Home

VCU Health System

Research in Patient Care Areas

VCUHS Policy

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Owner: Vice President, Chief Nursing Officer (CNO)
Author: Deborah Fisher, PhD, RN, Nursing Research Facilitator

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General Description

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

Back to Top

Policy

A. 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, both inpatient and ambulatory.

B. Investigators and personnel engaged in a research study must complete IRB-required human subjects training.

C. Psychiatry may have additional requirements related to Virginia oversight regulations for Behavioral Health facilities.

D. Principal 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).

E. Patients who are being seen in out-patient clinics for research purposes must be registered with the appropriate study billing information entered.

F. 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.

G. Additional requirements for investigational drug use are described in VCU Health System's Policy' Investigational Drugs' .

Back to Top

Procedures

1. **Facilities used for clinical research**

Whenever the clinical facilities of the VCU Health System are used for clinical research, the Principal 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

Forms/Documents Research document links including the Research Pre-Study Assessment Form

Back to Top
