**Conduct of Clinical Research in Patient Care Areas**

**VCUHS Policy**

**File Identifier:** PC.CP.004  
**Owner:** Vice President, Chief Nursing Officer (CNO)  
**Author:** Deborah Fisher  
**Revision #:** vl  
**Date Last Updated:** 10/10/2012  
**Status:** Approved and Released

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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**

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 (in-patient and out-patient).

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

C. 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).

D. 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.

E. 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.

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http://veuhspolicy.mcvh-vcu.edu/Policies/zav_PC.CP.004.htm  
6/13/2013
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.
Research Pre-Study Assessment Form

Manager: ___________________________ Date: ___________________________

Study Title: ___________________________

Principle Investigator: ___________________________

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<tr>
<td>1.</td>
<td>In what patient area/unit will this study be done?</td>
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<tr>
<td>2.</td>
<td>Could this study be done in the Clinical Research Center? <a href="http://www.cctr.vcu.edu/crc/index.html#POP">http://www.cctr.vcu.edu/crc/index.html#POP</a> If not, please explain.</td>
</tr>
<tr>
<td>3.</td>
<td>Planned number of visits to the area? Inpt ___ Outp ___</td>
</tr>
<tr>
<td>4.</td>
<td>Does the study require the use of unit/clinic personnel, equipment, supplies or other resources outside of the usual standard of care? If yes, list what would be needed:</td>
</tr>
<tr>
<td>5.</td>
<td>If yes to #4, will the study provide all resources needed?</td>
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<tr>
<td>6.</td>
<td>What are the plans to provide in-service training to unit/clinic personnel regarding the study protocol?</td>
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<tr>
<td>7.</td>
<td>What disciplines, other than nursing (OT, PT, Dietary, RT, ...) will need to be involved with patients on this protocol? Either through providing care or services outside the standard of care or will need to be made aware that the patient they are treating is a research subject.</td>
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<tr>
<td>8.</td>
<td>As required by IRB Policy and Procedure, Section V, V1 - are unit/clinic staff considered &quot;Key&quot; personnel for the study that would require CITI training in the Protection of Human Subjects participating in research? If you answered yes, online training is available at <a href="http://www.research.vcu.edu/irb/education.htm">http://www.research.vcu.edu/irb/education.htm</a></td>
</tr>
<tr>
<td>9.</td>
<td>What are the plans to keep unit/clinic staff informed regarding protocol changes and IRB approvals?</td>
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<tr>
<td>10.</td>
<td>What are the plans to assure that unit/clinic staff have access to the study protocol as a resource?</td>
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<tr>
<td>11.</td>
<td>What are the plans to assure unit/clinic staff have access to the participant's signed consent form? (It is recommended that the consent be placed in the front of the patient's medical record while the study is being conducted on the unit.)</td>
</tr>
<tr>
<td>12.</td>
<td>Does this study require the use of an Investigational Drug? If yes, how will staff be educated on the use of the drug? (VCUHS Policy and Procedure 4533)</td>
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<td>13.</td>
<td>What are the plans to assure that study staff, who are not part of the unit/clinic staff, meet the appropriate competencies and annual health standards for providing patient care on the unit/clinic.</td>
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<tr>
<td>14.</td>
<td>How will the unit/clinic staff be informed of the study outcomes once completed?</td>
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<td>15.</td>
<td>Is this a Nursing Research study? If yes, has the Nursing Research Advisory Council (NRAC) been notified?</td>
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Recommendations: ___________________________

Manager's signature: ___________________________ Date: ___________________________

Manager: Keep copy for files and send copy to NRAC at NRAC@mcvh.vcu.edu

Items to keep on file:
- Research Pre-study Assessment Form
- Copy of IRB approval letter (may be emailed to you prior to beginning study)
- Abstract of study (if available)
- Blank copy of consent