Completing an Assigned Ancillary Review

Human Research Protection Program

Last revised: 12/4/2023

This PowerPoint will guide you through how to complete an Ancillary Review in Huron.

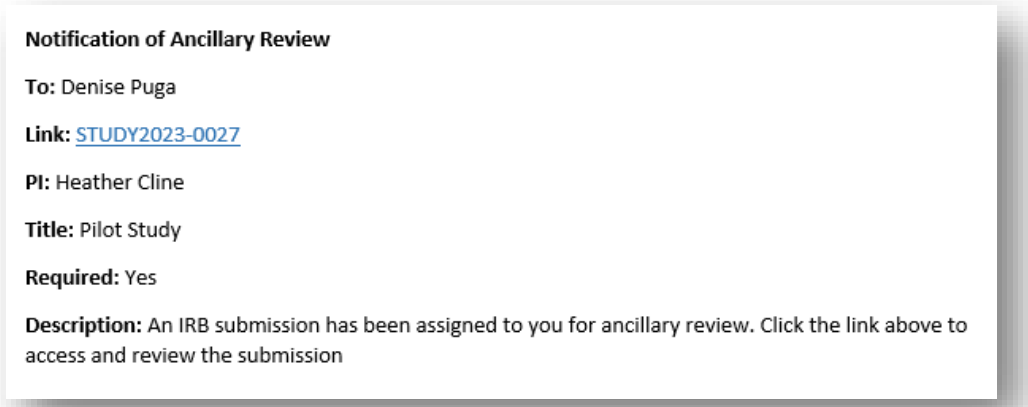
Accessing the study

The ancillary reviewer may access the study in one of two ways:

1. From the system generated email, click on the submission **link**.
   - If you are not logged into Huron, you will be directed to the login page.
   - If you are not automatically re-directed to the submission, you may access the study from your Dashboard (see next step).

2. From your **Dashboard,** locate the study requiring your ancillary review under **My Inbox**. Click on the **ID** or **Name** of the study to be directed to the study workspace to complete your ancillary review.

1



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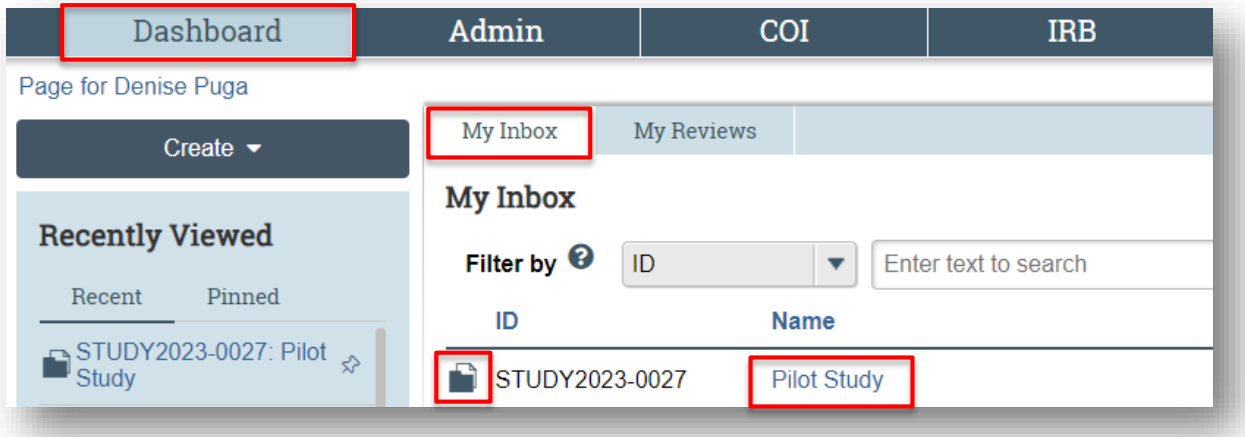
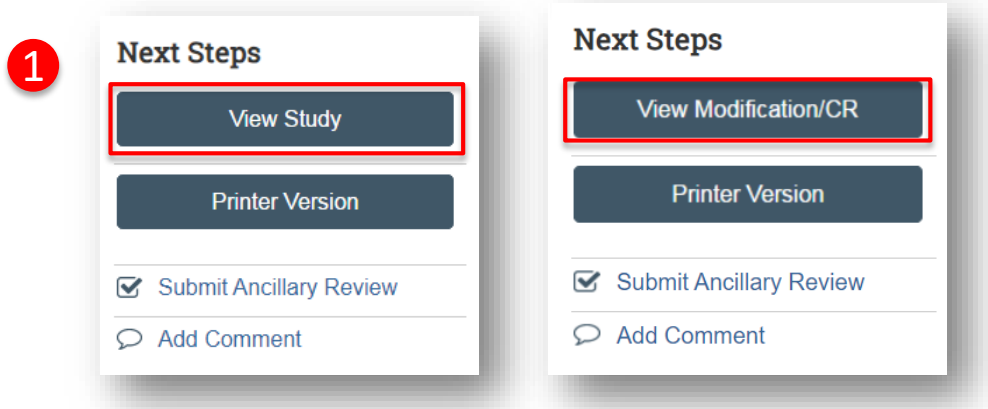


