

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &
IMPLEMENTATION**

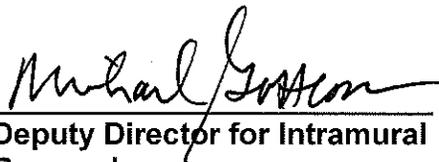
OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

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**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB
Chairs, IRB Administrators, Protocol Navigators**

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SOP 18 – PRIVACY AND CONFIDENTIALITY

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SOP 18 PRIVACY AND CONFIDENTIALITY

18.1 PURPOSE

This SOP discusses provisions for protecting the privacy interests of research subjects and maintaining the confidentiality of identifiable data collected during research.

18.2 POLICY

This policy establishes procedures for the NIH Human Research Protection Program (HRPP) to maximize research subjects' privacy and to maintain the confidentiality of their personally identifiable information. In its human research and record-keeping activities, the NIH HRPP follows the requirements of the Privacy Act, 5 U.S.C. 552a (see **References** and **Section 18.4.1**).

18.3 DEFINITIONS

- A. **Certificate of Confidentiality:** Certificates of Confidentiality (COC) are issued by the National Institutes of Health to protect identifying research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose **names or identifying characteristics of** research subjects in any civil, criminal, administrative, legislative or other proceeding, whether at the federal, state or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping to assure confidentiality and privacy to research subjects (see **Section 18.6.3** and **References**).
- B. **Coded Specimens or Data:** Coded specimens/data mean that: 1. identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and 2. a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens (see OHRP – Guidance on Research Involving Coded Private Information or Biological Specimens (2008) in **References**). **Once the code key**

is destroyed, specimens/data are then considered completely de-identified to all parties.

- C. **Confidentiality:** The protection of research subjects' privacy from disclosure of their personal, sensitive or private information to unauthorized persons. Methods used to ensure that information obtained by researchers about their subjects is not improperly divulged.
- D. **Individually identifiable:** Individually identifiable means that the identity of the subject is or may be readily ascertained by the investigator or associated with the information (45 CFR 46.102).
- E. **Identifying characteristics:** Identifying characteristics refers to the name, address, any identifying number, fingerprints, voiceprints, photographs, or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject (42 CFR 2a.2(g)).
- F. **Private information:** Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record. Private information must be individually identifiable i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects (45 CFR 102(f)(2)). In this context, "investigator" includes any member of the research team.

18.4 GENERAL NIH HRPP CONSIDERATIONS RELATED TO PRIVACY AND CONFIDENTIALITY

18.4.1 THE PRIVACY ACT

- A. The NIH follows federal law provided by the Privacy Act of 1974 as amended at 5 U.S.C. 552a (see **References**). This Act includes procedures:
1. For protecting records that can be retrieved by personal identifiers such as a name, social security number, or other identifying number or symbol, and

2. For persons to access their identifiable records and to request correction(s) of these records.
- B. In implementing the requirements of the Privacy Act, the NIH follows the Department of Health and Human Services Privacy Act Regulations.
1. The Privacy Act generally prohibits disclosure of personally identifiable records without the written consent of the individual(s) to whom the records pertain. There are some exceptions to this prohibition, (see NIH Privacy Act System of Records Notices #09-25-0099 and #09-25-0200 in **References**).
 2. The NIH has adopted standard language for inclusion in all NIH IRB approved consent documents which addresses research subjects' rights under the Privacy Act (see **Section 18.7.A.1**).
- C. NIH researchers and other employees who have questions about the Privacy Act or related issues should contact the Privacy Act Officer of his/her Institute or Center (see **References**).

18.5 PRIVACY

18.5.1 GENERAL CONSIDERATIONS

NIH researchers should respect the privacy of research subjects by providing a research environment free from unwanted intrusion consistent with applicable law. IRBs should assure that privacy protections are in place. **The IRB should consider** the circumstances **under** which **research staff interact with subjects and collect** their personal information.

18.5.2 SPECIFIC PRIVACY PROTECTIONS

Privacy protections, appropriate to the research, may include (but are not limited to):

- A. Utilizing recruitment and contact methods for potential research subjects that minimize adverse consequences of such recruitment or contact;
- B. Provision of private areas for obtaining consent;

- C. Provision of private areas for collecting information and for conducting examinations and **other** research procedures;
- D. Limiting the presence of research staff or others present during **data collection or other** procedures;
- E. Limiting information collected to that necessary to conduct the research; and
- F. Limiting information collected from research subjects about **individuals** who are not **enrolled in** the research (e.g., family members or other potential **subjects**).

18.5.3 PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITIES

The PI **must delineate within the protocol what steps will be implemented to protect research subjects'** privacy (see SOP 8 - Procedures and Required Documentation for Submission and Initial Review of Protocols). In addressing the privacy considerations described above, the PI will **consider** and include in the protocol, the following, as applicable:

- A. Methods used to identify and contact potential research subjects;
- B. Settings in which an individual will interact with an investigator;
- C. Appropriateness of all personnel present for research activities;
- D. Methods used to obtain information about research subjects;
- E. **The nature of the requested information and the justification for the amount of personal information requested; and**
- F. Information that may be deliberately or inadvertently obtained about individuals other than the research subjects and whether such individuals meet the regulatory definition of "human subject" (e.g., information about a family member **provided by a research** subject for a survey).

