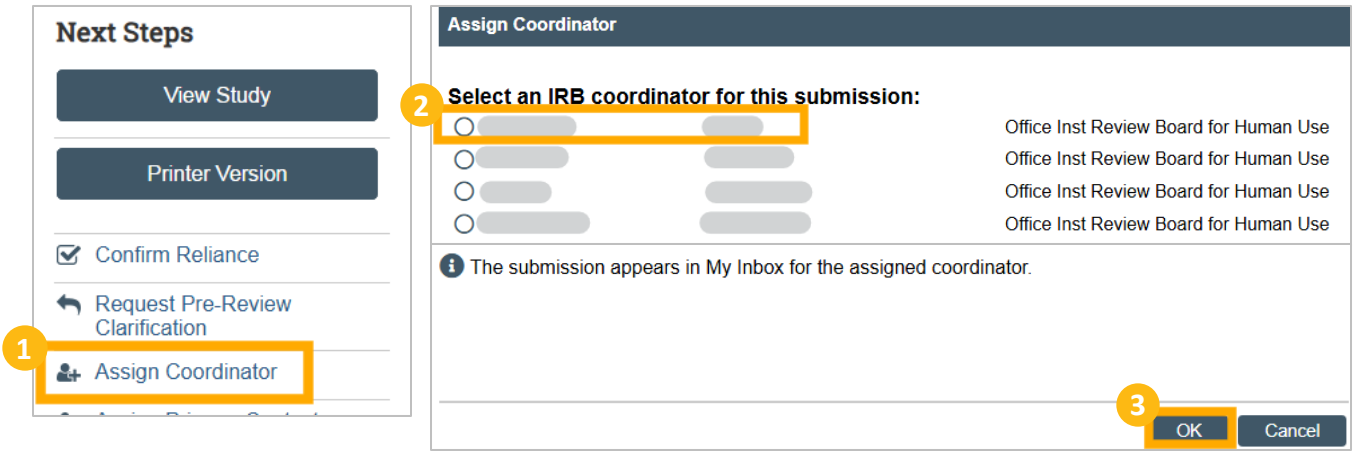
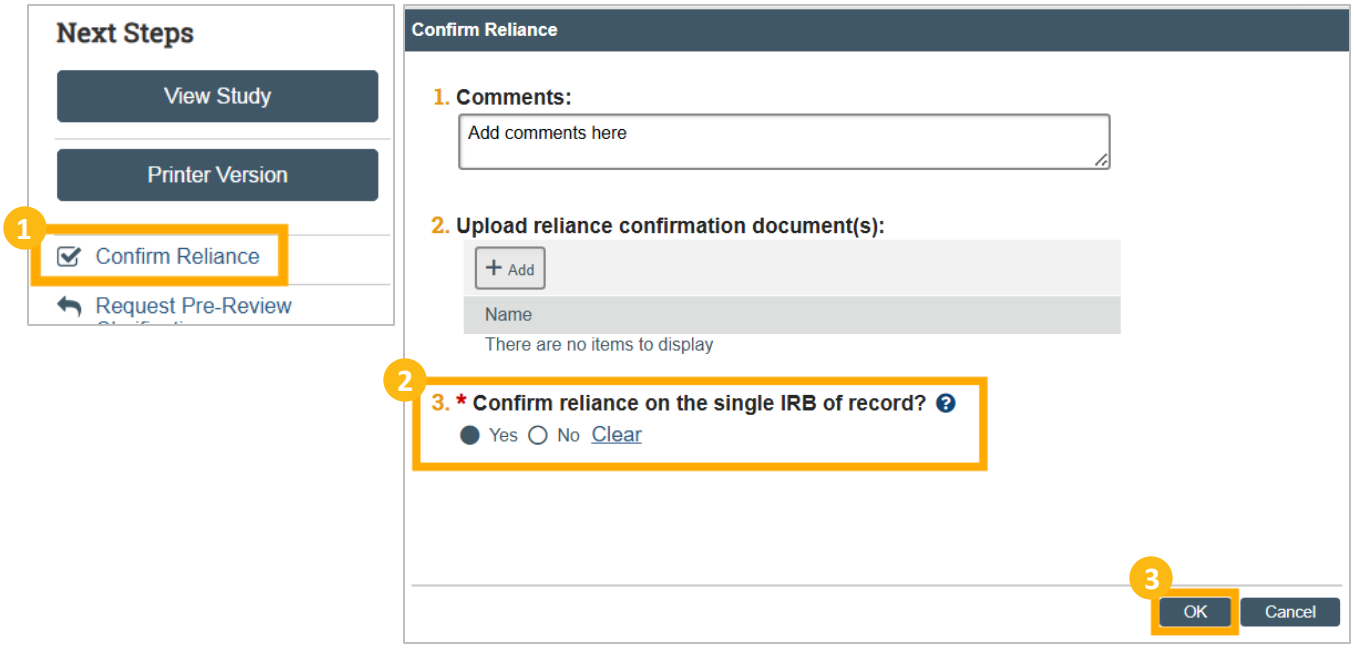
**This guide demonstrates how to conduct an external IRB review. It will cover how to: confirm reliance with an external IRB, record the sIRB decision, and update study details.**

