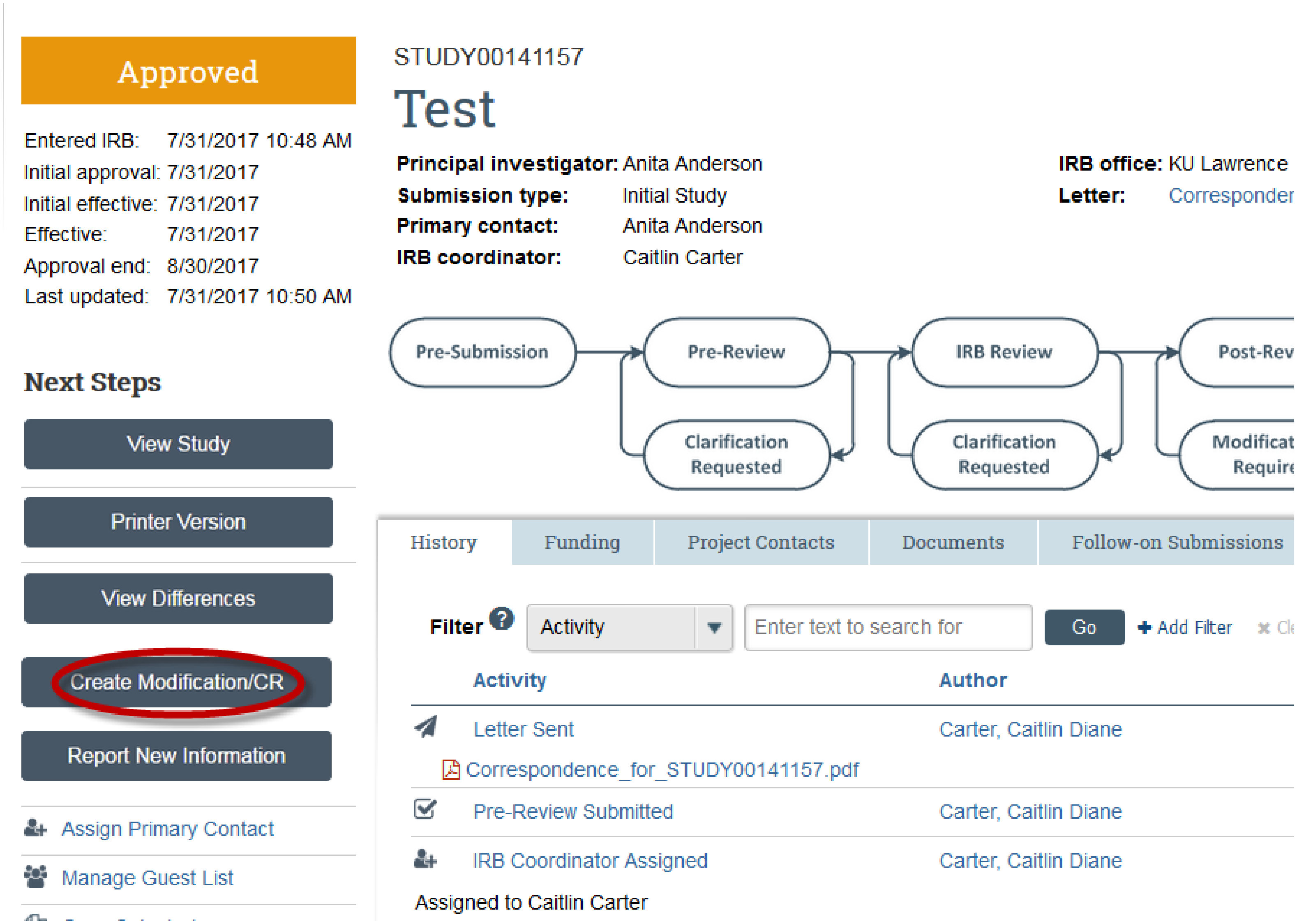
Creating a Study Team Modification in eCompliance

