Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Privacy and Confidentiality
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Center (Fred Hutch) that all research involving human research participants or the use of information about human research participants be planned and conducted in a manner that protects the privacy interests of the research participants and the confidentiality of any personal information about the research participants and their biospecimens. The Institutional Review Office (IRO) is responsible for establishing procedures to enable researchers to design and conduct their studies in compliance with all applicable laws, rules and regulations relating to privacy and confidentiality. In its review of research proposals, the Fred Hutch Institutional Review Board (IRB) will require that all reasonable measures be taken to protect the privacy of research participants and the confidentiality of information relating to research participants.

DEFINITIONS

See *HRP-001 - Glossary of Terms and Acronyms* for full definitions of the following:

Confidentiality

Covered Entity

HIPAA

Identifiable Private Information

Identifiable Sensitive Information

Individually Identifiable Health Care Information

Privacy

Private Information

Protected Health Information (PHI)

Sensitive Information

PRINCIPLES/OVERVIEW

Investigators are required to comply with all Fred Hutch policies relating to privacy and security and with the terms of this Policy in the design and conduct of research involving human subjects.

Fred Hutch requires annual confidentiality and information security training for investigators and scientific staff engaged in research involving human subjects and for IRO staff.

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 participants in research involving human subjects as well as the confidentiality of identifiable private information (including biospecimens) and individually identifiable health care information about such individuals.

The Fred Hutch IRB is responsible for assessing the degree to which a research study involving human subjects has been designed in a manner that will adequately address privacy and confidentiality issues. Where necessary or appropriate, the IRB will require that the investigator modify the design of the research study or the recruitment and enrollment procedures to satisfy any inadequacies identified by the IRB in relation to the protection of the privacy of research participants and the confidentiality of identifiable private, sensitive or individually identifiable health care information (including biospecimens) of potential or actual research participants.[1]

The Fred Hutch IRB will consider carefully issues of privacy and confidentiality at the point of initial and continuing review.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, employees of Fred Hutch, and investigators from other institutions who submit research studies to the Fred Hutch IRB for review and approval.

PROCEDURES

1. Privacy

Privacy refers to the sense of being in control of access that others have to us. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.

Examples:

- Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have a medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. The IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.
- Recruiting subjects immediately prior to a sensitive or invasive procedure (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.
- Asking subjects about sensitive topics (e.g., details about sexual behavior) may feel like an invasion of privacy to some individuals.

The protocol should describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects throughout the life of the study.

2. Confidentiality

Confidentiality refers to the obligation owed to research participants and potential research participants in relation to their individually identifiable information and biospecimens. The term "confidentiality" relates to *information* about research participants whereas the term "privacy" concerns research participants or potential research participants *as individuals*.

The protocol should describe the methods to safeguard research data and biospecimens including:

- how data/biospecimens will be stored and protected
- who has access to data/biospecimens
- who grants access to data/biospecimens and when access is restricted and removed
- the timing and methods for de-identifying and/or destroying identifiable information/biospecimens
- how you will ensure study reports and publications do not directly or indirectly identify participants or small groups of participants

The consent document(s) must disclose who may have access to identifiable participant records and biospecimens. The consent should also disclose any plans to re-contact participants after their participation has ended.

[1] HHS: 45 CFR 46.111(a)(7); FDA: 21 CFR 56.111(a)(7)

The protocol and consent form are reviewed by the IRB to determine whether the study adequately addresses the issues of both privacy and confidentiality.

3. Special Topics Related to Privacy and/or Confidentiality

The investigator should also consider the following topics that may be relevant to the research:

a. Research funded by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), Health Resources & Services Administration (HRSA), Biomedical Advanced Research and Development (BARDA), and Food and Drug Administration (FDA)

The majority of research funded by the NIH, CDC, HRSA, BARDA and FDA is automatically issued a Certificate of Confidentiality (CoC).

