

# PROTECT Tip Sheet for ANCILLARY REVIEWERS

**Audience:** This tip sheet shows the following ancillary reviewers how to view and submit their ancillary reviews (*\*if required, fig 1*): DEC, PRIA, PRAC, IBC, HFT, Pharmacy, Clinical Director, Branch Chief, Lab Chief, Chief Scientific Officer, IC Director, Scientific Director, Accountable Investigator, and in the case of Radiation Safety – the Clinically Authorized User)

## Overview:

PROTECT accommodates many Ancillary Reviews. These are set up by the study team using the **Manage Ancillary Reviews** activity. This activity gives the ancillary reviewer access to view (or read) the submission and, when required, sign off on it using the **Submit Ancillary Review** activity.

*Which ancillary reviews are required, and which are “blocking”?*

| IRB Submissions                                                                        |                                                                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| IBC                                                                                    | <b>Blocking</b><br>Must be managed and reviewer accepted before IRB submission is ASSIGNED FOR IRB REVIEW.                                                                                                                                                           |
| PRIA/Pharmacy                                                                          | <b>Not Blocking</b><br>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                                                                                   | <b>Not Blocking</b><br>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                                                                                    | <b>Blocking</b><br>Must be managed and reviewer accepted before IRB submission is IRB APPROVED.                                                                                                                                                                      |
| Human Fetal Tissue                                                                     | <b>Blocking</b><br>Must be managed and reviewer accepted before Initial IRB submission is IRB APPROVED.<br>Note: System does NOT block MODs involving HFT.                                                                                                           |
| Scientific Review Submissions                                                          |                                                                                                                                                                                                                                                                      |
| Lab Chief/<br>Branch Chief/<br>Accountable Investigator                                | <b>Not Blocking</b><br>Should be managed by study team prior to submitting the SRC Submission, if required by IC.                                                                                                                                                    |
| Clinical Director/<br>(Or IC Director/<br>Scientific Director -<br>if CD has conflict) | <b>Not Blocking</b><br>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><br>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><br>Should be managed and reviewer accepted before RSC starts specialist pre-review.                                                                                                                                                              |

figure 1

## Basic steps:

### Step 1 – How to receive/find your ancillary reviews

- You will be sent an e-mail notification when a study team member **Manages Ancillary Reviews**

(this assigns you as an ancillary reviewer and allows you to then see the submission). The notification contains a link directly to the submission workspace. Click on it to open it and review:

#### Notification of Ancillary Review

To: Tiffany Gommel

Link: **CR001148**

P.I.: Michail Lionakis

Title: Continuing Review for Study Ruxolitinib in APECED

Required: No

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

- You may also find your ancillary reviews by logging into [PROTECT](#) and going to your **Dashboard**: Click **'My Inbox' > 'My Reviews' > and click on the submission link in your inbox tab** to view more:

The screenshot shows the NIH PROTECT dashboard. The 'My Inbox' tab is selected, displaying a table of submissions. A red box highlights the submission CR001148, which is titled 'Continuing Review for Study Ruxolitinib in APECED'. The table columns include ID, Name, Date Created, Date Modified, State, Coordinator, and Parent ID.

| ID          | Name                                                                      | Date Created       | Date Modified     | State            | Coordinator     | Parent ID |
|-------------|---------------------------------------------------------------------------|--------------------|-------------------|------------------|-----------------|-----------|
| MODCR000714 | Modification and Continuing Review #1 for Study Biomarker guided MS trial | 10/24/2023 1:53 PM | 1/17/2024 9:13 AM | Committee Review | Brenna Hansen   | 1710083   |
| MOD0005522  | Modification / Update #5 for Study Alirocumab in AUD                      | 11/8/2023 10:00 AM | 1/17/2024 9:13 AM | Committee Review | Michael Chapple | 000036    |
| CR001148    | Continuing Review for Study Ruxolitinib in APECED                         | 11/14/2023 2:48 PM | 1/17/2024 9:12 AM | Committee Review | Emma Staller    | 000051    |

## Step 2 – Reviewing contents of the submission

- View the submission SmartForm (application)**

For initial reviews, you can review the SmartForm application <sup>1</sup> and Documents & Contacts tab <sup>2</sup> to review the IRB submission as well as any study documents and study team members:

The screenshot shows the NIH PROTECT submission workspace for MOD0005522: Modification / Update #5 for Study Alirocumab in AUD. The 'Documents & Contacts' tab is selected, displaying a list of study-related documents. The 'Next Steps' section shows a workflow diagram with 'IRB Review' highlighted. The 'Study Related Documents' table lists various documents, including drafts and final versions, with columns for Draft, Updated in Modification, Category, Is Active?, Final, Last Finalized, and Document History.

