

June 27, 2024, Release notes

New Feature for SRC Specialists to 'Close Scientific Reviews'

We have added a new activity called '**Close SR**'. The '**Close SR**' activity allows the Scientific Review Specialists at each IC to close **Approved Initial Scientific Review submissions** that no longer require review (e.g. The IRB study has been closed or the study is in data analysis). Once the SR specialist runs this activity the Approved Initial Scientific Review submission then moves to the 'SR Closed' state and can be later found on the Scientific Review tab > Archived tab.

Note: SRC Specialists may only close SRC Initial Reviews with this activity. If any SR Mods, Quads, or Annuals are in-process (not yet approved) when the Approved Initial Scientific Review is closed, the system will automatically discard these other SR submissions and move them all into a 'Discarded' state.

After the Initial Scientific Review moves to SR Closed state, the Study Team will receive an email notifying them that their IC SRC has closed their SR submission. The study team will no longer receive unnecessary system notification reminders to submit Annual and Quadrennial reviews.

In addition, when the SR project is closed, the question in the IRB MOD form that states: "Is Scientific Review required for this modification?" will now default to "no" (since SR is no longer needed).

Revised SRC User Guides:

SRC Researchers Guide

SRC Staff Guide

Located in PROTECT > SRC tab > *Help Center* tab > *Guides* tab

New Ancillary Review for Human Fetal Tissue Review

The intramural procedures for managing human fetal tissue (HFT) oversight review have changed and are found in the Sourcebook at: <https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations>

For new use of HFT, the PI must first initiate a new IRB protocol or modify an existing IRB protocol in PROTECT, and within PROTECT manage the "ancillary review" for the proposed use of human fetal tissue. The PI is required to download and fill out an HFT [ancillary review form](#) (located in the PROTECT Library) and have it signed by the Scientific Director or their delegate, and then attach the signed form to the HFT ancillary review in PROTECT. The HFT ancillary review form contains new fields that add additional criteria for the use of HFT and replaces the Intramural Research Program (IRP) use of "Attestation" forms. The review of the proposed use of HFT will be managed by the Agency Intramural Research Integrity Office. Only when the ancillary review is completed and the use of HFT is approved, will the IRB act upon the submitted protocol or modification.

The new process will ensure that human fetal tissue is used for non-transplantation research in the IRP only when scientifically justifiable, in the least amount possible to achieve scientific outcomes, and to ensure that the acquisition and use of human fetal tissue by the IRP complies with all applicable laws and HHS/NIH policies. This process has been approved by the Board of Scientific and Clinical Directors and by the Deputy Director for Intramural Research.

Researchers are reminded that they must secure approval prior to any new acquisition of, or commencing work with, human fetal tissue. Please contact kathryn.partin@nih.gov if you have any questions about using human fetal tissue.

New HFT User Guides:

HFT Researchers Guide

HFT Reviewer Guide

Located in PROTECT > IRB tab > Help Center tab > Guides tab

Revised Tip Sheets:

[PROTECT Training and Tip Sheets \(nih.gov\)](#)

Upcoming Education:

Please join us in the upcoming sessions to go over these recent changes in detail:

PROTECT Updates: June 2024 Release

Date: July 9, 2024

Audience: All system users

Content: The PROTECT Trainers will give an overview of the changes made in the PROTECT June 2024

Release: new Human Fetal Tissue Ancillary Review functionality in the system as well as the new Scientific Review Closure functionality.

Format: Teams Presentation, Recorded

Class link: [PROTECT Training and Tip Sheets \(nih.gov\)](#)

Close Scientific Review class

Date: July 10, 2024

Audience: Scientific Review Specialists

Content: The PROTECT Trainers will give a step-by-step demo of the workflow for closing an SR from the perspective of a SR specialist. This will be recorded and hosted on our website for later viewing.

Format: Teams Presentation, Recorded

Class link: [PROTECT Training and Tip Sheets \(nih.gov\)](#)