which allows sorting by institutions.
2. **IRB | FIX: Deferred or Disapproved submissions stay on meeting agenda**
Previously, if a submission received a Deferred or Disapproved determination during committee review and was subsequently discarded, the submission would be removed from both the

meeting agenda and the meeting workspace. With this update, submissions will now remain on the meeting agenda and workspace even after being discarded if they received a determination of Deferred, Disapproved, or Modifications Required from the committee.

3. IRB | FIX: Code that auto lapses studies has been corrected

Previously, studies in Suspended state were being moved to Lapsed after the expiration date had passed. Now, only studies in Approved, Human Research, Not Engaged, or Not Human Research states are moved to Lapsed after the expiration date has passed.

4. IRB | FIX: AAHRPP report update

The AAHRPP report format and layout have been edited to enhance clarity and improve the reporting process. This release includes several changes to report formats and data presentation.

5. RNI | NEW: New “Manage Tags” activity

IRB Staff will now have a “Manage Tags” activity on submission workspaces. These tags can only be applied on a per-submission basis and at this point, we have only put tags in the system that are specific to RNI submissions. IRB Staff will then be able to search for submissions that have been “tagged” using a new report called “Submissions with Tags”.

6. RNI | FIX: Study-side can no longer see RNI Pre-Review activity on History log

Previously, the study side could see comments and attachments entered via Submit RNI Pre-Review action. This has been fixed so they can NOT see these activities and the data entered on these activities by the HRPP Staff, because this information is private.