

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*): DEC, PRIA, IBC, HFT, Pharmacy, Clinical Director, Branch Chief, Lab Chief, Chief Scientific Officer, IC Director, Scientific Director, Accountable Investigator)

Overview:

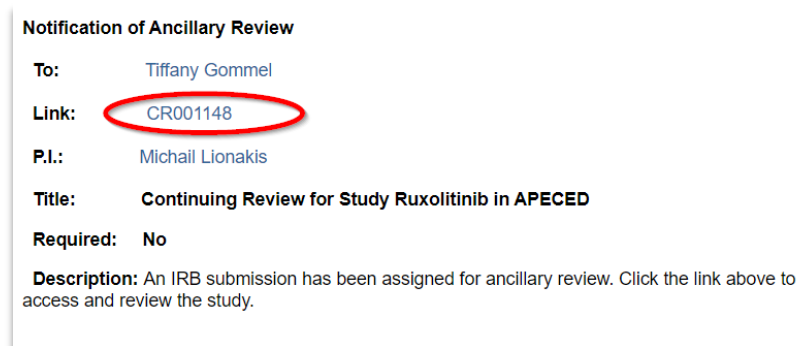
PROTECT accommodates many 'ancillary reviews'. These are set up by the study team using the **Manage Ancillary Reviews** activity. This activity gives the ancillary reviewer access to view (or read) the submission and, when required, sign off on it using the **Submit Ancillary Review** activity. The graphic below depicts which reviews are required, and which point in the workflow each submission is blocked if the ancillary review is incomplete.

| Review | Must be completed by |
|---|---|
| Scientific Review | Submission of study to IRB |
| Radiation Safety | Assigning of study to IRB Review |
| Institutional Biosafety | Assigning of study to IRB Review |
| DEC/HFT | IRB Approval |
| PRIA *Sign off not required | Not blocking – read only access |
| Pharmacy *Sign off not required | Not blocking – read only access |
| Accountable Investigator Branch Chief Lab Chief | Not blocking - Submission of study to SRC |
| Clinical Director | Not blocking - SRC Approval |
| Chief Scientific Officer | Not blocking - SRC Approval |

Basic steps:

Step 1 – Accessing your ancillary reviews

- You will be sent an e-mail notification when the study team member **Manages Ancillary Reviews** (assigns you as an ancillary reviewer). The notification contains a link to the submission workspace:



- You may also access your ancillary reviews by logging into [PROTECT](#) and going to your *Dashboard > My Inbox > My Reviews* Clicking on the submission link to be taken to its workspace:

Page for Molly Deol

My Inbox

Filter by ID Enter text to search + Add Filter X Clear All

| 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 |
| MOD005522 | Modification / Update #5 for Study Alocumab in AUD | 11/8/2023 10:00 AM | 1/17/2024 9:13 AM | Committee Review | Michael Chapple | 000036 |
| CR001103 | Continuing Review for Study Gulf War Illness (GWI) | 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 ¹ and Documents tab ²:

IRB > Alocumab in AUD > Modification / Update #5 for Study Alocumab in AUD

Committee Review

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

Principal Investigator: Falk Lehoff
Submission type: Modification / Update
Primary contact:

IRB office: NIH IRB
IRB coordinator: Michael Chapple
Regulatory authority: 2018 Requirements + FDA

Parent IRB: 000036
Link to PQS/OPS:

Next Steps: View Modification/CR, Printir Version, Submit Ancillary Review, Add Comment

Workflow: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

History: Contacts, Documents, Reviews, Related IRBs, Snapshots, Associated Projects, Training

| Draft | Updated in Modification | Category | Is Active? | Final | Last Finalized | Document History |
|----------------------------------|-------------------------|-----------------|------------|----------------------------------|--------------------|------------------|
| Version Date 09Nov2023 | Yes | IRB Protocol | yes | Version Date 15May2023 | 6/6/2023 7:47 AM | History |
| Alocumab package insert 2017.pdf | No | Drug Attachment | yes | Alocumab package insert 2017.pdf | 3/22/2023 11:56 AM | History |
| IND Exemption | No | Drug Attachment | yes | IND Exemption | 2/10/2023 8:49 AM | History |

