

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Research That Uses Facilities of the General Clinical Research Center (GCRC)	Date Effective April 19, 2005	Supercedes P&P dated March 17, 2005

BACKGROUND

The General Clinical Research Center (GCRC) at the Johns Hopkins Medical Institutions is funded by NIH and provides clinical space, hospitalization costs, laboratory support, equipment, supplies and computing support for clinical research conducted by Johns Hopkins investigators. The GCRC facilities include:

- the Johns Hopkins Hospital adult inpatient unit
- the Johns Hopkins Hospital adult outpatient unit
- the Johns Hopkins Hospital pediatric inpatient unit
- the Johns Hopkins Hospital pediatric outpatient unit
- GCRC neurobehavioral unit at Kennedy Krieger
- Sidney Kimmel Comprehensive Cancer Center
- GCRC at Johns Hopkins Bayview Medical Center.

JHSPH POLICY AND PROCEDURES

Investigators who wish to use GCRC facilities for their research must submit applications to CHR *and* the GCRC using forms provided by each Committee. Coordination of the GCRC submission and review is normally between the Principal Investigator and the GCRC. Information on the GCRC application procedure, review process and forms is available at: <http://www.hopkinsmedicine.org/gcrc/application/process.cfm>.

All applications for research that will use the GCRC must be reviewed and approved by both the CHR *and* the GCRC Advisory Committee before the GCRC will authorize use of its facilities, services or resources. CHR approval of new proposals, continuing review applications or amendments does not require prior approval by GCRC. GCRC approval can only be given to proposals already approved by CHR. When GCRC requests changes to the research, the investigators must submit the revised protocol to CHR for review and approval *prior* to initiating the study.

Investigators must submit a copy of any proposed *amendment* to an approved GCRC/CHR research project to GCRC *and* CHR for review. The amendment may not be initiated until approved by both Committees. A copy of the *CHR continuing review application* must also be submitted to GCRC for review.

The GCRC will not support research or other use of its services when CHR approval is pending, suspended, withdrawn or terminated.

CHR will copy the GCRC on all correspondence with investigators that concerns approvals (initial, continuing, amendment), suspension or withdrawal of approval, study termination or possible non-compliance when the investigator has indicated that GCRC facilities or resources will be used for the research.

GCRC Requirements

Details of GCRC requirements for investigators who will use GCRC facilities or resources may be found at the GCRC website: <http://www.hopkinsmedicine.org/gcrc/>.

The GCRC may also be contacted at 410 614 2717. Its office is located at Carnegie 446.

OHRP Requirement _____
FDA Requirement _____
AAHRPP Element _____