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Values: Efficiency, Excellence, Safety

Policy Number: TBD

Approved by: Executive Director
Medical Executive Committee

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Requesting use of the Clinical Research Unit for Conducting Clinical Research

Policy:

Prior to initiating a study on the Clinical Research Unit (CRU) the Medical Director and the Patient Service Manager (PSM) will review and approve appropriate Institutional Review Board (IRB) approved protocols.

Procedure:

1. Application submission: The Principal Investigator (PI) or the PI's Research Coordinator submit an application to request use of the CRU. An application can be obtained by calling CRU Administrative Assistant at 464-9000, or from the website www.upstate.edu/cru. If there are any questions or concerns regarding the application contact the CRU Medical Director or Patient Service Manager (PSM). The completed application must include:
 - a. A copy of the research protocol.
 - b. A letter indicating IRB approval.

2. Application Review Process: The Medical Director and CRU Nursing Management/staff will review the application, and will approve, disapprove, or suggest modifications to the protocol based on criteria. The PI will be notified of the CRU Application decision in writing. Criteria to conduct a study in the CRU includes, but is not limited to:
 - a. A study coordinator must be in place in order to conduct a study.
 - b. Feasibility of the CRU to conduct the study will be evaluated to include, but not be limited to:
 1. Equipment and supply needs.
 2. Nursing competency.
 3. Patient acuity and monitoring needs.

3. Following study approval the following will be completed.
 - a. The CRU protocol number and type will be assigned. The study will be designated as:
 1. Investigator initiated (Type A)
 2. Federally, or foundation funded (Type A)
 3. Combination of research and standard of care (Type B)
 4. Type C (non-research), evaluated by the CRU Medical Director and CRU Nursing Management/staff on an episodic basis
 5. Industry sponsored (Type D)

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c. Budget Planning: The PSM will review the protocol and estimate CRU visit fees based on the CRU leveling criteria. Please refer to the Guidelines for using the Clinical Research Unit leveling form for clarification. The PI or coordinator will contact the Director of the Clinical Trials Office at 464-5476 to assist with negotiating a budget that includes these fees.

d. Staff Education: The PI will schedule an educational in-service of the protocol before initiation of the study on the CRU to discuss the protocol and answer any questions the CRU staff may have.

Originating Department: Clinical Research Unit
Contributing Department(s): Clinical Trials Office

References: CM-I04 Investigational Drugs, R-08 Research Support from University Hospital, Guidelines for obtaining