Procedure
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: VII.E.1
Section: Committee Roles and Responsibilities
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: March 19, 2004
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Subject: Procedure for Review and Approval from Other University and Medical Center Committees and External Reviews

Procedure:
This procedure provides guidance on obtaining approval from other University and Medical Center Committees and external review resources, in conjunction with the Institutional Review Board (IRB) review of human research activities.

I. Investigator Responsibilities.
   A. The Investigator will clearly indicate on the "Human Subjects Research Application" the additional Committees in which approval will be required.
   B. When applicable, the Investigator will complete the Human Subjects Radiation Committee (HSRC) or Radioactive Drug Research Committee (RDRC) applications. The Investigator will follow the IRB procedures for submission to the HSRC and RDRC (See HRPP Procedure XII.B.1 and XII.D.1).
   C. The Institutional Biosafety Committee (IBC) review requirements and the Biologicals and Human Subjects Subcommittee (BHSS) review requirements can be accessed by contacting the Institutional Biosafety Officer (IBSO) (See HRPP Procedure VII.E.3). Most studies requiring BHSS approval will also be subject to IBC requirements (See HRPP Procedure VII.E.2).
   D. The Investigator is responsible for complying with HRPP Policy and Procedure VIC and VI.C.1 regarding the disclosure of potential conflicts of interest.
   E. It is the Investigator’s responsibility to assure other committee approvals are granted prior to the initiation of the research. In addition, a copy of other committee approvals should be forwarded to the IRB. Any changes required to an existing application should be submitted to the IRB as an amendment in accordance with HRPP Policy and Procedure III.J and III.J.1.

II. IRB Committee Responsibilities.
   A. The IRB will review the initial IRB application and verify if approval from other Committees is required prior to or in conjunction with IRB review and approval.
   B. Final IRB approval will not be granted for studies requiring HSRC, RDRC, and IBC approval.
   C. The IRB may review and approve the study requiring other Committee approvals. However, the Final Approval Letter (FAL) will state that the IRB approval has been granted, but it is the Investigator’s responsibility to obtain approval from any other required Committee before initiating the research.
   D. The IRB may, at its discretion, withhold final approval on a research proposal, pending other committee determinations.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will verify that all required Committee approvals have been identified in the IRB application. When applicable, the RCA will assure the Investigator has initiated a request for approval from other University and/or Medical Center Committees.
   B. The RCA will proceed with procedures for review and approval at the level in which the study qualifies.
   C. While pre-reviewing the initial documents for a new study requiring HSRC, RDRC, or IBC approval, the RCA will verify that the approval documentation has been
included, or will contact the Investigator for such documentation.

D. Approval letters from other University and Medical Center Committees are to be collected and saved with the study files.