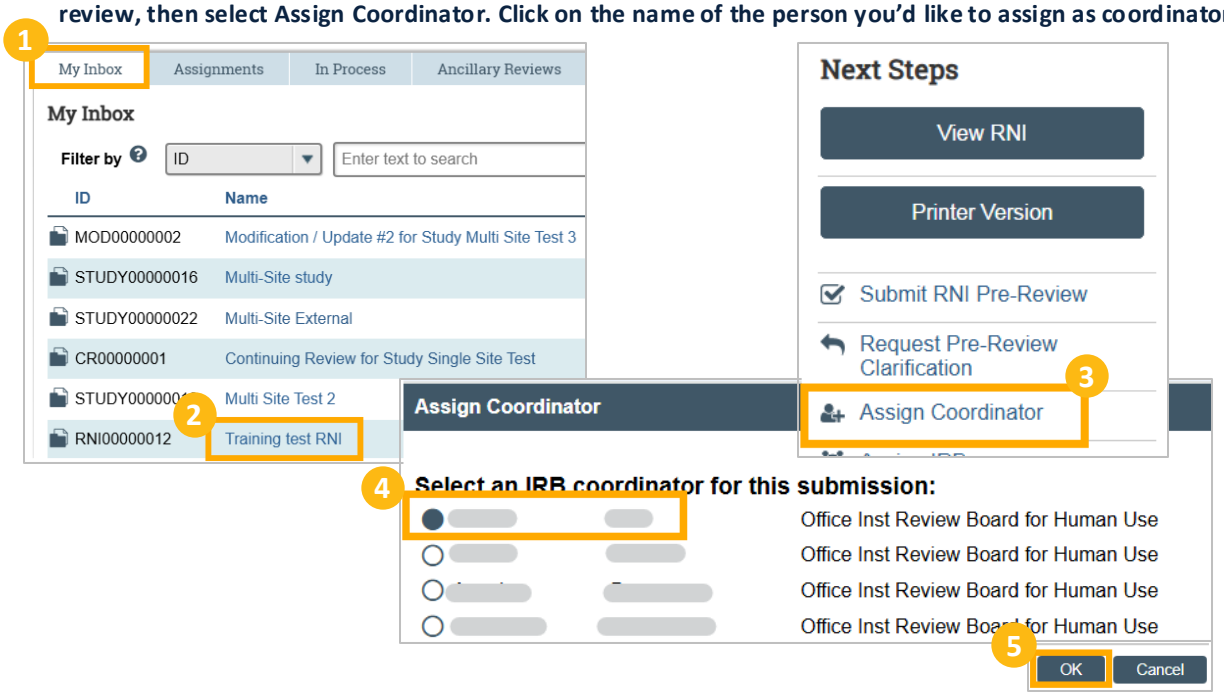
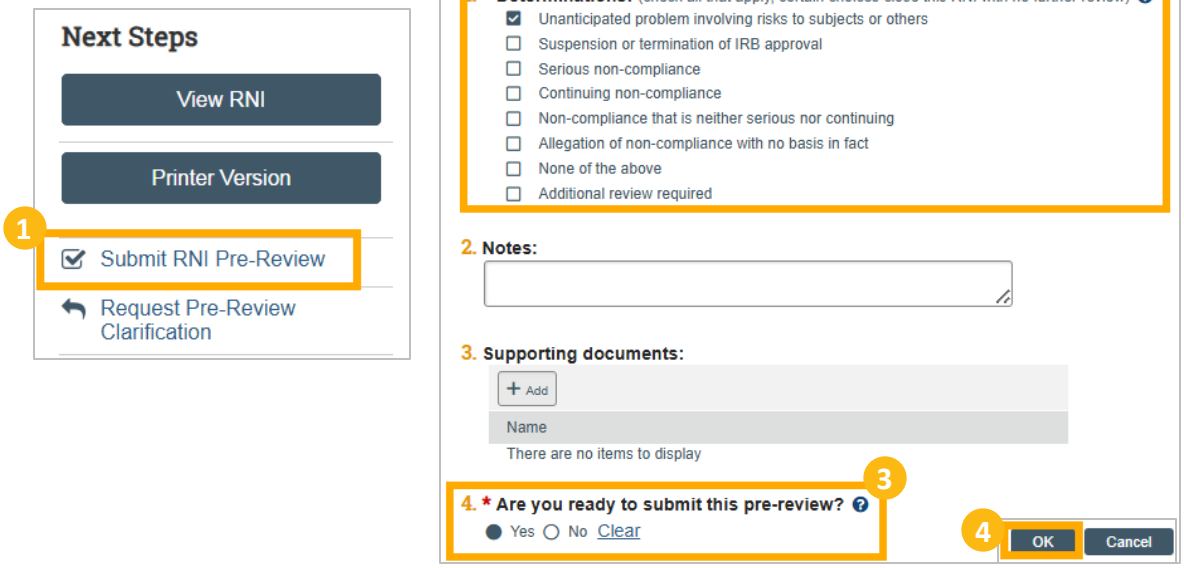
This guide explain how to conduct a pre-review, a designated review, and a committee review for Reportable New Information (RNI).

