

The GCRC at University Park  
**The Medical Staff**

**Purpose:** To define the role of the GCRC Medical Staff.

**Background:** The role of the GCRC is to facilitate human clinical research. The role of the GCRC Medical Staff is to collaborate with the PI in the performance of the PI's research project.

The GCRC at University Park is unusual in that most of the investigators utilizing the facility are not physicians. However, the GCRC must follow typical "hospital" procedures as given by the Commonwealth of Pennsylvania and the Joint Commission for Accreditation of Healthcare Organizations. These include the fact that most activities must take place under "orders" of a physician.

Also the GCRC guidelines state "All GCRC research subjects must receive optimal medical care. It is the responsibility of the principal investigator of the project to assure that appropriate medical care is provided to research subjects participating in his/her research proposals. This responsibility may be discharged either personally if the principal investigator is a physician, by a physician, co-investigator, fellow, resident or other physician who possesses the requisite clinical expertise, admitting privileges, and is familiar with the protocol."

**The Medical Staff:** The Medical Staff shall consist of physicians who may be assisted by physician assistants(s) (PA) or nurse practitioner(s) (NP). Such physicians and others may be employees of the University or may work on a sub-contract. The relevant laws of Pennsylvania shall govern the relationship of the physician(s) with the PA(s) and NP(s) and their practices.

**Role of the Medical Staff:**

- 1) **The GCRC Director and Associate Director have a responsibility given by the NIH to assure that all studies are performed within IRB approval and as safely as possible. The Medical Staff shares this responsibility.**
- 2) **The Medical Staff shall be responsible for the admission, care and discharge of all subjects in the GCRC, outpatient and inpatient.**
- 3) **Members of the Medical Staff shall be invited by the GAC as voting members of the GAC with special, but not unique responsibility for the medical aspects of a study.**
- 4) **A PI may request services from the Medical Staff such as screening subjects for studies or performance of specific medical procedures.**

- 5) **Assistance of the Medical Staff in the performance of research procedures may be requested by a PI, or may be mandated by the IRB, the GAC or the GCRC Director / Associate Director.**
- 6) **In addition the GCRC Medical Staff are available to the PI for collaboration throughout the process of development and execution of a research project (see appendix).**

**Qualifications of the Medical Staff:** Members of the Medical Staff will be properly licensed in the State of Pennsylvania. They will undergo appropriate Institutional credentialing and privileging procedures. Physician investigators may fulfill the roles and responsibilities of the Medical Staff, if they meet the credentialing and privileging criteria above.

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Appendix - GCRC medical staff collaboration with the Investigator:

Please contact us at [gcr@psu.edu](mailto:gcr@psu.edu).

- 1) **We will meet with you, the investigator during the GCRC application process. At this time we will collaborate with you on deciding how much the physicians, nurses and the nutrition department should be involved with the study. This meeting will result in nursing and nutrition orders for the study being generated, as well as the study flowsheet(s). We can help you craft inclusion / exclusion criteria and review other medical aspects of your study.**
- 2) **We suggest that we meet with you before you submit your study to the IRB or to an outside funding agency.**
- 3) **We are available to write letters to the IRB stating what services we, the medical staff, would be able to provide to the study after appropriate IRB and GAC review. If invited to do so, we can also state that we were involved in the crafting of the inclusion / exclusion criteria or in planning other medical aspects of the study.**
- 4) **We are available to have one of us sign the GAC application as the physician willing and able to take responsibility for admission of your subjects to the GCRC for execution of your study protocol.**