

# 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	<b>Blocking</b> Must be managed and reviewer accepted before IRB submission is ASSIGNED FOR IRB REVIEW.
PRIA/Pharmacy	<b>Not Blocking</b> 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	<b>Blocking</b> Must be managed and reviewer accepted before IRB submission is IRB APPROVED.
Human Fetal Tissue	<b>Blocking</b> Must be managed and reviewer accepted before Initial IRB submission is IRB APPROVED. <i>Note: System does not block MODs involving HFT.</i>
Scientific Review Submissions	
Lab Chief/ Branch Chief/ Accountable Investigator	<b>Not Blocking</b> Should be managed by study team prior to submitting the SRC Submission, if required by IC.
Clinical Director/ (Or IC Director/ Scientific Director - if CD has conflict)	<b>Not Blocking</b> Should be managed by the SRC Coordinator after SRC approval, but before the final SR approval letter is sent.
Chief Scientific Officer	<b>Not Blocking</b> Should be managed by SRC Coordinator after SRC approval, but before final SR approval letter is sent.
Radiation Safety Submissions	
Clinically Authorized User	<b>Not Blocking</b> 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](#).

### Ancillary Review

Ancillary reviews are reviews by additional committees or groups that may be required before IRB review and/or approval. The entities that need to provide a review will vary based on the protocol. Some commonly required ancillary reviews are summarized below. As an investigator, you should be aware of the additional ancillary reviews required and ensure these are completed and documented in PROTECT.

#### Information about each type of Ancillary Review at the NIH

- Scientific Review**  
Clinical protocols in the NIH Intramural Research Program that require IRB approval must undergo scientific review at the Institute/Center (IC) level...
- NIH Technology Transfer**  
NIH technology transfer helps move discoveries and inventions from NIH labs to public and private sectors for commercialization and public benefit.
- Radiation Safety Committee & Radioactive Drug Research Committee**  
Scans, tests, and procedures involving radiation that are specified in the protocol are considered research procedures by the Institutional Review Bo...
- Conflict of Interest Review**  
The Federal Government aims to eliminate or minimize actual or perceived conflicts of interest (COI) in clinical research to promote objectivity and ...
- NIH Institutional Biosafety Committee**  
The NIH Institutional Biosafety Committee (IBC) reviews and approves research protocols involving rDNA techniques or potentially infectious/toxic mat...
- Protocol Resource Impact Assessment (PRIA)**  
The PRIA is a prospective review to ensure that the Clinical Center (CC) has the expertise, equipment, and resources needed to successfully conduct c...
- NIH Human Fetal Tissue Review**  
The Human Fetal Tissue (HFT) ancillary review ensures that HFT is used only when scientifically justifiable and in the least amount necessary to achi...

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:

Dashboard | IRB (1) | Scientific Review | Radiation Safety | Help Center (2)

Submissions | Meetings | Reports | Library | Institutional Profiles | Help Center (2)

### Help Center

See the links below for printable guides and videos.

Guides | Videos

Name	Description
DEC Researcher's Guide	A step-by-step guide for the study staff on how to initiate a DEC Ancillary Review.
DEC Reviewer's Guide	A step-by-step guide for DEC reviewers that includes finding and reviewing an initial submission, viewing workspace, submitting the review and reviewing changed made in a modification.
External IRB Guide	A step-by-step guide for External IRB Process that includes the creation and submission of a Study using an External IRB, conducting the pre-review, responding to clarifications requested, confirming Reliance with an External IRB, recording the External
IBC Researcher's Guide	A step-by-step guide for the study staff on how to initiate an IBC Ancillary Review.
IBC Reviewer's Guide	A step-by-step guide for IBC reviewers that includes finding and reviewing an IBC ancillary review.
IRB Researcher's Guide	A step-by-step guide for the study staff that includes creating and submitting a study, responding to clarification requests, and getting started with modifications, continuing reviews, and new information reports.
IRB Reviewer's Guide	A step-by-step guide for IRB reviewers that includes finding and reviewing an IRB submission, viewing documents, requesting clarifications, entering reviewer's comments, and submitting the review.

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.)

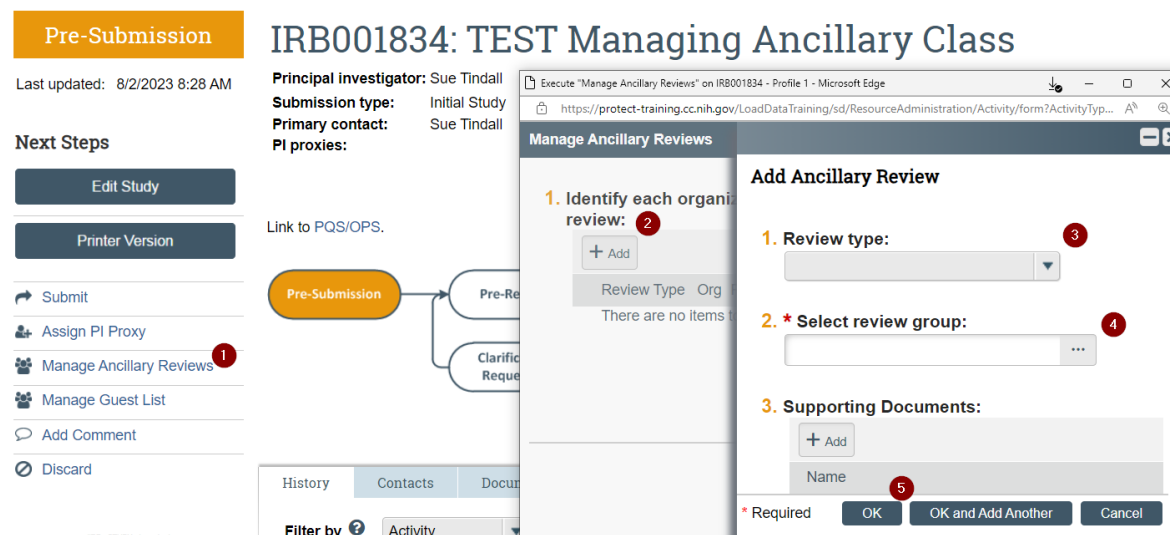


figure 4

### 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	Sidney Chen Joe Park Boonrod Dinapo Milly Deo Wade Boudie	yes	yes		
Human Fetal Tissue (HFT)	HFT	Kathy Fuchs	yes	yes		
PRIA	PRIA	Burna Singh Colleen Hodgson Annie Kellogg Madeline Deming Leslie Watson	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.