1. Go to ecompliance.ku.edu and log in using your KU ID and password.

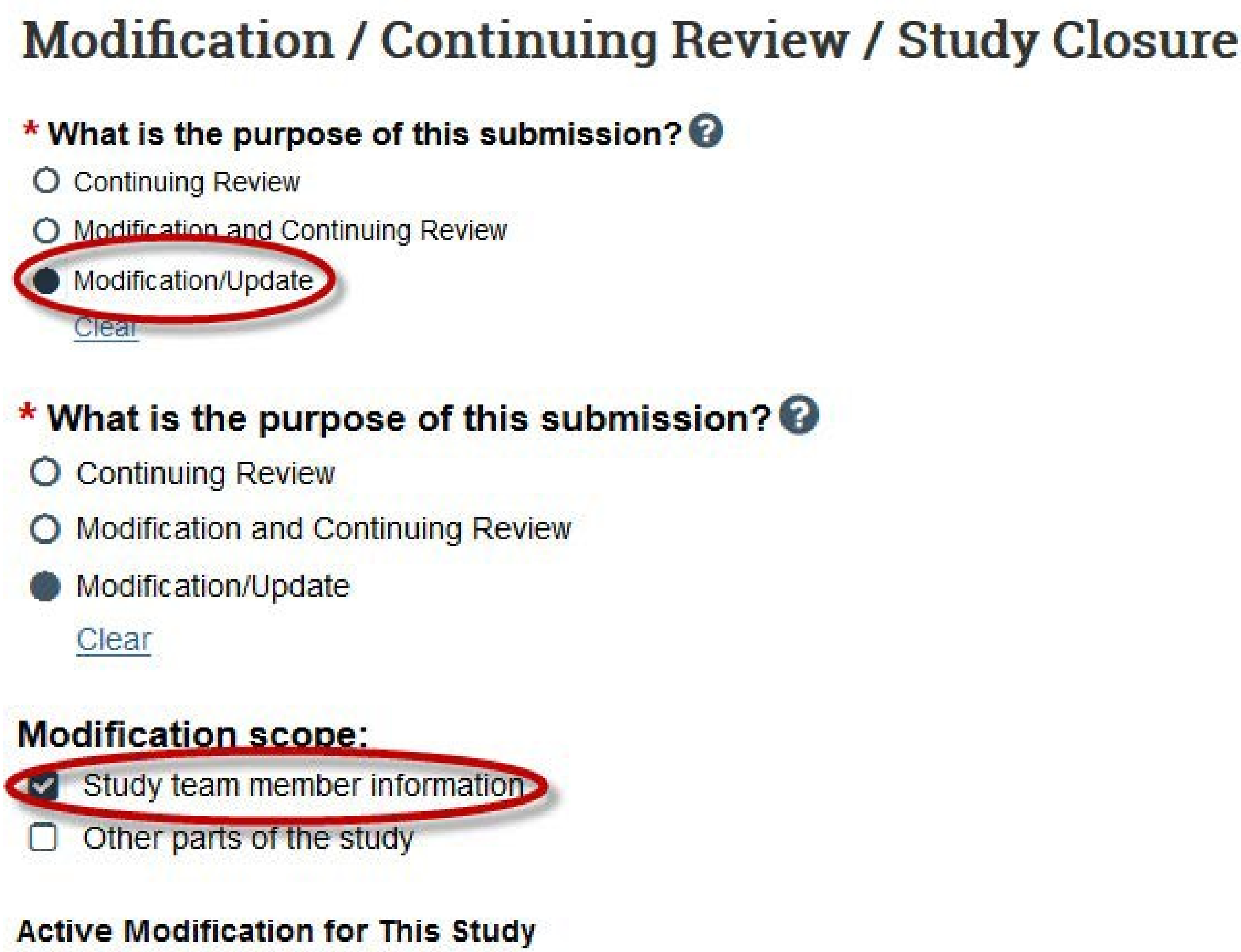
2. Access the study in the IRB by clicking the "IRB" link in the red banner, and clicking the "All Submissions" tab. *(See Guide for Accessing a Study)*

