



SOP #	CRSC-102
Effective Date	10-22-2013
Version #	1
Version Date	10-2-2013

Standard Operating Procedure COMIRB Continuing Review

Purpose: This SOP outlines completion of the COMIRB Continuing Review Form.

Procedure A. Initial Approval of the Protocol

1. The PI and primary contact receive the Initial IRB Certificate of Approval of the protocol from the IRB. This approval letter states the period of approval and the date on which the current approval will expire.
2. The Certificate of Approval is filed in regulatory binder/PI study-specific file (see Regulatory Document SOP).
3. A note (task, appointment, flag or reminder) is made in the site's predetermined system {*insert system here*} to remind the research team of the expiration date.
4. The CRV Due Date is the date the completed CRV is due to the IRB of recording in order to allow for sufficient IRB panel review time. As a courtesy, COMIRB sends out a reminder notice of the Continuing Review Expiration 75 days and 45 days prior to expiration; however each IRB has its own process and procedure.
5. The CRV Completion Date is the date the site will begin and/or finish completion of the IRB CRV form (form can be downloaded from the specific IRB's website). Sufficient time will be given to allow for collection/receipt of any applicable, CRV-required information (e.g.) DSMB reports, summary of adverse events, protocol and/or ICF revision—if applicable). **This date serves as the data cut -off date (i.e. any participants enrolled following this date will be counted in the following year's CRV)**
 - a. Screen Failure Date is the date an enrolled participant (i.e., after the participant signs the ICF) fails criteria for screening. The reason for the screen failure should be documented and reported to the IRB with the CRV. (Note: If the participant is determined to be ineligible prior to enrollment or signing the ICF, this would be considered a "Pre-Screen Failure" and does not need to be reported to COMIRB at continuing review)
 - b. The Withdrawal Date is the date the participant withdraws consent to participate in the study. The reason for withdrawal from the study should be obtained, documented in the accrual log and documented in the CRV. This includes participants lost to follow-up.
 - c. Vulnerable Population data including Non-English speakers; decisionally challenged; pregnant women; prisoners; children; and neonates should be documented in the CRV form if applicable.



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- d. Demographic information including gender (male/female) and ethnicity (Native American; Asian; Black; White; Hispanic; and Other) detailed on the enrollment log should be documented in the CRV form.
- e. The Participant's current study status should be documented in the CRV form.

Procedure B. Completion of specific elements of the Continuing Review Form

1. Protocol: Obtain the protocol number, initial approval date, expiration date and title information from the last review form (either initial or continuing) and/or corresponding approval letter.
2. Principal Investigator: If unknown, obtain information from PI or campus directory.
3. Indicate VA Involvement in this Study: Check the appropriate box.
4. Current Status: Select the option that corresponds with the status of the study at the time of completing the CRV Form.
5. Enrollment Data: Refer to the study-specific enrollment or accrual log for this information.
6. Amendments: Obtain this information from the IRB Submission Log for this study
7. New Information/Changes in the Field: Consider any changes in the relevant research and clinical practice landscape, including any serious adverse events and unanticipated problems encountered on this study prior to answering, new publications in literature that affect the risk/benefit analysis, or any new information that could affect a subject's willingness to participate.
8. Unanticipated Problems/Noncompliance: Obtain this information from the Unanticipated Problems Log and from outside sources if applicable (i.e. Safety Reports, Medwatch or Pharmaceutical company reports).
9. Data Safety Monitoring Reports: If the study has a DSMB, DSMC or SMC that generates reports, contact the DSMC chair or coordinator to request a copy of the latest report as of the "CRV Completion Date." If the study does not have a DSMB, DSMC or SMC, provide aggregate data of adverse events and unanticipated events as defined in COMIRB's policy.
10. Audits: Indicate whether the study has been audited by an entity other than the study team (include audit reports, PI corrective action plans, etc., if applicable, as supplemental documents in Continuing Review submission). Study lead site – if the study has a lead site (pharmaceutical, federal, and other) then the lead site should be contacted and this information collected



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11. Complaints: Obtain complaint information from the Unanticipated Problems log, if any, and query study team to determine whether any complaints were received. If any, submit information related to the complaint, e.g., nature, resolution, etc., as a supplemental document to the IRB.
12. Abstracts/Publications: Provide the IRB with copies of any/all abstracts and/or publications related to this study that have been published **since the last review**.
13. Investigator Relationship with Sponsor or Study Drug/Device: Query the PI and investigators to determine whether there have been any changes in the investigators' relationships with any Sponsors of the study or any products used in the study. If so, the investigators COI disclosure must be updated in the eRA (InfoEd) system, and the COI committee will need to review the conflict before the continuing review can be approved (unless the investigator is removed from the protocol).
14. Grant: Query the grant manager, OGC, and/or PI to determine if a new federal grant has been received for the research. If so, the new grant must be submitted with the continuing review.
15. Risk/Benefit Assessment: Assemble from the PI (and/or lead site, if applicable) and describe information related to:
 - a. New risks
 - b. New benefits
 - c. New alternate treatment information
 - d. Anything (including the above) that would/might affect a participant's willingness to continue participation
 - e. Literature and/or SOC changes that support/justify the study, changes to the study, or stopping the study.
16. Coordinating Center: Indicate whether UCD or one of our affiliates is acting as the coordinating center for the study.
17. HIPAA Update 2013: Indicate the applicable option, then refer to the COMIRB website for further information.
18. VA Specific Questions: Refer to the study-specific enrollment or accrual log, and the Unanticipated Problems log for this information.

Forms:



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COMIRB CRV form

Enrollment Log

Accrual Log

APPLICABLE REGULATIONS AND GUIDELINES

COMIRB	http://www.ucdenver.edu/academics/research/AboutUs/comirb/Pages/comirb-home.aspx
COMIRB CRV form	http://gcrs.ucdenver.edu/comirb/Continuing-Review-Form.pdf
OHRP Regulations	45 CFR 46.103.4
FDA Guidance Document	Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval
ICH Guidelines	ICH E6: Good Clinical Practice: Consolidated Guidance (1.31; 3.1.4; 3.3 and 8.3)
FDA	Title 21 Part 56.109
FDA	Title 21 Part 312.66