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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 participants 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 confidentiality of their personally identifiable information. In its human research and record-keeping activities, the NIH HRPP follows requirements of the Privacy Act (see References and Section 18.4.1, below).

18.3 DEFINITIONS

A. **Certificate of Confidentiality:** Certificates of Confidentiality are issued by the National Institutes of Health to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants 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 assure confidentiality and privacy to participants (see References below).

B. **Coded Specimens or Data**: For the purposes of these SOPs, coded data or specimens 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.

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. **Private information:** Includes 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 below). 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.

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B. In implementing the requirements of The Privacy Act, the NIH follows the Department of Health and Human Services Privacy Act Regulations (see References below).

    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, including those listed in Appendix A and Appendix B.

    2. The NIH has adopted standard language for inclusion in all NIH IRB approved consent documents which addresses 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 below).

18.5 PRIVACY

18.5.1 GENERAL CONSIDERATIONS

NIH researchers should respect the privacy of research participants by providing a research environment free from unwanted intrusion consistent with applicable law. In their review of research, IRBs should assure that protections are in place to protect the privacy of subjects and, to the extent possible or required, afford subjects some control over the timing and circumstances in which others have access to them and their personal information.

18.5.2 SPECIFIC PRIVACY PROTECTIONS TO BE CONSIDERED BY INVESTIGATORS AND IRBS

These include protections, appropriate to the research, during recruitment and contact of potential participants and during their research participation. Privacy protections may include (but are not limited to):

A. Utilizing recruitment and contact methods for potential participants that minimize adverse consequences of such recruitment or contact.

B. Provision of private areas for obtaining consent.

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C. Provision of private areas for collecting information and for conducting examinations and research procedures.

D. Limiting the presence of research staff or others present during procedures.

E. Limiting information collected to that necessary to conduct the research.

F. Limiting information collected from research participants about those who are not the subject of the research (e.g., family members or other potential participants).

18.5.3 PI RESPONSIBILITIES

A. The Principal Investigator will document in the written protocol, privacy protections appropriate to the specific research (see SOP 8, "Procedures and Required Documentation for Submission and Initial Review of Protocols").

B. In addressing the privacy considerations described in 18.5.2., above, the PI will address and include in the protocol the following, as appropriate to the specific research:

1. Methods used to identify and contact potential participants.

2. Settings in which an individual will interact with an investigator.

3. Appropriateness of all personnel present for research activities.

4. Methods used to obtain information about subjects and the nature of the requested information.

5. Information that may be deliberately or inadvertently obtained about individuals other than the individuals enrolled in the study and whether such individuals meet the regulatory definition of "human subject" (e.g., a subject provides information about a family member for a survey).

6. Justification for the amount of personal information required to answer the research question.

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18.5.4 IRB RESPONSIBILITIES

A. The IRB reviews the PI's plan related to privacy protections (see SOP 8 “Procedures and Required Documentation for Submission and Initial Review of Protocols”).

B. The IRB review will take into account the specific research and the considerations outlined in 18.5.2, above and 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 as appropriate to the type of research.

D. The IRB will review and approve language in informed consent document(s) related to privacy (see Section 18.7, below).

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 participant 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.

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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, “Determinations, Including Exemptions, Made by the NIH Office of Human Subjects Research Protections (OHSRP) Under 45 CFR 46").

18.6.2 IRB RESPONSIBILITIES

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

18.6.3 CERTIFICATE OF CONFIDENTIALITY

A. The Principal Investigator or the IRB may require a Certificate of Confidentiality (COC) for a research study (see References below).

B. 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 subjects or damage their financial standing, employability, insurability, or reputation. The COC does not protect against voluntary disclosure by an investigator or NIH, for example, in cases of abuse or reportable communicable diseases or when a research subject gives written authorization for release of identifiable information.

C. Types of research that may be eligible for a Certificate include, but are not limited to:
   1. Research on HIV, AIDS, and other sexually transmitted diseases (STDs).

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2. Studies that collect information on sexual attitudes, preferences, or practices.

3. Studies on the use of alcohol, drugs, or other addictive products.

4. Studies that collect information on illegal conduct.

5. Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community.

6. Research involving information that might lead to social stigmatization or discrimination if it were disclosed.

7. Research on participants' psychological wellbeing or mental health.

8. Genetic studies, including those that collect and store biological samples for future use.

9. Research on behavioral interventions and epidemiologic studies.

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

18.7 PRIVACY AND CONFIDENTIALITY LANGUAGE IN INFORMED CONSENT DOCUMENTS

A. The IRB will review and approve information provided in 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 other authorized people."

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 (see 18.6.3 above), appears in the consent document. Suggested consent language may be found at the Certificates of Confidentiality Kiosk (see References below).

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REFERENCES

A. The Privacy Act of 1974: http://www.justice.gov/opcl/privacyact1974.htm

B. Certificate of Confidentiality: http://grants.nih.gov/grants/policy/coc/index.htm

C. The Privacy Act of 1974 as amended at 5 U.S.C. 552a: http://www.justice.gov/opcl/privstat.htm

D. Department of Health and Human Services Privacy Act Regulations: http://www.access.gpo.gov/nara/cfr/waisidx_02/45cfr5b_02.html

E. IC Privacy Act Officers: http://oma.od.nih.gov/about/contact/browse.asp?fa_id=3

F. NIH Privacy Act System of Records Notices #09-25-0099, Clinical Research Patient Medical Records, HHS/NIH/CC: http://oma.od.nih.gov/ms/privacy/pa-files/0099.htm

G. 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: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

LIST OF APPENDICES

A. NIH Privacy Act System of Records Notices #09-25-0099, Clinical Research Patient Medical Records, HHS/NIH/CC

B. 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

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APPENDIX A: NIH PRIVACY ACT SYSTEM OF RECORDS NOTICES# 09-25-0099, CLINICAL RESEARCH PATIENT MEDICAL RECORDS, HHS/NIH/CC

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Information may be used to respond to Congressional inquiries for constituents concerning their admission to NIH Clinical Center.

2. Social Work Department may give pertinent information to community agencies to assist patients or their families.

3. Referring physicians receive medical information for continuing patient care after discharge.

4. Information regarding diagnostic problems, or having unusual scientific value may be disclosed to appropriate medical or medical research organizations or consultants in connection with treatment of patients or in order to accomplish the research purposes of this system. For example, tissue specimens may be sent to the Armed Forces Institute of Pathology; X-rays may be sent for the opinion of a radiologist with extensive experience in a particular kind of diagnostic radiology. The recipients are required to maintain Privacy Act safeguards with respect to these records.

5. Records may be disclosed to representatives of the Joint Commission on Accreditation of Hospitals conducting inspections to ensure that the quality of Clinical Center medical record-keeping meets established standards.

6. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

7. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in epidemiologic studies.

8. The Department contemplates that it may contract with a private firm for transcribing, updating, copying, or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records

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9. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

10.
    a) PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

    b) PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

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APPENDIX B: 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

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR Part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR Part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or

any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is, therefore, deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social security numbers, date of birth and other identifiers may be disclosed: (1) to the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in research studies.

7. PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the

provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

8. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.

10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.

11. Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

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