

VIRGINIA COMMONWEALTH UNIVERSITY HEALTH SYSTEM
POLICY AND PROCEDURE MANUAL

SUBJECT: POLICY NO.: 4002.00

APPROVED DATE: 04/17/09

Conduct of Clinical Research In EFFECTIVE DATE: 05/17/09
VCU Health System Patient Care Areas
Or Involving VCU Health System Patients

REVIEWED DATE:

SUPERSEDES NO.: NEW

I. PURPOSE:

To support the research mission of Virginia Commonwealth University (VCU) and the VCU Health System (VCUHS) and provide guidance for staff, faculty and students involved in IRB approved research activities that are planned to occur in any VCUHS patient care area or involving VCUHS patients.

II. POLICY:

A. Review and approval by the VCU IRB or an IRB formally contracted to serve VCU must be obtained prior to conducting any clinical research at the VCUHS.

B. All VCUHS employees who are involved in clinical research activities should be familiar with the basic requirements and responsibilities for performing clinical research, including guidelines for the protection of human subjects. Key personnel involved in a study must complete training as specified by VCU Office of Education and Compliance.

C. Principle Investigators and their research team are responsible for communicating in advance with the manager of any area that will be involved in planned research to ensure that they have adequate notification, time to prepare and sufficient resources.

D. All health care providers are responsible for reviewing the IRB approved informed consent document and assuring that the research subject (or legally authorized individual) has affixed his or her signature before performing any duties beyond standard or routine patient care activities. Where applicable the same procedure will be done for assent.

E. Additional requirements for investigational drug use are described in VCUHS Policy 4533 Investigational Drugs.

III. DEFINITIONS:

Institutional Review Board (IRB) - Any specifically constituted review body that has been formally designated to review and monitor biomedical research involving human subjects. Includes the Virginia Commonwealth University IRB and Western Institutional Review Board (WIRB)

IV. PROCEDURES:

A. Principle Investigators will work with the manager of patient care areas that will be involved in planned research to arrange for use of unit-based resources e.g. space, personnel, supplies, prior to the expected use of such resources.

B. The responsible manager will ensure that the patient care area has the required staff, materials, space and expertise to meet requests for assistance with the approved research protocol.

C. In general, nursing staff, clinical space, equipment and supplies are available to provide standard or routine patient care activities. Staff support, equipment and supplies that are beyond standard or usual care are not provided for research purposes by the unit or unit personnel.

D. The manager of involved sites will review the research protocol and consent form. As needed, the manager and research team will meet to discuss details, arrange in-service training and establish effective means of communication.

E. When Research Subjects are being studied, a copy of the approved protocol and signed informed consent document must be available at all times. Those persons participating in the implementation of the study must be aware of the study and their specific responsibilities.

F. The investigator is responsible for the conduct of the study as specified in the IRB/WIRB approved protocol. Deviations from the approved protocol will be documented and reported to the IRB/WIRB.

V. RESOURCES:

A. VCU Office of Education and Compliance Oversight. Available from the VCU Intranet under Education/research, then VCU Research, Education and Compliance

B. Nursing Research Council

C. The Office of Research Subject Protection 827-1735

VI. REFERENCES:

A. VCUHS Policy 4533.00 Investigational Drugs

B. VCU IRB Website for IRB P&P.

VII. REVIEW REQUIREMENTS:

A. VCU Office of Research Subject Protection

B. Nursing Research Council

C. Compliance Services

