

Tips for Continuation Review of an IRB Approved Study

In order to allow both the IRB and Investigator time for any resulting dialogue and deliberation, respond to the **1st continuation review (CR) reminder notice**. If you can not get the CR materials to ORI by the deadline date provided on the form, call either Karen Larson at 257-3038 or Karen.Larson@uky.edu, or Gail Cadwallader at 257-6071 or gcc@email.uky.edu for medical CR; or Pam Stafford at 257-1639 or pastaf3@email.uky.edu for nonmedical CR.

Submit two sets of materials. Always submit the document(s) that contain the original signature and a copy (e.g. CR form, cover page). In a few cases, only one copy of the document may be requested.

Do not send double-sided copies except for the complete current protocol, Investigator Brochure, and a new or revised grant application.

#3 - When applicable, copies of signed consent documents should be submitted – original signed consent documents should be kept by the PI for no less than six years after the study is closed.

#4 - “Clean” consent forms refer to the currently approved consent form (or version with requested modifications incorporated into it) without the “IRB approval” stamp. The “clean copy” will be stamped with the new approval period. It contains no highlighting.

#6 - For studies for which IRB approval will remain active, a complete current copy of the protocol/research description needs to be submitted with the CR materials even if the IRB already has a copy. To ensure the copy is current, the protocol/research description should be updated to include modifications/ revisions previously approved by the IRB.

#7 - A protocol summary and status report on the progress of the research is required for all protocols undergoing Full CR. The IRB will not review the protocol for continuation unless these items are included. See #7 on the CR report form for details about this request.

#8 - If subjects were enrolled since initial review or since the last CR, whichever is applicable to your study, submit copies of the signed consent forms for the last two subjects enrolled in the study. Review the copies to make sure the Principal Investigator (PI) has signed on the Signature of Investigator line.

#9 - If you receive federal funding, your funding agency may ask for a HHS Protection of Human Subjects Certification Form (HHS 310 form). If you are not receiving federal funding, then you do not need a HHS 310 form. If you find at a later date that you do indeed need a HHS 310 form, you may contact ORI and we will prepare one for you.

#10 - If the study is open for data analysis only, mark #10b – do not also mark the third item in #10a.

#11 - Always check the estimated project end date. An extension may be needed if the study should remain under IRB approval. For example: If all research procedures have been completed, and all subjects have completed their last study visit, but identified subject data analysis is ongoing the study must remain under IRB approval.

#12 - The number of subjects enrolled should include all individuals that signed a consent form regardless of whether or not they participated in the study. If the study does not involve subjects signing a consent form, count the number of individuals on whom a sample or information was collected. If your study has not previously undergone CR, the total number of enrolled subjects that have not been previously reported to the IRB will be the same number as the total enrolled since activation of your study.

If number of subjects currently enrolled exceeds the number the IRB originally approved, be sure to update #12d on the CR report form.

#14 – The total of the numbers listed in the subject demographic information section should equal the total number of subjects enrolled since the activation of the study listed on the second line of #12b.

#15 - If adding a new off-site facility to the study, complete and submit Form N. The IRB is charged with ensuring that the off-site facility meets specific criteria, and if receiving federal funds, additional measures may need to be taken prior to initiating research procedures at an off-site facility. Contact ORI for assistance.

#19a – Recent “relevant literature” means significant, important or noteworthy literature that has some sensible or logical connection with the issue being investigated.

#19b – “Interim findings” are momentary, short-term or transient findings that develop while the research is ongoing until something more complete and permanent can be established.

To discuss their implications for subject participation means to inform the IRB of anything that is implied or involved as a natural consequence of the literature or findings that might change the subject’s willingness to stay in this study.

If submitting literature and/or interim findings, please highlight the pertinent sections which discuss the implications for subject participation.

#21 - Submit a complete list of all study personnel using the study personnel list template, http://www.research.uky.edu/ori/ORIForms/60000-Study_personnel_List_Template.doc.

