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:

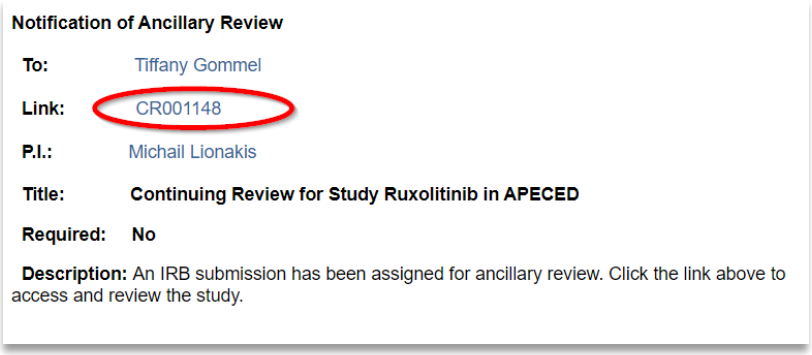
PROTECT accommodates many 'ancillary reviews'. These are set up by the study team using the **Manage Ancillary Reviews** activity. This activity gives the ancillary reviewer access to view (or read) the submission and, when required, sign off on it using the **Submit Ancillary Review** activity. The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



Notification of Ancillary Review

To: Tiffany Gommel

Link: CR001148

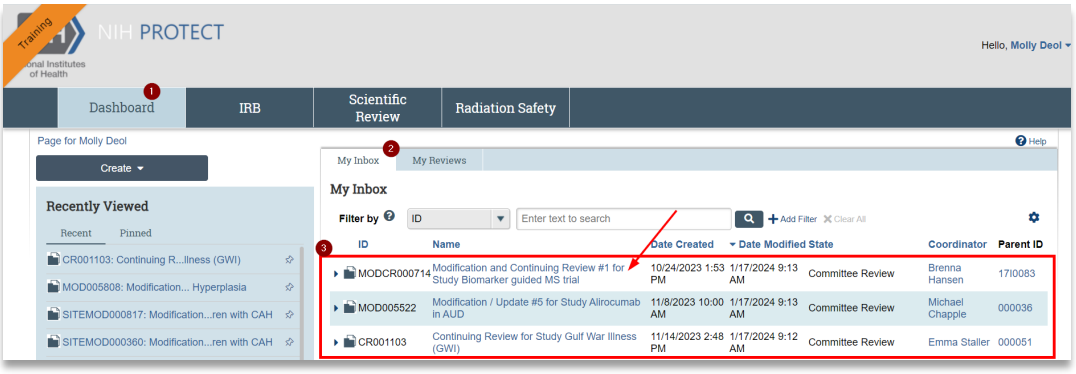
P.I.: Michail Lionakis

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.

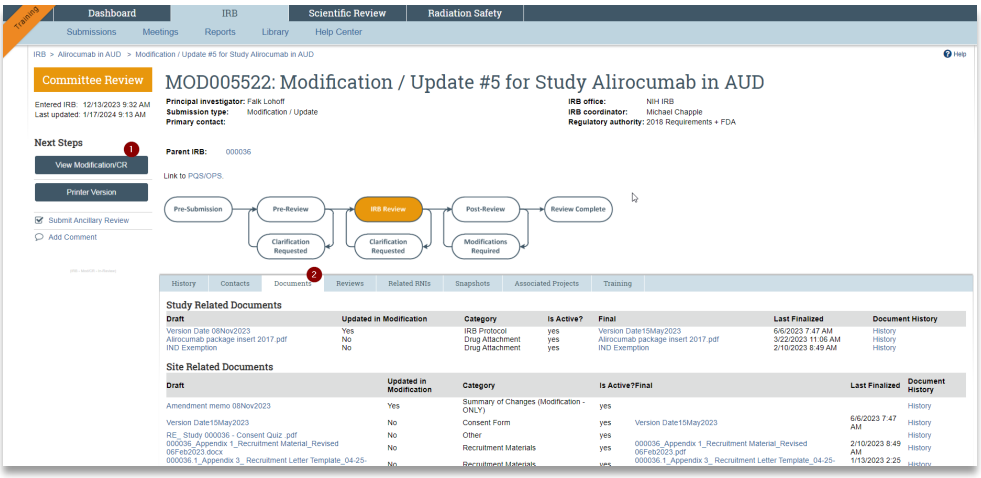
- You may also access your ancillary reviews by logging into PROTECT and going to your *Dashboard > My Inbox >My Reviews Clicking on the submission link to be taken to its workspace:*



