


| Standard Operating Procedures for Clinical Research at USF Health Morsani CRC | | | |
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|  | PRIVACY AND CONFIDENTIALITY | | |
| | SOP#: 202 | EffectiveDate:01/01/2015 | Version#:1.0 |
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PURPOSE: The purpose of this SOP is to ensure adequate provisions are implemented to protect the privacy interests of study subjects and confidentiality of data for clinical trials conducted at the CRC in accordance with applicable local, state and federal regulatory authorities.

SCOPE: This SOP applies to the Investigator(s) and all research team members who conduct clinical research studies at the CRC.

RESPONSIBILITY: The Investigator(s) and all study team members are responsible for ensuring that privacy and confidentiality of data is protected throughout the course of each study and upon completion of study related procedures.

DEFINITIONS:

Confidentiality: Refers to the treatment of information/records/data that one has disclosed in a relationship of trust with the expectation that it will not be divulged to anyone without permission and in ways that are consistent with the understanding of the original disclosures.

Identifiable: the identity of the subject is or may be readily ascertained or associated with the information; data can be linked to specific individuals either directly or indirectly through coding systems. This would also include some demographic information, or other unique information or key details that would allow individual identification to be deduced (e.g., using internet search engines or other means).

Privacy: The right one has to control the extent, timing, and circumstances for sharing information about oneself with other individuals. Privacy also includes the reasonable expectation there will be no intrusions into one's physical space or intrusions upon the individual's privacy interests under normal conditions.

Sensitive information: Information about an individual that may be harmful or embarrassing to reveal. This may include information about sexual attitudes, preferences or practices, use of alcohol, drugs or other addictive products, illegal conduct, psychological well-being or mental health, private records (e.g., medical or academic records), or other information that, if released, could reasonably be damaging to an individual's financial standing, employability, or reputation.

PROCEDURE:

1. The investigator is responsible for designing and conducting research studies that protect to the fullest extent possible both the privacy of the individuals who are potential or actual research subjects in research involving human subjects as well as the confidentiality of identifiable private information and individually identifiable health care information about such individuals.

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PROCEDURE (cont):

2. Investigators are required to describe the steps, recruitment methods and data storage details in their IRB initial submission. To ensure compliance with USF HIPAA policies, Investigators must also identify how they may be accessing a research subject's identifiable private health information.
3. Privacy:
 - 3.1 The Investigator and his/her research team must be mindful that a loss of privacy may result in economic, legal, or social risks to participants. Examples of privacy risks include:
 - private records are used without permission
 - individuals are observed or recorded without their knowledge
 - an investigator joins a group for the purpose of observing them for research (participant observation)
 - a survey or interview involves sensitive or invasive questions
 - a survey or interview collects private information about third parties (e.g., a parent, child, sibling, or spouse)
 - participants are selected on the basis of a stigmatizing or sensitive condition, diagnosis or characteristic (e.g., HIV status, sexual orientation, victims of abuse).
 - 3.2 The research team may use a variety of methods to protect the privacy of research participants to include:
 - use of a private setting for completing sensitive surveys or interviews
 - collecting only the minimal amount of information necessary
 - avoiding or limiting collection of identifiable information, and/or signatures
 - discrete recruitment methods to eliminate identification of participants based on a stigmatizing or sensitive condition
 - redesigning study to avoid or minimize intrusions
 - debriefing procedures
 - 3.3 Informed Consent.
 - Unless the IRB has otherwise waived the requirement for informed consent, participants must be informed of the research, the sensitive nature of any questions or procedures, and allowed to skip questions.
 - The IRB may waive the requirement for informed consent when research meets specific conditions.
4. Confidentiality:
 - 4.1 Investigators must describe their plans to store the research data, the methods used to code or de-identify the data, the length of storage and when the data will be destroyed for each research project in their IRB initial submission. Examples include the following:

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PROCEDURE (cont):