18.5.4 IRB RESPONSIBILITIES

- A. The IRB reviews the PI's plan related **to protecting research subjects' privacy** (see SOP 8 - Procedures and Required Documentation for Submission and Initial Review of Protocols).

- B. As part of its review, the IRB will consider the specific research activities in the protocol, the protections outlined in **Section 18.5.2**, and the requirements of SOPs 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs), 7A - Requirements for Expedited Review of Research by NIH Institutional Review Boards, 7B - Requirements for the Conduct of Research Review at a Convened NIH Institutional Review Board (IRB) Meeting, and 8 - Procedures and Required Documentation for Submission and Initial Review of Protocols.
- C. The IRB will determine whether adequate procedures are in place to protect the privacy of subjects, in the context of the specific research activities included in the protocol.
- D. The IRB will review and approve language in informed consent document(s) related to privacy (see **Section 18.7**).

18.6 CONFIDENTIALITY

18.6.1 PI RESPONSIBILITIES

- A. The PI is responsible for assuring that all investigators follow the plan in the written protocol for protecting the confidentiality of information and data provided by research participants. The protections provided should be commensurate with the risk of harm from improper disclosure.
- B. Consideration will be given to appropriate confidentiality protections during recruitment and contact of potential participants, and during research participation. Confidentiality protections may include (but are not limited to):
 1. When possible, coding or de-identifying collected information and labels on subject data and samples by irreversibly stripping individually identifiable information or by replacing private and individually identifiable information with a non-identifiable code. The key to the code should be kept securely and separately from the data and samples.
 2. Maintaining subject information in encrypted form.
 3. Maintaining subject information in secured databases and computers.

4. Maintaining paper records in locked files or rooms.
 5. Maintaining subject samples in locked storage.
 6. Limiting access to samples and data to authorized personnel.
- C. In order to interact with subjects for research purposes and/or access their private information, prospective NIH IRB approval or an exemption from the NIH Office of Human Subjects Protections (OHSRP) is required (see SOP 6 – **Processes for** Determinations Made by the NIH Office of Human Subjects Research Protections (OHSRP)).

18.6.2 IRB RESPONSIBILITIES

The IRB will review the protocol to assure that confidentiality protections provided by the PI (see **Section 18.6.1**) are consistent with NIH requirements and commensurate with the degree of risk of harm from improper disclosure.

18.6.3 CERTIFICATE OF CONFIDENTIALITY

A PI may request or the IRB may require a Certificate of Confidentiality (COC) for a research study (see **Section 18.3.A** and **References**). Certificates of Confidentiality are granted by the Federal government, upon request and in its discretion, for studies collecting information that, if disclosed, could have adverse consequences for **research** subjects or damage their financial standing, employability, insurability, or reputation. The COC does not protect against voluntary disclosure by an investigator or **the** NIH, for example, in cases of abuse or reportable communicable diseases or when a research subject gives written authorization for **the** release of identifiable information. Types of research that may be eligible for a **Certificate of Confidentiality** include, but are not limited to:

- A. Research on HIV, AIDS, and other sexually transmitted diseases (STDs);
- B. Studies that collect information on sexual attitudes, preferences, or practices;
- C. Studies on the use of alcohol, drugs, or other addictive products;
- D. Studies that collect information on illegal conduct;

- E. Studies that gather information that if released could be damaging to a subject's financial standing, employability, or reputation within the community;
- F. Research involving information that might lead to social stigmatization or discrimination if it were disclosed;
- G. Research on subjects' psychological wellbeing or mental health;
- H. Genetic studies, including those that collect and store biological samples for future use; and
- I. Research on behavioral interventions and epidemiologic studies.

The PI is responsible for obtaining and maintaining the COC during the research study and providing COC documentation to the IRB (see **Section 18.6.3.A**).

18.7 PRIVACY AND CONFIDENTIALITY LANGUAGE IN INFORMED CONSENT DOCUMENTS

- A. The IRB reviews and approves language in the informed consent documents related to privacy and confidentiality.
 - 1. NIH has standard language, approved by the NIH Office of General Counsel (OGC), which is included in all NIH consent documents (NIH 2514-1):

“Confidentiality: When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of

Congress, law enforcement officials, or authorized **accreditation organizations.**”

IRBs may require additional language in the body of the consent, as they deem appropriate, but any change in the NIH standard language requires prospective approval by NIH OGC.

- B. The IRB will assure that adequate information about the Certificate of Confidentiality (COC), when applicable, appears in the consent document (see **Section 18.6.3**). Suggested consent language may be found at the Certificates of Confidentiality Kiosk (see **References**).

REFERENCES

- A. The Privacy Act of 1974, 5 U.S.C. 552a:
<http://www.justice.gov/opcl/privacyact1974.htm>
- B. Certificate of Confidentiality Kiosk:
<http://grants.nih.gov/grants/policy/coc/index.htm>
- C. Certificate of Confidentiality Regulations, 42 C.F.R. Part 2A
- D. IC Privacy Act Officers:
<http://oma.od.nih.gov/public/Lists/AllDMSContacts/Privacy%20Coordinators.aspx>
- E. NIH Privacy Act System of Records Notices #09-25-0099, Clinical Research Patient Medical Records, HHS/NIH/CC:
<https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0099.htm>
- F. NIH Privacy Act System of Records Notices #09-25-0200, Clinical Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD:
<https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0200.htm>