

## UK Office of Research Integrity (ORI) Continuing Review Tips

For full-review, pre-2019 expedited and FDA-regulated protocols, the IRB approval period can extend no longer than one year after the start of the approval period. In accord with federal regulations, the IRB conducts a Continuing Review (CR) prior to continue the IRB approval.

It is critical to complete the CR in a timely manner to allow time for IRB review and IRB requested revisions, if any, and to prevent a lapse of IRB approval. If a lapse of approval occurs, no research activities may be conducted and a new application would need to be submitted to continue the research.

The following are tips or explanations to guide investigators in completing the CR report.

- **Advance awareness:** When you receive your initial IRB approval, take a quick look at the [sample Continuation Review \(CR\) Report](#) to develop a systematic plan for collecting the requested information as the study progresses.
- **CR Reminders:** You will begin receiving prompts to complete the CR approximately three months in advance of the expiration date. Respond to the first notice. Submission of the CR close to the end of the current approval period may result in a lapse of approval as the IRB may not have adequate time to review the CR materials.

CREATE NEW

Application

Modification Request (MR)

Continuation (CR) or Study Closure

- On your dashboard in E-IRB, click **Create New... Continuation Review (CR)**: You will see a list of protocols eligible for Continuing Review.
- **CR involves TWO processes:** 1). Complete the CR report page. 2) Update all applicable sections of the application (e.g., subject demographics, research description, etc.)
- **SAVE** the CR Report each time you leave the page to update sections of the application. Click **SAVE** at the bottom of each section of the application you edit or change.
- At CR, **remove all old attachments** that are no longer in use or not applicable. Removed attachments are always available for review under Protocol History.
- **Item 2, Signed consent/assent forms:** Before attaching copies of the signed consent forms, check the signature on the 'name of [authorized] person obtaining informed consent' signature line to make sure it is legible. If it is not, print the name underneath the signature. This also applies to the 'signature of investigator' line.

*While Completing the CR:*

*Save the CR report each time you leave the page to update sections of the application.*

- **Item 3, Informed Consent:** If requesting changes to the consent/assent/cover letter, submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted) for stamping. After this step, please delete any outdated consent/assent/cover letter you have replaced, as the outdated copy will no longer be relevant to the application moving forward.
- **Item 5, Enrolled subjects:** The CR Report asks for the number of subjects enrolled. The IRB considers a subject “enrolled” when the subject signs a consent document. In cases where the IRB approves a waiver for the informed consent requirement or a waiver of documentation of informed consent, any individual on whom data has been collected should be counted as an “enrolled” subject.  
**Note for studies imported into E-IRB:** To catch the system up at the first Continuing Review, insert the TOTAL enrolled since the beginning of the study in the second field (number of subjects not previously reported to the IRB).
- **Item 6, Data Safety and Monitoring:** If a data safety monitoring plan or board are applicable to the study include any reports, literature, meeting minutes, or assessments related to safety monitoring activities even if no safety issues have been identified and the recommendation is for the research to continue.
- **Item 11, Study personnel:** Ensure personnel are up to date on their human subjects protection training. <https://research.uky.edu/office-research-integrity/faqs/human-subject-protection-hsp-training>
- **Item 12, Progress of Research:** Update applicable sections of the research description including changes based on revised versions of sponsor protocols. The IRB expectation is that the Research Description is current and up-to-date. For reference when summarizing modifications approved since the initial or last continuing review, refer to the Protocol History.
- **Item 14, Subject demographics:** The CR Report includes a demographic table that requests a breakdown of the total number of subjects enrolled by ethnic /racial category and gender. The sum total number of subjects listed in the demographic table (#14) should equal the number in the fourth box under #5, total number of subjects enrolled (or records/specimens reviewed) since activation of the study. When the numbers do not match, provide a brief explanation.
- After saving the completed CR report, go to the **Submission Section** and click Submit to send the report to ORI.