**Procedure**

Department: HUMAN RESEARCH PROTECTION PROGRAM
Policy Number: VI.A.1
Section: Investigator Responsibilities
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: March 19, 2004
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**Subject: Procedure for Assuring Investigator Qualifications**

**Procedure:**
This procedure outlines the necessary qualifications for Investigators to conduct human subjects research under the jurisdiction of the HRPP.

I. **Investigator Responsibilities.**
   A. Prior to submitting research applications for the review and approval of the IRB the Investigator will
      1. Complete the required IRB training on human research protections (initial and continuing);
      2. Disclose any conflicts of interest of the Investigator or key study personnel
      3. Assure that other Investigators and key study personnel have completed the required IRB training (initial and continuing) and are familiar with the proposed research;
      4. Assure other Investigators and key study personnel are competent and licensed if applicable, relevant to the scope and complexity of the research conducted.
      5. Conduct research in accordance with the ethical principles of The Belmont Report, federal and state regulations, Institutional policies and procedures, HRPP policies and procedures, and if applicable, Good Clinical Practice standards.
   B. All students and fellows conducting human subjects research under the jurisdiction of the IRB will enlist faculty advisor to provide oversight to his or her project
   C. The student or fellow will obtain the signature of his or her faculty advisor on their IRB application for research

II. **IRB Committee Responsibilities.**
   A. The IRB reviewer will assure that Investigator is competent and licensed, if applicable, relevant to the scope and complexity of the research conducted.
   B. The IRB reviewer may request additional information, qualification documentation, or licensure to assure competence in performing proposed research activities

III. **HRPP Regulatory Compliance Analyst (RCA) Responsibility.**
   A. The RCA will verify all Investigators and key study personnel have completed the required IRB human research protections training.
   B. The RCA will assist Investigators and key study personnel in the completion of required IRB training if not already completed.
   C. If needed, the RCA will assist Investigators and key study personnel in the appropriate reporting of conflicts of interest.

IV. **HRPP Administrative Assistant (AA) Responsibilities.**
   A. The AA will verify all Investigators and key study personnel have completed the required IRB training upon receipt of a new IRB application.
   B. The AA will not process IRB applications until all Investigators and key study personnel have completed the required IRB training.
   C. The AA will contact the Principal Investigator (PI) or study contact when required training of all Investigators and key study personnel is incomplete and inform the PI that the study cannot be processed by the IRB until required training is complete. The AA will document the name of the person called, the date called, the discussion and the response in the IRB database.
References:
HRPP Policy VI.C
HRPP Policy VIII.A