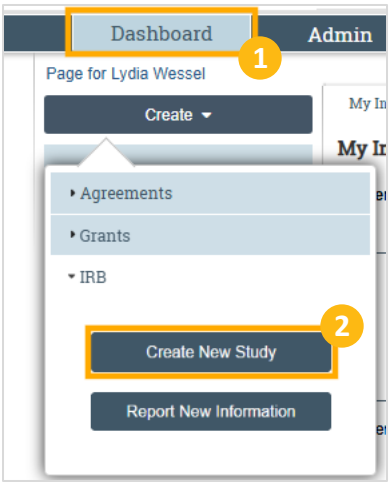
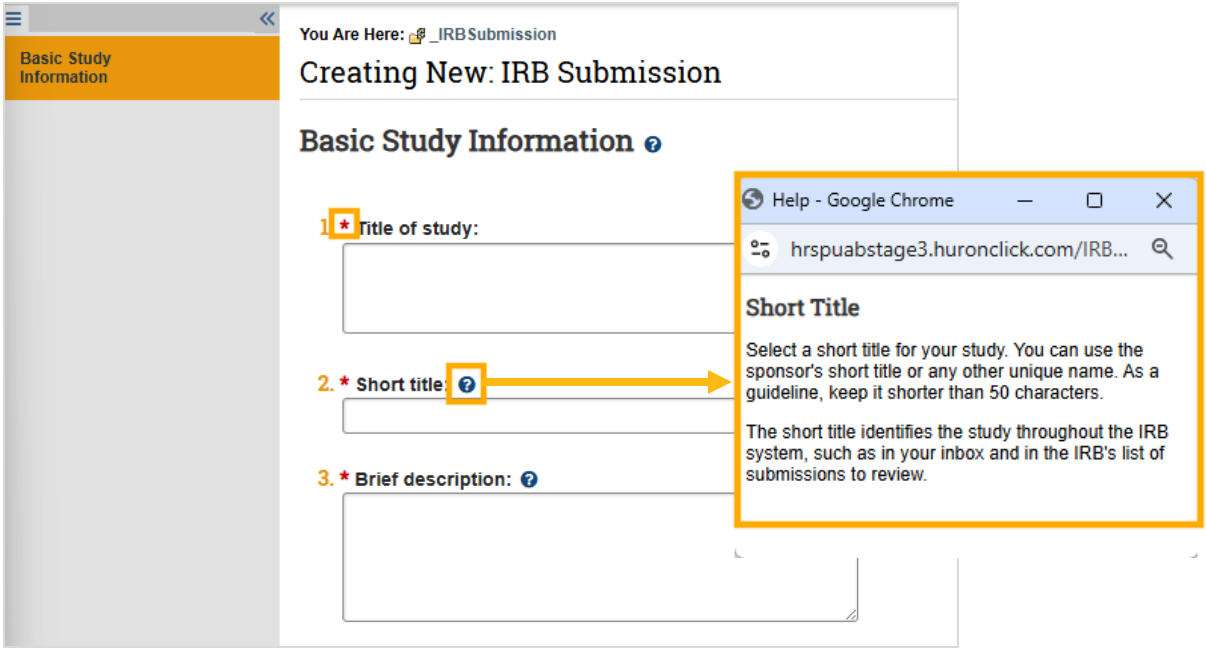
Create and Submit a Single Site Study

This guide explains how to create and submit a single-site study.