| Draft                              | Updated in Modification | Category        | Is Active? | Final                              | Last Finalized     | Document History |
|------------------------------------|-------------------------|-----------------|------------|------------------------------------|--------------------|------------------|
| Version Date 08Nov2023             | Yes                     | IRB Protocol    | yes        | Version Date 15May2023             | 6/6/2023 7:47 AM   | History          |
| Alirocumab package insert 2017.pdf | No                      | Drug Attachment | yes        | Alirocumab package insert 2017.pdf | 3/22/2023 11:06 AM | History          |
| IND Exemption                      | No                      | Drug Attachment | yes        | IND Exemption                      | 2/10/2023 8:49 AM  | History          |

- **Review any attachments attached to the Ancillary Review**

You may also click the 'Reviews' tab on the workspace to see any documents the study team has attached to their ancillary review for you to see:

**Pre-Review**  
 Entered IRB: 6/18/2024 5:40 PM  
 Last updated: 6/20/2024 10:15 AM

**Next Steps**  
 View Study  
 Print Version

Submit Pre-Review  
 Request Pre-Review Clarification  
 Manage Participating Sites  
 Assign Coordinator  
 Assign Primary Contact  
 Assign PI Proxy  
 Assign IRB  
 Manage Ancillary Reviews  
 Manage Guest List  
 Add Comment  
 Add Private Comment  
 Copy Submission  
 Withdraw  
 Discard

Principal Investigator: [Redacted]  
 Submission type: Initial Study  
 Primary contact: [Redacted]  
 PI proxies: [Redacted]

IRB office: NIH IRB  
 IRB coordinator: [Redacted]

Letter:

Link to PQS/OPS:

Workflow: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete  
 Clarification Requested (between Pre-Submission and Pre-Review, and IRB Review and Post-Review)  
 Modifications Required (between Post-Review and Review Complete)

History | Contacts | Documents | Sites | IRB Assignment Details | **Reviews** | Snapshots | Associated Projects | ...

There is no Pre-Review to display at this time.  
 There is no Non-Committee Review to display at this time.  
 There is no Committee Review to display at this time.

**Ancillary Reviews**

| Review Type | Organization | Person                                                                                                                                                                                                                      | Reqd | Accepted | Comments | Docs                                                                                          |
|-------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|----------|----------|-----------------------------------------------------------------------------------------------|
| DEC         | DEC: NHLBI   | Shema Teymourian<br>Patricia Reilly<br>Haley Gottfried<br>Andre Jobst<br>Karan Doleon<br>James DeBili<br>Azza Alamin                                                                                                        | yes  |          |          | 2 IRB002084_List of study AIs_18JUN2024.pdf                                                   |
| Pharmacy    | Pharmacy     | Leslie Anforth<br>Janell Krack<br>Paula Barton Mann<br>Crystal Lu<br>Ying Cheung<br>Gerald Overman<br>Christie Colter<br>Willy Li<br>Shiny Telscher<br>Robbie Kattappuram<br>Schaun Norman<br>Reem Shalabi<br>Nicole Rinker | yes  |          |          | 3 Fostamatinib package insert.pdf<br>Fostamatinib-invBrochure-V22_Final_30May2023_signed_.pdf |

- You may want to use the 'Compare' feature to see what is changing if it is a Modification. Also, in the case of any submission, the 'Compare' button will show you changes that were made if submission went back and forth between the IRB and the study team in Pre-Review. *Note that there are little pencil icons on the left bookmark bar to show you which pages of the application have changes on them. You can click on these page names and the form will auto navigate to those pages.*

NIH PROTECT  
 National Institutes of Health

**Compare**

Changes found on 2 steps:

**Modification / Continuing Review**

Modification Summary  
 Modification Details

▼ IRB00001012

Basic Study Information

Local Requirements  
 Study Scope  
 Local Research Locations  
 Drugs  
 Devices  
 Local Site Documents

You Are Here: Alirocumab in AUD > Modification / Update #5 for S...

Reading: MOD005522

**Modification / Continuing Review / Study Closure**

\* What is the purpose of this submission?  
☐ Continuing Review  
☒ Modification / Update  
☐ Modification and Continuing Review

1 To change the PI, choose 'Other parts of the study/site' scope  
**Modification scope:**  
 Other parts of the study

Active Modification For This Study

\* Is Scientific Review required for this modification?  
☒ Yes ☐ No

\* Does this action require review by your IC DEC office?  
☐ Yes ☒ No

The sections of the submission form, the study team members, and the study documents that have been revised will show as changes in a call-out box like this:

## Local Site Documents ?

### 1. Consent forms: ?

| Document                                                                             | Category     | Active | Date Modified | Document History        |
|--------------------------------------------------------------------------------------|--------------|--------|---------------|-------------------------|
| <a href="#">View</a> 13HG0053.1 Standard consent 20JUN2024.docx(0.07)                | Consent Form | yes    | 6/21/2024     | <a href="#">History</a> |
| <a href="#">View</a> 13HG0053.3 Healthy Volunteer consent 20JUN2024.docx(0.05)       | Consent Form | yes    | 6/21/2024     | <a href="#">History</a> |
| <a href="#">View</a> 13HG0053.5 ASSENT- Healthy Volunteer 31AUG2023.docx(0.03)       | Consent Form | yes    | 8/31/2023     | <a href="#">History</a> |
| <a href="#">View</a> 13HG0053.2 ASSENT- Standard Patient 31AUG2023.docx(0.03)        | Consent Form | yes    | 8/31/2023     | <a href="#">History</a> |
| <a href="#">View</a> 13HG0053.6 CONSENT - Off-Site Patient 31AUG2023.docx(0.02)      | Consent Form | yes    | 8/31/2023     | <a href="#">History</a> |
| <a href="#">View</a> 13HG0053.7 ASSENT - Off-Site Minor Patient 31AUG2023.docx(0.03) | Consent Form | yes    | 8/31/2023     | <a href="#">History</a> |