3. Click the "Create Modification/CR" button.



4. Choose “Modification” if you want to change part(s) of your study.

5. To add or remove study team members, click “Study Team” under Modification Scope. Click“Continue”.

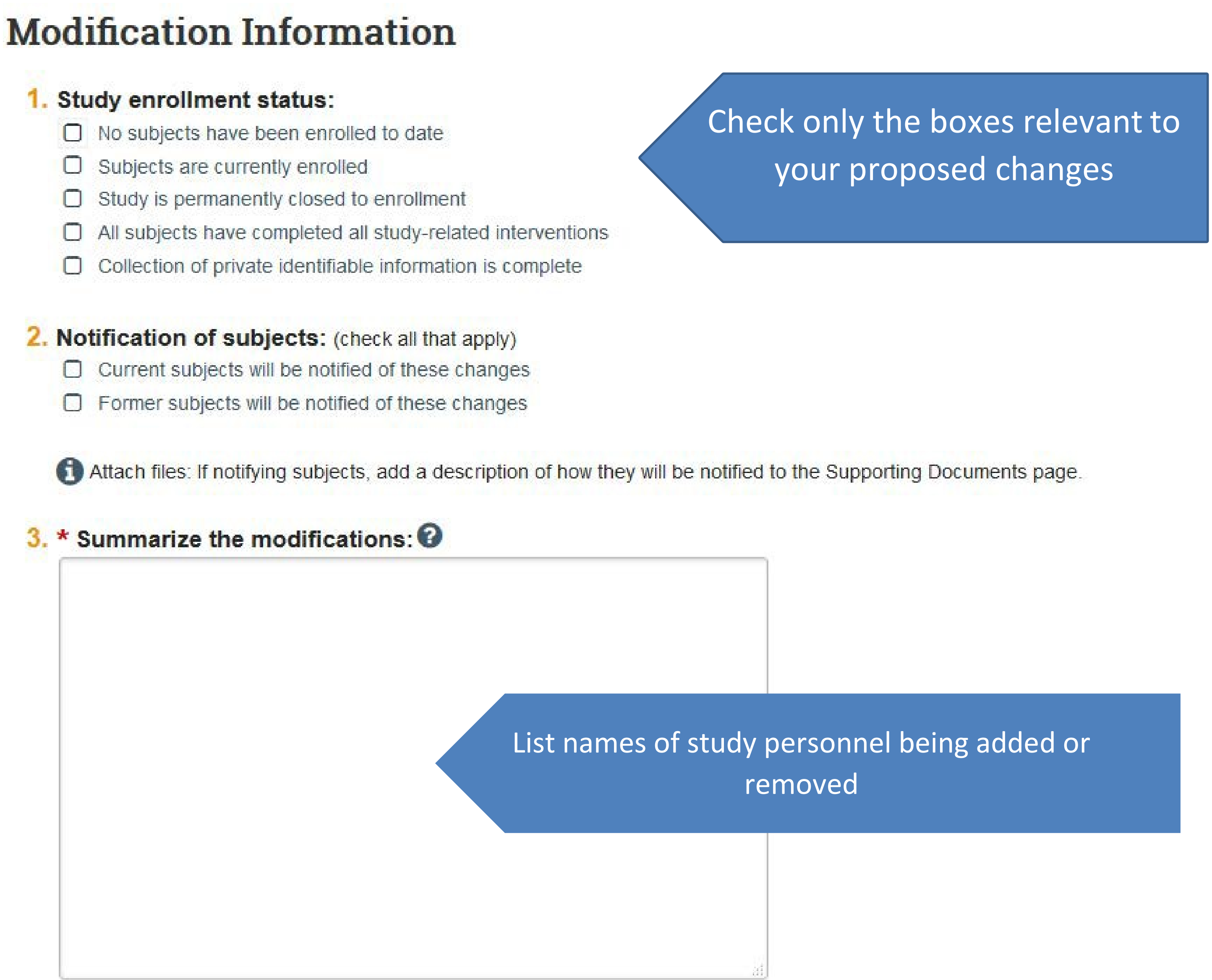


6. On the Modification Information page you can provide information about the changes you are requesting. Check all boxes that are relevant to your modification.