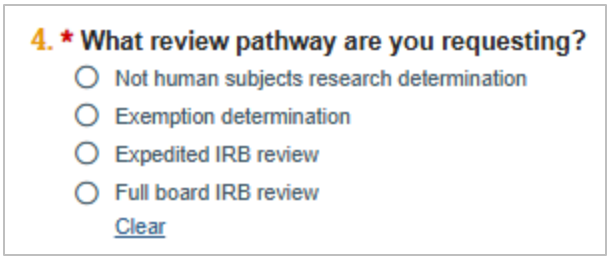
1. **From the Dashboard, click the Create New Study button, this will open the smartform.**

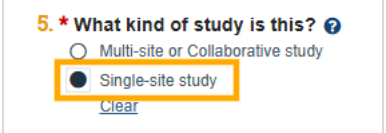


2. **Complete the necessary fields in the smartform. Note: A red asterisk means the field is required and the question mark icon means there is help text available for that field.**



3. **Select a review pathway, and for the "What kind of study is this?" question, select "Single-site study".**

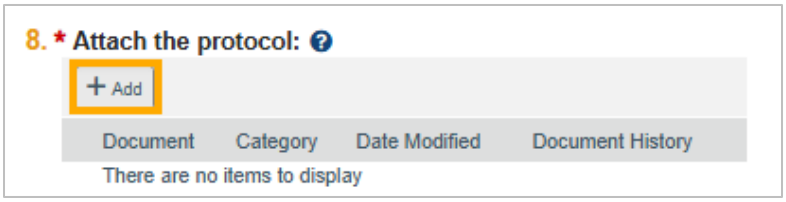




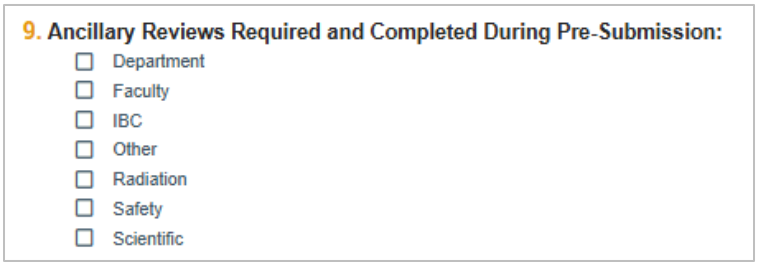
4. For question seven, "Local principal investigator", you will automatically be chosen as the Principal Investigator. *If the PI is someone else, click the three dots to select a person.*



6. Attach the study protocol. For information about how to fill out the study protocol, see the Protocol Documents Overview job aid.



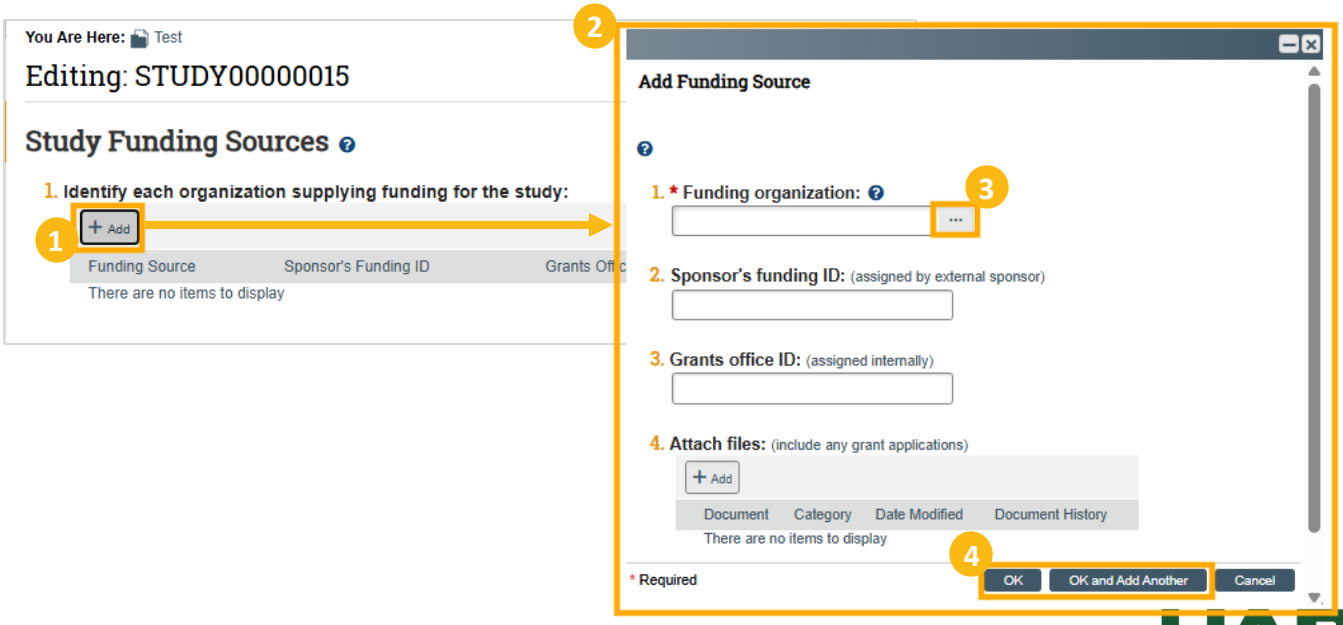
7. Select any required ancillary reviews.



