


Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	PROTECTING CONFIDENTIAL INFORMATION		
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PURPOSE: The purpose of this SOP is to establish guidelines for ensuring the confidentiality of study subjects who participate in clinical research trials at the CRC.

SCOPE: This SOP applies to all research personnel involved in the implementation and coordination of clinical research studies at the CRC.

RESPONSIBILITIES: The investigator and study staff are responsible for ensuring the protection of confidential information for all study participants.

DEFINITIONS:

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject


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

Direct Access: Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

electronic Protected Health Information (ePHI): means information that is transmitted by electronic media or maintained in any electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card

Integrity: means the property that data or information have not been altered or destroyed in an unauthorized manner.

Protected Health Information (PHI): 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

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Definitions (cont.):

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.

PROCEDURE:

1. All study staff shall not disclose to anyone, other than those persons directly connected with the study and the protocol, any data, material, or information disclosed to the study site by the sponsor as described in the clinical trial agreement (CTA).
2. Study staff may describe the study to a potential participant during subject recruitment and answer questions to the person's satisfaction within the limits of protecting the confidential information as defined above.
3. Designated research personnel will store all study related documents, including regulatory and subject records, in a secure location with access limited to appropriate study personnel.
4. All study staff will maintain confidentiality of PHI for each subject.
5. Study personnel will identify subject specific data, including the source document chart (when separate from medical record), only with initials and study subject number where appropriate per federal regulations regarding medical records.
6. All study staff will be compliant with HIPAA regulations when applicable.
7. The research designee will remove personal identifying information from raw data and replace with coded identification.
8. Study team will keep any materials received with personal identifying information in locking cabinets, offices or suites when not being used in project activities.
9. After data entry, any materials received with personal identifying information will be stored or returned to the project in a manner approved by the PI.
10. Any materials with personal identifying information on them that are to be discarded will be placed in appropriate ShredGreen receptacle in CRC to be shredded.
11. Computer Files: Computer data files should contain only coded id information, not personal identifiers

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PROCEDURE (cont.):

12. When computerized names and addresses are needed, they will be kept separately from other project data
13. The PI and study staff will ensure that all computer files will be password protected.
14. The PI will not include identifying information in publications.
15. Any computer disks with personal identifying information that are to be discarded will be placed in ShredGreen receptacle in CRC for proper destruction.
16. Personal identifying information will not be sent via email.
17. Authorization from the Principal Investigator is needed prior to giving data sets and analysis results to anyone outside the project.
18. If working with sensitive or stigmatizing activities, a Certificate of Confidentiality may be obtained from the National Institutes of Health for federally funded studies.

REFERENCES:	NIH: Clinical Research and the HIPAA Privacy Rule		
	FDA 21 CFR Part 312.60: Institutional Review Boards		
01/01/2015	DHHS 45 CFR Part 16: Protection of Human Subjects		
RELATED POLICIES:			
APPENDICES:			
REVISION HISTORY:	Keep a running history of all revision dates.		