

Investigator Oversight

Version: 1.0
Date: 10/15/2008
Approved by: Interim Vice Chancellor for Research
AAHRPP REF#: 134
AAHRPP Elements: III.2.C

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

POLICY:

- I. UIC HSPP policy recognizes only one PI per research protocol. Co-Investigators are defined as sub-investigators and not the PI. In multi-center studies with a non-UIC lead site, the UIC investigator is considered the PI for purposes of UIC HSPP policy.
- II. The PI is required to provide continuous and appropriate oversight of their research protocols and staff, and assume ultimate responsibility for all study related activities, including delegation of responsibilities.

PROCEDURE:

- I. It is the responsibility of each PI to ensure that each subject is adequately informed and freely consents to participate in the research. The PI must personally assure that every reasonable precaution is taken to reduce risks to the study participants, including subjects who are enrolled initially but prove to be screen failures or for whom data is incomplete, un-useable, and/or otherwise eliminated during analysis.
- II. It is the responsibility of each PI to delegate responsibility to the research staff in a manner that is commensurate with the staff's training and qualifications.
- III. It is the responsibility of each PI to assure that all procedures associated with the research are performed in accordance with the protocol, including the schedule of events as applicable, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the applicable laws, regulations, and policies, including but not limited to, Illinois Law, UIC Medical Center policies and procedures, and UIC OVCR policies and procedures.
- IV. The PI must assure adherence to the study protocol and monitor the informed consent process.
- V. The PI must assure there are appropriate facilities and resources to conduct the research.
- VI. It is the responsibility of the PI to be available to the research staff as needed and to regularly review research processes and address any deficiencies identified through

quality improvement processes. The PI may also contact UIC OPRS to schedule an external assessment of his or her research through an on-site visit and a regulatory audit of the protocol file at UIC. The PI is responsible for maintaining documentation of any quality improvement process for their specific studies.

VII. It is the responsibility of the PI to assure that adequate staff, resources, and professional practices and standards of care are maintained at external performance sites.

VIII. It is the responsibility of the PI to respond to all UIC IRB requests for additional information in regards to verifying expertise, training, education, and resources adequate to perform research involving human subjects. The PI must assure there are appropriate facilities and resources to conduct the research.

IX. It is the responsibility of the PI and any international institution or site to assure that the resources and facilities are appropriate for the nature of the research.

REFERENCES:

[21 CFR 312.53\(c\)\(1\), 21 CFR 312.60, 21 CFR 312.61, 21 CFR 312.62, 21 CFR 812.43\(c\)\(4\), 21 CFR 812.100, 21 CFR 812.140](#)