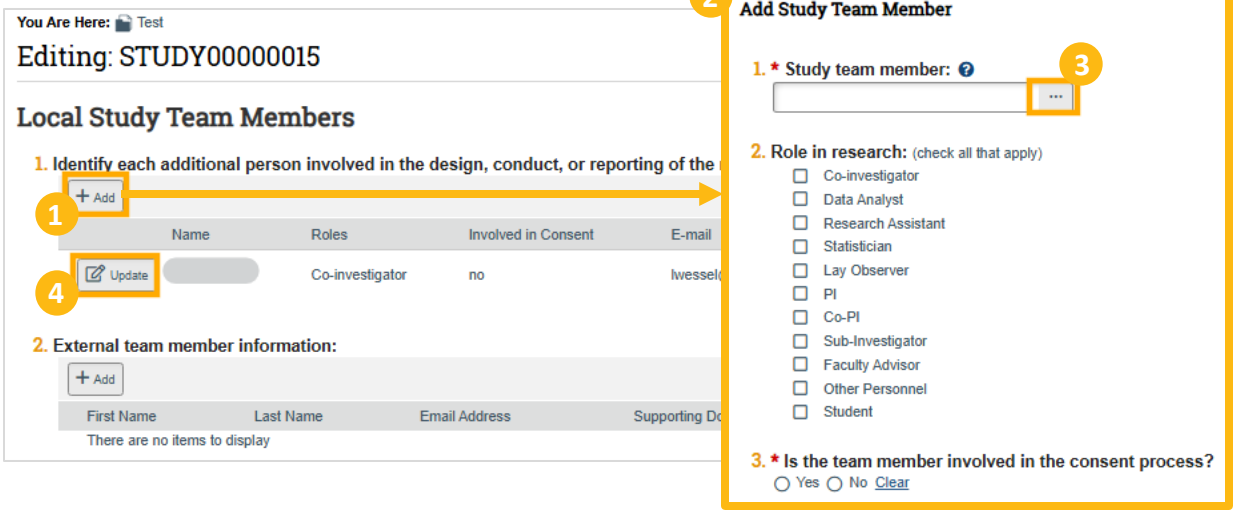
8. After completing all questions on the page, click Continue to save your answers and move to the next page.



