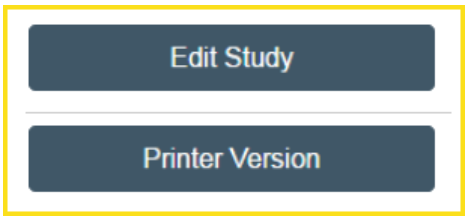
Next Steps Before Submitting an Initial Study

Once you have completed your study SmartForm (application), return to the study workspace and review the Next Steps menu before submitting your study to the IRB. The Next Steps menu includes several actions that may need to be completed after the SmartForm is finished but before the study is submitted.

Not every action will apply to every study. Review the options below to determine which Next Steps are applicable to your study. **Submit** should be completed last, after all applicable actions have been completed.

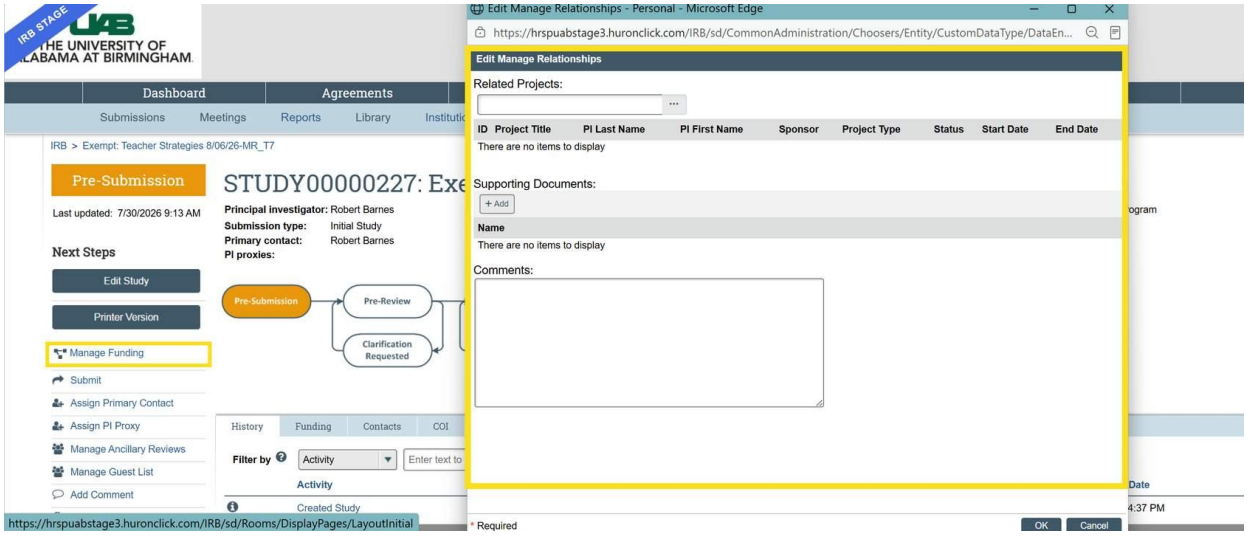
1. Edit Study and Printer Version

Select Edit Study to return to the SmartForm and make changes to the study before submission. Select Printer Version to view a printable version of the study.



2. Manage Funding

In the SmartForm, you only identify the study's funding organization or source, such as NIH. Use **Manage Funding** to connect **the applicable funding proposal** from the Grants module to the study record in the IRB module.



