

PP-702 STANDARD OPERATING PROCEDURE FOR INFORMATION ACCESS CONTROL

1. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the steps taken to ensure that subject personal health information (PHI) is controlled and access to such information is limited to authorized research staff for approved purposes only. Adequate password protection is vital to safeguarding PHI and must be limited to research staff who require access to this information. Therefore, each user of PHI will be identified and allowed access to information based on his/her assigned password.

2. SCOPE

This SOP applies to all research staff with access to private health information.

3. APPLICABLE REGULATIONS AND GUIDELINES

None

4. REFERENCES TO OTHER APPLICABLE SOP'S

GA-102	Responsibilities of the Research Team
GA-103	Training and Education
DM-502	Electronic Data Management

5. ATTACHMENTS

None

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in conducting clinical trials at this research site. This includes the following:

- Principal investigator
- Sub-investigator
- Research coordinator
- Support staff

7. DEFINITIONS

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

Personal Health Information: Information that is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual;

the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and identifies the individual; or when there is a reasonable basis to believe the information can be used to identify the individual. (Under HIPAA regulations at 45 CFR 164, PHI (Protected Health Information) also includes: Individually identifiable health information that is: (i) Transmitted by electronic media; (ii) Maintained in any medium described in the definition of electronic media at §162.103, or (iii) Transmitted or maintained in any other form or medium.)

8. PROCESS OVERVIEW

A. Access of PHI via computer

9. PROCEDURES

A. ACCESS OF PHI VIA COMPUTER

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research Director/Manager	PI and Research Director/Manager will ensure documentation is available for Sponsors and Regulatory Agencies stating that the site maintains all computer systems and passwords per the current CFRs.
PI Research Director/Manager	Ensure that each individual who has been assigned a password is responsible for its safekeeping. Stress that divulging a password may result in a disciplinary action.