Use the “Summarize the modifications” section (required) to clearly describe the changes you are requesting.

1. In lay terms, summarize the key changes being proposed.
2. Summarize the reason for the changes.

It is also helpful to list the names of study personnel you are adding or removing here.



Modification Information

1. **Study enrollment status:**
   - ☐ No subjects have been enrolled to date
   - ☐ Subjects are currently enrolled
   - ☐ Study is permanently closed to enrollment
   - ☐ All subjects have completed all study-related interventions
   - ☐ Collection of private identifiable information is complete

Check only the boxes relevant to your proposed changes

2. **Notification of subjects:** (check all that apply)
   - ☐ Current subjects will be notified of these changes
   - ☐ Former subjects will be notified of these changes

Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.

3. * **Summarize the modifications:**

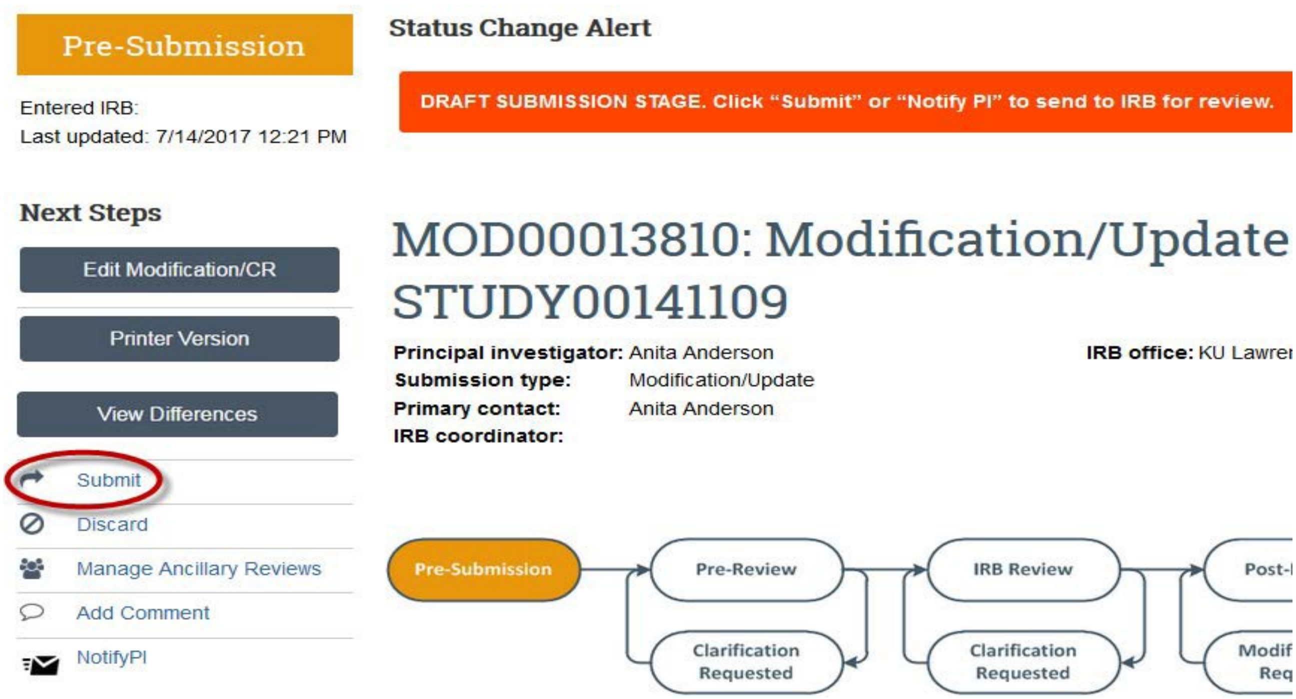
List names of study personnel being added or removed

