PROTECT Tip Sheet for *Research Teams:* *"Managing Ancillary Reviews"*

What are ancillary reviews in PROTECT?

Ancillary reviews are reviews that can be managed and signed off in the system, if required. The study team can manage these reviews on either the IRB, Scientific Review, or Radiation Safety workspaces, and assign an ancillary "reviewer" access to the project so they can view it (and sign off on it, if required). Some of these reviews are considered "blocking" and the system will stop the submission from moving forward in the workflow if the ancillary reviewer has not submitted their review by a certain timepoint in the workflow.

Which ancillary reviews are handled in the system, and which are "blocking"?

IRB Submissions	
IBC	**Blocking** Must be managed and reviewer accepted before IRB submission is ASSIGNED FOR IRB REVIEW.
PRIA/Pharmacy	**Not Blocking** Just allows reviewer read-only access to the submission and sends them a notification. We do still ask, for this purpose, that study teams manage these reviews when a submission requiring these reviews is initially submitted or modified.
DEC	**Blocking** Must be managed and reviewer accepted before IRB submission is IRB APPROVED.
Human Fetal Tissue	**Blocking** Must be managed and reviewer accepted before Initial IRB submission is IRB APPROVED. ***Note: System does not block MODs involving HFT.***

Scientific Review Submissions	
Lab Chief/ Branch Chief/ Accountable Investigator	**Not Blocking** Should be managed by study team prior to submitting the SRC Submission, if required by IC.
Clincal Director/ (Or IC Director/ Scientific Director - if CD has conflict)	**Not Blocking** Should be managed by the SRC Coordinator after SRC approval, but before the final SR approval letter is sent.
Chief Scientific Officer	**Not Blocking** Should be managed by SRC Coordinator after SRC approval, but before final SR approval letter is sent.

Radiation Safety Submissions	
Clinically Authorized User	**Not Blocking** Should be managed and reviewer accepted before RSC starts specialist pre-review.

figure 1

Where can I learn more about the various ancillary reviews?

You can read more about some of NIH ancillary reviews on our website here - [NIH Ancillary Reviews](#).