Pre-Review:

1. **You will start by conducting a pre-review. To do this, from My Inbox, click on the name of the RNI that you want to review, then select Assign Coordinator. Click on the name of the person you'd like to assign as coordinator and click OK.**



2. **Review the RNI, then click Submit RNI Pre-Review. Select the determination. The following determinations are deemed not serious: Non-compliance that is neither serious nor continuing, Allegation of non-compliance with no basis in fact, and None of the above. Add any necessary notes or supporting documents, then if you are ready to submit the pre-review, check Yes, then click OK.**

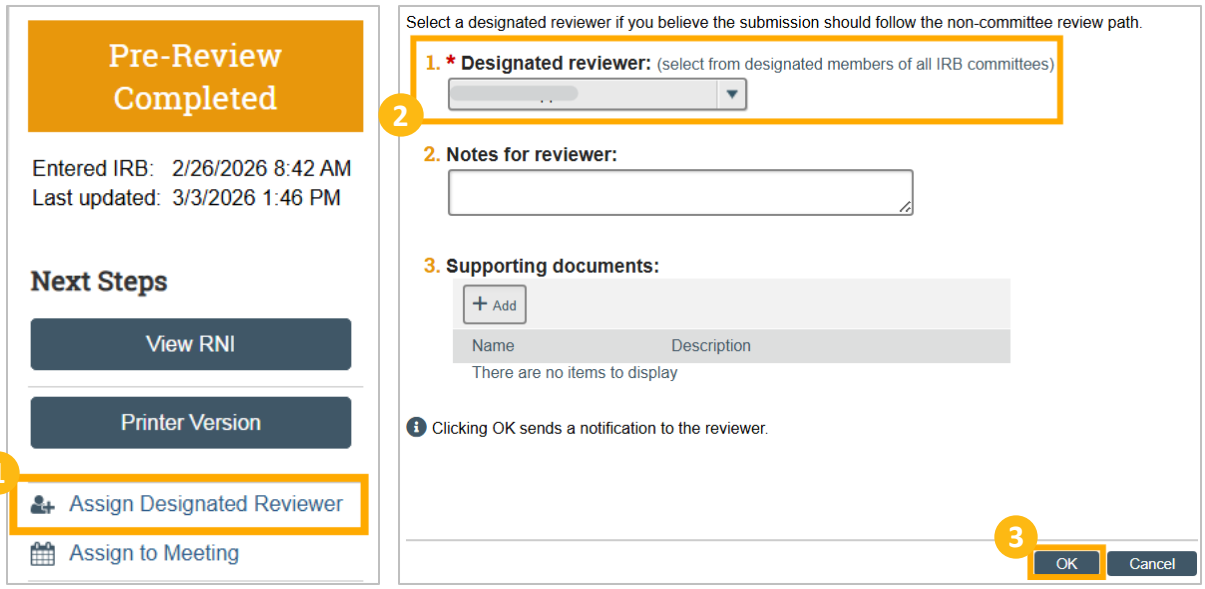


An RNI that is not serious will transition to the Acknowledged state and an email is sent to the study team indicating the review is complete. The following determinations are serious: Unanticipated problem involving risks to subjects or others, Suspension or termination of IRB approval, Serious non-compliance, and Continuing non-compliance. If a serious determination or Additional review required is selected, the submission requires review.