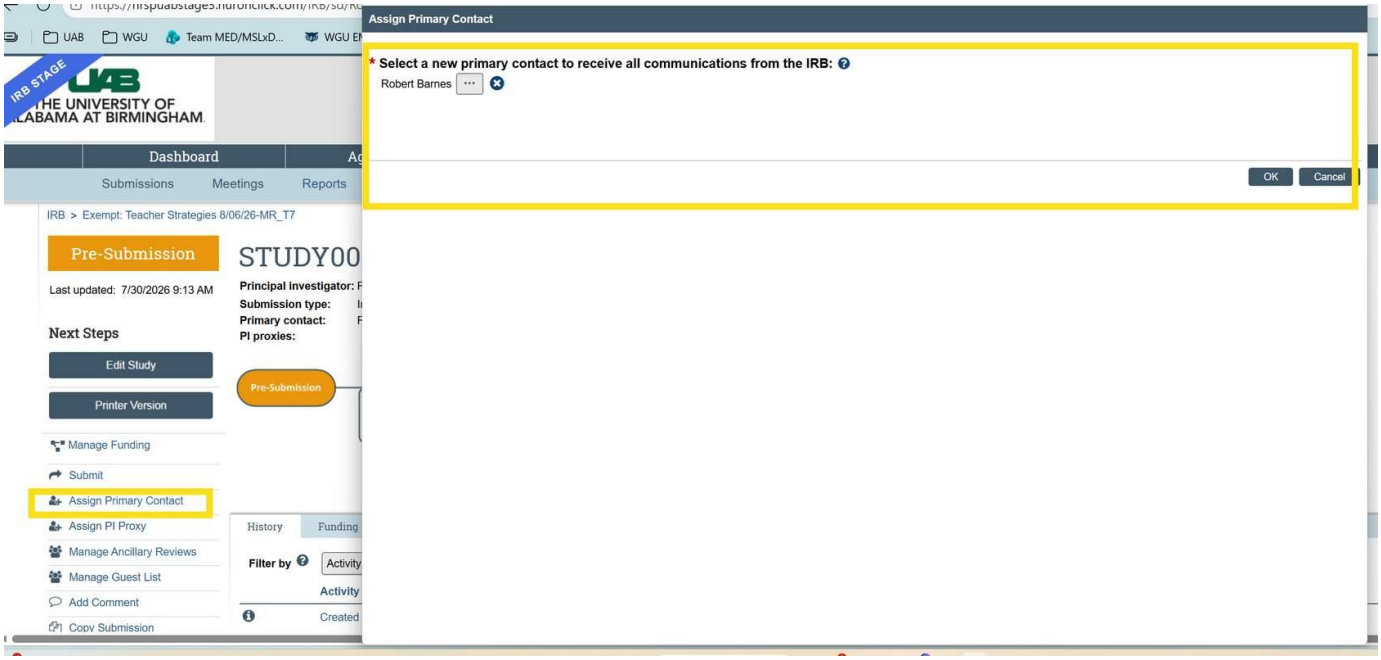
Note:

Once the funding proposal is connected, it will appear under the **Related Projects** tab in the study workspace.

Next Steps Before Submitting an Initial Study

3. Assign Primary Contact

Use **Assign Primary Contact** to designate the individual who will serve as the primary contact for the study. The Primary Contact will receive **communications and notifications from the IRB**, along with the **PI and PI Proxy**.



Note:

The Primary Contact cannot submit the application to the IRB. Only the PI or an assigned PI Proxy can submit the application.

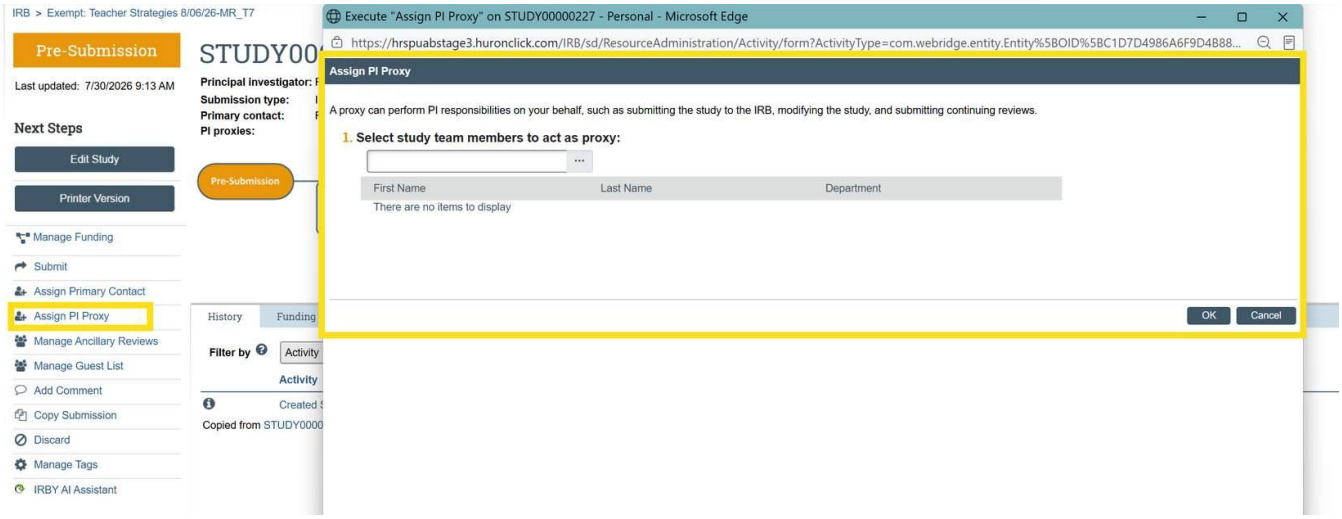
Next Steps Before Submitting an Initial Study

