

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title Comprehensive Cancer Center / Clinical Research Office	Date Effective April 19, 2005	Supercedes P&P dated March 14, 2005

BACKGROUND

The Sidney Kimmel Comprehensive Cancer Center (SKCCC), an NCI designated comprehensive cancer center, is charged with reviewing all cancer-related research conducted within the Johns Hopkins institutions. The SKCCC responsibility includes scientific review, good clinical practice, and data and safety monitoring. The SKCCC is also responsible for following the progress of all cancer-related studies conducted at the Johns Hopkins Institutions.

JHSPH POLICY AND PROCEDURES

All cancer-related research proposals must be submitted to the SKCCC Clinical Research Office (CRO) prior to their being submitted to CHR. The CRO will screen each proposal to determine whether it requires formal review by the SKCCC's Clinical Research Review Committee (CRC). If a submitted study does not require review by the CRC, the investigators will be notified in writing and the application may then be submitted to CHR for review.

The CRC reviews the following studies:

- all therapeutic cancer trials,
- all clinical research performed by faculty with primary appointments in the Department of Oncology,
- all clinical research performed by Cancer Center members,
- all clinical research conducted using cancer center resources, and
- certain non-therapeutic cancer research, such as studies on the epidemiology or prevention of cancer.

Investigators whose studies fall into one of the above categories should submit all new applications, and continuing review applications for therapeutic cancer trials, to the SKCCC for review and approval prior to submitting the applications to CHR.

CHR will not review any cancer-related trial application unless it is accompanied by a letter from the CRC indicating either that the trial is exempt from CRC review or that it has been approved by CRC. Trial applications referred directly to CHR without such a letter will be forwarded to CRC without review. CHR will routinely copy the SKCCC on all correspondence from CHR to investigators, including letters that describe any study

changes required by CHR. The time from submission to approval by the CRC is approximately 1 month.

The SKCCC Clinical Research Office (CRO) is responsible for coordinating reviews with the CRC. The CRO staff is located in Room 1101 in the 550 Building and may be reached at (410) 955-8866. They can provide details regarding the CRC review requirements and time frame estimates for completing their review. E-mail requests can be sent to jhcccro@jhmi.edu.

For more information, please visit the CRO website: <http://cro.onc.jhmi.edu>