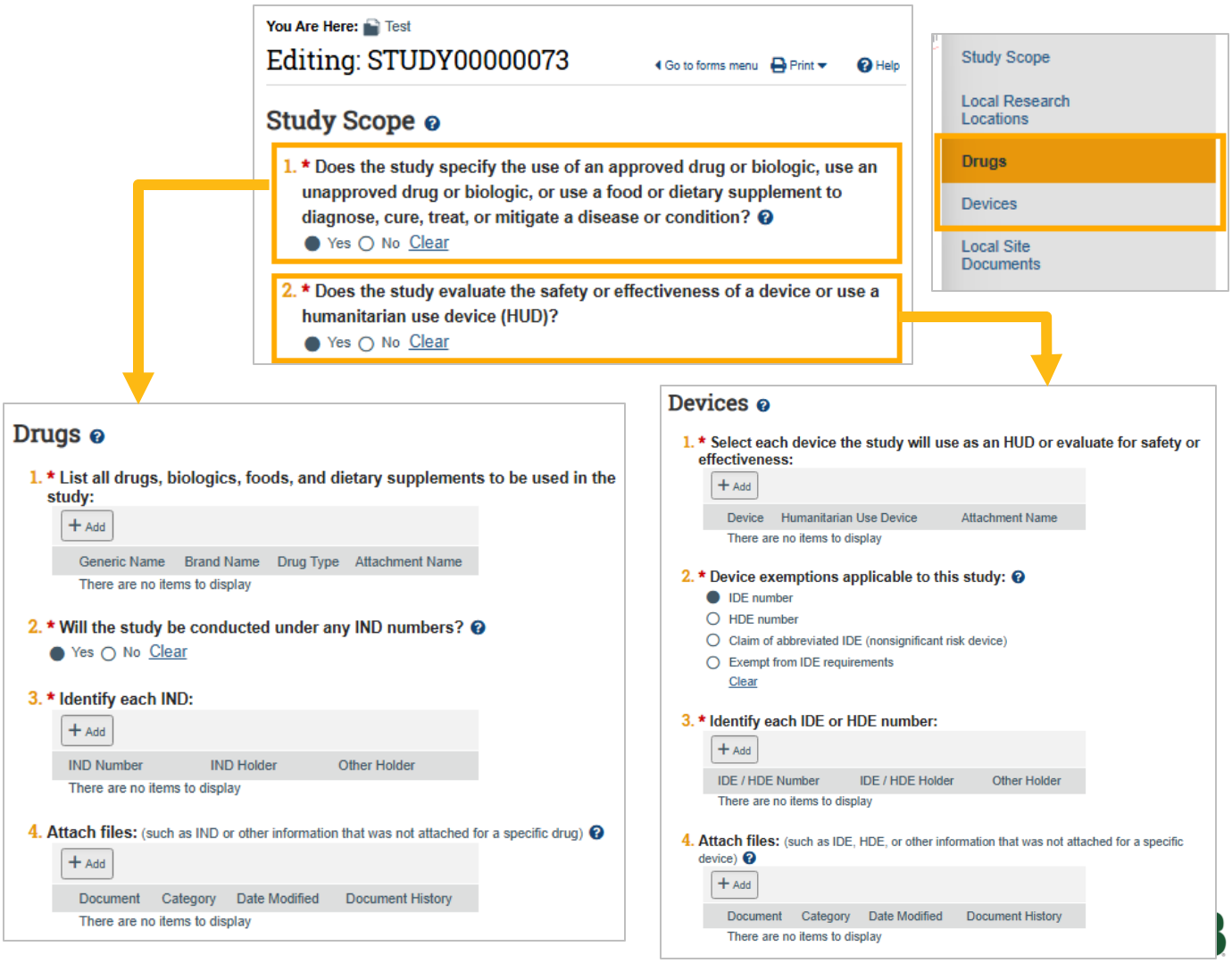
9. Identify the study's funding sources. These can be external or internal to UAB. To add the funding source, click Add and complete the funding source information. Click on the three dots to choose from the list of organizations, complete the remainder of the page, then click OK or OK and Add Another if you wish to add multiple funding sources. When complete, click Continue.



