PROTECT June 22, 2023 Release Notes

We have installed a patch in PROTECT that has fixed/changed several issues, outlined below. For your future reference, our "release notes" describing any updates to PROTECT will be posted on our website, here.

Attached documents must now be marked as active (or not)
In the IRB study form and Scientific Review form, for every document type, there is a new mandatory question that asks: *Is this document active? Yes/No*.

Documents that are "active" are those that are currently being used in the study. Documents that that are no longer "active" (inactive) are those that have been retired and no are longer in use, e.g., a consent document for a cohort that has been completed or a recruitment material that is no longer being used. For those types of documents, you should select "no" (not active).

The status of each document (*Is Active? Yes/No*) will be displayed on the *Documents* tabs of the IRB and SRC project workspaces as well so users may easily identify these as such. The status of each document will also be displayed in the IRB, SRC, and RSC applications wherever documents appear.

Automatic notifications to remind the study team to submit a SR Quadrennial Review

PROTECT will now send notifications to the study teams to remind them to submit their Quadrennial Reviews. The 'Quadrennial Due Date' in the system is set behind the scenes as 4 years minus 1 day from the Initial Review's Approval Date. The system will use this date to send Quadrennial Review Reminder Notifications at 90, 60, and 30 days prior to this date.

Scientific Reviews are now correctly appearing in the Chief Scientific Officer's (CSO) Inbox
Previously, the CSO ancillary review group were not seeing the project in their Inbox when it was assigned in an approved state. This has been fixed so that it will correctly appear in their inbox regardless of the workflow state the project is in.

The PI Proxy can now see the 'Report Continuing Review Data' and 'Correspond with Site' activities
For a multi-site study where NIH is the Reviewing IRB, PIs could see the 'Report Continuing Review Data' and 'Correspond with Site' activities but the PI Proxy could not. This has been fixed so the proxy now has these activities.

The 'My Reviews' tab now shows only projects where the logged in user is assigned as reviewer
The My Reviews tab was working inconsistently and displaying projects where the user was not a reviewer on the project, making the tab not as helpful as intended. This has been revised so that the 'My Reviews' tab shows only projects where the logged in user is assigned as reviewer.

When reviewers sign off on (Submit) the RSC and SRC ancillary reviews, a notification will now go to study teams
Previously, the study teams were not notified when the RSC and SRC ancillary reviewers Submitted Ancillary Reviews. They had to track this by looking on the Reviews tab for the project. The study teams (PI, Proxy(ies) and primary contact) will now also get an email notification when the RSC and SRC ancillary reviewers submit their ancillary review.

Ancillary Reviewers' Assigned Actions appear in inbox/my reviews tabs only after submission to IRB
Previously, once a study team member "managed an ancillary review" and added a reviewer (ex. DEC), the action would appear in the reviewers' *My Inbox* tab. This was inconsistently occurring before the action was submitted to the IRB for review (in the pre-submission state) appearing that it was ready to be reviewed by the ancillary reviewer. The IRB ancillary reviews should not be initiated until the

submission is complete and submitted to the IRB. IRB ancillary reviewers will now only see the action in their *My Inbox/My Reviews* tab once it has left the Pre-Submission state and been Submitted to the IRB.

Actions no longer remain in ancillary review dashboard inbox if review not accepted
Previously, if the outcome of an ancillary review was denied (they did not "accept" the ancillary review), that submission would remain in the reviewer's dashboard inbox (making those assigned think it was still an action item). Now, whether the ancillary reviewer accepts the review or denies it, the submission will be removed from the inbox of the assigned reviewers for all modules (IRB, SRC, RSC) once completed.

E-mail notifications for comments will now display the content of comment in the body of the email
When a private or public comment was added in the workspace, the recipient of the notification saw only a link to the comment in the notification e-mail. Now, the content of the comment will display in the actual email that is sent to the recipient. This means the recipient can view the comment without having to log into the system. The function is present in all modules (IRB, SRC, RSC).

Display protocol short title on SRC submissions
Previously, on the Scientific Review workspace only the IRB Parent Study number would appear in the heading. We have added the protocol short study title to also appear in the heading. The caption for the protocol number is updated to read "IRB Parent Study ID" and the protocol short title will be listed underneath the protocol number after the caption "IRB Parent Study Title".

Links to IRB Expedited Actions Report removed from SRC and RSC meeting workspaces
The IRB expedited actions report was displaying in the meeting workspace of SRC and RSC meetings. This link should not be visible to SRC and RSC members and does not need to be on these workspaces. We have removed the IRB expedited actions report from the SRC and RSC committee meeting workspaces.