- See the Certificate of Confidentiality webpage for more information. The investigator must consider whether the research uses identifiable sensitive information.
- The Certificate of Confidentiality limits what information the investigator may disclose about participants to, and allows the investigator to withhold the names of research participants from, all persons not connected with the conduct of research. Investigators with this Certificate generally cannot be compelled to identify research participants in any federal, state, or local civil, criminal, administrative, or legislative proceedings.
- Note: This refers only to funding or other support, not to whether the regulatory entity has oversight over the research. For example, research subject to FDA oversight but not funded by FDA does not automatically receive a Certificate of Confidentiality.

Information, including biospecimens, protected by a Certificate of Confidentiality are protected **for perpetuity**. Subrecipients, contractors, and any other recipients of information protected by a Certificate (e.g., secondary researchers) are expected to be informed of the Certificate and that they are also subject to the requirements of 42 U.S.C. 241(d).

Expiration of CoC protections differs depending on the circumstances under which it was issued and the agency issuing the CoC.

- CoCs issued as a term of the grant or contract: The CoC expires when the funding expires, including any no-cost extensions.
- Other CoCs: Check with the issuing agency for information about expiration.

If the Certificate may no longer be in effect and the investigator is still collecting research data, The Fred Hutch IRB strongly recommends that you apply for a new CoC in order to cover any new data collected from already enrolled participants or any new participants.

If you do **not** plan to apply for a new CoC and you had CoC language in the consent form, you may need to update the consent form or notify all participants to ensure they are aware this protection is no longer available to any data collected after the CoC's expiration. The notification process may not be required depending on the language that was originally included in the consent form.

If the study has completed all enrollment and data collection, there is no need to request a new Certificate or notify participants.

NOTE: Regardless of whether a Certificate of Confidentiality protects the research, if an investigator receives a legally based request for information (e.g., public records request; legal subpoena; grand jury investigation), the investigator should immediately contact the Fred Hutch Office of the General Counsel for further guidance.

b. Studies of illegal, sensitive, or socially or politically unacceptable activities:

i. Certificate of Confidentiality

In studies proposing the collection of information that, if disclosed, could have negative consequences for research participants in relation to their financial status, employability, insurability or reputation, the IRB may require a Certificate of Confidentiality be obtained from a federal agency. See the IRB Certificates of Confidentiality webpage for more information.

ii. If a Certificate of Confidentiality is not used:

In research in which the participant's participation, response, and the investigator's knowledge of respondents may be of interest to a court of law (such as information about illegal activities), the research participant should be informed of this possibility in the consent form.

In addition, some research, especially where illegal, sensitive, or socially or politically unacceptable activities are being researched, the protection of research participants' rights may be enhanced by an assurance from the investigator that the written report will not be disseminated in any form until the research participants have had an opportunity to read and modify the portions that relate to them. To the extent permissible under applicable law, such an assurance should be included in the consent form.

c. Identification of Research Participants

i. If written consent is not required, any identifiable private information (including on biospecimens) or individually identifiable health care information on data collection forms, questionnaires, and other records should be removed, stricken, or otherwise made indecipherable as soon as noted by the investigator, even if such use is unintentional.

ii. In those instances where it is necessary to identify research participants, identification on data collection forms, questionnaires, and other records should be by code, with the code translation to be kept separate from the data. The code should **not** be an identifiable number, medical record number, or a Social Security Number. Rather, a code should be established solely for the purpose of the study. Both the code translation and the data should be kept in a secure place, such as a locked file cabinet accessible only to the investigator, to his or her authorized staff, and to others identified in the IRB application.

iii. Where information will be computerized, no names or other identifying information should be entered. The study code number should be the only computerized identifier. The code translation should not be entered into the computer.

d. Approach to Research Participants

Perhaps the most sensitive of all research issues is the approach to research participants. For this reason, the procedures of all studies should include an approach to research participants which avoids coercion or an invasion of privacy.