4. Assign PI Proxy

A PI Proxy is a study team member designated by the Principal Investigator (PI) to perform certain actions on the PI's behalf in myUABResearch. The PI must assign the proxy, and only individuals already listed on the study team can be selected**. Assigning a PI Proxy is a two-step process.** The individual must first be added appropriately to the study team by the PI in the SmartForm. The PI then uses **Assign PI Proxy** from Next Steps to formally designate that individual as a proxy.

Note:

This Next Steps activity is the **second** part of assigning a PI Proxy. See the **Assign PI Proxy** job aid for complete instructions.



Note:

A PI Proxy does not need to complete the required human subjects research training if they are serving only in an administrative capacity and are not involved in the conduct of the research.

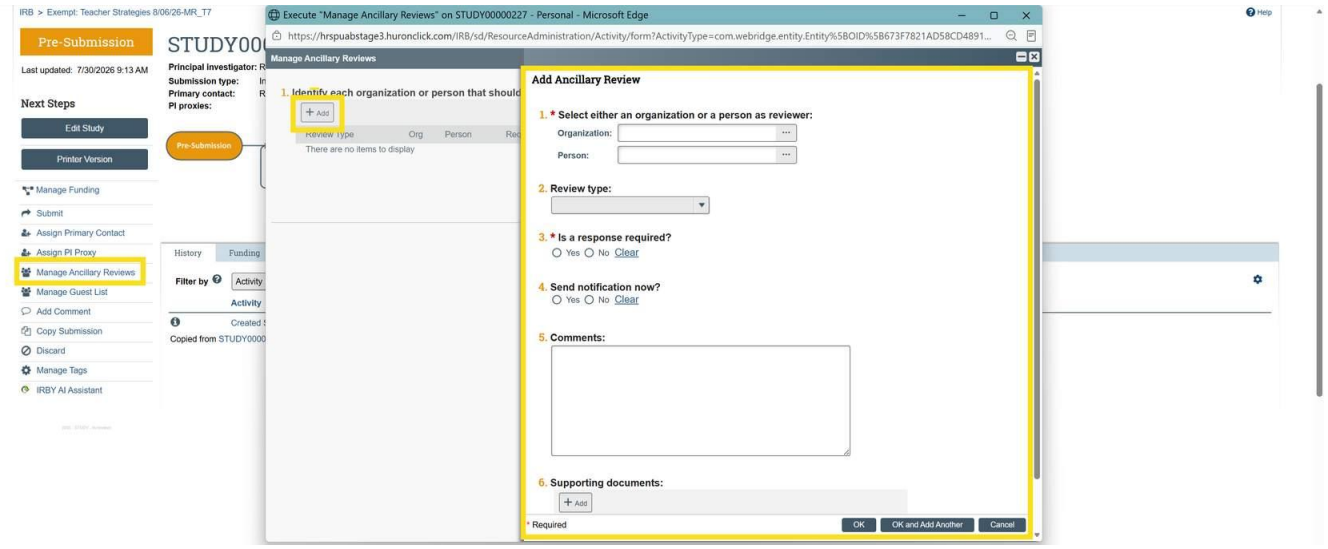
Next Steps Before Submitting an Initial Study

5. Manage Ancillary Reviews

The SmartForm identifies the ancillary review that may be needed. Use **Manage Ancillary Reviews** to route the study within myUABResearch to the organization or individual who should conduct the ancillary review.

