OBJECTIVE

To describe policies and procedures to ensure the protection of participant privacy and confidentiality and recordkeeping of their research records.

GENERAL DESCRIPTION

Federal regulations require that research involving human participants include adequate provisions to protect the participants' privacy and to maintain the confidentiality of their data. This SOP describes requirements for protecting privacy and confidentiality in research involving human subjects, including the use of National Institutes of Health (NIH) Certificates of Confidentiality.

Definitions

Private information: Information about behavior that occurs in a context in which an individual can reasonably assume that no observation or recording is taking place or information which has been provided for specific purposes by an individual and which he or she can reasonably expect will not be made public.

Privacy: The principle that participants have control over the extent, timing, and circumstances of sharing their private information with others.

Confidentiality: The principle that investigators will not divulge information to others without the permission of the participant. This is important because participants make this disclosure on a voluntary basis based upon a relationship of trust with the investigators.

It is important to note the distinction between "privacy" and "confidentiality" in the context of human participant research. Generally, privacy refers to the people involved in the research and the methods of gathering information from them. Confidentiality refers to the obligations of researchers and institutions to appropriately protect information disclosed to them by research participants.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Research Personnel, Institutional Review Board (IRB) Office Staff, IRB Members, IRB Chairs

PROCEDURES

A. Privacy

1. Investigators must take into consideration that reasonable assumptions regarding privacy will vary from culture to culture, setting to setting, and may vary among generations. Research procedures should be designed so that they to respect the privacy of the target participant population.

2. Invasions of privacy can occur if subjects are asked questions that they find intrusive. If a survey instrument or an interview script contains questions that individuals are likely to find intrusive, they must be informed about the nature of the questions in advance in the Informed Consent Form. This includes studies about sexual behavior, childhood abuse, use of psychotropic medications, and other personal topics. The survey instrument or interview process must be designed so that participants may choose not to answer any question that makes them uncomfortable, or that they want to skip for any reason.

B. Confidentiality

1. Researchers must provide confidentiality to their participants by appropriately protecting information the participants disclose. The potential risk of harm to participants if identifiable data were inadvertently disclosed is the key factor for determining what kinds of protection are needed.

2. Confidentiality procedures must be described during the informed consent process. This is to allow participants to determine what measure of control over their personal information they are willing to relinquish to the investigators.

3. If investigators plan to retain individually identifiable data that if inadvertently disclosed could place participants at risk of harm, investigators need to design procedures to protect the data during collection, storage, analysis, and reporting. These procedures could include creating keys linking subjects' names to unique numbers associated with the data, storing encrypted data on secure servers, removing identifiers when data collection is completed, reporting data in aggregate, and creating pseudonyms in articles or presentations.

4. Consent forms should clearly explain who will have access to identifiable data, both in the present and in the future, and describe any future uses of the data, if applicable.

C. Certificates of Confidentiality

1. Certificates of Confidentiality are issued by NIH to protect the confidentiality of research data. These certificates prohibit disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in a few other specific situations. This includes attempts to force involuntary disclosure (e.g., by subpoena) of sensitive information to any civil, criminal, administrative, legislative, or other proceeding at the federal, state, or local level.

2. NIH funded investigators are automatically issues a Certificates of Confidentiality through their award. Other Department of Health and Human Services (HHS) agencies issue Certificates of Confidentiality to investigators they fund.

3. Certificates of Confidentiality are not limited to federally funded research. They may be requested for any biomedical, behavioral, or other type of research in which identifiable sensitive information is collected.

4. NIH defines “sensitive” to mean that disclosure of the identifying information could have adverse consequences for participants or be damaging to their financial standing, employability, insurability, or reputation. Examples of sensitive information include, but are not limited to, information about the following:
    - Genetics
    - Psychological well-being of participants
    - Participants' sexual attitudes, preferences, or practices
    - Substance abuse or other illegal risk behaviors
    - Litigation related to exposures under study

5. Not all activities are eligible for a Certificate of Confidentiality. To be eligible, an activity must meet all of the following criteria:
    - Defined as research involving human subjects
    - Involves collection of personally identifiable information
    - Has been reviewed and approved by an IRB
    - Involves collection of information that if disclosed would significantly harm the participant.

6. Certificates of Confidentiality do not eliminate the need for investigators and the IRBs to assure that appropriate data security measures are in place to protect research participants' identifiable information.

7. Participants must be informed about the protections provided by a Certificate of Confidentiality and any exceptions to these protections. Informed consent documents should describe the protections and any limitations of a Certificate, including voluntary disclosures by research participants, releases of information authorized in writing by participants, and voluntary disclosures made by investigators (described below).

8. A Certificate of Confidentiality does not prevent an investigator from voluntarily disclosing sensitive information. For example, Certificates of Confidentiality cannot be used to protect research participants from disclosures of their sensitive information. This includes information such as evidence of child abuse, threats of violence to self or others, reasonable knowledge that a felony has been (or is being) committed, or reportable communicable diseases, by investigators who are subject to mandatory reporting requirements under U.S. or Florida law (or other states as applicable). An investigator's intention to report such (or other) information must be specified in the consent form.

9. For more information on Certificates of Confidentiality, see the National Institutes of Health "Certificates of Confidentiality" website at https://humansubjects.nih.gov/coc/index.

D. Recordkeeping

1. As appropriate to the research and as specified by applicable regulations and institutional policy, investigators are responsible for maintaining documents, which individually and collectively permit evaluation of the conduct of the research and the quality of the data produced. The IRB recommends keeping a research binder that contains, at a minimum, the following documents:
   a. New Protocols Submission, amendments, and continuing reviews as approved by the IRB;
   b. the grant, contract and/or signed agreement between the investigator and the funding agency;
   c. forms used to obtain and document consent/assent;
      i. current IRB approved forms;
      ii. documentation of consent/assent for each subject, if applicable;

d. any written recruitment materials and other written information given to subjects, this includes but is not limited to;
    i. recruitment flyers
    ii. recruitment emails
    iii. cover letters
    iv. brochures
e. data collection forms including source documents and case report forms;
f. accountability records of investigational products;
g. correspondence from the IRB including approval memos;
h. any reports from monitoring and auditing bodies;
i. reports of unanticipated problems/serious adverse events;
j. approvals from regulatory authorities, if applicable.

2. Investigators are responsible for maintaining signed documents and IRB records for a minimum of 36 months after study closure. Investigators are responsible preventing accidental or premature destruction of these documents.

3. All records must be stored in a manner consistent with this SOP and as outlined in their approved IRB protocol submission to prevent breaches of confidentiality.

4. For research under the authority of the FDA or other regulatory or funding agency, investigators are responsible for retaining the signed documents and IRB records for the period specified in the applicable regulations if the requirements are longer than 36 months after completion of the study. For multi-site studies, investigators must consult the study sponsor regarding retention requirements, but must maintain records for a minimum of 36 months after study closure.

REFERENCES

21 CFR 56.111
45 CFR 46.111
OHRP Institutional Review Board Guidebook: “Privacy and Confidentiality” (1993)