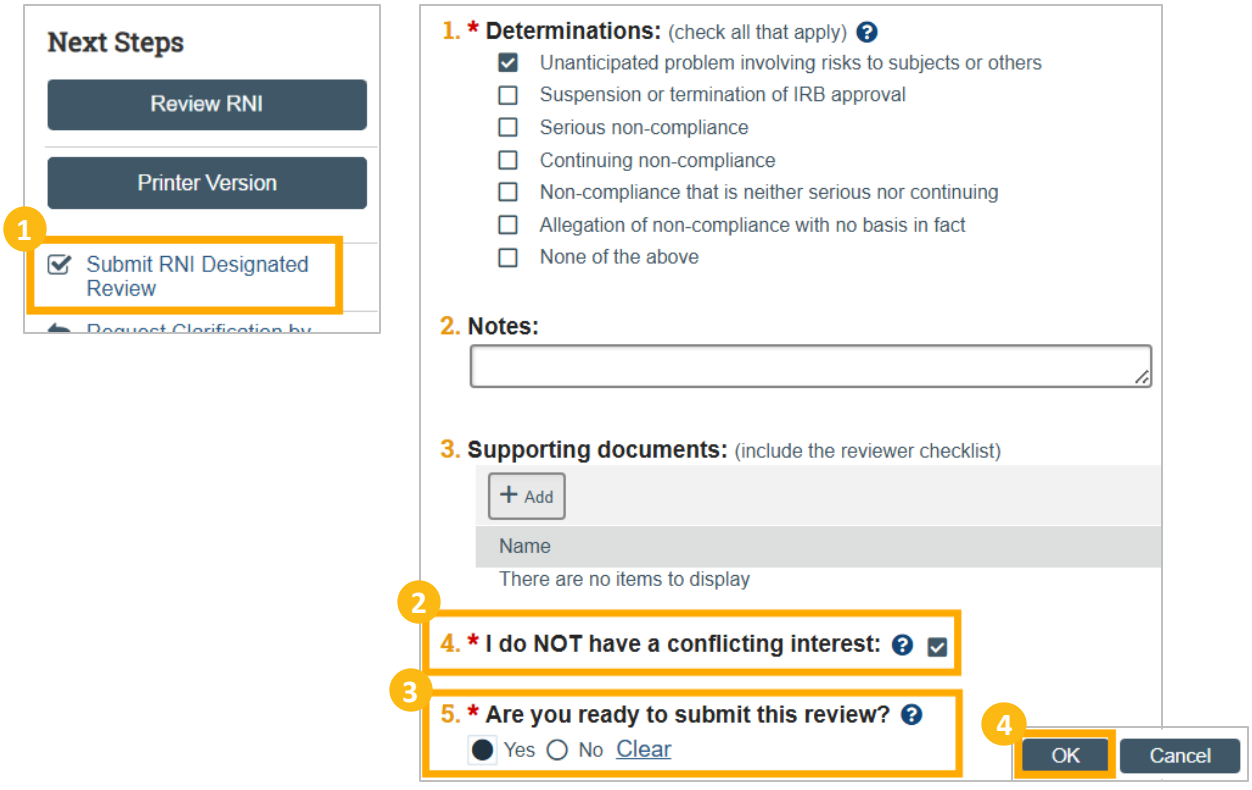
After completing the process of selecting a serious determination, either assign a designated reviewer, or assign it to a meeting. You may also add a related submission if needed.

Designated Review:

1. **To assign a designated reviewer: After the Pre-Review is complete, select Assign to Designated Reviewer. Select the designated reviewer from the drop-down list, add any necessary notes or supporting documents, then click OK.**



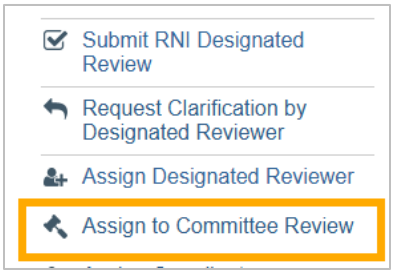
2. **After reviewing the RNI, select Submit RNI Designated Review. The information you selected during the Submit RNI Pre-Review will carry over. Check the box to confirm that you do not have a conflicting interest. When you are ready to submit your review, click Yes for the question, "Are you ready to submit this review?". Then click OK. Note: A key different in the RNI workflow is that if the determination is serious, a committee review will follow.**