▼ Differences

**BY** Brenton Yanos • modified 17 minutes ago • version 5.3 (MOD008248: Changes submitted to IRB)

- **Changed:** 13HG0053.1 Standard consent 20JUN2024.docx
- **Changed:** 13HG0053.3 Healthy Volunteer consent 20JUN2024.docx

## Step 3 – Requesting info & Submitting your Ancillary Review

- **Request any additional information you might need to complete the review:**  
Click the **'Add Comment'** activity on the lefthand side of the workspace and fill out the form.

### Committee Review

Entered IRB: 12/13/2023 9:32 AM  
Last updated: 1/17/2024 9:13 AM

#### Next Steps

[View Modification/CR](#)

[Printer Version](#)

☒ Submit Ancillary Review

[Add Comment](#)

## MOD005522: Modification

**Principal investigator:** [Paul L. Landon](#)  
**Submission type:** Modification / Update  
**Primary contact:**

**Parent IRB:** 000036

[Link to PQS/OPS.](#)

Pre-Submission

Pre-Review

Clarification Requested

**NOTE: You are identifiable in the History Log if you use this activity:**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |          |           |         |              |           |                     |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-----------|---------|--------------|-----------|---------------------|----------|
| History                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Contacts | Documents | Reviews | Related RNIs | Snapshots | Associated Projects | Training |
| <div>Filter by  <div>Activity </div> <div>Enter text to search </div> <div>+ Add Filter  Clear All</div></div> <div>Activity <div>Author</div></div> <div> Comment Added <div>Deol, Molly</div></div> <div>Comments you add in the Add Comment box appear here in the History log for all to see.</div> |          |           |         |              |           |                     |          |

- The **Add Comment** activity does not send the submission back to the study team for edit, but it does notify them that you, the ancillary reviewer, has requested additional information in the History Log, and they respond by also using **Add Comment**. You will not get an email when they do this, but you can check back and see if they have entered a response to you in the History Log using **Add Comment**. *NOTE: Alternatively, if you do not feel comfortable reaching out to the study team in the system, you can always contact the PI or the Primary Contact via email to gain the missing information.*
- Submit your review: *(If required\* see fig 1)*

Click the **'Submit Ancillary Review'** activity on the submission workspace to enter your review.

Committee Review

Entered IRB: 12/13/2023 9:32 AM  
Last updated: 1/17/2024 9:29 AM

MOD005522: Modification / Upd

Principal investigator: Falk Lohoff  
Submission type: Modification / Update  
Primary contact:

Next Steps

View Modification/CR

Printer Version

☒ Submit Ancillary Review

Add Comment

Parent IRB: 000036

Link to PQS/OPS.

Pre-Submission

Pre-Review

Clarification Requested

IRB Review

Clarification Requested

*\* Note as outlined in the graphic on page 1 that PRIA and Pharmacy are the only two Ancillary Reviews that do NOT perform the 'Submit Ancillary Review' activity in the system. They are just given Read-Only access to the studies/submissions to be able to conduct their Resources and Drug reviews internally.*

Complete the short form seen below. <sup>1</sup> Check off your ancillary review you are submitting. <sup>2</sup> Accept the review. <sup>3</sup> Enter any comments. <sup>4</sup> Upload any required attachments for your review. Click OK. The submission will then leave your My Inbox tab on your Dashboard since you are done completing your review. The study team also gets notified that you have completed your review. Your review is finished and it will appear as complete on the Reviews tab for everyone to see.

Submit Ancillary Review

1. \* Select the review you are submitting:

| Organization                                         | Person | Review Type              | Required | Accepted |
|------------------------------------------------------|--------|--------------------------|----------|----------|
| <input checked="" type="checkbox"/> HFT <sup>1</sup> |        | Human Fetal Tissue (HFT) | yes      |          |

2. \* Do you accept the proposed study? <sup>2</sup>

☒ Yes
☐ No
[Clear](#)

3. Comments: <sup>3</sup>

Reviewed and I have approved

4. Supporting documents: <sup>4</sup>

+ Add

| Name                                                                  |
|-----------------------------------------------------------------------|
| PROTECT Tip Sheet for Ancillary Reviewers 05.07.2024_DRAFT.docx(0.01) |

## Questions/Help

For questions and support about the PROTECT system, please [submit a ticket](#) and our trainers will assist you.