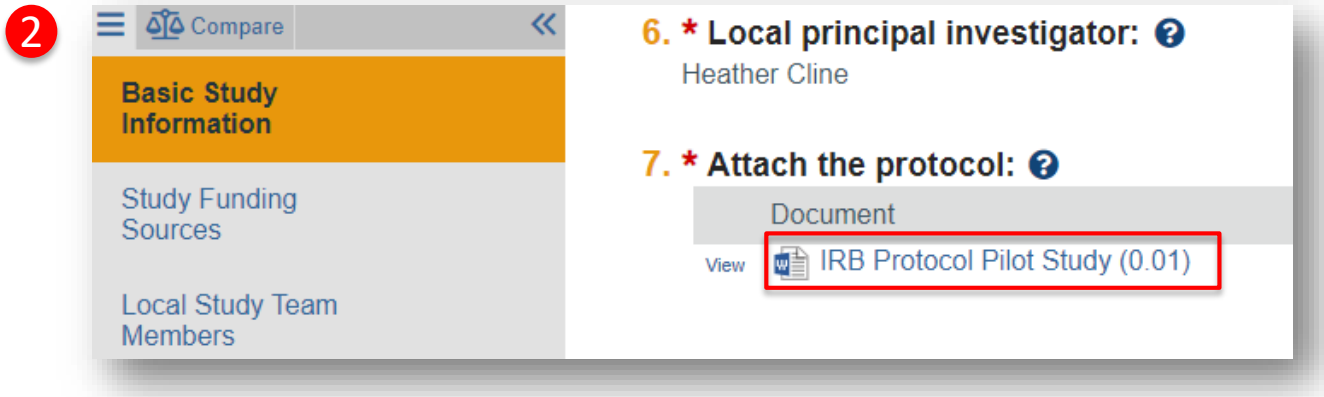
Reviewing the study and supporting study documents

1. To access the full study, click:
   - **View Study** for new studies or
   - **View Modification/CR** for modifications to an existing study

2. To view any document attached to the study, click on the document name. A copy of the document will be automatically downloaded to your desktop.

