12.7 HIV-POSITIVE SUBJECTS AND SUBJECTS WITH AIDS

A. Confidentiality

OHRP Guidance for Institutional Review Boards for AIDS Studies Federal guidelines indicates, "*perhaps the most sensitive aspect of AIDS research from the perspective of the rights and welfare of the subjects is the matter of confidentiality… Improper disclosure could have the most serious consequences for research participants, by threatening family relationships, job security, employability, or ability to obtain credit or insurance. In light of these risks, special precautions should be taken to preserve confidentiality, and potential subjects should be advised with care of the limits of that confidentiality, so they can make thoughtful, informed decisions, in light of their own circumstances, as to whether to participate.*" (OPRR Reports, Guidance for Institutional Review Boards for AIDS Studies, December 26, 1984)

The Report recommends that investigators and IRBs pay special attention to the design of HIV studies to ensure that administrative, management and technical safeguards are implemented to protect against unauthorized use and disclosure of information. Additionally, the Report indicates that, "where identifiers are not required by the design of the study, they are not to be recorded. If identifiers are recorded, they should be separated, if possible, from data and stored securely, with linkage restored only when necessary to conduct the research. No lists should be retained identifying those who elected not to participate. Subjects must be given a fair, clear explanation of how information about them will be handled."

B. Communicable Disease Reporting

In accordance with the Statutes of the State of Illinois, the Institution is responsible for the timely reporting of those diseases and conditions declared to be contagious, communicable and dangerous to public health as identified in the Illinois Department of Public Health Communicable Disease Code (e.g. HIV, Sexually Transmitted Infections, etc.). This full policy is available on the Medical Center's Administrative Policy SharePoint site.

Researchers that will test for one or more of the communicable diseases as identified by the Illinois Department of Public Health are required to follow this reporting policy. The informed consent documents are to state to potential participants when such reporting will occur; noting that this reporting will not include any identifiable information of the participant.

References:

1. Strong, C; Minimal Risk in Research Involving Pregnant Women and Fetuses; J Law Med Ethics. 2011 Fall; 39(3):529-38.