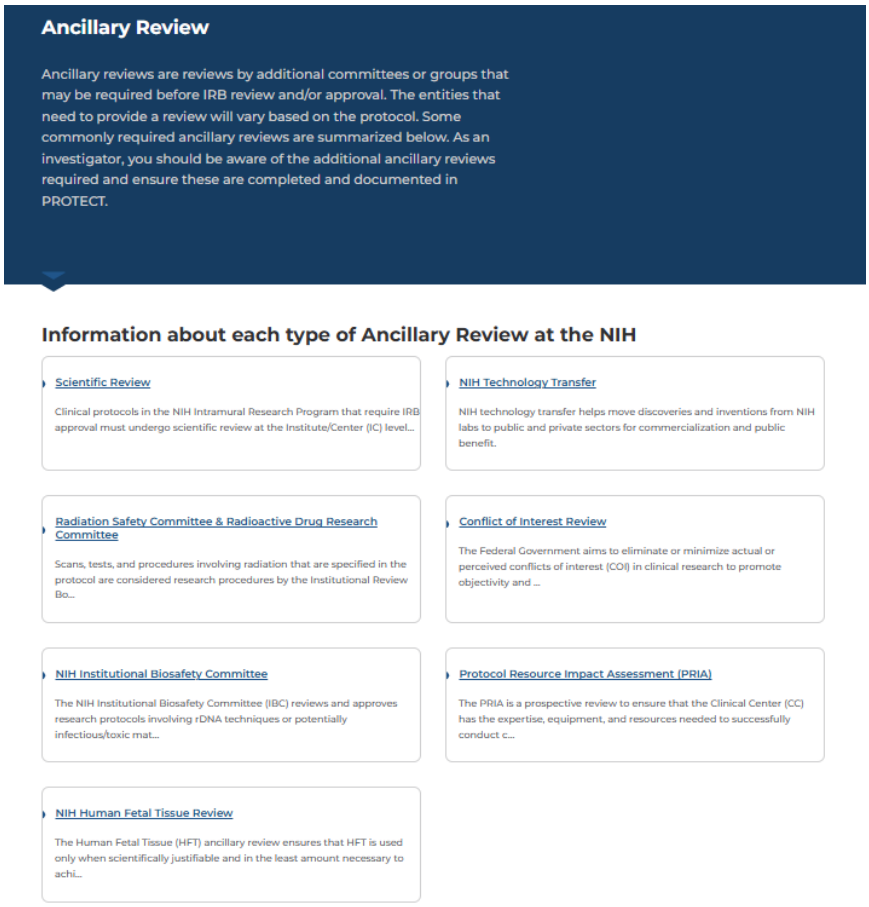

figure 2

Where can I learn more about how to manage ancillary reviews in PROTECT?

The PROTECT system contains user guides for each user role type: Researchers, Reviewers, and Committee Staff. Within these guides are instructions for researchers on how to manage the ancillary reviews and how each behaves in the system. These guides can be found in PROTECT as shown below using the numbered steps:

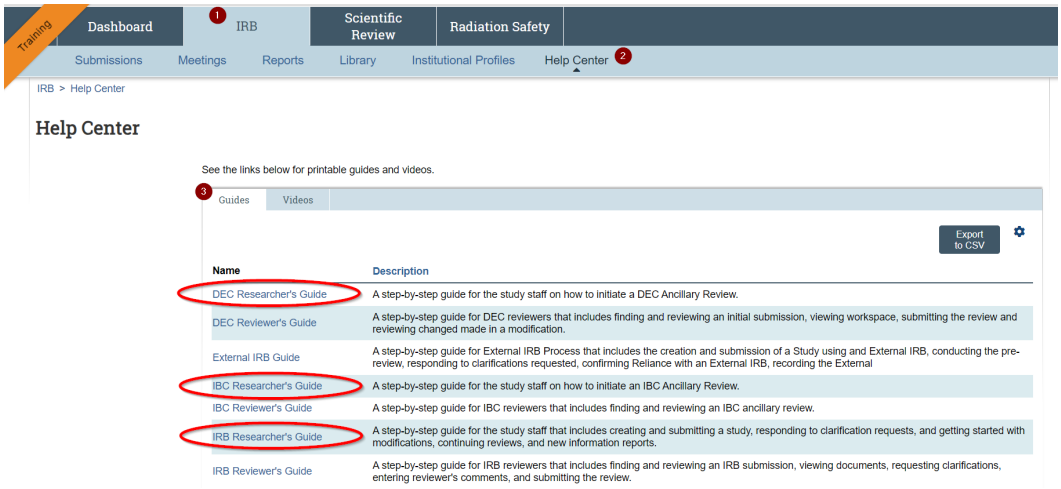

figure 3

How do I manage ancillary reviews?

NOTE: See relevant user guides in figure 3 for specific instructions. In addition, 'Quick Steps' are below.

- Go to the workspace for your respective ancillary review (See *figure 1* for which workspace each ancillary type gets managed on.)
- 1 Click the ***Manage Ancillary Reviews*** activity.
- 2 Click ***Add***.
- 3 Choose a ***Review Type***. (Ex. DEC, PRIA, IBC)
- 4 Select a ***Review Group***. (Ex. DEC: CC, or DEC: NCI). * Choosing the correct ***Review Type*** and ***Review Group*** allows each group the read access they need. NOTE: If you choose the wrong group, they won't see the submission and you will have to revise it so that the correct users see the submission.
- 5 Click ***OK*** to finish. *(**NOTE:** For IRB ancillaries, like DEC, HFT, or IBC, the reviewer will only see the review in their inbox and get an email notification once the project is submitted to IRB and is in the IRB's dashboard. For Scientific Review ancillary types, like Branch Chief, the reviewer sees it and can do their review right away since those signoffs are required prior to IRB submission.)*