3. You may exit the study by clicking **Exit** at the bottom of the page.



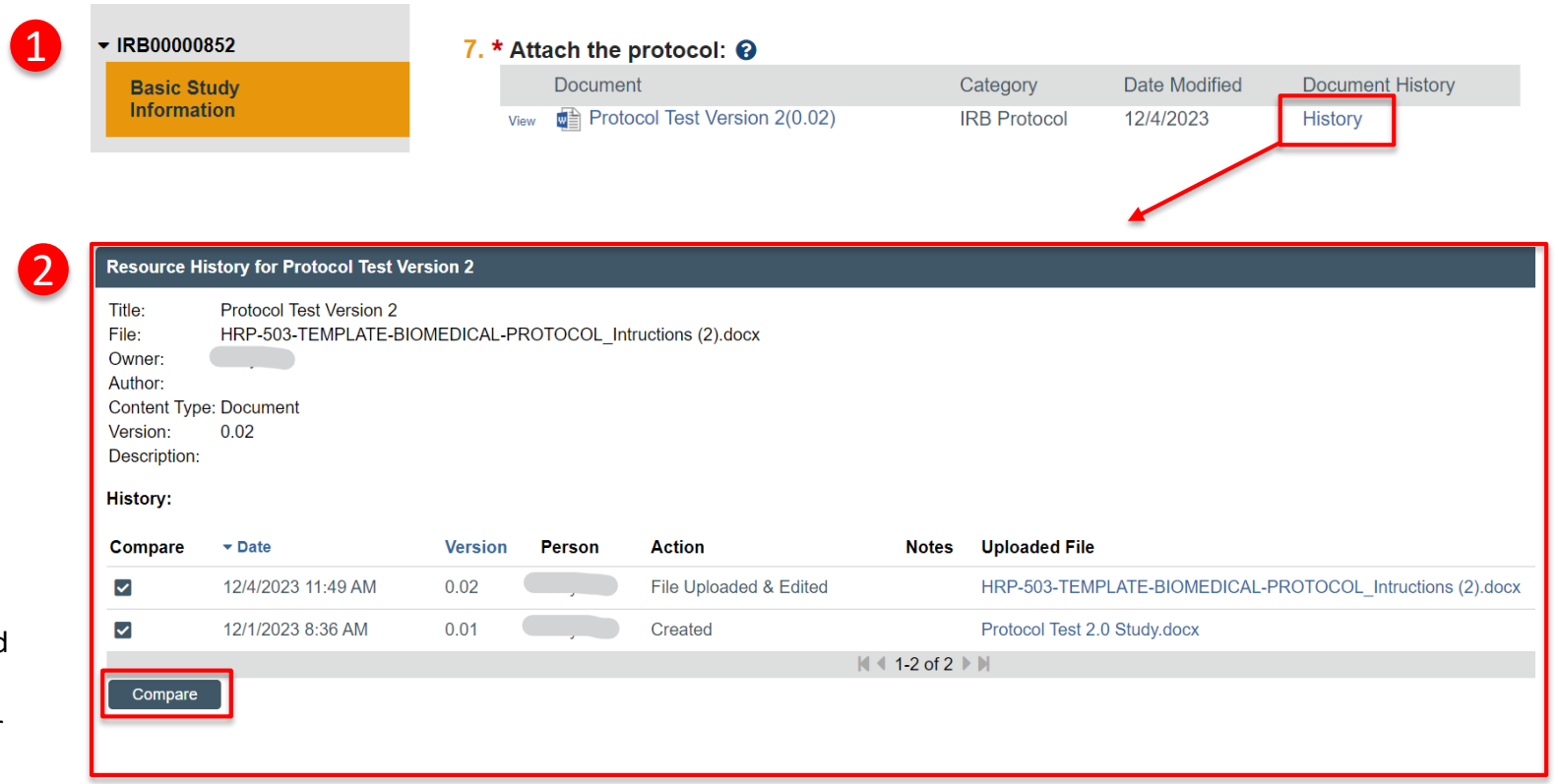


Reviewing the study and supporting study documents

If you are reviewing a modification or want to confirm a change you requested, you may use the document history to access and compare different versions of a document.

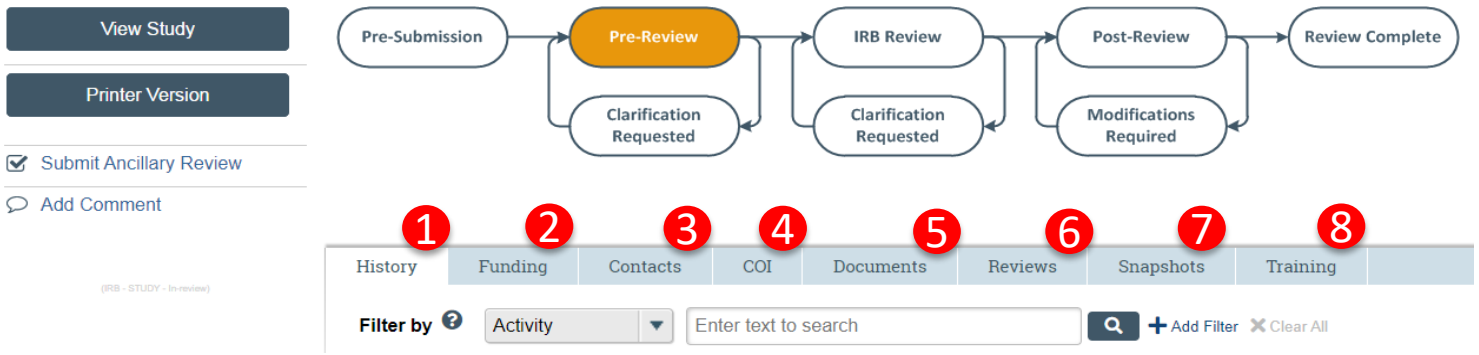
1. To view the history of a document, click **History** and a popup window will appear.

