

**Cancer Center /Institutional Review
Board Coordination**

310 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-4995 Fax: 312 413-0238
www.research.uic.edu/protocolreview/irb

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POLICY:

1. The UIC Cancer Center Protocol Committee (CC-PRC) reviews all cancer-related research at UIC, or conducted by UIC faculty, including research activities performed at the JBVAMC. The CC-PRC performs a full review (complete scientific and feasibility) of new clinical trials that have not been peer reviewed and supported by NIH mechanisms (R01s, U01s, PO1s, and P50s) and the NCI CTEP or Cancer Control Protocol Review Committee. The CC-PRC performs a limited review (feasibility, accrual projections, investigator qualifications, conflict of interest, etc.) of new clinical trials that have already undergone peer review as noted above. Refer to the *Cancer Center Protocol Review Committee Policies and Procedures (July, 2004)* for additional details.
2. The UIC CC-PRC review replaces the Departmental Review (Appendix F) for the initial convened review protocol submission process.
3. Final IRB approval of new protocols will not be released until documentation of CC-PRC approval is received.

PROCEDURES:

- I. Initial Protocol Review.
 - A. Investigators submit their proposed cancer-related research studies to the Cancer Center (CC) prior to submission of the IRB application. The UIC CC staff review the protocols in accordance with CC-PRC policies and procedures.
 - B. CC staff assesses the submission and notifies investigators if the research protocol is eligible for limited CC-PRC review and therefore, the protocol may be submitted to the IRB for review in parallel to the CC-PRC review. Otherwise, if the protocol requires full CC-PRC review, investigators must obtain CC-PRC approval prior to submitting the protocol to OPRS for IRB review.
 - C. Investigators include either the CC-PRC approval letter (protocol requiring full CC-PRC review) or an acknowledgement from the CC (protocol eligible for limited CC-PRC review) with their protocol application to the IRB.
 - D. OPRS staff screens the initial protocol applications to determine whether the study involves cancer-related research and is subject to the CC-PRC review.

If so, OPRS staff ensures that the application includes the CC-PRC approval letter or CC acknowledgement.

- E. OPRS staff denotes in RiSC (under “Additional Reviews”) that the research protocol is subject to CC-PRC approval. This action ensures that the CC is included as a copy on correspondence from the IRB (OPRS) to the investigator.
- F. If the protocol application does not include the necessary CC approval letter or acknowledgement, OPRS staff may return the protocol submission without review back to the investigator.
- G. Although a protocol application may be scheduled for review prior to CC-PRC approval, final IRB approval will not be issued without final CC-PRC approval. OPRS staff will ensure that the investigator has submitted this documentation before issuing IRB approval.
- H. OPRS provides the CC a copy of the IRB approval notice.

II. Continuing Protocol Review.

- A. For CC research studies, in addition to the IRB, investigators must submit a continuing review to the CC. The CC review cycle is based upon the approval period (no less than once a year) established by the IRB.
- B. The investigator submits the CC-PRC Continuing Review Form to the CC in parallel to submission of the Continuing Review application to the IRB. In contrast to initial review, CC-PRC 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 CC and OPRS, and retained in the respective file.

III. Other Submissions (Amendments, Final Reports, Complaints, Protocol Violations, UPIRSOs, and Non-Compliance Findings).

- A. The OPRS handles the submission (Amendments, Final Reports, Complaints, Major Protocol Violations, UPIRSOs, and Allegations of Non-Compliance) in accordance with the respective UIC HSPP policies and procedures.
- B. For CC research studies, following IRB review of the submission, the OPRS sends the CC a copy of the correspondence to the investigator.

IV. Institutional Reporting.

- A. In accordance with UIC HSPP reporting policy, for CC research studies, the CC also receives a copy of the report sent to institutional officials, supporting agency heads, and regulatory agencies including:
 - 1. UPIRSOs
 - 2. Continuing and/or Serious Non-compliance
 - 3. IRB suspension
 - 4. IRB termination

V. Quality Assurance/Improvement Findings.

- A. If the OVCR Quality Improvement Program conducts a directed or routine Quality Improvement Review of a CC protocol, the OVCR Associate Director for Research Compliance will disseminate a copy of the final report to the CC.
- B. If the CC 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 HSPF policy and procedures.

REFERENCES:

[Cancer Center Protocol Review Committee Policies and Procedures \(July, 2004\)](#)