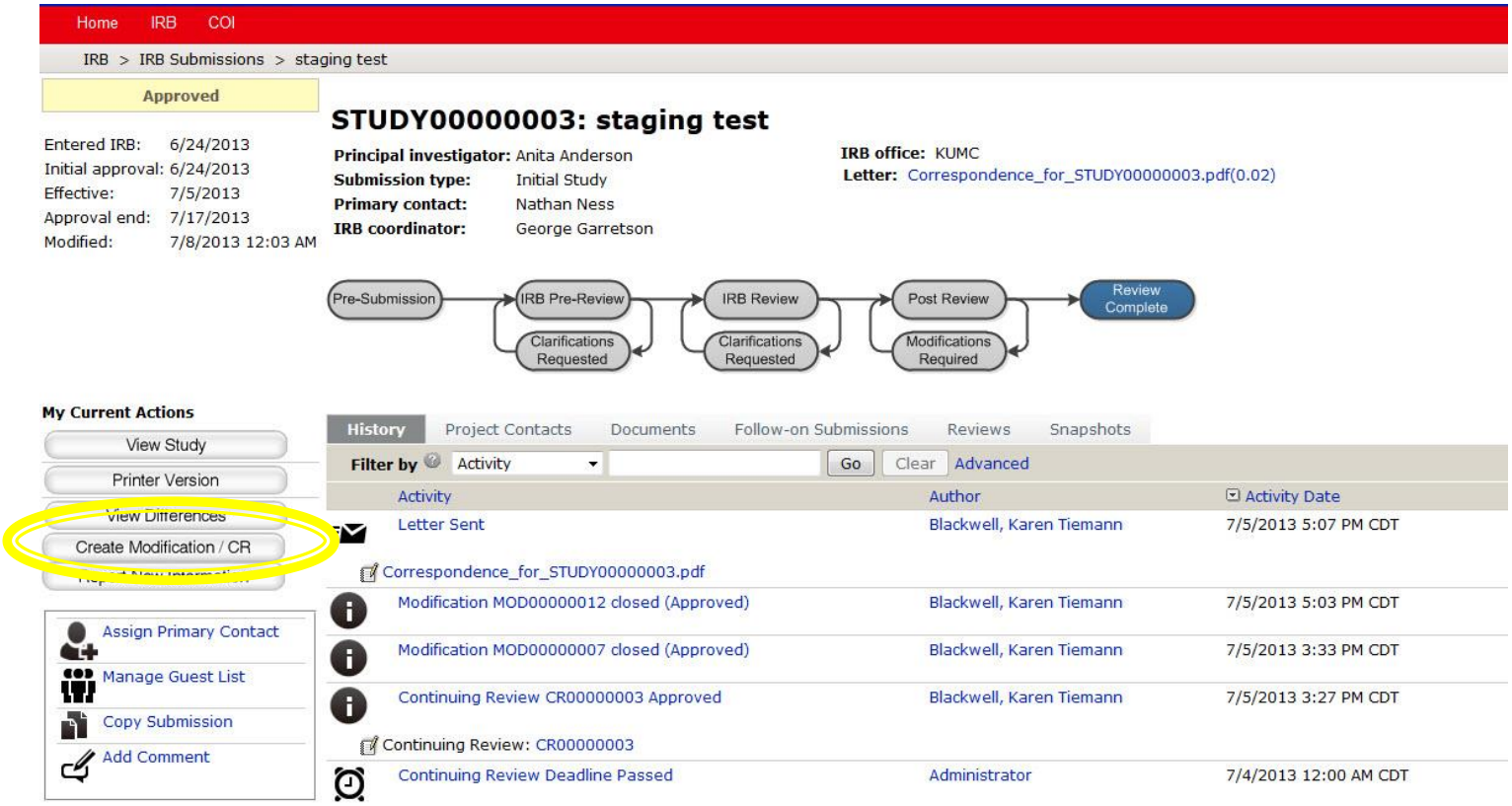
Create a Continuing Review in eCompliance