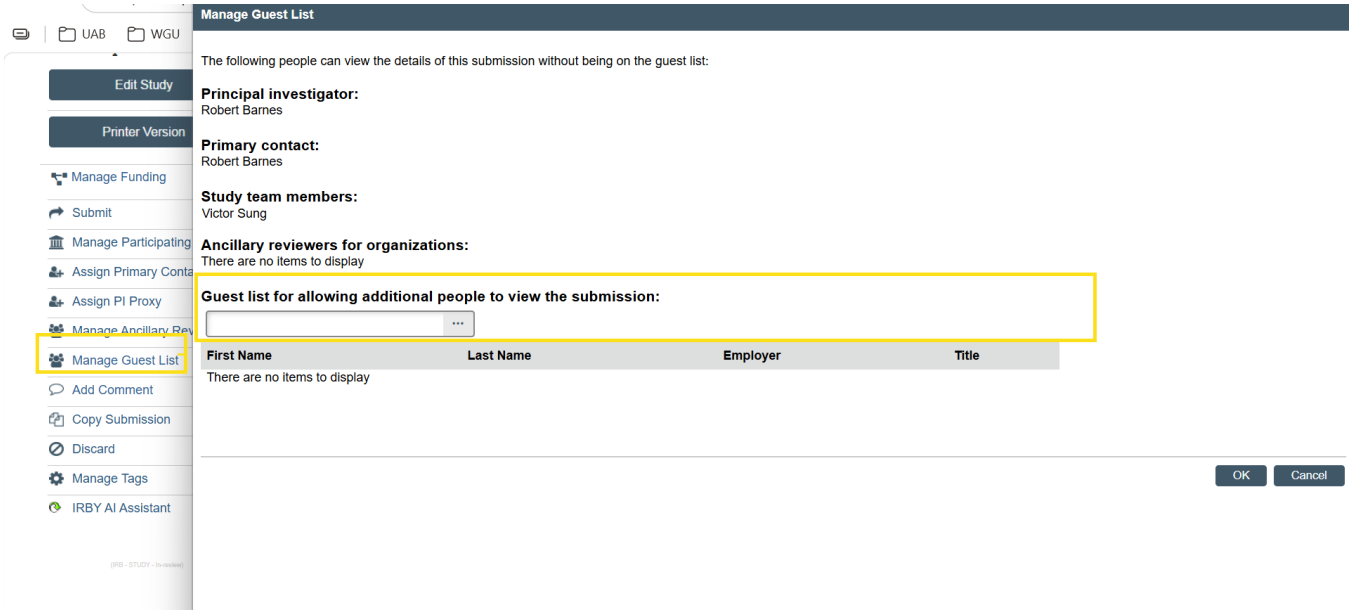
Note:

See the **Manage Ancillary Reviews** job aid for additional instructions.



6. Manage Guest List

Use **Manage Guest List** to give additional individuals **read-only access** to the submission. Guests can view the study but are not study team members and cannot make changes or perform study team actions.



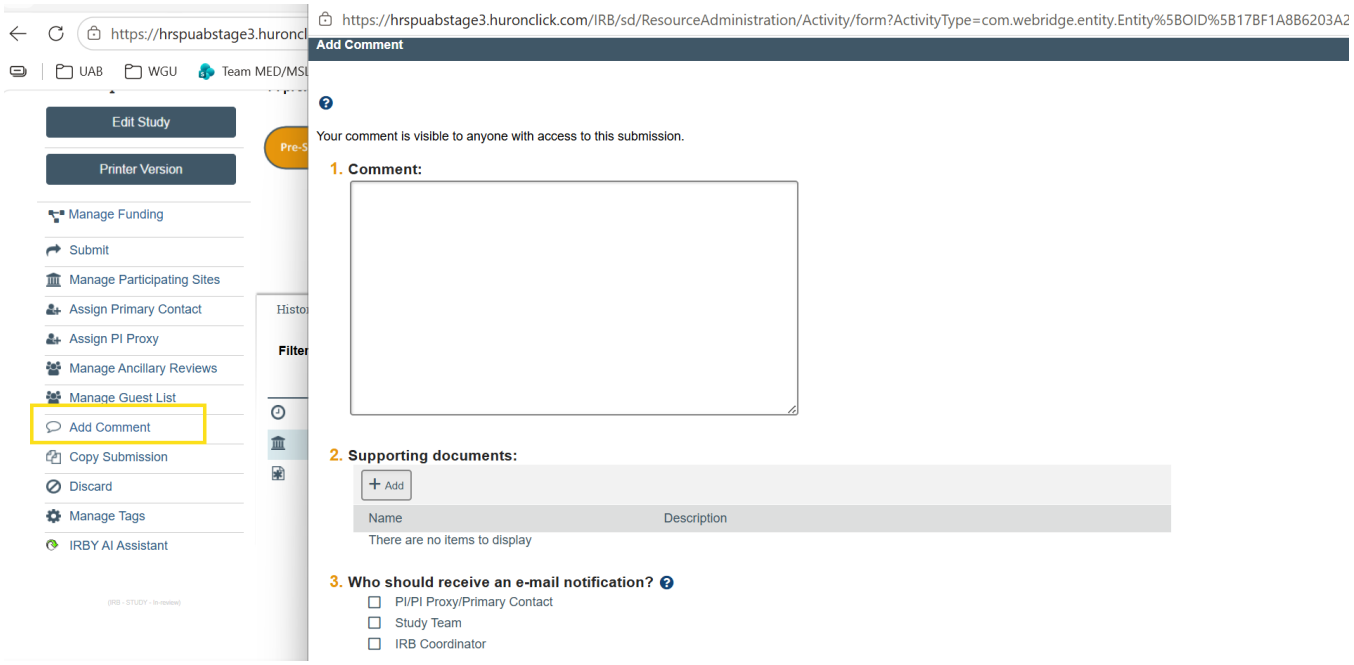
Next Steps Before Submitting an Initial Study