- Identification of Research Subjects: Research data should be at a minimum coded to ensure the confidentiality of subjects. Investigators should also be mindful when reporting on their research and to ensure that all data reported in papers, abstracts, etc. does not include any identifiable information by which either the investigator may identify the subject or the subject may identify themselves. At the end of the project or an earlier opportunity, it is recommended that the Investigator destroy the key code and effectively de-identify the data.
- Storage of Research Data: Project data should be stored in a manner consistent with project procedures such as password-protected computers, jump/USB drives, password-protected spreadsheets and/or databases with limited accessibility, locked filing cabinets, and/or locked offices.
- Length of storage of research data: For more information, please refer to *USF HRPP Policy and Procedures Manual: Records Retention and Accessibility* which states that the PI must retain all study records for a minimum of five (5) years from the time the study is closed by the IRB. For FDA regulated studies, Investigators review and follow the required length of storage as described in the protocol.

4.2 The research team will be aware that research may involve confidentiality risks when collecting information about sensitive topics such as:

- illegal activities
- substance abuse
- sexual orientation
- health or psychological conditions
- undesirable work behavior
- other information that may be painful or embarrassing to reveal

4.3 The Investigator and study team will adhere to the recommendations for securing electronic research data as outlined in the Recommended HIPAA Privacy Practices.

4.4 Research personnel are encouraged to use a variety of measures to protect confidentiality of data. More stringent measures will be required when data is highly sensitive, and/or potentially identifiable. Some of the methods that may be utilized include:

- eliminate or maximize collection of direct or indirect identifiers, including signatures
- replace identifiers with a code; retaining the code in a separate location
- remove identifiers as soon as possible
- use participant-generated codes composed of a combination of elements (e.g., first 2 letters of home town, year of graduation, last 3 letters of pet's name) to link separate data sets
- physical security measures: e.g., locked offices, locked cabinets

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PROCEDURE (cont):

- electronic data safeguarding measures using current IT security standards: e.g., user passwords and authentication, firewalls, anti-virus programs, encryption, isolation from networks, etc.
- obtain a Certificate of Confidentiality for federally funded studies to protect sensitive data from forced disclosure to legal authorities (refer to NIH website)

4.5 Informed Consent

- Unless waived by the IRB, informed consent is required and participants must be informed of the extent to which the confidentiality of information collected about them will be maintained. This may include disclosure of:
 - any risks of a breach of confidentiality, and measures to minimize this possibility
 - the parties who will access their information
 - any further data sharing, mandated reporting of disclosures
 - use and eventual disposition of recordings (audio, video)
 - any limitations on confidentiality of their information

4.6 Mandatory Reporting

- Certain information (e.g., harm to self or others, reportable diseases or conditions) collected in the course of a research project may be subject to state mandated reporting requirements. When an investigator anticipates the possibility of obtaining such information, participants or their guardians must be informed of the possibility of disclosure of their information to appropriate authorities.

5. Research Data Collection Tools

- 5.1 A description of the tools ((records, photographs, questionnaires, surveys, videotapes, audiotapes) to be utilized should be provided to the research subject.
- 5.2 Research subjects should be informed (in the consent document) of their right to refuse to answer any questions and should be given an estimate of the length of time needed to complete the activity.
- 5.3 All use of records, photographs, films, videotapes, and audiotapes to be made or to be used for the research project must be described in the informed consent document for the research subject. The informed consent document should also describe the use of the materials and describe provisions for erasure or destruction if requested by the research subjects.

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| REFERENCES: | 21 CFR 56 | |
| | 38 CFR 17.33(a), 17.33(f), 17.278, and 17.500-17.571 | |
| | 45 CFR 46 | |
| | 45 CFR 164 | |
| | Freedom of Information Act (FOIA) | |
| | Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards | |
| | Privacy Act of 1974, 5 U.S.C. § 552a | |
| | Recommended USF HIPAA Privacy Practices | |
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| RELATED POLICIES: | USF HRPP Policy and Procedures Manual | |
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| APPENDICES: | None | |
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| REVISION HISTORY: Keep a running history of all revision dates | | |
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