

Title:	Identification and Use of Legally Authorized Representatives
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Signature/date</i>
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Policy:	2.25

POLICY STATEMENT

Investigators at the Fred Hutchinson Cancer Research Center (FHCRC) 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 FHCRC 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

“Legally Authorized Representative” means an individual, or judicial or other body, under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research (45 CFR 46.102 (c) and 21 CFR 50.3((I)).

“Legally **E**ffective **C**onsent” refers to a consent the documentation for which contains the legally required elements; involves a process that both provides sufficient opportunity for a prospective research participant to consider whether to participate and minimizes the possibility of coercion or undue influence; and, includes a consent discussion and/or consent document that is both (i) understandable to the participant or the participant’s **L**egally **A**uthorized **R**epresentative, and (ii) free of exculpatory language. 45 CFR 46.116; 21 CFR 50.20

REFERENCES

21 CFR Part 50, Subpart B
 21 CFR Part 56, Subpart C
 45 CFR 46.111(a)(4)
 45 CFR 46.116
 45 CFR 46.117
 45 CFR 46.204
 45 CFR 46.305
 45 CFR 46.404–407
 45 CFR 46.408
 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

PRINCIPLES/OVERVIEW

In its human subjects research, FHCRC 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.

INDIVIDUALS AFFECTED BY THIS POLICY

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.

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 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:

- Court-appointed guardian, if any;
- Designated Proxy (such as an individual with a Durable Power of Attorney for Health Care), if any; ,
- Spouse;
- Adult child;
- Parent; and
- Adult Sibling(s).

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.

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

2. Use of Legally Authorized Representatives

The IRB must approve the consent process described in the application, 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. A copy of the form is given to the subject or the subject's Legally Authorized Representative. 45 CFR 46.117(a); 21 CFR 50.27(a).

SUPPORTING DOCUMENTS

None