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

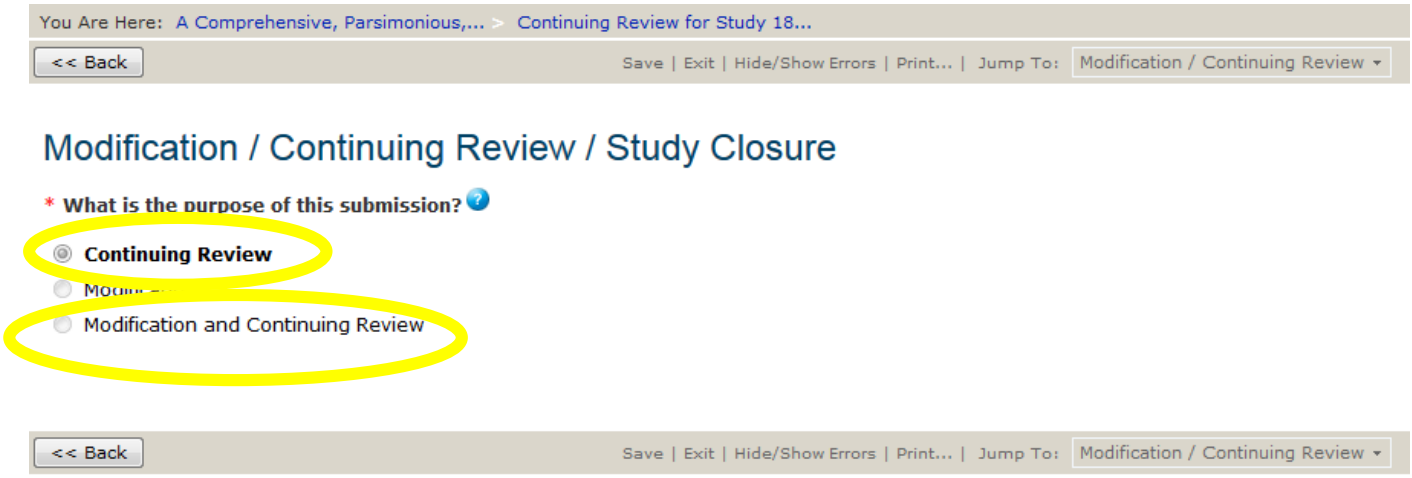
STEP 2: Access the study in the IRB "Active" tab *(See Quickstart Guide for Accessing a Study)*

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



STEP 4: Choose "Continuing Review" or "Modification and Continuing Review."

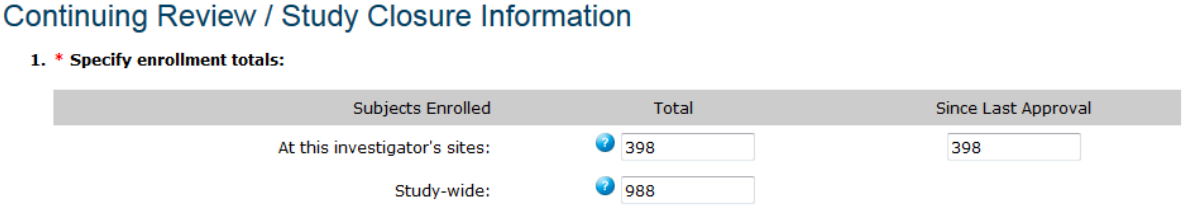
Choose "Continuing Review" only when **no** changes need to be made to the study. Choose combination "MOD/CR" when you need to make changes **and** want to renew the study for another 12 months.



STEP 5: If requesting a Modification/Continuing Review, select the scope of the change, then click "Continue."

STEP 6: Complete the Continuing Review/Study Closure

STEP 6a. Indicate how many people have participated in your study.



STEP 6b. Check only the research milestones that apply to this specific study. If none apply, you are not required to check any boxes.

Research milestones: (select all that apply)

- [ ] Study is permanently closed to enrollment
- [ ] All subjects have completed all study-related interventions
- [ ] Collection of private identifiable information is complete
- [ ] Analysis of private identifiable information is complete
- [ ] Remaining study activities are limited to data analysis
- [ ] Study remains active only for long-term follow-up of subjects

STEP 6c. Indicate if any study team members, including the PI, have any previously undisclosed financial conflicts of interest.

* **Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?**

○ Yes ◉ No Clear

STEP 6d. The next section helps the IRB determine if the risks and/or benefits have changed since you originally submitted the study. In most cases, all the boxes should be checked to confirm that the statement is TRUE.

Check the items that are true since the last IRB continuing review for all sites involved in the study:

- [x] NO subjects experienced harm (expected or unexpected)
- [x] NO subjects experienced benefit
- [x] NO subjects withdrew from the study
- [x] NO unanticipated problems involving risks to subjects or others
- [x] NO complaints about the study
- [x] NO publications in the literature relevant to risks or potential benefits
- [x] NO interim findings
- [x] NO multi-center trial reports
- [x] NO data safety monitoring reports
- [x] NO regulatory actions that could affect safety and risk assessments
- [x] NO other relevant information regarding this study, especially information about risks
- [x] In the opinion of the PI, the risks and potential benefits are unchanged
- [x] All modifications to the protocol have been submitted to the IRB
- [x] All problems that require prompt reporting to the IRB have been submitted

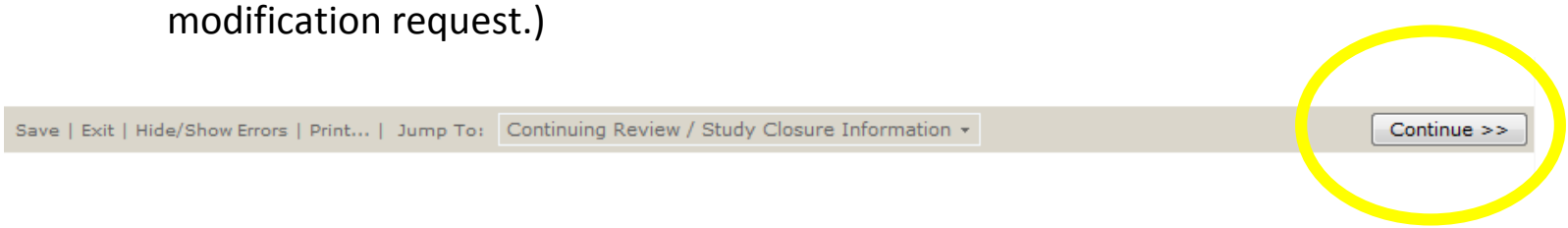
STEP 6e. If any boxes were left unchecked, submit a document that explains why. Do NOT upload consent forms or any other study related materials here.