2. From the popup window, you will be able to access and compare different versions of the document:
   - Select the two documents you wish to compare and click **Compare**.
   - A Word document will automatically download to your computer. The document will highlight any changes detected between the two selected items.
   - ***Note:*** The compare function is only available for Word documents.



Study Workspace

You may also use the Study Workspace to quickly access basic study information, such as study personnel and sponsor information.

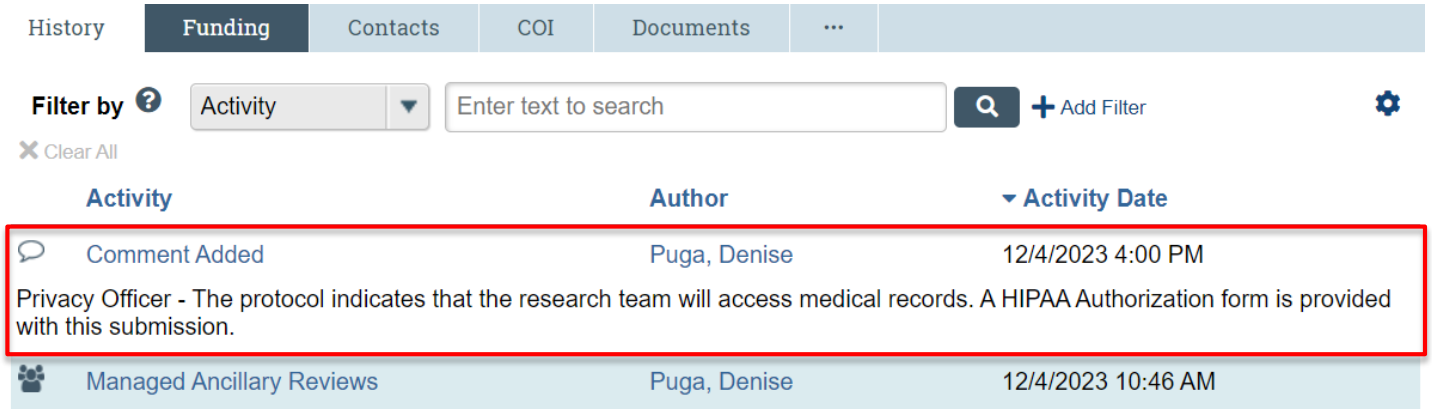


1. **History**: This tab lists the activity taken on a submission including any comments, attachments, or correspondence added.
2. **Funding**: Provides all funding sources associated with the submission along with related grant information, if applicable.
3. **Contacts**: This tab lists all TAMU individuals with study involvement (i.e., PI, Study Team, Other Study Members, Guests).
4. **COI:** This tab identifies the status of any conflict of interest and how it is managed (note: does not include TTI and TEEX personnel).
5. **Documents**: This tab includes all study related and site related documents including documents on drugs, devices, and international research, if applicable.
6. **Reviews**: This tab will list all ancillary reviews including the reviewers' comments, and Reviews containing the latest pre-review, committee and/or non-committee reviews, determinations (e.g., approval date), review/risk level, notes, missing materials, and checklists completed by the reviewers.
7. **Snapshots**: Provides a snapshot of the entire study including attachments submitted at different states of the submission (e.g, approved stated, pre-submission state).
8. **Training:** This tab includes all CITI training of the individuals/key personnel listed on the study with the exception of non-TAMU researchers.

History tab

When completing your ancillary review, visit the **History** tab. The History tab *may* contain additional information pertinent to your review.

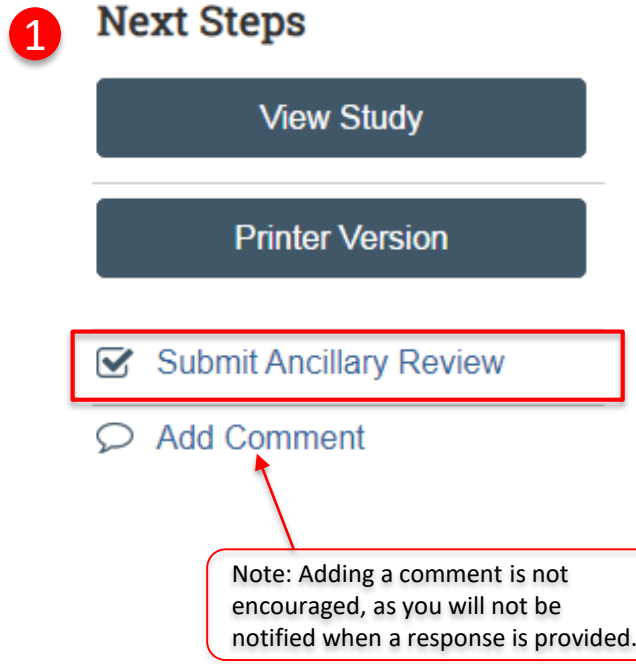
In the example provided in this slide, the IRB coordinator is providing the Privacy Officer with information relevant to their review of the study.