**Confirm Reliance with an External IRB:**

1. **Start from the study workspace and click Assign Coordinator. Assign the IRB Coordinator and click OK.**




2. **After reviewing the submission, confirm reliance by clicking Confirm Reliance. Complete the form and click OK.**

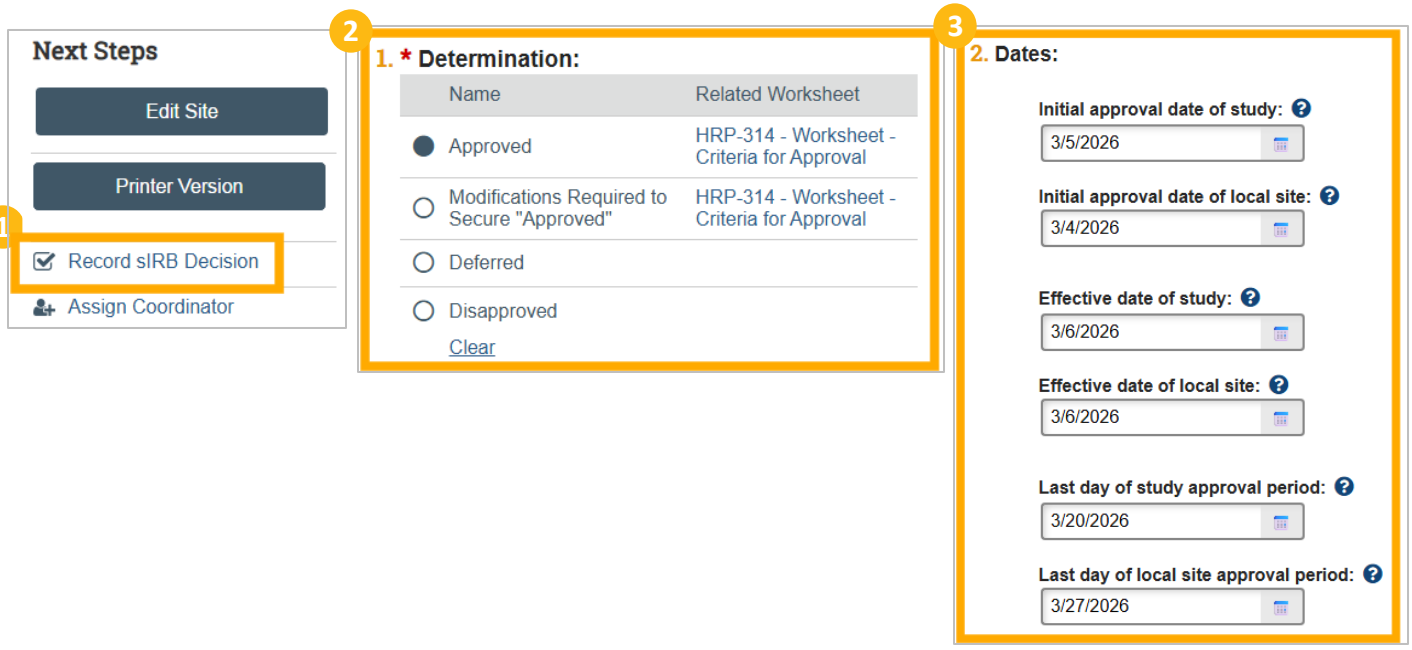



3. **The submission is now in the "Pending sIRB Review" state, next notify the external IRB acting as the IRB of record that your UAB has confirmed reliance. If you are working with a multi-site study, you can communicate using the IRB exchange, but if this is a single-study you must contact them through other channels.**