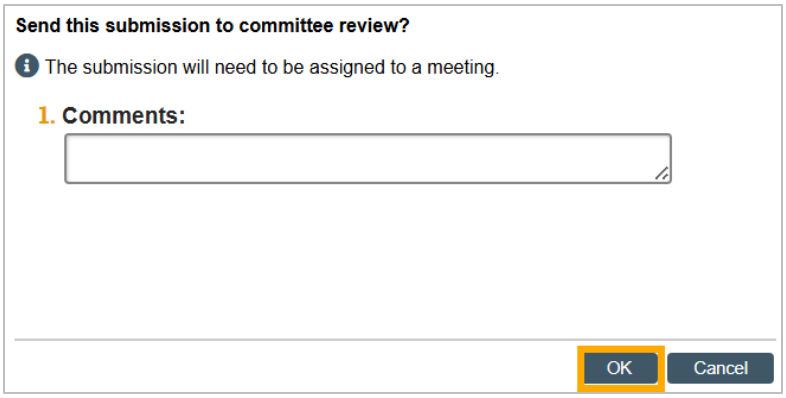


3. **The IRB Coordinator will now assign the RNI to a meeting of the full committee.**

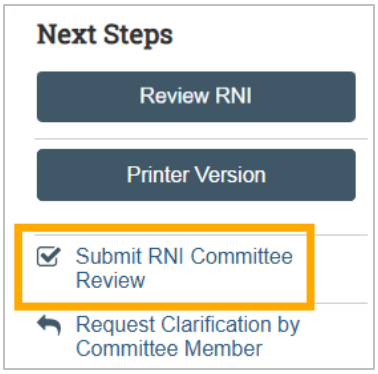
Committee Review:

1. **To assign to committee review, select Assign to Committee Review, add a comment if needed, then click OK. For information about the committee review process, see the Meeting Management Guide.**





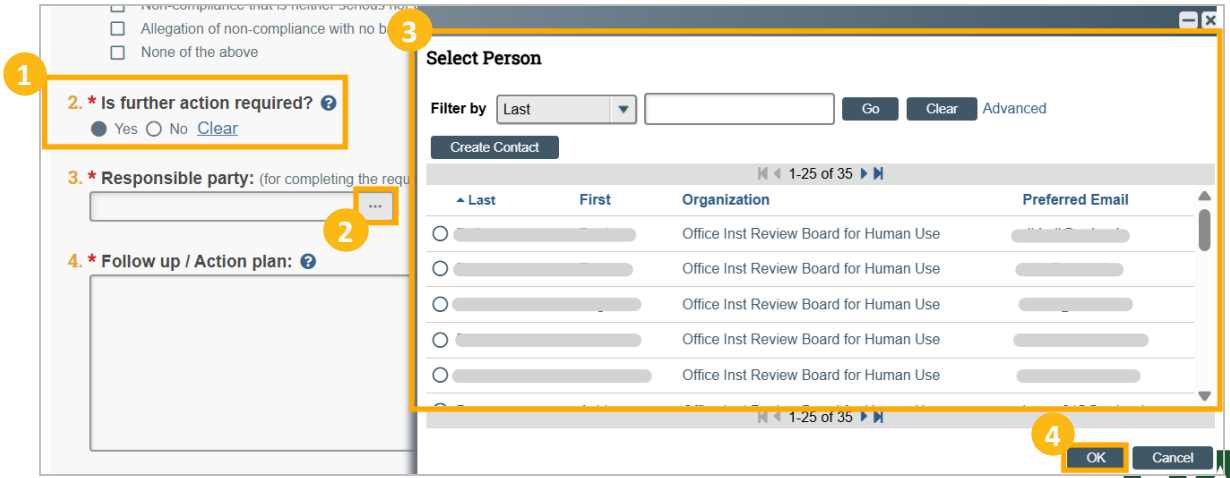
2. **The RNI was determined to be serious, and a committee review meeting was held. To submit the committee decision, select Submit RNI Committee Review. The previous selections have carried over, but the committee can modify these as needed. If the committee determines that the RNI is not serious, it will transition to Acknowledged and an email will be sent to the study team.**