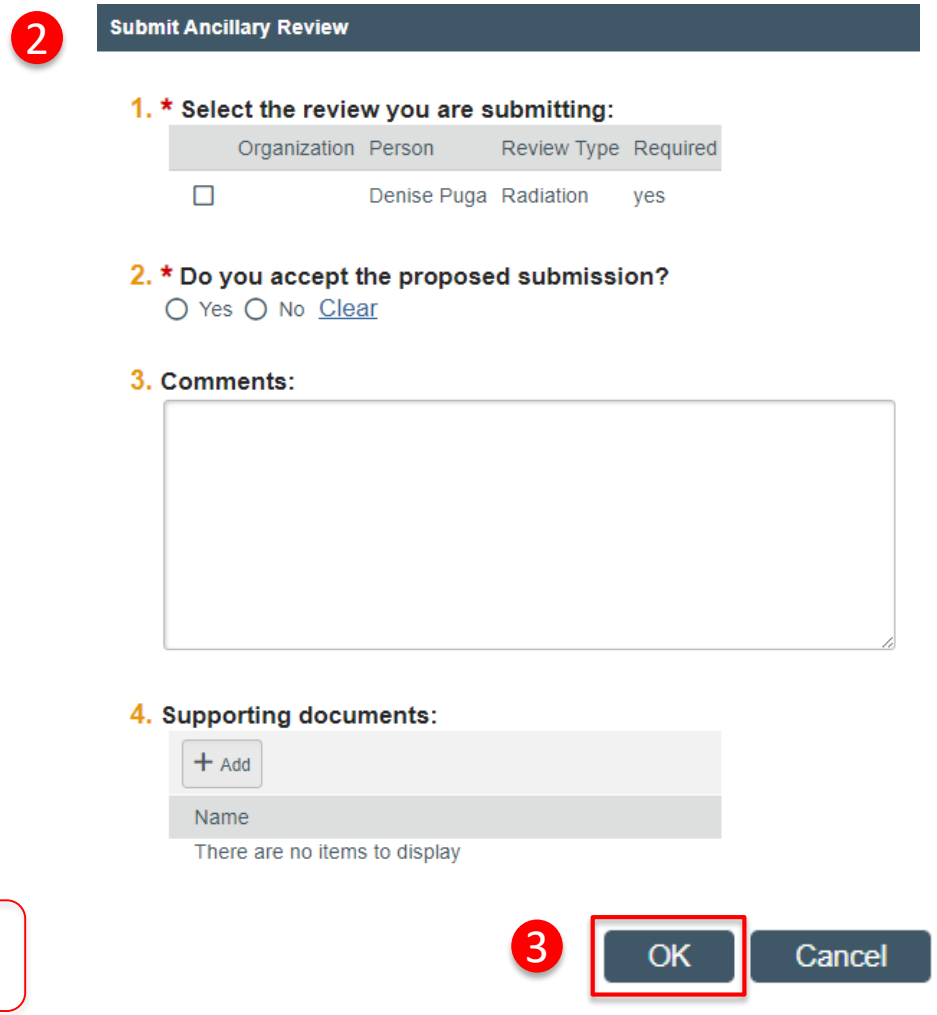


Submitting your ancillary review

Once you have reviewed all pertinent items and information, please submit your ancillary review by:

1. Click **Submit Ancillary Review** and a pop-up form will appear.
2. Complete the pop-up form:
   - All questions marked with a red asterisk (*) require a response.
   - **Question 2**:
     - Select ***Yes*** if the submission is okay to proceed.
     - Select ***No*** if additional changes or actions are required.
   - Use **Question 3** to communicate any findings or pending items to the IRB office.
3. Click **OK**

