

PROTECT Tip Sheet for Research Teams: “Managing Ancillary Reviews”

What are ancillary reviews?

Ancillary reviews are reviews that can be managed and signed off in the PROTECT system, if required (*figure 1 shows which are required and by when*). The study team can manage these reviews on either the IRB, Scientific Review, or Radiation Safety submissions. 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.

Which ancillary reviews are required, 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.
PRAC	Not Blocking NOTE: Study Teams are not required to manage this themselves. Is managed by IRB Analyst when required. Is signed off on by Heather Bridge.
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.
Clinical 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 at NIH IRP?

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 achl...	

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:

See the links below for printable guides and 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 submission, such as a new IRB Study or a MOD, etc. (See *figure 1* for which workspace each ancillary type gets managed on.)
- **1** Click the **Manage Ancillary Reviews** activity on the left.
- **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 reviewers for each group to have the read-access they need.
- **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 Pre-Review state. 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.)

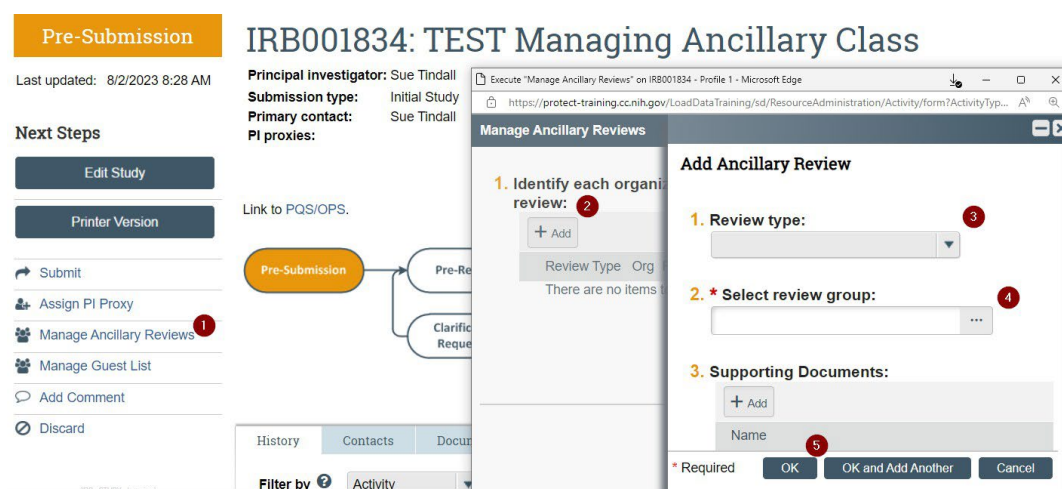


figure 4

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

Reviewers receive the email notification below (*figure 5*) once the ancillary review activity is run, and in the IRB case, when the IRB project is submitted and it is in Pre-Review state. They can then see the project in their **Inbox** and in the **My Reviews** tab, from their PROTECT Dashboard.

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 on the study. 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 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 Ford Deborah Drago Molly Ford Blake Rindole	yes	yes		
Human Fetal Tissue (HFT)	HFT	Kathy Foster	yes	yes		
PRIA	PRIA	Burke Singh Colleen Hodgson Annie Kellogg Madeline Dearing Leslie Watson	yes			

figure 7

How do I CHANGE an Ancillary Review if assigned incorrectly?

If the wrong ancillary review type or review group (ex. wrong DEC IC) was selected, you will have to **DELETE** your entire Ancillary Review and start over if you want the newly assigned ancillary reviewers to get email notification of their review.

IMPORTANT: Clicking **UPDATE** on the Manage Ancillary Review activity and using this activity to correct an ancillary review will place the item in the new reviewer’s inbox, but will **NOT** send an email.

Manage Ancillary Reviews

1. Identify each organization or person that should provide additional review:

+ Add

Review Type	Org	Person	Reqd	Accepted	Comments	Docs
Update DEC	DEC: CC		yes			

Update does not send new reviewers emails!

Instead, follow these steps to revise an ancillary if it was set up incorrectly:

The screenshot shows the 'Manage Ancillary Reviews' page in the PROTECT system. On the left is a sidebar with a 'Pre-Submission' banner and a list of 'Next Steps' including 'Edit Study', 'Printer Version', 'Submit', 'Assign Primary Contact', 'Assign PI Proxy', 'Manage Ancillary Reviews', 'Manage Guest List', and 'Add Comment'. The main content area is titled 'Manage Ancillary Reviews' and contains a section '1. Identify each organization or person that should provide additional review:'. This section has an '+ Add' button and a table with columns: Review Type, Org, Person, Reqd, Accepted, Comments, and Docs. A table row is visible with 'DEC' in the Review Type column, 'DEC: CC' in the Org column, and 'yes' in the Reqd column. An 'Update' button is next to this row. A red callout '1' points to the 'Manage Ancillary Reviews' link in the sidebar with the text 'Run this activity to correct it'. Another red callout '2' points to a small 'X' icon in the top right of the table with the text 'Click the X to delete the incorrect Ancillary...'. A third red callout '3' points to an 'OK' button at the bottom right with the text 'Click OK to finish, and go Manage Ancillary Review correctly on your workspace'.

1. Run this activity to correct it

2. Click the X to delete the incorrect Ancillary...

3. Click OK to finish, and go Manage Ancillary Review correctly on your workspace

Questions

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