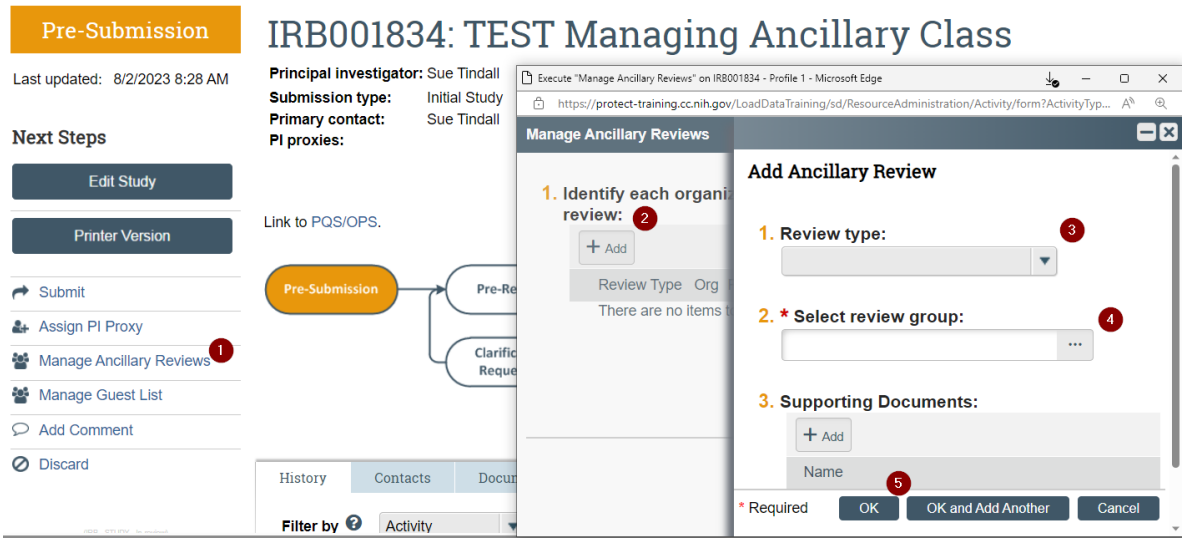

figure 4

How do ancillary reviewers know they have been assigned an ancillary review?

Reviewers receive the email notification below (*figure 5*) once the IRB project is submitted. They can then see the project in their inbox and in the My Reviews tab.

Template:IRB_A_Submit_AncillaryReview_Organization NIH

Notification of Ancillary Review

To: Tiffany Gommel

Link: IRB001834

P.I.: Sue Tindall

Title: **TEST Managing Ancillary Class**

Required: **No**

Description: An IRB submission has been assigned for ancillary review.
Click the link above to access and review the study.

figure 5

How do I know that an ancillary reviewer has submitted their ancillary review?

Once reviewers run the Submit Ancillary Review activity, the system sends the notification below (figure 6) to the PI, Proxies, and Primary Contact. You may also view the Reviews tab (figure 7) of a submission at any time to check status of reviews. You should see a "Yes" under the accepted column next to the review if the reviewer has accepted and completed their review.

Template:NIH: Ancillary Review Submitted

Notification of Ancillary Review

To: Tiffany Gommel

Link: IRB001834

P.I.: Sue Tindall

Title: TEST Managing Ancillary Class

Description: Your ancillary review has been completed in PROTECT.

Click the link above to access and review the study.

figure 6

Ancillary Reviews

Review Type	Organization	Person	Reqd	Accepted	Comments	Docs
DEC	DEC: CC	[redacted]	yes	yes		
Human Fetal Tissue (HFT)	HFT	[redacted]	yes	yes		
PRIA	PRIA	[redacted]	yes			

figure 7

Questions

For additional questions or help using the PROTECT system, please submit a PROTECT Help Desk ticket and our IT staff will assist you.