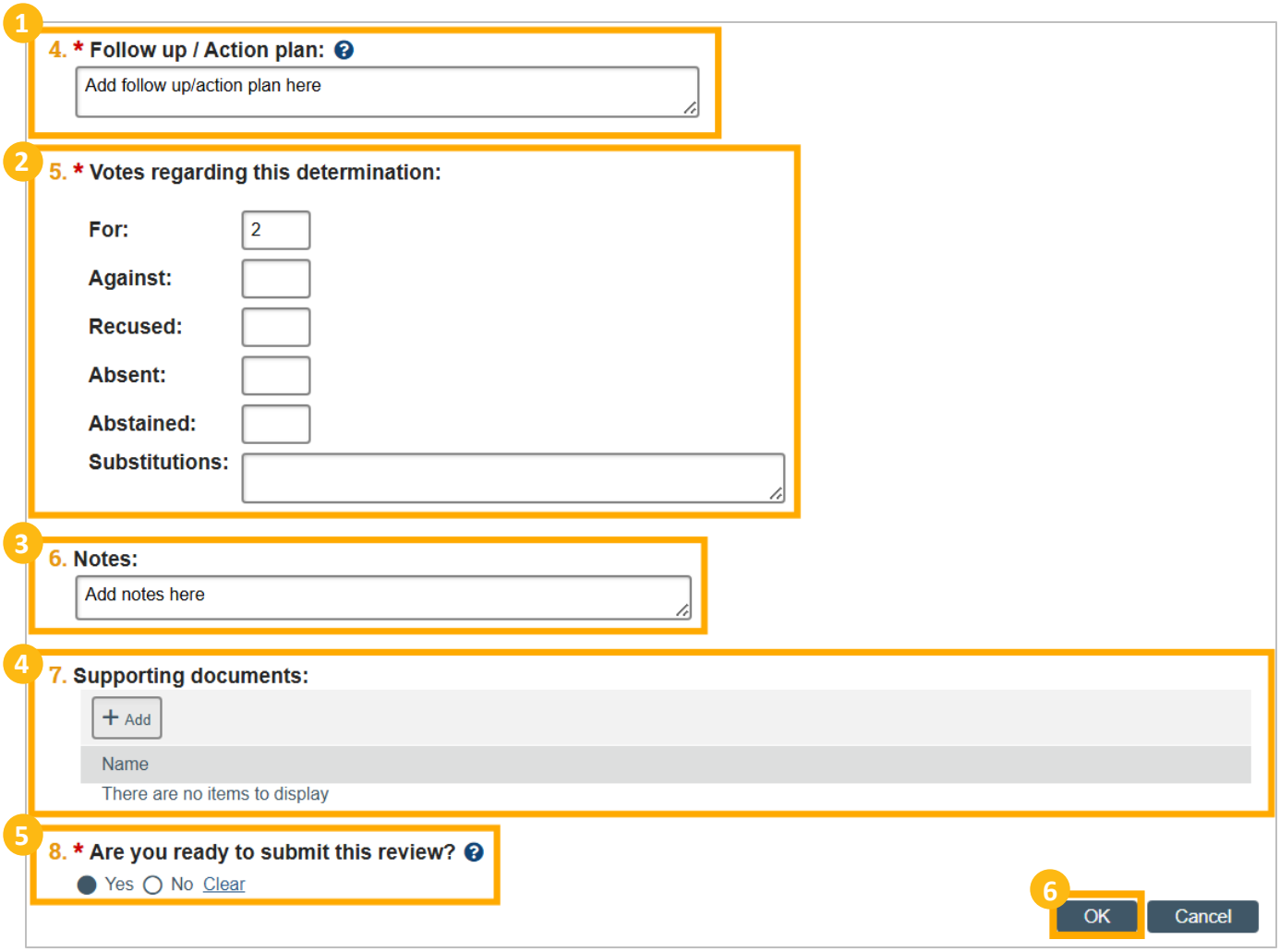
3. **In the Submit RNI Committee Review, if no further action is required, select No and complete the rest of the form.**



4. **If further action is required, select Yes and select the responsible party by clicking on the three dots, selecting a name, then clicking OK. This is the person who will complete the required action.**



4. **Add a follow up/action plan for the responsible party, record the votes, add notes, and attach any supporting documents. When you are ready to submit the review, click Yes, then click OK.**



After submitting the committee review, the RNI will transition to the Post-Review state.