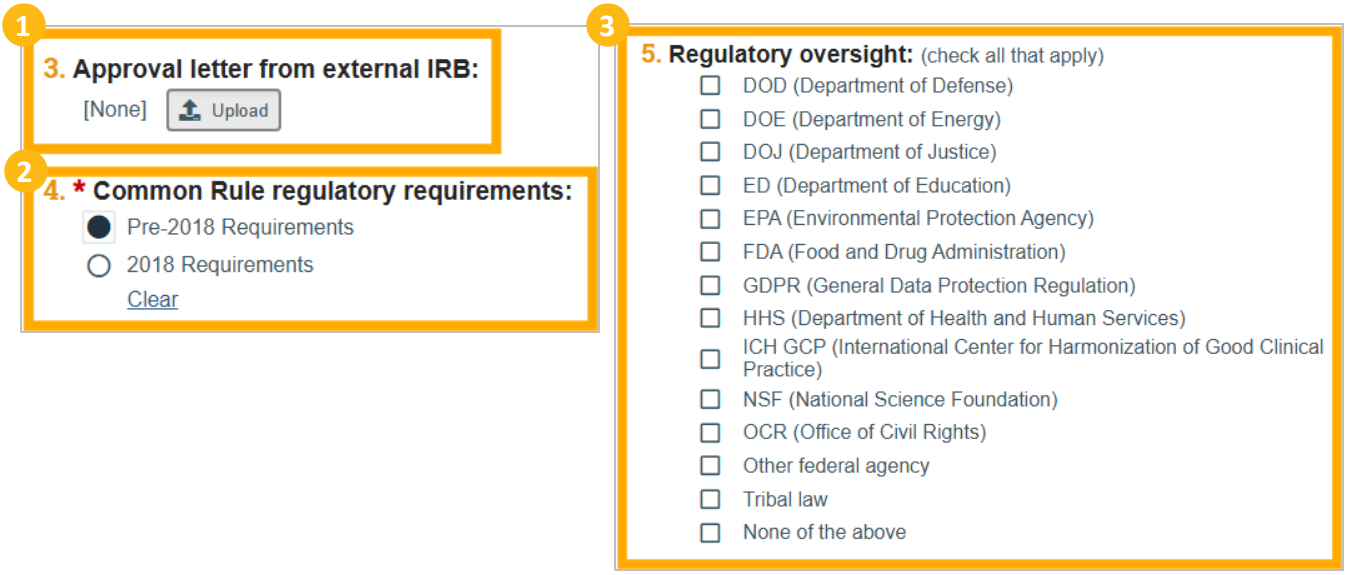


**Record the sIRB decision:**

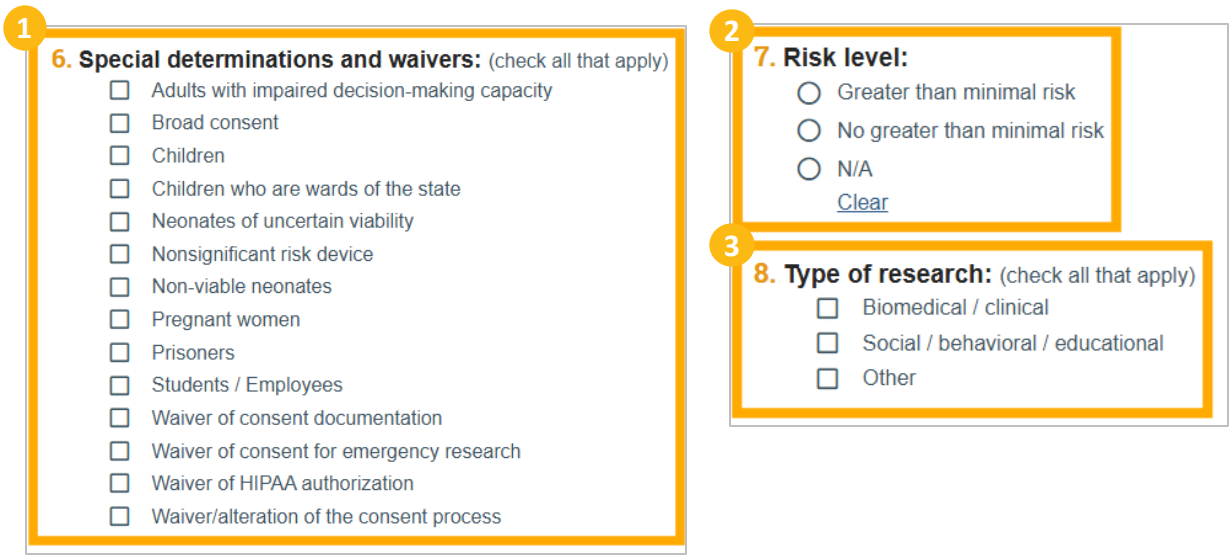
1. **After receiving the determination from the external IRB, record their decision by clicking Record sRIB Decision. Select the determination, Initial approval date, Initial effective date, and the Last day of study approval period. Note: the last day of the study approval period is what triggers the continuing review notification.**




2. **Upload the approval letter from the external IRB (if available), select the Common Rule regulatory requirements, and the Regulatory oversight.**



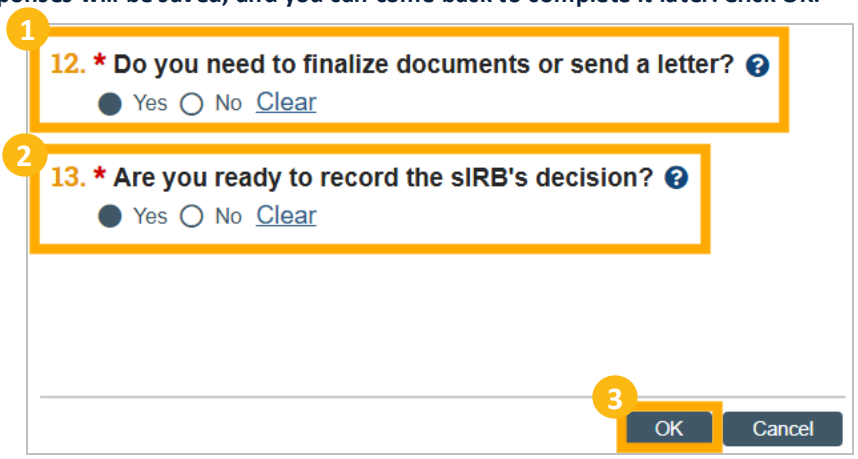
3. **Select all applicable Special determinations and waivers. The Risk level and Type of Research will be unchanged from the earlier versions of the IRB.**




4. **Select Additional study features; this is for reporting purposes. Add any necessary comments or supporting documents.**




5. **Select Yes or No for "Do you need to finalize documents or send a letter?". If you select No, the submission will move directly to the Review Complete state. Select Yes to the question, "Are you ready to record the sIRB's decision?". If you select No, your responses will be saved, and you can come back to complete it later. Click OK.**




**After recording the external IRB's decision, the submission will move to either Post Review or Review Complete. In the Post Review state, you can finalize documents, prepare and send the determination letter, and edit the sIRB decision. Once the determination letter is sent, the submission will move to the Review Complete stage.**