Step 2 – Reviewing contents of the submission

- **View the submission SmartForm (application)**

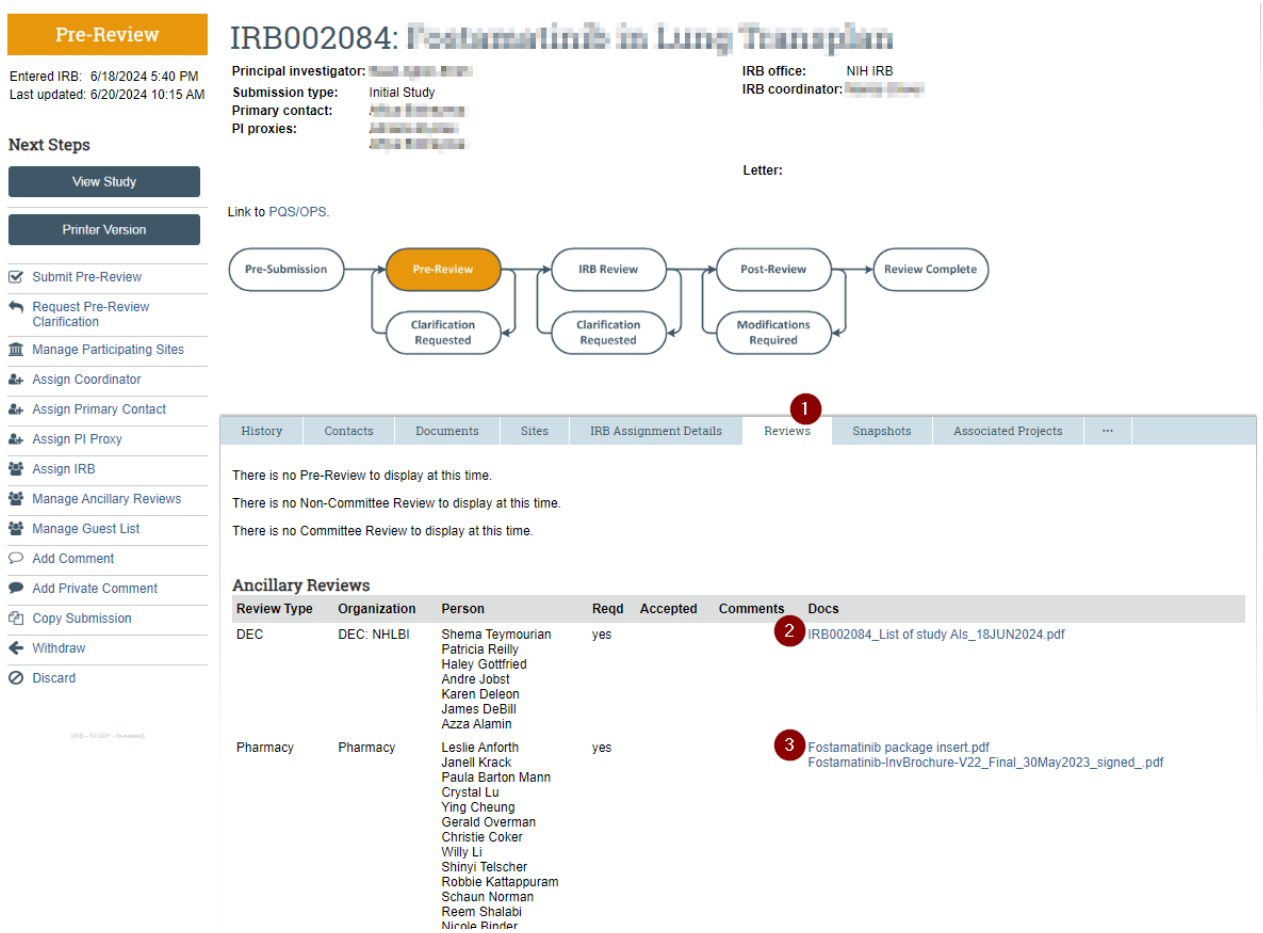
  For initial reviews, you can review the SmartForm application 1 and Documents tab 2 :