| Draft | Updated in Modification | Category | Is Active? | Final | Last Finalized | Document History |
|---|-------------------------|--|------------|--|-------------------|------------------|
| Amendment memo 08Nov2023 | Yes | Summary of Changes (Modification - ONLY) | yes | | | History |
| Version Date 15May2023 | No | Consent Form | yes | Version Date 15May2023 | 6/6/2023 7:47 AM | History |
| RE_Study 000036 - Consent Quiz.pdf | No | Other | yes | | | History |
| 000036_Appendix 1_Recruitment Material_Revised 09Feb2023.docx | No | Recruitment Materials | yes | 000036_Appendix 1_Recruitment Material_Revised 09Feb2023.pdf | 2/10/2023 8:49 AM | History |
| 000036_1_Appendix 3_Recruitment Letter Template_04-25- | No | Recruitment Materials | yes | 000036_1_Appendix 3_Recruitment Letter Template_04-25- | 1/13/2023 2:25 | History |

- Review any documents associated with the Ancillary Review

You may also click the 'Reviews' tab on the workspace to see any documents the study team has

NIH PROTECT

National Institutes of Health

Compare

You Are Here: Variability in MMT

Reading: IRB001707

Go to forms menu Print Help

Basic Study Information

- Title of study:**
[Redacted]
- Short title (Limited to 30 characters including spaces):**
[Redacted]
- Brief description:**
[Redacted]

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](#)

[Printer 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](#)

IRB002084: Fostamatinib in Lung Transplan

Principal investigator: [\[Name\]](#)
Submission type: Initial Study
Primary contact: [\[Name\]](#)
PI proxies: [\[Name\]](#)

IRB office: NIH IRB
IRB coordinator: [\[Name\]](#)

Letter:

Link to PQS/OPS:



1

| 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 Patricia Reilly Haley Gottfried Andre Jobst Karen Deleon James DeBill Azza Alamin | yes | | 2 | IRB002084_List of study Als_18JUN2024.pdf | | |
| Pharmacy | Pharmacy | Leslie Anforth Janell Krack Paula Barton Mann Crystal Lu Ying Cheung Gerald Overman Christie Coker Willy Li Shinyi Telscher Robbie Kattappuram Schaun Norman Reem Shalabi Nicola Rinter | yes | | 3 | Fostamatinib package insert.pdf Fostamatinib-InvBrochure-V22_Final_30May2023_signed_.pdf | | |

- You may want to use the Compare feature to see what is being requested to change if this is a Modification. Also, in the case of any submission, 'Compare' will show you changes that were made back and forth in Pre-Review via Clarifications Requested by the IRB analyst. Note that there are little pencil icons to show you which pages of the application have changes on them. You can click on these page names to navigate to those pages, just as you would bookmarks.

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

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 and documents that have been revised will show the changes in a call-out box like this:

Local Site Documents

1. Consent forms:

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

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 more 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

MOD005522: Modificat

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

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

Next Steps

[View Modification/CR](#)

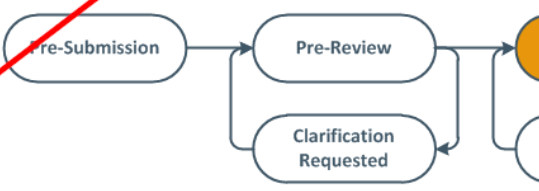
[Printer Version](#)

[Submit Ancillary Review](#)

Add Comment



Parent IRB: 000036


[Link to PQS/OPS.](#)



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

History [Contacts](#) [Documents](#) [Reviews](#) [Related RNIs](#) [Snapshots](#) [Associated Projects](#) [Training](#)

Filter by  Activity  [+ Add Filter](#) [X Clear All](#)

| Activity | Author |
|---|-------------|
|  Comment Added | Deol, Molly |

Comments you add in the Add Comment box appear here in the History log for all to see.

- 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 a request for them to reply with additional information in the History Log 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*)*

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

Committee Review **MOD005522: Modification / Update**

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

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.

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graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[IRB Review]
    B --> D[Clarification Requested]
    D --> B
    C --> E[Clarification Requested]
    E --> C
  
```

** 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 conduct their Resources and Drug reviews.*

Complete the short form seen below. **1** Check off your ancillary review you are submitting. **2** Accept the review. **3** Enter any comments. **4** 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.

Submit Ancillary Review

1. * Select the review you are submitting:

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

2. * Do you accept the proposed study? **2**

Yes No [Clear](#)

3. Comments: **3**

Reviewed and I have approved

4. Supporting documents: **4**

+ 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.