

Continuation Review Tips

In accord with federal requirements, the IRB approval period can extend no longer than one year after the start of the approval period. When you receive your initial IRB approval it may be worth your time to take a quick look at the sample Continuation Review (CR) Form to develop a systematic plan for collecting the requested information as the study progresses.

Prior to the study expiration date, ORI will provide you with a CR Form pre-populated with protocol specific information. Be sure to inform ORI of any address change so that we can ensure you receive the form. Return the completed CR Form in a timely manner to allow time for IRB review and IRB requested revisions, if any, and to prevent a lapse of IRB approval. Submission of the form 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. If a lapse of approval occurs, no research activities may be conducted until the IRB approves the study to continue. Consider these tips when completing the form.

- **Pre-populated information:** The CR Form will include pre-populated information, (e.g., estimated project end date, number of subjects to be enrolled, subject and research attributes etc.) based on the information you initially provided in Form A– General Information Sheet (GIS). If you need to make changes to the information, make the changes on the CR Form rather than submitting a new Form A –GIS.
- **Enrolled subjects:** The CR Form 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.
- **Subject demographics:** The CR Form 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 (#6c) should equal the total number of subjects recorded previously under total number of subjects enrolled or records/specimens reviewed since activation of the study (#6a, second part). When the numbers do not match, provide a brief explanation.
- **Research description/sponsor protocol:** The sponsor protocol or research description (Form B) must be submitted even if there are no changes to the document.
- **Signed consent forms:** Before submitting 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 on the **copy** for the IRB, (do not submit or print on an original signed consent form). This also applies to the *‘signature of investigator’* line. If a waiver of documentation has been approved, submit a copy of the approved cover letter used to enroll subjects.

- **Study personnel:** Submit a copy (from GIS, form A) of the current study personnel. Include this list even if no changes are being made. If changes to the list are requested, indicate who is being added and who is being removed. Ensure personnel are up to date on their human subjects protection training. http://www.research.uky.edu/ori/human/Human_Research_Mandatory_Education.htm
- **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.
- **Progress report:** If the CR requires review by the full IRB, federal policy requires that all members of the board receive a summary and status report on progress of the research. You may use the most recent funding or regulatory agency progress report. If a sponsor or regulatory report is not available please provide sufficient detail on study progress and any new or relevant information, published or unpublished, since the last review. For example you may summarize the research description with added enrollment data and findings if any.
- **Requested changes:** Requested changes to the protocol, research description, and informed consent documents, not previously approved by the IRB, should be underlined or highlighted for easy identification.
- **Closure of study:** Upon closure of a study, the IRB conducts a final review (FR). To submit a final review, complete all sections of the FR Form, include all required documents, if they have not been previously reported to the IRB, and attach a final abstract. There are two circumstances when IRB approved active protocols may be closed by the PI and/or the IRB to avoid yearly CR submissions. Please see the following link for qualifications for these circumstances: <http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#StudyClosure> and select “Two circumstances when IRB approved active protocols may be closed by the PI and/or the IRB”
- **Submission details:** Submit the original and one duplicate set of the completed CR Form and the requested documents. All documents must be single sided. Please do not use staples. It is recommended that you keep a complete set of the documents, as submitted to the IRB, for your records.

Additional information is available in the ORI/IRB Continuation Review SOP or contact the ORI for assistance.