i. Minimizing the appearance of coercion

The investigator should stress the voluntary nature of participation and whenever possible, avoid the use of his/her own patients, clients, employees, and students. Investigators should solicit research participants through methods such as bulletin board notices, advertisements in newspapers, website, and announcements in classes other than his/her own.

ii. Use of an Intermediary

In order to avoid an invasion of privacy, it may be necessary for an investigator to enlist the cooperation of other professionals and organizations as intermediaries. This is appropriate when an investigator has not had prior contact with prospective research participants and has not obtained their names from a publicly available source. An intermediary is an individual who, for other purposes, has contact with the prospective research participant. The intermediary does not obtain consent from the prospective research participant to participate in a research activity, rather the role of the intermediary is to obtain permission from the prospective research participant to release his or her name and address or telephone number to the investigator. The investigator then would make the contact regarding the study and obtain consent. The intermediary who is willing to assist an investigator in this way should not take a strong advocacy position in favor of a particular research activity.

iii. Use of a Public List

When the investigator obtains names through a public list (e.g., telephone book), the name of the source should be included in the initial approach letter.

iv. Use of the Cancer Surveillance System (CSS) data

There are strict guidelines for how and when CSS data can be accessed because it is a database of all cancer cases in the state. Individuals in the CSS database likely do not know

their information is collected there, so CSS needs to pre-review all approach methods. Investigators should contact CSS directly prior to submitting an IRB application that requests to use CSS as a data source. Review the "Accessing CSS Data for Research" section on the Cancer Surveillance System (CSS) webpage for more information.

e. Use of Questionnaires, Scales, Inventories, and Interviews

A description of the questions to be asked (including, where appropriate, examples of the most personal and sensitive questions) should be provided to the research participants. Research participants should be informed (in the consent document and on the survey instrument itself) of their right to refuse to answer any questions, and an estimate should be given of the length of time needed to complete the activity.

f. Use of Recordings, Photographs, Films, Videotapes, and Audiotapes

All recordings, photographs, films, videotapes, and audiotapes to be made or to be used may require the informed consent of the research participant under applicable state law. Washington state law requires consent for these types of activities.

Where such data are to be used on public and private occasions, research participants must be allowed to review and, if desired, to erase, or to destroy those portions which they consider to be damaging in any regard. Provisions for such erasure or destruction must be included in the consent form and readily granted to research participants.

However, if such records are to be used solely within training or research limits clearly specified to the research participant before any data are obtained, provision for post-review by the research participant is not required. Use of these records is then considered privileged communication for a clearly delineated and identified group, and for a given period of time.

g. Use of Social Security Numbers (SSNs)

i. The use of research participants' Social Security Numbers generally should not be allowed except to satisfy Internal Revenue Service requirements or other institutional requirements. The SSNs of research participants, not employed by Fred Hutch, should be obtained from all research participants who may receive monetary compensation exceeding $600.00 during a calendar year. The consent form should include a statement that the research participant's SSN may be needed for tax purposes.

ii. The names of research participants, Social Security Numbers, and payments should be kept in a secure place separate from the study data. The SSN should not be used as an identifier on data collection forms and should be destroyed when no longer required.

iii. If obtaining research participants' Social Security Numbers for any other reason besides compensation is an essential part of the study design, the PI must provide the following information to the IRB:

- justification for obtaining SSNs
- a statement in the Informed Consent Document(s) or other documents research participants see that is it optional for research participants to provide their SSNs
- the method in which SSNs will be stored
- when and how SSNs will be destroyed.

4. Health Insurance Portability Accountability Act (HIPAA)

Use or disclosure of protected health information ("PHI") for research purposes requires a HIPAA authorization from the research participant unless an IRB-approved waiver is obtained or some other exemption under HIPAA applies. The HIPAA authorization form is different from the consent form. If the research involves the use and disclosure of PHI, the IRB needs to review the research for compliance with HIPAA and all other applicable Washington State and federal laws.[2]

The IRB reviews the application/consent/protocol to determine how the study obtains a HIPAA Authorization, just as the IRB reviews how the study's consent form is delivered.