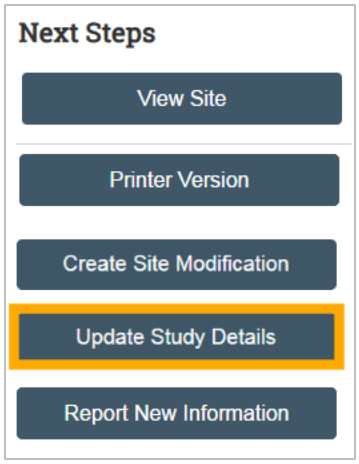
UAB

# External IRB Review – *Update Study Details*

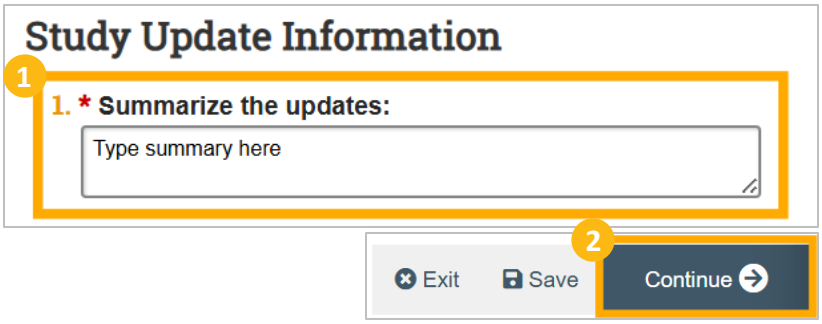


**Update Study Details:**

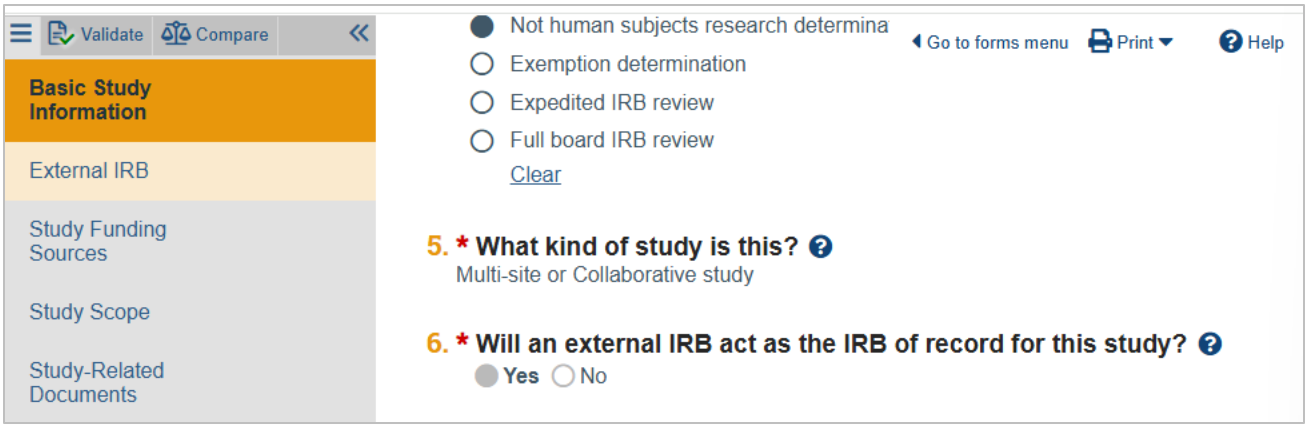
1. **Click Update Study Details, Note: The Update Study Details button will appear under next steps only when the submission is in the Active or Review Complete stage.**




2. **The Study Update Information page will appear. Type your summary of the updates, then click Continue.**



