



<b>Title:</b>	Privacy and Confidentiality
<b>Policy:</b>	2.12
<b>Version:</b>	5.00
<b>Effective Date:</b>	February 24, 2020
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Meghan Scott, IRO Director
	 <span style="float: right;">2/21/2020</span>
	<i>Signature/date</i>

Version History	Effective Date
4.00	01-21-2019
3.04	07-03-2017
3.03	01-31-2012
3.02	04-01-2011
3.01	12-07-2011
3.00	08-01-2007
2.00	05-07-2007
1.00	12-06-2006

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**POLICY STATEMENT**

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It is the policy of Fred Hutchinson Cancer Research 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. 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.

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## DEFINITIONS

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See *IRB Glossary of Terms and Acronyms* (050) 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**

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## PRINCIPLES/OVERVIEW

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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 provides confidentiality and information security training for investigators and scientific staff engaged in research involving human subjects.

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 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 of potential or actual research participants.<sup>1</sup>

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

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## INDIVIDUALS AFFECTED BY THIS POLICY

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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.

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<sup>1</sup> HHS: 45 CFR 46.111(a)(7); FDA: 21 CFR 56.111(a)(7)

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## PROCEDURES

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### 1. Privacy and Confidentiality

The IRB *Application for Review* forms include questions about privacy and confidentiality. The responses are reviewed by the IRB Chair or IRB Committee to determine whether the study adequately addresses these issues. Examples include the following:

a. Research funded by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA)

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

- See <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html> for more information. The investigator must consider whether the research uses identifiable, sensitive information.
- 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).

If the Certificate may no longer be in effect and the investigator is still collecting research data:

- i. If the study's federal funding will be ending, and the federal funding was the basis for an automatically issued Certificate of Confidentiality, the investigator should request a CoC for continuity of protections.
- ii. If the research data collection will continue beyond the expiration date on the Certificate, the investigator should request an extension from the federal agency who issued the Certificate at least 3 months prior to the expiration date.

If you do **not** plan to apply for an extension 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.

If the study has completed all enrollment and data collection, there is no need to extend/continue the Certificate.

**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, a Certificate of Confidentiality issued by a federal agency may be required. For more information about Certificates of Confidentiality, please go to the <http://grants2.nih.gov/grants/policy/coc/>.

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.

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, 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 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, 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 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 consent 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.

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) 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 Records, Photographs, Films, Videotapes, and Audiotapes

All records, photographs, films, videotapes, and audiotapes to be made or to be used for other than the sole purpose of benefiting the individual require the informed consent of the research participant.

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

- i. The use of research participants' Social Security numbers should not be allowed except to satisfy Internal Revenue Service requirements or other institutional requirements. The Social Security numbers 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 social security number 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 data. The Social Security number should not be used as an identifier on data collection forms and should be destroyed when no longer required.
- iii. However, if obtaining research participants' Social Security numbers is an essential part of the study design, the PI must provide the following information to the IRB:
  - justification for obtaining Social Security numbers

- a statement in the Informed Consent Document(s) or other documents research participants see that is it optional for research participants to provide their Social Security numbers
  - the method in which social security numbers will be stored
  - when and how Social Security numbers will be destroyed.
- iv. For on-going studies, the PI submits a *Research Modification Form* (062) along with documents to be approved.

## 2. 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, then the IRB needs to review the research for compliance with HIPAA and all other applicable Washington State and federal laws.<sup>2</sup>

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.

### a. New Application:

As applicable the investigator submits:

- the pre-approved stand-alone *HIPAA Authorization for the Use of Patient Information for Research* (0206)
- a description of the method(s) proposed for accessing PHI
- *HIPAA Supplement and Waiver of Authorization* (0208) requesting a full or partial waiver of authorization
- *HIPAA Authorization Template Language* contained within a research consent form

Note: Review by the Office of the General Counsel is required if HIPAA language is contained within the consent form or if the HIPAA Authorization proposed for use is substantially different than the pre-approved stand-alone HIPAA Authorization. Stand-alone HIPAA Authorizations WILL NOT receive IRB approval dates.

### b. Revisions to Previously Submitted HIPAA Forms:

- i. Revisions to a currently approved stand-alone HIPAA Authorization to a research consent. The investigator submits the following to the IRO:

- a cover memo outlining the changes.
- one (1) copy of the revised *HIPAA Authorization for the Use of Patient Information for Research* (0206) for inclusion in the IRB file.

Note: IRO staff will route the cover memo and revised HIPAA Authorization for review by the Office of General Counsel. No review is required by the IRB. These forms WILL NOT receive IRB approval dates.

- ii. Revisions to consent forms which have HIPAA language contained within the consent forms. The investigator submits:

- a *Research Modification Form* (062)
- one (1) copy of the revised Consent form with tracked changes.

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<sup>2</sup> HHS: 45 CFR 164.508, 164.512(i)(1)(i)(A)

Note: These modifications are reviewed by the Office of General Counsel and receive IRB approval.

- iii. Status Change. The investigator submits a *Research Modification Form (062)* and as applicable the following should be submitted:
  - *HIPAA Authorization for the Use of Patient Information for Research (0206)*
  - *HIPAA Authorization Template Language* contained within a research consent form
  - *HIPAA Supplement and Waiver of Authorization (0208)*

Note: These changes are reviewed and approved by the IRB. The review by the Office of the General Counsel is required if HIPAA language is contained within the consent form. Stand-alone HIPAA Authorizations WILL NOT receive IRB approval dates.

c. Use of HIPAA Forms not pre-approved by Fred Hutch OGC (“Other HIPAA Authorization(s)”).

- i. Stand-alone Other HIPAA Authorization to a research consent

If the use of an Other HIPAA Authorization is required, the investigator submits:

- a cover memo outlining request to use an Other HIPAA Authorization forms
- one (1) copy of each of the Other HIPAA Authorization forms to be included in the IRB file. These forms will not receive Fred Hutch IRB approval dates.

- ii. Other HIPAA Authorization Language contained within the Fred Hutch Consent Form(s). The investigator submits:

- a *Research Modification Form (062)*
- one (1) copy of the revised Consent form with track changes and one (1) original clean copy

Note: These modifications will be reviewed and approved by the IRB and the Office of the General Counsel. The IRB staff follows the instructions per the *Screener: HIPAA Legal (0259)*.

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## SUPPORTING DOCUMENTS

HIPAA Authorization Form (0206)  
HIPAA Supplement and Waiver of Authorization (0208)  
IRB Glossary of Terms and Acronyms (050)  
Research Modification Form (062)  
Screener: Legal (0259)

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## 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>