

**Clinical Research Center/
Institutional Review Board
Coordination**

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POLICY:

The UIC Clinical Research Center (CRC) reviews research to be performed at the UIC Clinical Research Center. The CRC performs a scientific, feasibility and utilization assessment of all new clinical research studies.

- I. The UIC CRC review replaces the Departmental Review (Appendix F) in the initial protocol submission process.
- II. Final IRB approval of new protocols will not be released until documentation of CRC review has been received.

PROCEDURES:

- I. Initial Protocol Review.
 - A. Investigators submit their proposed research studies to the CRC prior to submission of the IRB application to OPRS for IRB review.
 - B. Investigators include the CRC approval letter or documentation of conditional CRC approval with their protocol application to the IRB.
 - C. OPRS staff screens the initial protocol applications to determine whether the study involves the use of the Clinical Research Center and is subject to the CRC review. If so, OPRS staff ensures that the application includes the appropriate CRC approval letter.
 - D. OPRS staff denotes in RiSC (under "Additional Reviews") that the research protocol is subject to CRC approval. This action ensures that the CRC is included as a copy on correspondence from the IRB (OPRS) to the investigator.
 - E. If the protocol application does not include the necessary CRC approval letter or acknowledgement, OPRS staff may return the protocol submission without review back to the investigator.
 - F. Although a protocol application may be scheduled for review prior to CRC approval, final IRB approval will not be issued without final CRC approval. OPRS staff will ensure that the investigator has submitted this documentation before issuing IRB approval.
 - G. OPRS provides the CRC a copy of the IRB approval notice.

II. Continuing Protocol Review.

- A. For CRC research studies, in addition to the IRB, investigators must submit a continuing review to the CRC. The CRC review cycle is based upon the approval period (no less than once a year) established by the IRB.
- B. The investigator submits the CRC Continuing Review Form to the CRC in parallel to submission of the Continuing Review application to the IRB. In contrast to initial review, CRC approval is not required for the issuance of Continuing IRB approval.
- C. Following the issuance of continuing review approval, copies of the approval notices are exchanged between CRC and OPRS, and retained in the respective file.

III. Other Submissions (amendments, final reports, complaints, protocol violations, unanticipated problems and other events requiring prompt reporting, and non-compliance findings).

- A. The OPRS handles the submission (amendments, final reports, complaints, major protocol violations, unanticipated problems and other events requiring prompt reporting, and allegations of non-compliance) in accordance with the respective UIC HSPP policies and procedures.
- B. For CRC research studies, following IRB review of the submission, the OPRS sends the CRC a copy of the correspondence sent to the investigator.

IV. Institutional Reporting.

- A. In accordance with UIC HSPP policy *Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance*, for CRC research studies, the CRC also receives a copy of the report sent to institutional officials, supporting agency heads, and regulatory agencies, including but not limited to:
 - 1. Unanticipated problems and other events requiring prompt reporting;
 - 2. Continuing and/or serious non-compliance;
 - 3. IRB suspension; and/or
 - 4. IRB termination.

V. Quality Assurance/Improvement Findings.

- A. If the OVCR Quality Improvement Program (QIP) conducts a directed or routine Quality Improvement audit of a CRC protocol, the OVCR Associate Director for Research Compliance will disseminate a copy of the final report to the CRC.
- B. If the CRC conducts an audit or inspection of an IRB approved study, a copy of the final report will be provided to the OVCR Associate Director for Research Compliance. The OVCR Associate Director for Research Compliance forwards the report to the IRB and/or OPRS Director in accordance with UIC HSPP policy and procedures.

REFERENCES:

NA

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 6/18/09	1.0, 12/22/08	Deleted reference to SAC since disbanded; clarified that institutional reporting includes but is not limited to the examples listed.