



Conduct of Clinical Research in Patient Care Areas

VCUHS Policy

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Author: Deborah Fisher

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General Description

Purpose: To provide guidance for staff, faculty and students involved in research in patient care areas of Virginia Commonwealth University Health System (VCUHS).

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Policy

0. This policy applies to situations in which institutional review board (IRB) approved subject enrollment, research observations, interventions, or data collection activities are planned to occur in patient areas (in-patient and out-patient).

0. Investigators and personnel involved in a study must complete IRB-required human subjects training.

0. Principle Investigators (or their designee) must arrange use of unit-based resources with the Nurse Manager (or equivalent) for the given patient care area, **prior** to the expected use of such resources (e.g., space, personnel, supplies).

0. All health care providers are responsible for reviewing the IRB approved informed consent document and assuring that the research subject (or family member) has affixed his or her signature before performing any duties beyond standard or routine patient care activities.

0. Additional requirements for investigational drug use are described in VCUHS Policy' [Investigational Drugs](#)'.

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Procedures

1. Facilities used for clinical research

Whenever the clinical facilities of VCUHS are used for clinical research, the Principle Investigator (PI) and their research team have the responsibility to fully consult with the Nurse Manager (or equivalent) for the specific patient area well in advance of any proposed start date. The PI or designee must provide a proposed start and end date for research activities on the unit.

2. Request for assistance

The responsible Nurse Manager (or equivalent) must have sufficient time to determine that the patient area has the required staff, materials, space and expertise to meet requests for assistance with the approved research protocol.

3. Standard patient care activities

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.

4. Consent

The Nurse Manager (or equivalent) for the intended site will review the protocol and consent form and meet with the research team to discuss the details, arrange in-service training, assure both accuracy and confidentiality of the data that will be generated, and establish effective means of communication.

5. Availability of approved consent

When research subjects are being studied, a copy of the approved protocol and signed informed consent document must be available at all times. All staff involved in the conduct of the study must be aware of the content in the signed consent.

6. Investigator responsibility

The investigator is responsible for the conduct of the study as specified in the IRB/Western IRB approved protocol. The investigator follows IRB reporting requirements during the conduct of the study.

7. Completion of unit-based research

The Principle Investigator should formally inform the Nurse Manager (or equivalent) when unit-based research activities are completed and provide the unit with a summary of findings when the study results are available.

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Related Documents & Resources

The following is a list of resources related to the current document.

VCUHS Policy

PH.SP.005

[Investigational Drugs](#)

Other Related Documents The Office of Research Subject Protection (804) 827-1735

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Definitions/Resources

Definitions: Institutional Review Board (IRB)

Any specifically constituted review body that has been formally designated to review and monitor research involving human subjects.

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Web Based Resources

VCU IRB Written Policies & Procedures.

http://www.research.vcu.edu/irb/wpp_guide.htm

[The Office of Research Integrity and Ethics. Director: Monika Markowitz, PhD. 827-2157](#)

<http://www.research.vcu.edu/oeco/contactus.htm>

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Forms/Documents

Forms/Documents

1. Research Pre-Study Assessment Form URL

<http://nursingresearchcouncil.mcvh-vcu.edu/documents/documentdetails.aspx>

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Author/Stakeholder Sign-Offs

Author Deborah Fisher; Lauren Goodloe; Lou Usry

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VCU Office of Research Subject Protection	5/01/2012
Nursing Research Advisory Council	5/01/2012

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