3.09 PROTECT Release Notes

The available states for the "Manage Ancillary Review" activity have been updated
Users were accidentally running "Manage Ancillary Reviews" activity on the parent study when they intended to manage ancillaries for follow-on submissions such as a MOD. There is no valid use case when a user would need to manage ancillaries after a study is in a Review Complete state like Active/Approved. The Manage Ancillary Reviews activity will no longer be available in the following states: Active, Approved, External IRB, Human Research, Inactive, Lapsed, Not Engaged, Not Human Research, Suspended, Terminated, Updates Complete.

Scientific Review is now working correctly for studies reviewed by an external IRB
For external IRB study update and site modifications, there is now a question in place that asks: "Is Scientific Review required for this modification?". If yes, then the "Initiate SRC Modification" button will appear in the workspace and SR modifications can now be created for all external IRB studies by the PI/proxy. The IRB workflow has been updated so that this is a blocking question for IRB review and now the IRB can finalize the letter when SRC review is not required.

The "Initiate SRC Modification" button was not appearing for the proxy to create a SR modification for studies reviewed by the NIH IRB. This has now been fixed and SR modifications can now be created for all NIH IRB studies by both the PI and proxy.

The "initiate scientific review" button was not available for the migrated external IRB studies for either the PI or proxy. This has now been fixed and for a migrated external IRB protocol, this button is available for the PI/proxy to initiate the first AR or Quad review for a migrated protocol (same as the studies reviewed by the NIH IRB).

When the first scientific review project has been created (either as a MOD or as an AR/Quad review) for the migrated external IRB studies, there will now be an "associated projects" tab on protocol workspace to track all of the SR reviews moving forward.

All Study Team Members now have the "manage ancillary review" activity and will be able to do this for studies they are listed on.
Previously, only the PI and Proxy had access to the "Manage Ancillary Reviews" activity. Now, all study team members (as they have read/write access to the study) will also have the Manage Ancillary Reviews activity available for them to run in the IRB, SRC, and radiation modules.

The Scientific Review AR and SR QR form now include an attachment field
There is now a question on the Scientific Review Quad and Annual Review SmartForms where users can upload attachments to accompany the submission.

The "Is SRC Review Required" question was modified on the MOD and MODCR form and removed from the CR form

There was a question on the MOD/CR form that was not accurate because it asked if Scientific Review was required for this Continuing Review, and SR is not ever required for IRB CR. It has been revised to read, "Is Scientific Review required for this modification?". Also, the hide/show for this question has been revised to only show if Mod or Mod/CR check boxes are selected.

Ability to Discard a SRC submission
Users will now be able to run a Discard activity on Scientific Reviews for IRs, Mods, Annuals, and Quads when they create them in error.

Correspondence letters can be re-generated and re-sent after the submission is moved out of the Post-Review state
SRC specialists will now be able to run the "Prepare Letter" and "Send Letter" activities when the SRC submission is in the "Approved", "Disapproved", or "Modifications Required" state. The submission will stay in its current state, but the correspondence letter will be updated accordingly when the Prepare Letter activity is run, and the same recipients should receive a notification with an updated letter when the Send Letter activity is run.

"Assign Specialist" activity is now available in all states of the SRC workflow
SRC specialists will be able to run the "Assign Specialist" activity on Scientific Review submissions in any state. Previously, the option to "Assign Specialist" for an SRC submission was only available prior to a pre-review being submitted.

The branch/lab chief, if a member of the study team, will now have the "submit ancillary review activity" in SRC
There was a COI rule in place where the Branch/Lab Chiefs did not have the activity to Submit Ancillary Review if they were also a member of the study team. We had a work around where we were having them "Add Comment" on the History log to note their signoff. Branch Chiefs/Lab Chiefs will now be able to see the Submit Ancillary Review activity in EVERY state of the Scientific Review submissions workflow up until post-review. Once the action is in post-review, the person signing off as the CD/SD etc. cannot also be a member of the study team.

The Radiation Safety Submission form has been updated to accept decimal values
In the Radiation Safety Submission form where users enter the effective dose from a study and where users enter the mCi administered dose of a radionuclide, the data fields only accepted whole numbers. These values were revised to accept decimal values (e.g., 0.089 rem or 5.5 mCi). On the RSC project workspace, "Total effective dose from all studies" was also revised to display decimals. In addition, the following two reports were revised to show decimal values: RSC Submissions: Radiography Scan & RSC Submissions: Radionuclides and Compounds.

When adding a Participating Site, the organization chooser has been updated to exclude internal/NED organizations
Previously, when adding a pSite to a protocol, the organization and person chooser was showing all of the internal NIH organizations and people in NED along with the external organizations and people. The

choosers have been updated to display only the external organizations and people with external accounts, making it easier to find the institution/person that you want to select.

New Custom Report

On the IRB tab, under reports, custom reports, there is now a report that will display all of the devices that are currently in PROTECT. You can use this report/search feature to see if a device you need is on the choice list before you enter a request to add a new device.