7. You can now add or remove a person from your study team. Click "Finish" when you are done making changes.

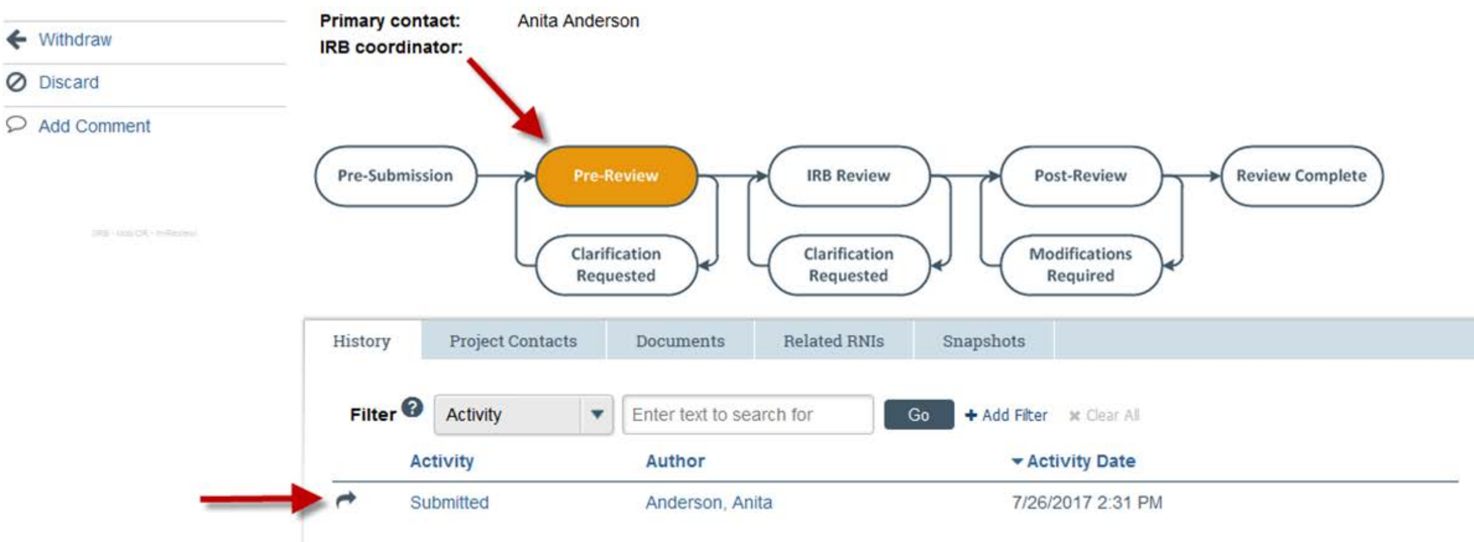
****Note: Only current KU faculty/staff/graduate students will show up in this list. Undergraduates may not show up in this list. If you need an undergraduate added to eCompliance, please contact HRPP by telephone with their 7-digit KU ID (785- 864-7385), or send an encrypted email to irb@ku.edu.**

If you have an external study team member (e.g. not affiliated with KU in any way) working on your project, please contact irb@ku.edu for additional information on adding external members to your study team.

8. In order to submit your modification for review by HRPP staff, **<u>click the "Submit" button on the left side of the screen.</u>** If you are not the PI on the project, then the PI will need to log in and click the "Submit" button. The system will ask you to enter your KU ID and password.



9. Once the study is submitted, the flowchart will change from "Pre-Submission" to "Pre-Review" and the History Activity will show that the study has been "Submitted". There will also be a green banner at the top of your screen for a few seconds to show submission.



Looking for something else? There is more information available on the HRPP website:

Quickstart

- ✓ Creating a Single-Site Study
- ✓ Creating a Multi-Site Study
- ✓ Continuing Review
- ✓ Accessing a Study
- ✓ Changing Principle Investigator
- ✓ Adding Funding
- ✓ Creating an External IRB Study
- ✓ Modification
- ✓ Responding to Clarifications
- ✓ Closing a Study

Guides

- ✓ Student Ancillary Review Guide
- ✓ Faculty Supervisor Ancillary Review Guide