

<b>Title:</b>	Privacy and Confidentiality
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Karen Hansen, IRO Director
	<i>Signature/date</i>
<b>Effective Date:</b>	August 1, 2007
<b>Policy:</b>	2.12

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**POLICY STATEMENT**

It is the policy of Fred Hutchinson Cancer Research Center (FHCRC) 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 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 FHCRC 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**

**Privacy:** means an individual's right to be free from unauthorized or unreasonable intrusion into his/her private life and the right to control access to individually identifiable information about him/her. The term "privacy" concerns research participants or potential research participants as individuals whereas the term "confidentiality" is used to refer to the treatment of information about those individuals.

**Confidentiality:** means the treatment that must be afforded to individually identifiable information about research participants or potential research participants. Confidential treatment of information in the context of research is required for all non-public information that has been disclosed by or about research participants to researchers with the expectation that it will not be disclosed to others without permission. The term "confidentiality" relates to information about research participants whereas the term "privacy" concerns research participants or potential research participants as individuals.

**HIPAA:** means the federal law called the Health Insurance Portability and Accountability Act that regulates, among other things, the disclosure of protected health information ("PHI") about patients treated by most health care providers and organizations in the United States ("Covered Entities"). In the context of human subjects research, HIPAA establishes a federal standard for the manner in which the confidentiality of PHI will be maintained by Covered Entities and prescribes a process through which researchers can obtain PHI about patients who are sought by researchers to be research participants or potential research participants.

**Identifiable Private Information:** means information about a living individual that is used for research purposes and 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 that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Under the OHRP regulations, private information must be individually identifiable (i.e., the identity of the research participant 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.

**Individually Identifiable Health Care Information:** means any information that identifies or can readily be associated with a patient and directly relates to the patient's health care. Individually identifiable health care information is the term generally used to describe information subject to protection under the Uniform Health Care Information Act which has been adopted in many states, including Washington State.

**Sensitive Information:** means identifiable private information or individually identifiable health care information relating to an individual's private activities or practices. Examples include: sexual preferences or practices; history of treatment for use/abuse of alcohol or drugs; information relating to a person's mental health history or treatment for mental illness or disease; HIV status; financial information such as social security numbers or private health insurance; or criminal history or background.

**Protected Health Information (PHI):** means information about a patient that is protected from unauthorized use or disclosure by a Covered Entity under the terms of the privacy regulations of the Health Insurance Portability and Accountability Act ("HIPAA").

**Covered Entity:** means those individuals, organizations and institutions required to comply with HIPAA with respect to the use and disclosure of Protected Health Information or PHI. Examples of covered entities include hospitals, clinics, health care professionals and health plans.

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## REFERENCES

45 CFR 46.111(a)(7) (OHRP regulation re: privacy and confidentiality protections)  
45 CFR 46.102(f)(2) (OHRP definitions of identifiable and private information)  
45 CFR Parts 160 and 164 (HIPAA Security and Privacy regulations)  
21 CFR 56.111(a)(7) (FDA regulation re: privacy and confidentiality protections)  
RCW 70.02 (Uniform Health Care Information Act as codified in Washington State)  
OHRP Compliance Activities: Common Findings and Guidance # 3 & #4 & #65

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## PRINCIPLES/OVERVIEW

Investigators are required to comply with the FHCRC Policy *Privacy and Security of Confidential Health Information* and the terms of this Policy in the design and conduct of research involving human subjects.

FHCRC provides confidentiality 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 FHCRC 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.

The FHCRC 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 Institutional Review Office (IRO) staff, IRB members, employees of FHCRC and investigators from other institutions who submit research studies to the FHCRC IRB for review and approval.

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## **PROCEDURES**

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### **1. Privacy and Confidentiality**

The IRO Application Form includes 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. 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 the National Institutes of Health (NIH) may be required. For more information about Certificate of Confidentiality, please go to the <http://grants2.nih.gov/grants/policy/coc/>.

The use of a Certificate of Confidentiality allows the investigator to withhold the names of research participants from all persons not connected with the conduct of research. Investigators with this authorization 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 on 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.

b. 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.

c. 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.

d. 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.

e. 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.

f. Use of Social Security Numbers

- i. The use of research participants' Social Security numbers should not be allowed except for satisfying Internal Revenue Service requirements. The Social Security numbers of research participants not employed respectively by FHCRC 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 FHCRC's Accounts Payable Manager requires this information.
- 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. Once the FHCRC's Accounts Payable Manager receives the research participant's Social Security number, the study should immediately destroy the number by a method approved by FHCRC.
- 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 *Protocol Modification Form* along with documents to be approved.

**2. Health Insurance Portability Accountability Act (HIPAA)**

Use or disclosure of protected health information ("PHI") for anything other than treatment, payment or healthcare operations generally requires an 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.

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

a. New Application:

The investigator submits:

- a completed *HIPAA Supplement Form*
- a description of the method(s) proposed for accessing PHI

As applicable, the investigator may need to submit:

- *HIPAA Waiver of Authorization for Use of Protected Health Information*
- *HIPAA Authorization to Use, Create and Share Health Information for Research*
- *HIPAA Authorization Template Language to Insert in a Research Consent Document*

Note: The review by the Office of the General Counsel is required if HIPAA language is inserted within the consent form.

b. Revisions to Previously Submitted HIPAA Forms:

- i. Revisions to a currently approved Separate PHI Authorization to a Research Consent. The investigator submits:
  - a cover memo outlining the changes.
  - one (1) copy of the revised *HIPAA Authorization to Use, Create and Share Health Information for Research* for inclusion into the IRB file. Note: These updated forms WILL NOT receive IRB approval dates.
- ii. Revisions to consent forms which have HIPAA language inserted within the consent forms. The investigator submits:
  - a Protocol Modification Form
  - one (1) copy of the revised Consent form with tracked changes.

These modifications are reviewed by General Counsel and receives IRB approval.

- iii. Status Change. The investigator submits a *HIPAA Supplement* Form and as applicable the following should be submitted:
  - *HIPAA Waiver of Authorization for Use of Protected Health Information*
  - *HIPAA Authorization to Use, Create and Share Health Information for Research*
  - *HIPAA Authorization Template Language to Insert in a Research Consent Document*

These changes are reviewed and approved by the IRB. Note: The review by the Office of the General Counsel is required if HIPAA language is inserted within the consent form.

c. Use of Other Covered Entities' HIPAA Forms

iv. Separate PHI Authorization to a Research Consent

If a Covered Entity requires the use of their own HIPAA forms, these forms will be used in place of the FHCRC HIPAA forms. The investigator submits:

- a cover memo outlining the covered entity's request to use their HIPAA forms
- one (1) copy of each of the covered entity's forms to be included in the IRB file. These forms will not receive FHCRC IRB approval dates.

v. Inclusion of Covered Entity's HIPAA Language into FHCRC Consent Forms. The investigator submits:

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

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*.

## **SUPPORTING DOCUMENTS**

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FHCRC Confidentiality Training for Investigators and Research Staff  
FHCRC Privacy and Security of Confidential Health Information  
IRB Policy 1.5 Conflict of Interest.doc  
HIPAA Supplement  
HIPAA Waiver of Authorization for Use of Protected Health Information  
HIPAA Authorization to Use, Create and Share Health Information for Research  
HIPAA Authorization Template Language to Insert in a Research Consent Document  
Screener: Legal  
Protocol Modification Form  
Screener: New Application  
Screener: Continuation Review Report  
Protocol Modification Screener  
Application for Review  
Continuation Review Report