

PROTECT April 19, 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](#).

General Fixes

DEC review question for MOD and CR forms

Up until this time, there was no logic built into the IRB workflow for CRs/MODs to block IRB approval if DEC review was not completed. This has now been fixed and a new trigger question “Does this action require review by your IC DEC office?” now appears on both the MOD, CR and MOD/CR forms. If you answer “yes” to this question, then the action will not be able to be approved by the IRB until DEC approval has been completed.

‘Finalize Updates’ activity - Hide activity from PI/Study Team

The Finalize Updates activity was incorrectly appearing for the PI/Study Team for external single site studies when this is an IRB Staff activity. We have revised this, so it no longer appears for the PI/Study Team.

Scientific Review (SR) committee name on parent SR application

There was a bug where the SR Committee Name was disappearing on the parent study application after a MOD was created that required Scientific Review for migrated protocols. This has been fixed so that the committee’s name remains on the parent study application.

Consent stamp on External IRB studies

The consent stamp was not working on external IRB studies (both single site and multisite). This has been fixed and a stamp with the NIH IRB number will now appear on the finalized documents for these studies. The date of approval will not appear as it is the external IRB who has approved the consent (not the NIH IRB).

Parent ID Number displays on My Reviews and My Inbox

On the *My Reviews* and *My Inbox* tabs of the Dashboard, users will now see a Parent ID column. This, in most cases, will display the parent study number. In some cases, such as RSC projects and RNIs, it will not be able to show the parent study number.

Expedited Scientific Reviews showing on Reviews tab

The SR specialists could not see the expedited non-committee reviews under the Reviews tab for the submission. They were only seeing the Final Reviewer’s comments. This has been fixed.

Revised question text on Local Study Team Members question

Question 2 on the Local Study Team Members page has been revised as follows:

Q2. List external team member(s) who are engaged in this research project, work as part of the NIH team at the NIH site, under the direction of the NIH PI, and who are not in NED:

(For example, non-NIH investigators covered by the NIH FWA via an IIA or FWA Coverage Agreement, or those relying on the NIH IRB via a reliance agreement only when the above conditions apply. Do not add collaborators who are not engaged in human subjects research in this section.)

Permissions/Access Fixes

Scientific Review Coordinators (SRC) unable to view parent study/follow-on submissions

Some SRC coordinators reported being unable to view parent studies and the follow-on submissions for the scientific review submissions they had access to. A permissions fix has been implemented to repair this.

Proxy unable to see the study

Users reported being added as proxies to a study but still not being able to view the study. A permissions fix has been implemented to repair this.

DEC Ancillary Reviewers lost access to their reviews

DEC Ancillary Reviewers reported having access to some of their reviews and then no longer being able to view them. A permissions fix has been implemented to repair this.

Study team members lost access to their studies

Study team members reported losing access to some of their studies. A permissions fix has been implemented to repair this.

MOD/CR button being displayed for Study Team

Some study team members reported not being able to see the 'Create MOD/CR' button on some of their studies. A permissions fix has been implemented to repair this.