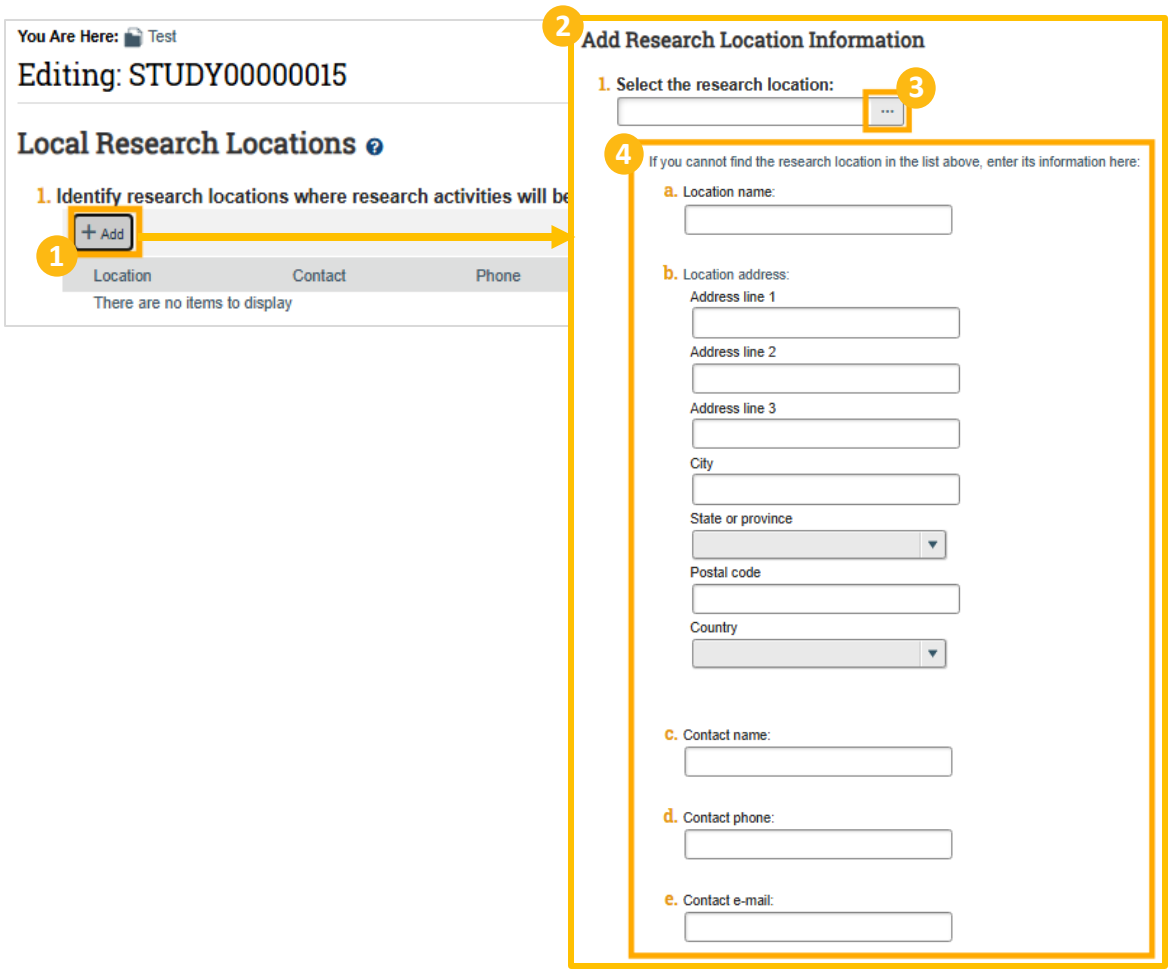
10. Click Add to identify the local study team members. Click on the three dots to access the list of available personnel. Select their role in the research and if they will be involved in the consent process. When complete, click OK or OK and Add Another to add additional personnel. Ensure the information is accurate and click Update to change any existing information. When complete, click Continue.



