PROTECT July 12, 2023 Release Notes

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

ALL Projects (IRB/RSC/SRC)| New columns added to Dashboard's 'My Inbox' and 'My Reviews' tab
We have added additional columns to the My Inbox and My Reviews tabs on the Dashboard. These new columns will provide additional information and make the submissions easier to identify from the dashboard. These were added to the "My Inbox" and "My Reviews" tabs of the Dashboard as well as the "My Inbox" tab of the IRB Central Staff Dashboard and the SRC Central Staff Dashboard. The additional columns added are:

1. PI Last Name
2. PI first name
3. IC (of PI)
4. Parent protocol expiration date

ALL Projects (IRB/RSC/SRC)| Submit Ancillary Review email notifications now go out for all follow-on submission types
When we turned on email notifications for IRB/RSC/SRC ancillary reviews in a recent release, they were only working on <u>initial</u> submissions. They are now working on <u>all</u> follow-on submission types (MODs, CRs, etc.)

Scientific Review Project | 'Deferred' outcome and workflow has been added
Users who are SR specialists or designated (expedited) reviewers will now be able to select an outcome of "Deferred" on the *Submit Committee Review* and *Submit Expedited Review* activities in the Scientific Review (SR) project. As such, when this outcome is selected, and the Deferred letter is sent to the research team using the Send Letter activity, the SR will transition to a new 'Deferred' state on the upper left-hand side of the workspace. This places the SR back in the research team's court in an editable state where they may address the requirements from the SR and then submit back to the SRC so they may resume their review.

Scientific Review Project | SR projects that are "Waived" will not receive annual/quad review deadline reminder emails
One scenario was overlooked when considering when SRC deadline reminders should be sent - when SRs are waived, they do not require reminders emails to tell users to submit Annual or Quadrennial reviews. We have fixed this so that those are no longer sent if a determination of "Waiver Approved" is selected on the *Submit Committee Review* activity or *Submit Expedited Review* activity for any SR submission.

Scientific Review Project | SRC Specialists can now "Update Documents" for an SR meeting
SRC Specialists can now run the *Update Documents* activity on an SR meeting workspace, allowing them to add additional documents for the committee to review at that meeting. These documents will then appear on the Supporting Documents tab of the SRC meeting workspace.

Scientific Review Project | Display of documents in a SR MOD has been fixed
The documents displaying on the SR form with a MOD have been incorrectly displaying the IRB approved

versions, not the documents updated on the existing MOD that is in process. This has been fixed so that the documents that are updated with the MOD will display in the SR MOD workspace.

NOTE: When we went live with PROTECT, we did not migrate any SRC or RSC projects from iRIS, only the IRB project. The first time you create any type of SR or RSC project in PROTECT, the system codes it as an "initial review" (even if it is a MOD/AR/QUAD review form). If the first SR project created in PROTECT is a MOD (such as in the case of a migrated study), the system will code it as an initial review, and documents updated in the MOD are <u>not</u> going to pull into the SRC form or Documents tab on the SR workspace for those actions. Users will need to go to the IRB MOD workspace/form to view the docs associated with this SRC MOD.

Eventually, this will not be a problem as an AR, at minimum, should be in the system for all protocols within one year, after which point this will no longer be an issue.

IRB Project | 'Manage Guest List' activity now available for Single Site External studies
Previously, the *Manage Guest List* activity was not available for Single Site External studies. This has been fixed and study teams should be able to run this now on all studies.

IRB Project | IRB 'Unassigned' tab now has accurate 'Parent Protocol #'
On the IRB Project tab, Unassigned sub-tab there is a column called 'Parent Protocol #'. This was Not displaying the IDs for all types of actions previously. This has now been resolved for all actions types except RNI.

IRB Project | IRB Meeting workspace agenda and printable agenda are in same order *(IRB Staff Use Only)*
Previously, the agenda items on the IRB meeting workspace and the agenda items that appear on the IRB meeting printable agenda and minutes documents were in differing orders, creating some confusion for IRB members and IRB staff when preparing for and conducting the meeting. These are aligned now so that the order of submission types being reviewed flow in the same order in both places now, making it easier for users to conduct their work before, during, and after the meetings. Also, this same order has been applied to the IRB Meeting Minutes to assist the staff with finalizing post-meeting activities.