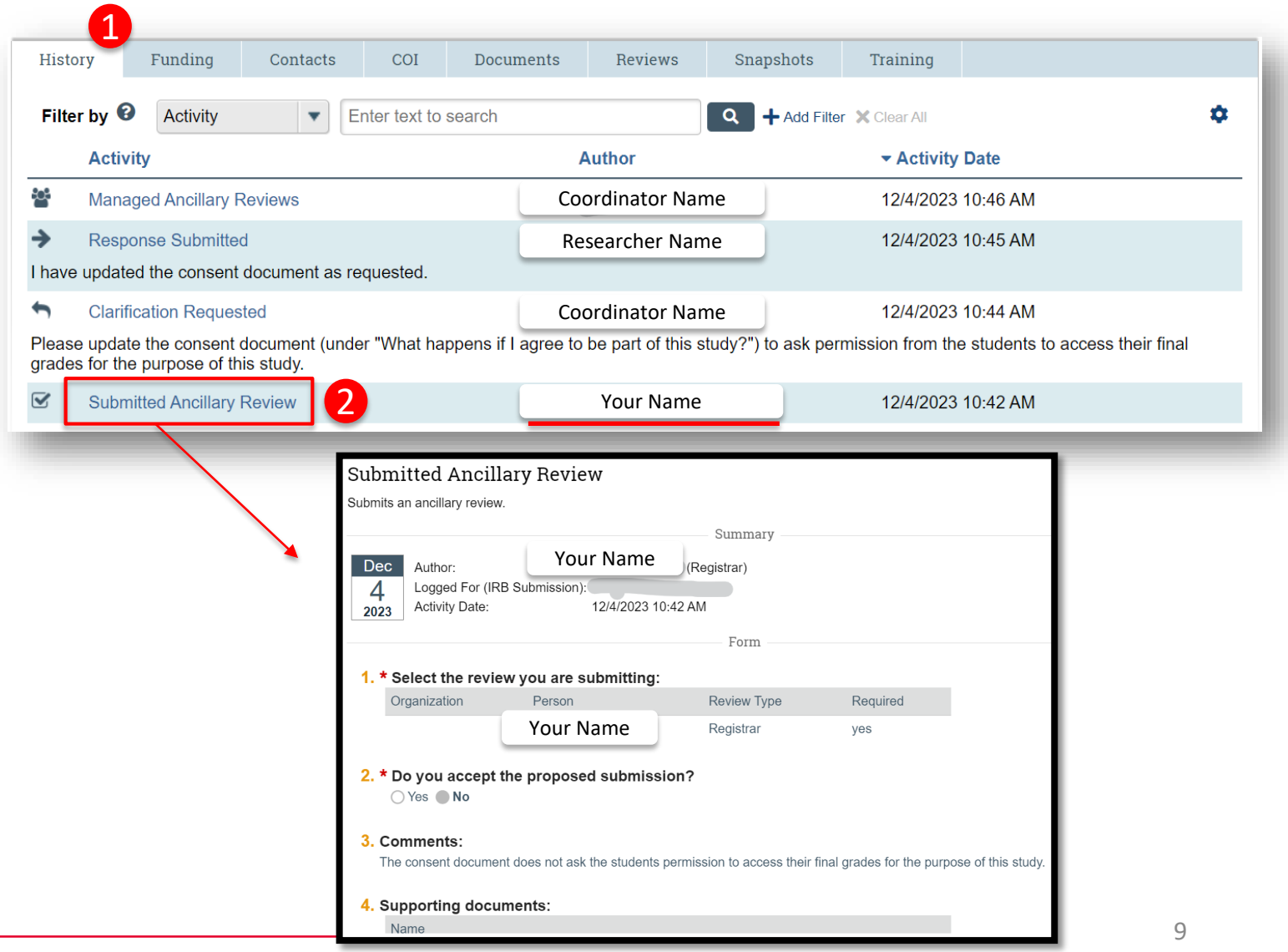




How to view your previous comments on a study

If you requested additional information or changes to a submission prior to accepting it, the IRB coordinator will re-assign you the submission once the investigator has addressed your comments.

1. Use the **History** tab on the Study Workspace to view your initial review
2. Click on **Submitted Ancillary Reviewer** with your name as the Author
3. A pop-up window will appear with your previous review and comments



How to view the investigator's response

Once you submit your ancillary review, the IRB staff will communicate to the investigator the findings of your review. Use the **History** tab to view the investigator's response:

1. You may view the researcher's response under **Response Submitted.** Note the Author's name to ensure the response is from the research team.

   IMPORTANT! If you have requested changes that require revisions to study documents, such as the research protocol or consent document, you will need to navigate to the IRB application to see the updated document. Please revisit Slides 4 and 5 for instructions on how to view and compare study documents.