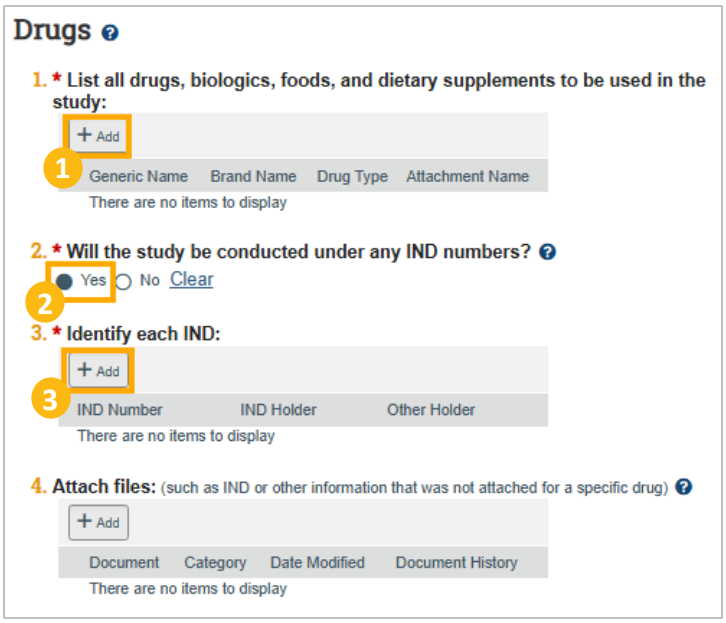
11. On the Study Scope page, identify details of your research that may require additional information. Answering Yes will add additional page(s) to the study after the Local Research Locations page. Click Continue to move to the next page.



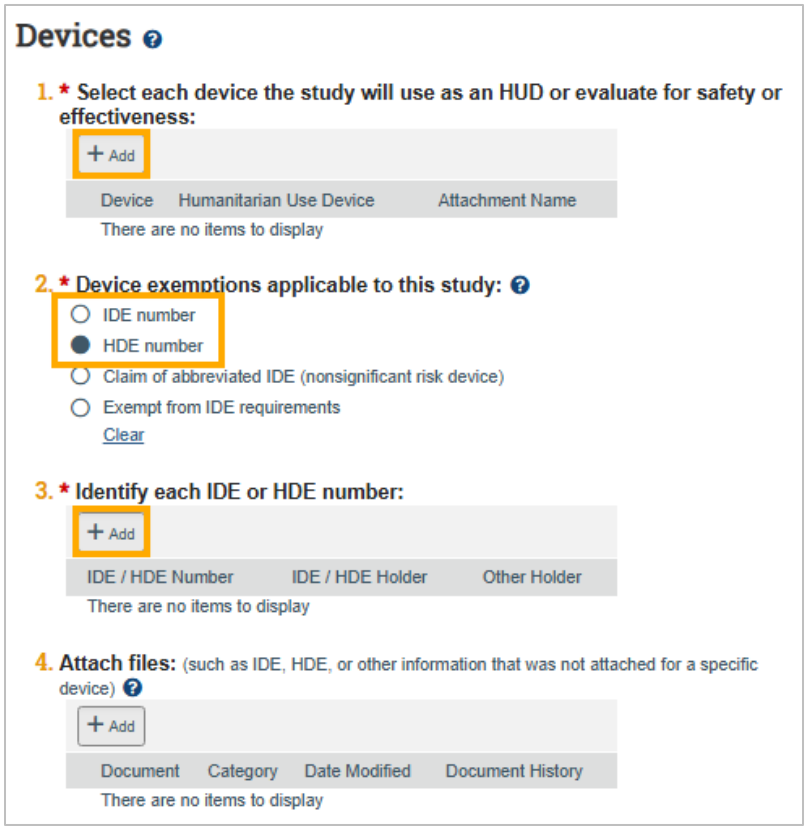
12. On the Local Research Locations page, click the Add button to add any locations outside of UAB where research activities will take place. Click the three dots to open the list of research locations and select one. If you cannot find the research location in the list, enter its information on this page. When complete, click OK or OK and Add Another.