Note:

Once added as a guest, the guest can locate and view the study by selecting the **IRB** tab and navigating to **All Submissions**.

7. Add Comment - Communicating with the HRPP

Throughout the lifecycle of a study, use **Add Comment** in the Next Steps section to communicate with the HRPP about a specific study or submission. This includes communication related to the initial study, modifications, continuing reviews, RNIs, and study closure. Rather than communicating by email, use **Add Comment** so that study-specific questions, responses, and HRPP guidance are documented in myUABResearch and remain part of the study record.



Note:

Comments added to a study are recorded in the History tab and can be viewed by all individuals with access to the study. When selecting **Add Comment**, you can also choose who should receive an e-mail notification that the comment was added, such as the **PI/PI Proxy/Primary Contact, Study Team, or IRB Coordinator.**

Select notification recipients based on the purpose of your comment. For example, you may notify the IRB Coordinator when providing information related to the submission, or a PI Proxy may notify the PI that an application has been submitted.

Remember, selecting notification recipients determines who is alerted about the comment, not who can view it in the study's History.

Next Steps Before Submitting an Initial Study

Important: Add Comment is not a Clarification Request response.

If the IRB has issued a Clarification Request, follow the clarification response process. See **the Responding to a Clarification Request** job aid for instructions.

Additional Next Steps Options

8. Copy Submission

Use Copy Submission to create a copy of the current submission that can be used as the starting point for another submission.

9. Discard

Select Discard to permanently discard the submission. Use this option carefully.

10. Manage Tags

Manage Tags is used by HRPP staff and does not need to be completed by study teams.

11. IRBY AI Assistant

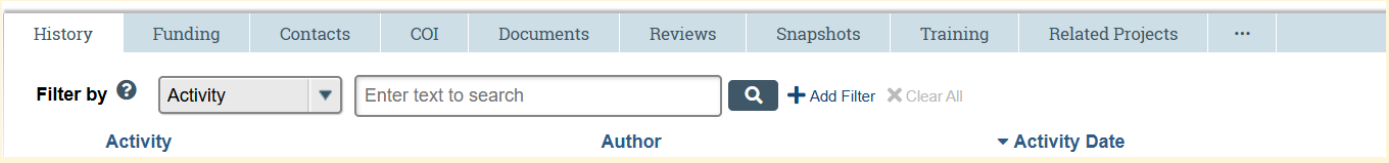
The IRBY AI Assistant is an AI-powered submission review tool that reviews the SmartForm and attachments during Pre-Submission. Its goal is to identify incomplete sections, highlight areas that may require clarification, and help reduce back-and-forth between HRPP staff and study teams by helping ensure submissions are complete before review.

Important: Review the Study Workspace Tabs

In addition to completing **Next Step**, take a moment to review the **tabs in the study workspace**. These tabs provide a quick way to confirm that important study information and connections are reflected in the study record.

Review applicable tabs such as **Funding, Contacts, COI, Documents, Reviews, Training, and Related Projects**. For example, confirm that required training information is current, applicable reviews and documents are reflected, and any funding proposal connected from the Grants module appears under **Related Projects**.

Information is populated or maintained automatically by myUABResearch, but reviewing these tabs is a good final check before submission to make sure the study record reflects the information you expect.



Next Steps Before Submitting an Initial Study

12. Submit - Complete This Last

After you have completed the study and reviewed all applicable Next Steps activities, select **Submit**. This sends the study to the IRB and moves the submission from Pre-Submission to Pre-Review.