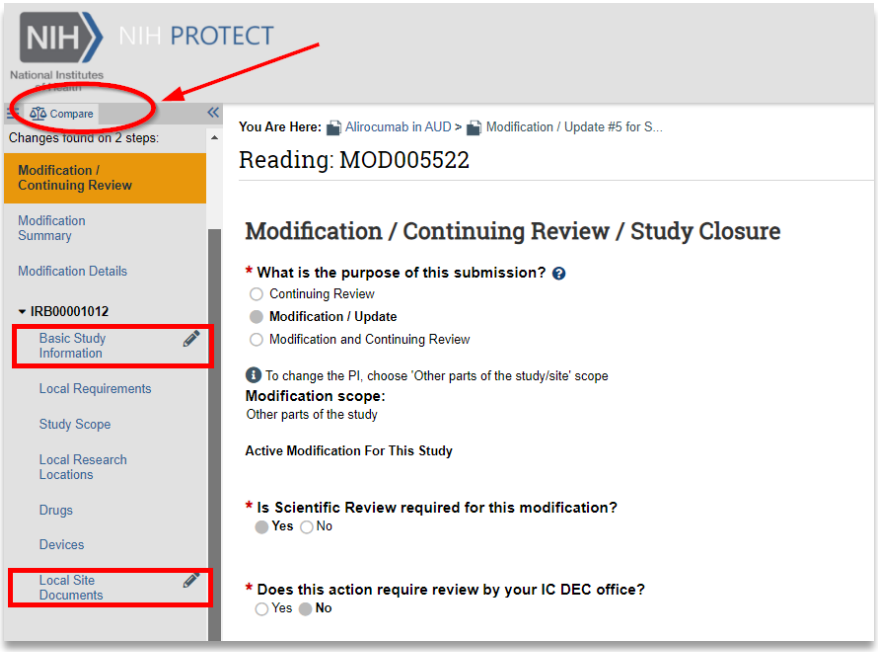
- **Review any documents associated with the Ancillary Review**

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

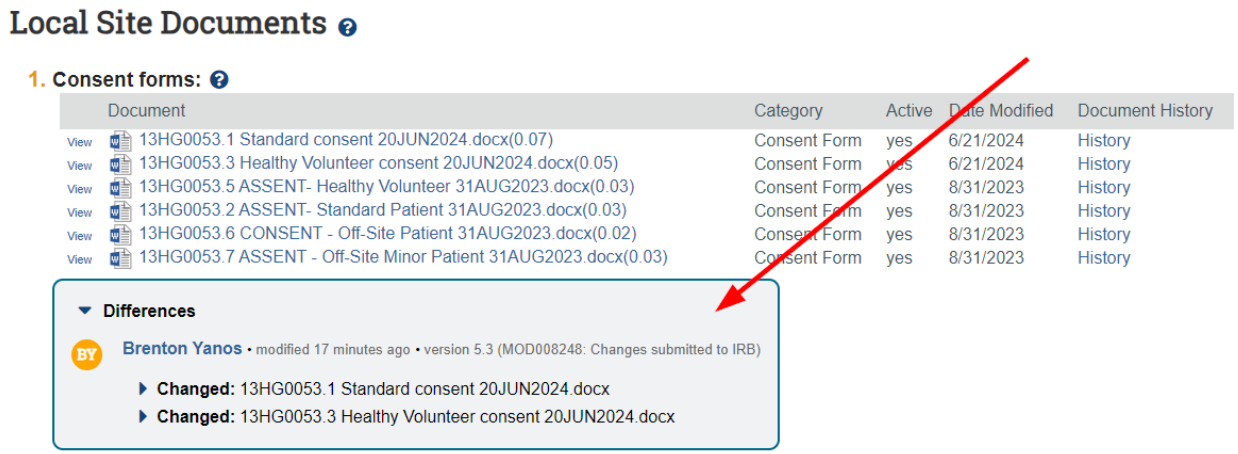
attached to their ancillary review for you to see:



- **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.*

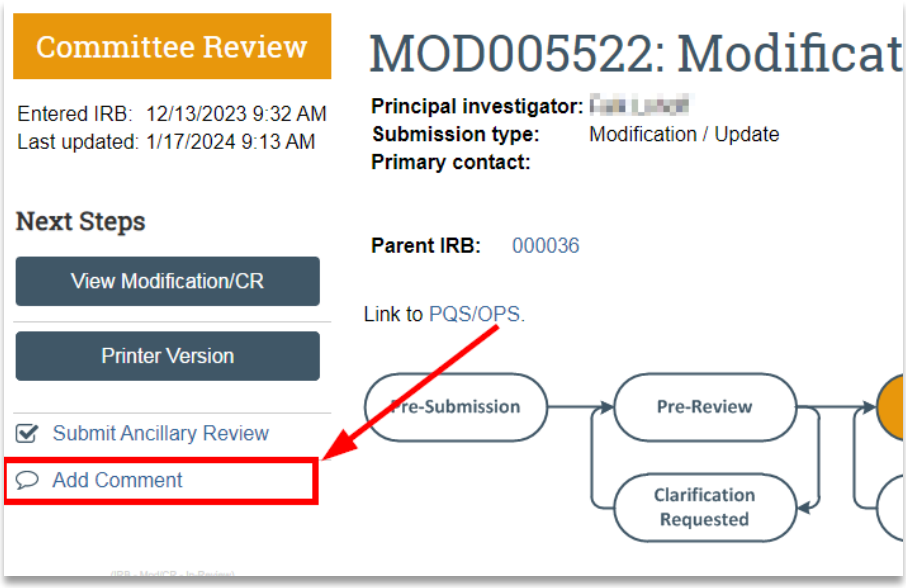


The sections and documents that have been revised will show the changes in a call-out box like this:

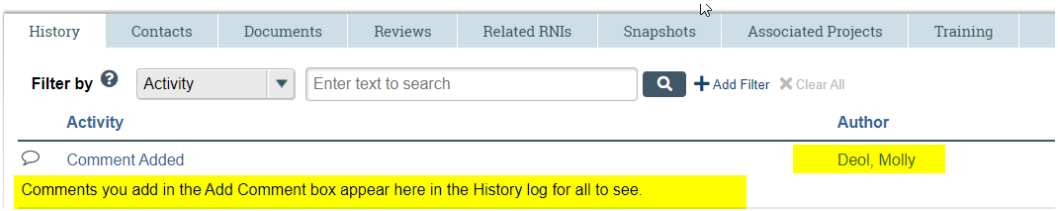


Step 3 – Requesting more info & Submitting your Ancillary Review

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



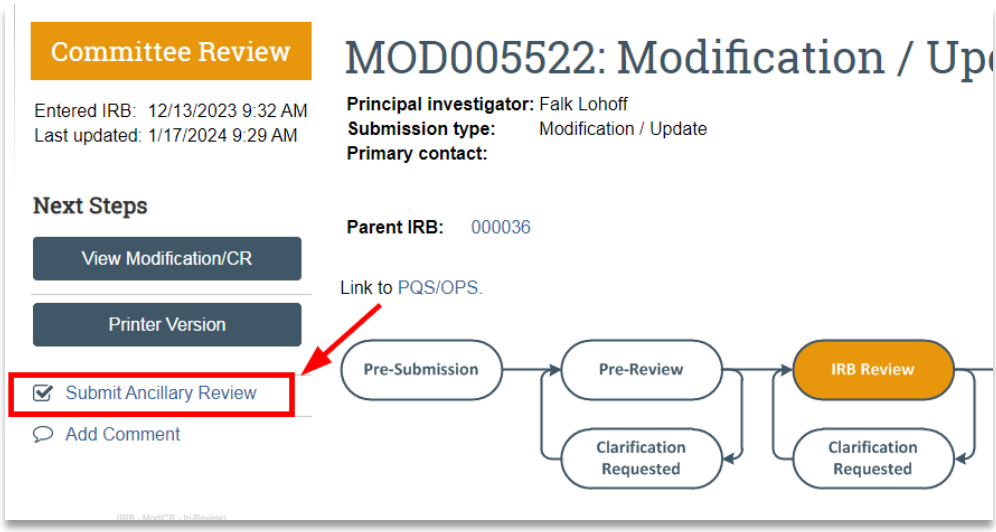
NOTE: You are identifiable in the History Log if you use this activity:



- The **Add Comment** activity does <u>not</u> 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.*

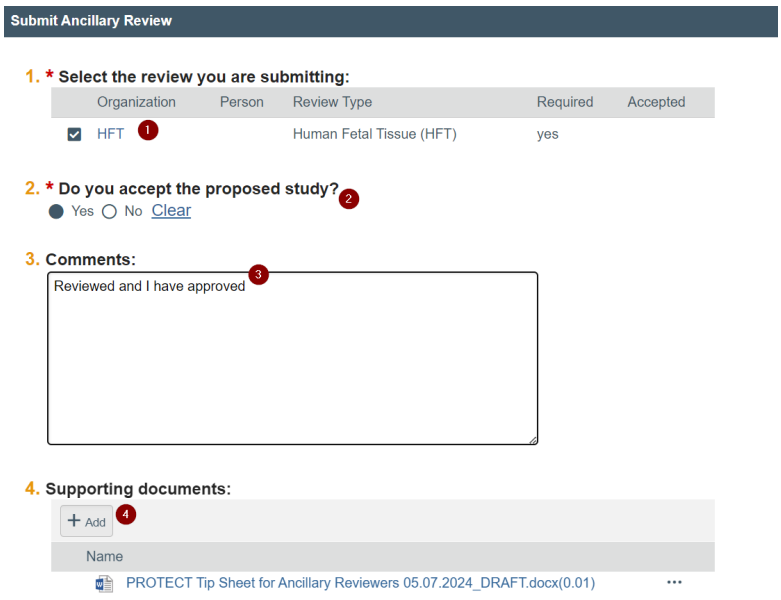
- <u>Submit your review:</u> *(If required*)*

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



** 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. ❶ Check off your ancillary review you are submitting. ❷ Accept the review. ❸ Enter any comments. ❹ 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.



Questions/Help

For questions and support about the PROTECT system, please submit a ticket and our trainers will assist you.