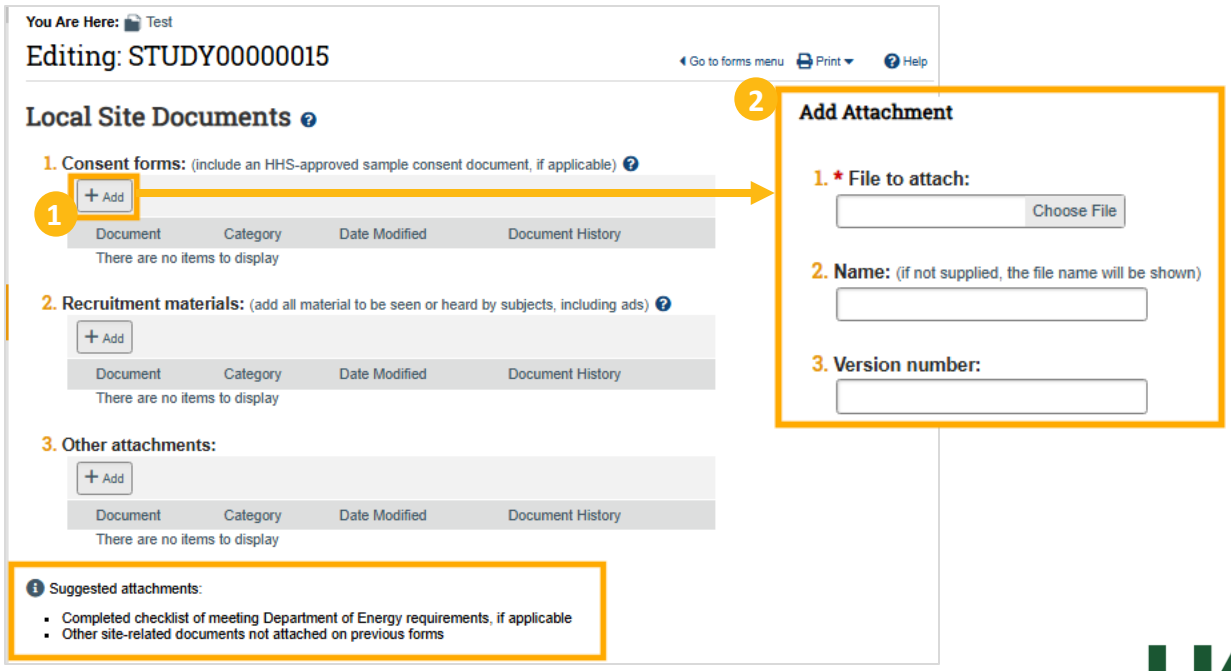
13. If the Drugs page appears, click Add to list out all drugs, biologics, foods, and dietary supplements to be used in the study. If you select Yes to the question, "Will the study be conducted under any IND numbers?" you must identify each IND. Attach any necessary files and click Continue.