This list should include all SP who are currently listed on the protocol and those to be added to the protocol. Highlight new SP and indicate who should be removed from the list.

The entire General Information Sheet (GIS), Form A does not need to be submitted with a change to SP.

#29 – If the answer is yes, #30 must be addressed.

#30 – The written summary of all problems/adverse events may be presented as a list or chart or in any way that is organized and easily read; however, the summary must include the PI’s qualitative and quantitative assessment of the severity and the outcome of the events. The PI’s signature on the assessment is not necessary, but it does assure the IRB that the PI is attentive.

#31 – “...under the purview...” means does this research fall under the scope or range of the FDA’s jurisdiction.

Study Personnel Policy for Obtaining Signatures on Consent Forms:

General study personnel: Only those individuals on an IRB approved study personnel list designated as PI, co-investigator, or “authorized to obtain informed consent” should be providing information or explanations to the participant about the study. The individual that interacts with the participant in this regard should write their name on the line provided for “Name of [authorized] person obtaining informed consent” on the consent document.

Change in Principal Investigator (PI):

Currently approved PI should provide a signed memo indicating that protocol responsibilities are being turned over to {Name of New PI}. Along with the memo, the new PI should submit:

- a completed Form Z, Signature Assurance Sheet;
- a completed Form Y, Disclosure of Financial Interest Form (for non-externally-funded research); or
- a completed Form X, UK Staff/Faculty Disclosure of financial Interest Form (for externally-funded research).

Change the address on front page of CR/FR report form – can cross-out old address and write next to it the new address.

Update additional PI information on last page of CR report form, Q. #34.

VA Issues:

If VA patients are not being recruited for your study, the consent form should not contain any VA verbiage. If however, you are recruiting VA patients, both a UK consent form, and a VA consent form (VA Form 10-1086) should be submitted for approval. Review the UK and VA template consent form documents as the language in each document is specific to UK and the VA. This is a VA requirement, not an IRB requirement.

Check Question #16 on the CR report form to answer accordingly regarding VA involvement (Yes/No).

Modifications:

If requesting changes or updates, which would typically be requested using the Modification Request Form (e.g. changes to SP, research procedures, consent/assent forms, etc...), during continuation review a Modification Request Form is not necessary. The specifics regarding the change(s) can be noted on the cover page or memo.

Be aware of submitting changes to the protocol that affect the consent/assent form around the time the CR has been submitted (or vice versa). Without notifying the ORI that two separate submissions are pending, or the ORI does not notice this, the wrong consent/assent form version may be issued for the next approval period.

If separately submitting ANY materials to be included with CR, or a response to a request for additional information for continuation review, be sure to clearly denote Continuation Review and the IRB number on a post-it note, cover memo, email, etc...

Closures:

When informing the IRB about closure to subject enrollment or the request for study closure, be sure to use the appropriate wording in your cover memo so the IRB does not confuse your request.

“Closed to enrollment” - no new subjects will be enrolled but the study remains under IRB approval.

“Study Closure” or “inactivate IRB approval” – all research activities are complete, including data analysis.

The exception – if all research activities are complete except data analysis, and the data is de-identified, the IRB can inactivate approval as long as certain conditions are met (see Two circumstances... document).

If you have received a CR report form, but you want to close your study, please complete the CR report form with responses to appropriate questions indicating you do not wish for IRB approval to continue. Based on your responses and the materials submitted, the IRB will consider it a Final Review (FR) report form and your protocol will be processed for closure.

If subjects were enrolled since initial review or since the last continuation review, whichever is applicable to your study, you are still required to submit copies of the signed consent forms for the last two subjects enrolled, as well as a final abstract with your FR report.

If the study was never initiated, the IRB will accept a memo for closure with the following items addressed:

The study was never initiated;

No subjects were enrolled in the study; and

The study can be closed and IRB approval inactivated.

If one or more of the items do not apply to your study, you should complete a FR report form.