[2] HHS: 45 CFR 164.508, 164.512(i)(1)(i)(A)

a. New Application:

As applicable, the investigator submits:

- A stand-alone HIPAA Authorization, preferably the template form in use at the Cancer Consortium or one of its member institutions
- A description of the method(s) proposed for accessing PHI
- *HRP-257 - FORM - HIPAA Supplement* requesting a full or partial waiver of authorization

Note: Review by the Office of the General Counsel is required if HIPAA language is contained ("blended") within the consent form or if the HIPAA Authorization proposed for use is substantially different than the Cancer Consortium's stand-alone HIPAA Authorization templates.

Stand-alone HIPAA Authorizations **do not** receive IRB approval stamps.

If a waiver or alteration of HIPAA is approved by the IRB, the approval letter will include that determination. The letter represents the formal granting of the waiver. Investigators will not receive a signed copy of the HIPAA Supplement itself, as this is for IRO records only.

b. Revisions to Previously Submitted HIPAA Forms:

i. For revisions to a HIPAA Authorization that the IRB previously reviewed, the investigator submits the following to the IRO:

- A Modification to "other parts of the study" in Hutch IRB. The brief description outlines the changes to the HIPAA authorization.
- A copy of the revised HIPAA Authorization.

IRO staff routes the Modification for review by the Office of General Counsel using the Ancillary Review activity in Hutch IRB. Once OGC has reviewed and approved the revised HIPAA language, IRO staff administratively approves the Modification in Hutch IRB and issues an administrative approval letter.

Revised stand-alone HIPAA authorization forms **do not** receive IRB approval stamps.

ii. For revisions to consent forms which have HIPAA language contained within the consent forms, the investigator submits:

- A Modification to "other parts of the study" in Hutch IRB.
- Use the **Update** functionality to upload the new clean version of the consent form containing HIPAA language.

IRO staff routes the changes to the HIPAA language for ancillary review by OGC. The Modification goes for IRB review as usual, and the OGC ancillary review must be completed before the Modification can be formally approved.

c. Use of HIPAA Authorizations forms that are not the templates approved by the Cancer Consortium or one of its member institutions:

i. If the investigator requests to use a stand-alone HIPAA Authorization that is not one of the vetted Cancer Consortium templates, the investigator submits this as part of their Initial Study or Modification submission in Hutch IRB.

Unless the investigator provides documentation of OGC approval of the stand-alone, non-template HIPAA language, IRO staff sends the submission for OGC review using the ancillary review activity, and the OGC ancillary review must be completed before the submission can be formally approved.

Stand-alone HIPAA authorization forms **do not** receive Fred Hutch IRB approval stamps.

ii. If the investigator requests to use HIPAA Authorization language contained within a local consent form, the investigator submits this as part of their Initial Study or Modification submission in Hutch IRB.

Unless the investigator provides documentation of OGC approval of the blended HIPAA language, IRO staff sends the submission for OGC review using the Ancillary Review activity,

and the OGC ancillary review must be completed before the submission can be formally approved.

SUPPORTING DOCUMENTS

HRP-001 - Glossary of Terms and Acronyms

HRP-257 - FORM - HIPAA Supplement

REFERENCES

45 CFR 46.111

45 CFR 164.508

45 CFR 164.512

21 CFR 56 111

42 U.S. Code § 241

RCW 70.02 (Uniform Health Care Information Act as codified in Washington State)

OHRP Compliance Activities: Common Findings and Guidance # 3 & #4 & #65

NIH Policy for Issuing Certificates of Confidentiality https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

CDC: https://www.cdc.gov/od/science/integrity/confidentiality/applinst.htm

FDA: https://grants.nih.gov/grants/guide/notice-files/NOT-FD-19-002.html

VERSION HISTORY

Version	Effective Date
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