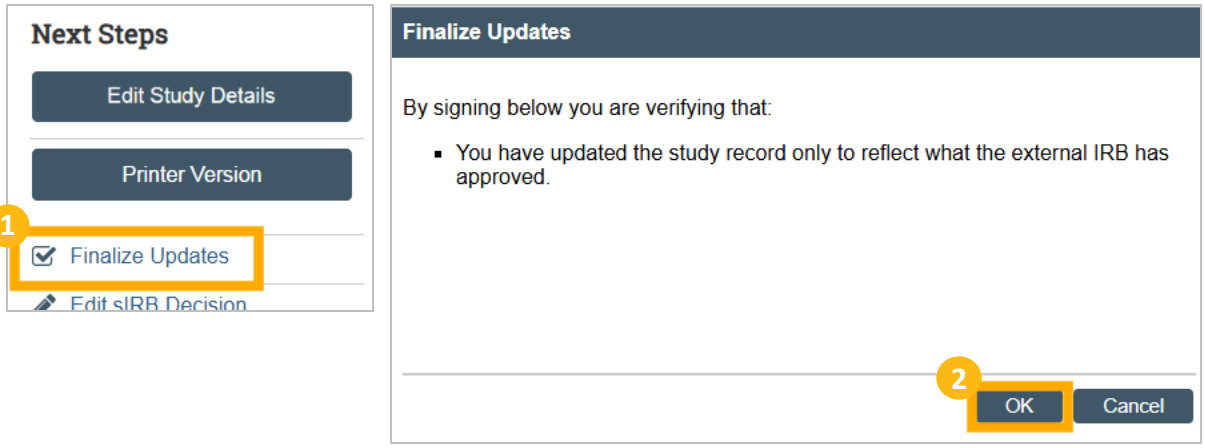

3. **You are now taken to the original submission, you can update any field in the submission except for the following questions: "What kind of study is this?", "Will an external IRB act as the IRB of record for this study?", and "Which IRB should oversee this study?". Note: for a multi-site study, only study information pages will appear.**

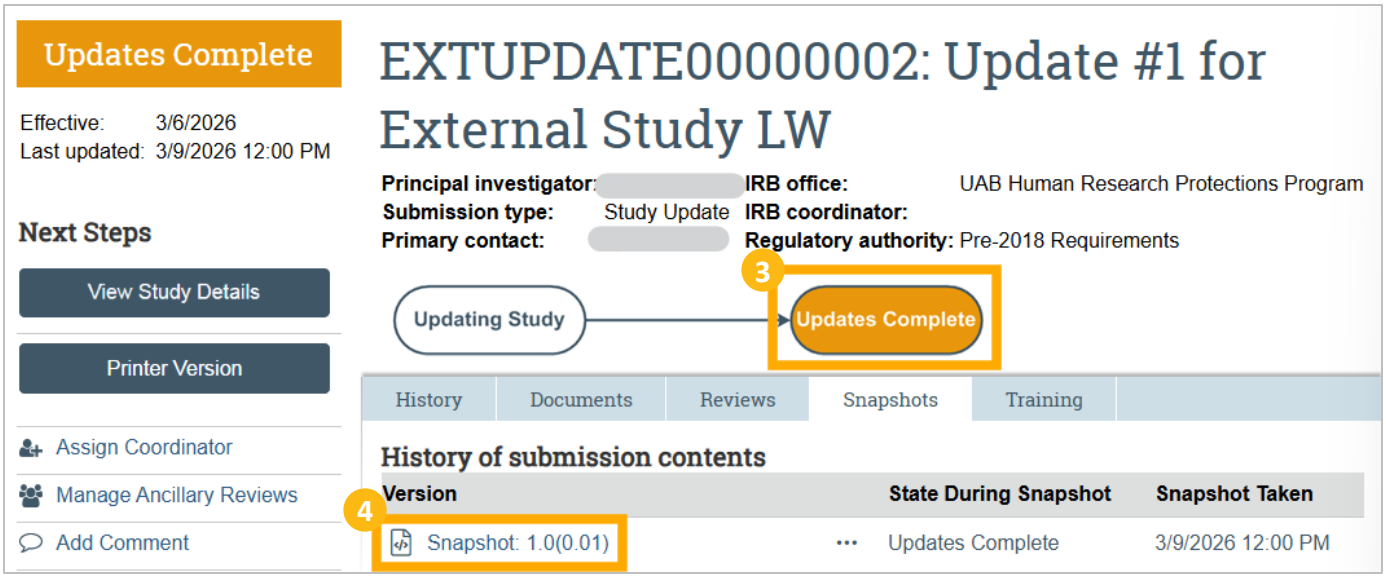



4. **When you have completed your updates, click Save, then Exit.**



5. **You are now taken back to the update workspace, click Finalize Updates, then click OK. The update will advance to the Updates Complete stage and a notification is sent to the local IRB team informing them of the update. The finalized update will trigger a snapshot of the submission so the two versions can be compared.**




**You have now completed the process of updating study details, to view the changes made, use the breadcrumb trail at the top of the screen to return to the original study, then click View Site/Study, then Compare. Both the PI and IRB Coordinator can update study details, but the IRB Coordinator can also update the sIRB decision.**

