

The GCRC at University Park

Protecting Confidential Subject Information Policy

(March 2005)

Purpose:

To clarify for both investigators and subjects how information about research subjects received during the course of a study conducted at the GCRC is obtained, stored and potentially released.

The Policy:

- 1) Medical information obtained during the course of a study at the GCRC will / will not be shared with the subject's personal physician(s) based on a specific consent to do so that all GCRC study participants are asked to sign (see page 2).
- 2) Release of research information is handled by the research team based on the consent form.
- 3) Medical information that may be pertinent to a study will / will not be obtained from the subject's personal physician(s) based on a specific consent to do so (see page 2).
- 4) It is a requirement of the NIH GCRC program that research records, including medical information, be stored in a locked file for 7 years for subjects 18 years old or older, or until the age of 27 for subjects less than 18 years old. During this time the record will be available to the research team(s) of the study(ies) that the subject has participated in or is currently participating in, and to GCRC clinicians, if needed. The record is then destroyed. De-identified copies of the records may be released to the research team.
- 5) Because the GCRC staff are health care professionals, occasionally research subjects choose to share important sensitive information with them, that they at first may not want to share with the non-GCRC study team. In such instances, the GCRC staff will first remind the subject that the Principal Investigator (PI) is in charge of the research study and that therefore the subject should share the information with the PI. However, if the subject insists that the information be kept confidential even from the PI, the GCRC staff will inform the subject that the information must be shared with the Research Subject Advocate (RSA), a physician responsible for all research subject issues. The RSA will then determine, on a case-by-case basis, how to best handle the information. In addition the confidential information will not be entered into the regular GCRC medical chart, but will be documented with the RSA.



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Authorization to Release or to Obtain Health Information

To release information to my physician. (Please check and initial only one of the statements in this section)

- I give my permission to the medical staff of the General Clinical Research Center (GCRC) at University Park to release results of my medical evaluation to myself and to my physician (Dr[s].....). I understand that these test results may reveal important health history information for my medical record. Research test results are addressed by the research consent form. *My Initials* _____
- I do not give permission to the medical staff of the General Clinical Research Center (GCRC) to release results of my medical evaluation to my physician. I request that the medical staff send copies of any test results only to me. *My Initials* _____

To obtain health information from my health care provider (Please check and initial only one of the statements in this section.)

- I give my permission to my physicians to release the results of pertinent medical tests to the medical staff of the General Clinical Research Center (GCRC) at University Park. These results will be reviewed by GCRC medical clinicians and by the study investigators as part of my medical history as it relates to my participation in a GCRC research study. *My Initials* _____
- I do not give permission to the General Clinical Research Center (GCRC) to obtain health information from my physicians. I understand that by declining to provide test results from my physician the GCRC clinicians and the study investigators may not have a complete understanding of my medical history as it relates to the research study and for that reason I may not be eligible to participate in a GCRC research study. *My Initials* _____

I understand that medical visits at the GCRC are related to a research study and are not, and should not be considered, a substitute for regular medical evaluation and follow-up with my personal physician.

I understand that it is a requirement of the National Institutes of Health GCRC program that my research record, including medical information, be stored in a locked file for 7 years if I am 18 years or older, or until the age of 27 if I am less than 18 years old. During this time the record is available to the research team(s) of the study(ies) that I participated in and to GCRC clinicians, if needed. The record is then destroyed. If I volunteer for future research projects at the GCRC, my stored medical information will be available for review by the GCRC clinical staff and the investigators of the study for which I volunteer.

Subject signature _____ *Initials* _____ Date _____

Witness _____ Date _____