

The GCRC at University Park  
**Complex Diseases**  
and/or  
**Research Procedures that Impart  
more than Minimal Risk**

**PURPOSE:** To provide guidelines regarding standards and expectations in the GCRC for situations where investigators, as part of their research, propose to deal with subjects with a complex disease(s) or propose to perform procedures that impart more than minimal risk to subjects.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine or psychological examinations or tests. (Code of Federal Regulations, Title 45, Part 46)

**POLICY:** The GCRC recognizes that IRB review focuses on the protection of human subject safety and evaluates the risks of research procedures according to the Code of Federal Regulations, Title 45, Part 46. Therefore, IRB review and approval must be obtained prior to initiating any research protocol that involves human subjects, including proposed modifications to previously approved protocols. In each case it must be clear from the IRB documents that the investigator has identified the individual(s) who will perform each study procedure that imparts more than minimal risk.

If the research involves the study of subjects with a complex disease(s) or procedure(s) that impart more than minimal risk, then either the PI or one of the named collaborators must be a physician with demonstrated expertise in the disease(s) under study and/or the procedures that impart more than minimal risk. The physician must also have clinical privileges for any study procedures that require such privileges. When risks relate to more than one disease or procedure, then appropriate expertise must be demonstrated among the investigators.

With reference to the paragraph above, if a non-physician investigator proposes to perform a procedure that imparts more than minimal risk, his or her competency/expertise must be confirmed in writing by the physician with demonstrated expertise and/or clinical privileges as above.

If during the GAC research protocol review, there is a concern under this policy about investigator qualifications to perform a procedure(s) which imparts more than minimal risk or about the competency of the research team in the disease(s) under study, the

GAC may refer such questions to an ad hoc subcommittee. The subcommittee will report back to the GAC with a recommendation.