Continuation Review Tips

It’s time to get the materials together for Continuation Review (CR)...These hints may help keep those finicky emails (about the details) out of your Inbox!

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 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 competed CR Form in a timely manner to allow time for IRB review and to prevent lapse of approval. Consider these tips when completing the form.

• The CR Form will include pre-populated information, (e.g., estimated project end date, number of subjects to be enrolled, 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.

• Requested changes made to the protocol, research description, and informed consent documents that have not been previously approved by the IRB, should be underlined or highlighted for easy identification.

• 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.

• 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.

• The sponsor protocol or research description (Form B) must be submitted even if there are no changes to the document.

• 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 photocopy for the IRB, (do not submit or print on an original signed consent form). This also applies to the ‘signature of investigator’ line.

• Submit one original and one copy, (both single-sided), of the completed CR Form and the requested documents.

• 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.

- 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.

- 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 documentation and attach a final abstract.

Additional information is available in the ORI/IRB Continuation Review SOP or contact the following ORI Professional Associates for assistance:

- Continuation Review for Medical IRB # 1 & 2
  Gail Cadwallader email: gcc@uky.edu phone: 859-257-6071
- Continuation Review for Medical IRB # 3 & 6
  Karen Larson email: karen.larson@uky.edu phone: 859-257-9819
- Initial and Continuation Review Nonmedical IRB
  Andrew Hedrick email: andrew.hedrick@uky.edu phone: 859-257-1639