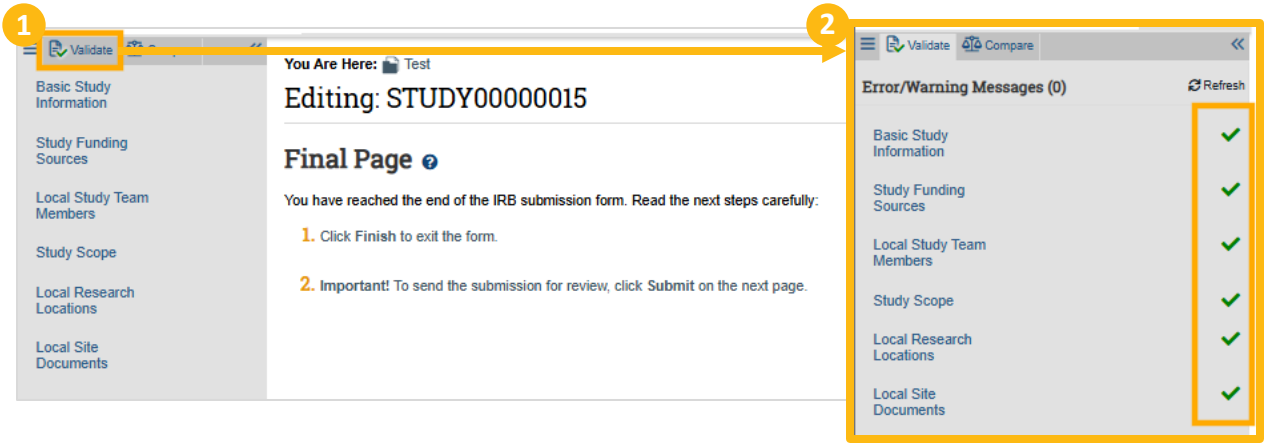
14. **If the Devices page appears, click Add to list out each device the study will use as an HUD or evaluate for safety or effectiveness. For question 2, if you select IDE number or HDE number, you must identify each IDE or HDE number. Attach any necessary files and click Continue.**



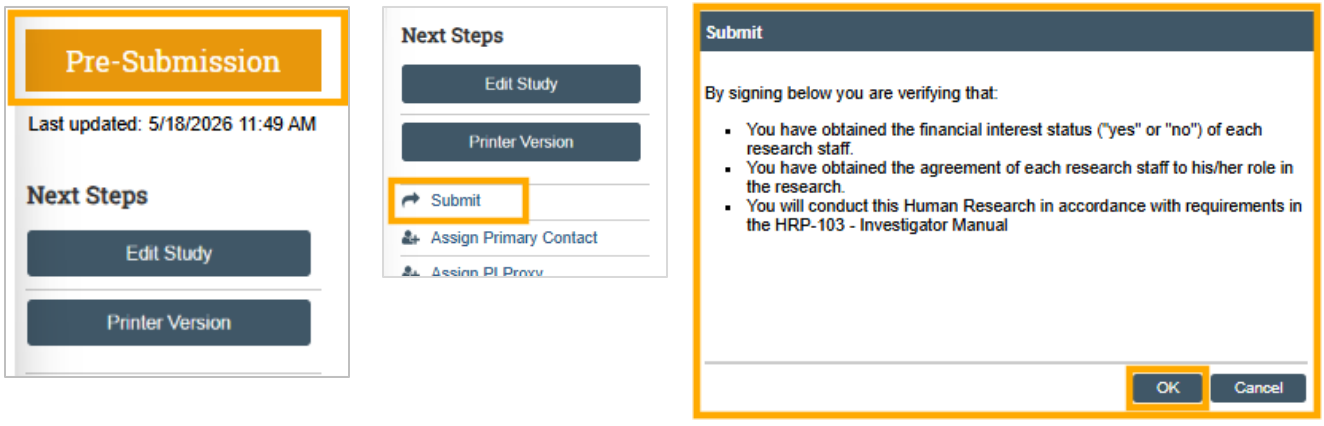
15. **If your study will include consenting participants, use the Local Site Documents page to attach consent forms and recruitment materials using the Add button. You can use the template in the HRPP toolkit listed in "Suggested attachments" to make sure your informed consent complies with the Health and Human Services standards. When you've finished adding attachments, click Continue.**



16. On the final page, click Validate to check for errors. If there is an error, you will see a red circle with a white line through it by the page where the error occurred, if there are no errors, there will be a green check mark next to the page. Once you have corrected your errors, click Save and Exit. If there are no errors, click Finish.



17. You are now taken back to the study workspace, and the study is in the Pre-Submission state. To submit the study, click Submit, read the verification statement, and click OK. IMPORTANT: You must click "Submit" after completing the single site study form or your study will not move to the pre-review state



You have created and submitted a single site study. The study is now in the pre-review stage.