Attach supporting documents: (include an explanation of each item left unchecked above)

Add

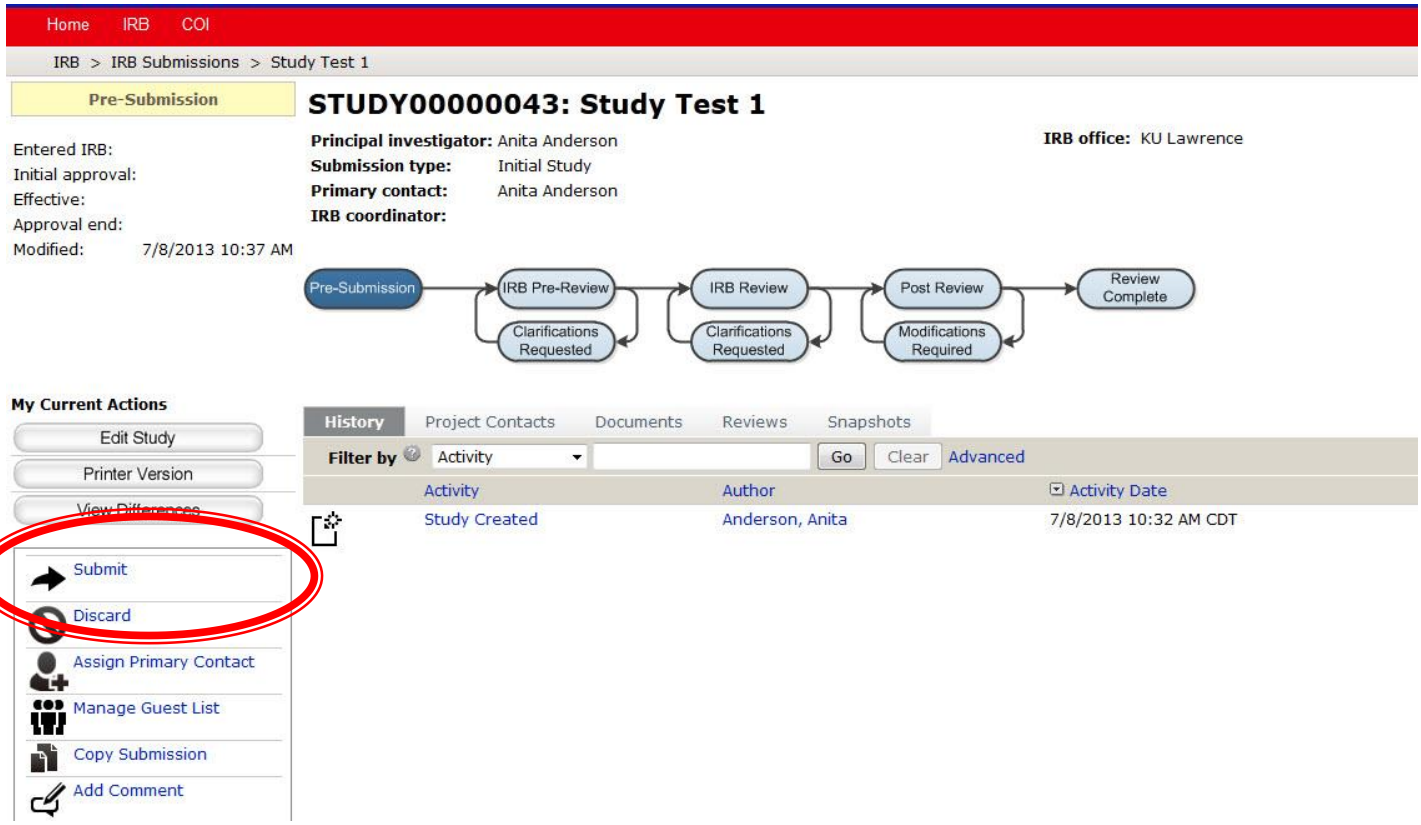
Name
There are no items to display

STEP 7: Click the "Continue" button. (If Modification and Continuing Review was selected, you will now be able to complete your modification request.)



STEP 8: Click the "Finish" button.

STEP 9: In order to submit your continuing review for evaluation by HSCL staff, **click the "Submit" button on the left side of the screen.** If you are not the PI on the project, then the PI will need to log in and click the "Submit" button.



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

Quickstart

- ✓ Creating a Study
- ✓ Modification and Continuing Review
- ✓ Continuing Review Determination Guide
- ✓ Closing a Study

Guides

- ✓ Student/Faculty Supervisor Submission Guide
- ✓ Study Submission Guide

FAQs

- ✓ eCompliance FAQs