

Institutional Review Board

Title:	Identification and Use of Legally Authorized Representatives
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

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3.00	09-30-2019
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POLICY STATEMENT

Investigators at the Fred Hutchinson Cancer Center (Fred Hutch) are responsible for obtaining legally effective informed consent prospectively from each research participant or a legally authorized representative for such participant, as required by the Fred Hutch Institutional Review Board (IRB) and by applicable regulations for the protection of human research subjects, including 45 CFR 46.116 and 21 CFR 50.20. The identification and use of legally authorized representatives may be required when prospective research participants are unable to provide legally effective informed consent for participation in research or to authorize use of their confidential information for research purposes.

DEFINITIONS

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

Assent

Informed Consent

Legally Authorized Representative

Legally Effective Consent

PRINCIPLES/OVERVIEW

In its human subjects research, Fred Hutch obtains legally effective informed consent from research participants or their Legally Authorized Representatives, writes consent forms that enable understanding and voluntary decisions, retains proper documentation, alters or waives the consent process when appropriate, protects vulnerable populations (including seeking assent from those who cannot give consent), makes exceptions in emergencies, and conducts observation of the consent process when necessary or appropriate.¹

¹ HHS: 45 CFR 46.111(a)(4); FDA: 21 CFR 50.20

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to Institutional Review Office (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.

The requirements in this policy relating to the identification and use of legally authorized representatives are not intended to preempt any applicable international, federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) which may impose additional or different requirements.

PROCEDURES

1. Identification of Legally Authorized Representative

The process for identifying a Legally Authorized Representative is generally controlled by state law. For studies involving children (individuals under the age of 18 years that have not been determined to be emancipated), the parent or guardian of the research participant is generally considered the Legally Authorized Representative. For research conducted in Washington State individuals in the following categories should generally be selected in order of succession to act as the Legally Authorized Representative for adult research participants who lack the capacity to provide legally effective informed consent:

1. Court-appointed guardian, if any;
2. Designated Proxy (such as an individual with a Durable Power of Attorney for Health Care). if any;
3. Spouse;
4. Adult child;
5. Parent; and
6. Adult Sibling(s).
7. Adult grandchildren of the patient who are familiar with the patient;
8. Adult nieces and nephews of the patient who are familiar with the patient;
9. Adult aunts and uncles of the patient who are familiar with 10 the patient;
10. Any adult who:
 - i) Has exhibited special care and concern for the patient;
 - ii) Is familiar with the patient's personal values;
 - iii) Is reasonably available to make health care decisions;
 - iv) Is not any of the following:
 - (1) A physician to the patient or an employee of the physician; the owner, administrator, or employee of a health care facility, nursing home, or long-term care facility where the patient resides or receives care; or a person who receives compensation to provide care to the patient; and
 - (2) Provides a declaration as described below.

Attempts must be made to identify and request consent **from the first existing person in the above list**, even if another relative is more conveniently available. For example, if a married person does not have a designated proxy or court-appointed guardian, the investigator must obtain permission from the spouse, even if an adult child or parent is present and available. Similarly, if a divorced person has adult children and does not have a designated proxy or court-appointed guardian, then the investigator must obtain permission from an adult child, even if a parent is present and available.

An adult who meets the requirements described in section 10, above, shall provide a declaration, which is effective for up to six months from the date of the declaration, signed and dated under penalty of perjury, that recites facts and circumstances demonstrating that he or she is familiar with the patient and that he or she: (I) Meets the legal requirements (II) Is a close friend of the patient; (III) Is willing and able to become involved in the patient's health care; (IV) Has maintained such regular contact with the patient as to be familiar with the patient's activities, health, personal values, and

morals; and (V) Is not aware of a person in a higher priority class willing and able to provide informed consent to health care on behalf of the patient.

For research conducted in other states or jurisdictions, investigators should seek assistance from the Fred Hutch IRO or the Fred Hutch Office of the General Counsel to identify the Legally Authorized Representative rules and regulations that may apply.

If there is no applicable local law addressing the issue of who may serve as the Legally Authorized Representative, institutional policy may determine an individual recognized as acceptable for providing consent in the nonresearch context on behalf of the prospective participant to the participant's participation in the procedure(s) involved in the research.

2. Use of Legally Authorized Representatives

The IRB must approve the consent process described in the study submission, as well as the content and language of all research consent forms to be used in the study. The purpose of review is to ensure that Legally Effective Consent is obtained. The investigator will describe and the IRB will review the process through which an assessment is made as to the need to identify and use a Legally Authorized Representative in studies in which participants may be unable to provide Legally Effective Consent.

3. Documentation

Informed consent is documented in a written consent form, properly signed and dated by the participant or the participant's Legally Authorized Representative. A copy of the form is given to the participant or the participant's Legally Authorized Representative.²

SUPPORTING DOCUMENTS

HRP-001 - SOP - Glossary of Terms and Acronyms

REFERENCES

21 CFR Part 50.20

21 CFR 50.27

45 CFR 46.111

45 CFR 46.116

45 CFR 46.117

FDA Information Sheets: FAQ Informed Consent Process

FDA Information Sheets: A Guide to Informed Consent & FAQ: Informed Consent Document Content

RCW 70.02.030 Authorization to Access Health Care Information

RCW 42.48 Statute prescribing rules for research by state agencies, including the University of Washington and the Washington State Department of Health

RCW 7.70.065 Description of individuals authorized to consent for others not competent to consent for themselves

RCW 11.88.010 Definition of "incompetency" to provide informed consent

RCW 13.64 Emancipation of minors

² HHS: 45 CFR 46.117(a); FDA: 21 CFR 50.27(a)