

Institutional Review Board

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ATTENTION: THIS POLICY IS DIVIDED INTO TWO SECTIONS. PLEASE NAVIGATE TO AND REFERENCE ONLY THE SECTION THAT APPLIES.

Section 1: Pre-2018 Requirements Applies to ongoing research approved by the IRB on or before January 20, 2019.

Section 2: 2018 Requirements Applies to research approved by the IRB on or after January 21, 2019.

SECTION 1: PRE-2018 REQUIREMENTS

This section applies to ongoing research approved by the IRB on or before January 20, 2019.

All references in this section to 45 CFR 46 are to the pre-2018 requirements of the Common Rule.

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 the legally authorized representative, as required by the Fred Hutch Institutional Review Board (IRB) and by the regulations for the protection of human research subjects.¹

Informed consent documents used in studies of human subjects are approved by the IRB. Approvals and consent documents are maintained by the Institutional Review Office (IRO) in each protocol file.

DEFINITIONS

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

[Pre-2018 Requirements of the Common Rule](#)

[Assent](#)

[Common Rule](#)

[Elements of Consent](#)

[Impartial Witness](#)

[Informed Consent](#)

[Legally Authorized Representative \(LAR\)](#)

[Legally Effective Consent](#)

[Vulnerable Population](#)

[Witness](#)

PRINCIPLES/OVERVIEW

In its human subjects research, Fred Hutch obtains informed consent from research participants, 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.

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.

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.²

PROCEDURES

For all research it considers, the IRB reviews the informed consent process and documentation.

¹ HHS: 45 CR 46.116; FDA: 21 CFR 50.20

² HHS: 45 CFR 46.116(e); FDA: 21 CFR 50.25(d)

1. Informed Consent Process

Informed consent is a process, not just a form. During a study, all communication (oral or written) with research participants is part of the process of informed consent. The IRB must approve not only all written documents shared with research participants, but also the plans for approach, recruitment, and other interactions during the study.

The principal investigator (PI) must state in the application who will obtain consent from research participants. This may be limited to physicians or physician's assistants, or may include other research staff. If medical judgment is needed in order to adequately explain the risks and benefits of the study, consent must be obtained by a physician or other qualified, and licensed, health care provider as appropriate. Refer to [Appendix A](#) for guidelines about who is presumptively qualified to obtain informed consent.

Consent forms must include the elements of consent described in 45 CFR 46.116 or in 21 CFR 50.25 when applicable.³

Consent forms should be written in language understandable to the research participant or the representative.⁴ Consent authors are encouraged to keep scientific and medical terminology to a minimum, and to write in "plain language" at about an 8th-grade reading level.

Several consent form templates (also called model consents) are available to help investigators and research staff write plain-language forms. The substance of the templates is approved by the IRB and they are posted to the [IRO website](#). Sample language in all templates is targeted to be at or below an 8th-grade reading level. The templates are intended as guides only. Where sample language does not suit a particular study, it may be departed from, provided the resulting form meets all requirements for content and is approved by the IRB.

2. Review

The IRB must review and approve the proposed consent process described in the application as well as the content and language of all research consent forms to be used in the study.⁵ The purpose of review is to ensure that legally effective consent is obtained. "Legally effective consent" refers to consent whose documentation contains the legally required elements; the process provides the prospective participant or LAR sufficient opportunity to consider whether to participate, and minimizes the possibility of coercion or undue influence; and the information given to the participant or the LAR is in language understandable to the participant or LAR, and free of exculpatory language.⁶

To this end the IRB review includes, but is not limited to, the considerations described below. If circumstances arise where the principal investigator or study team would like to obtain consent from participants in a way that differs from the approved consent process, the consent plan must be updated and submitted for IRB approval before that method is used.

a. Review of Consent Process

The IRB reviews the consent process in the light of information provided in the application:

- Where will consent be obtained, and by whom?
- When will consent be obtained (relative to study procedures; the underlying question is whether participants have enough time to think about the study before consenting to join it)?
- Will consent take place in person or remotely (via phone, videoconference, etc.)?
- How is the consent process documented (e.g., chart note)?
- How will the research participant's understanding of the research be confirmed?
- How will the consent process, in particular the approach, protect the privacy of research participants?

³ HHS, basic elements: 45 CR 46.116(a), additional elements: 45 CFR 46.116(b); FDA, basic elements: 21 CFR 50.25(a), additional elements: 21 CFR 50.25(b)

⁴ HHS: 45 CFR 46.116; FDA: 21 CFR 50.20

⁵ HHS: 45 CFR 46.111(a)(4)-(5); FDA: 21 CFR 56.111(a)(4)-(5)

⁶ HHS: 45 CFR 46.116; FDA: 21 CFR 50.20

- What is the nature of the involvement of research participants under 18 years of age, if any?
- Has a request for waiver of consent been made?

b. In Person Consenting

The consent process generally should take place in person, especially for research studies involving more than minimal risk. All signatures are obtained in ink on a paper consent form. All appropriate signatures are completed on the consent form. Unless an alternative approach is described clearly in the submission, the IRB assumes this is the type of consent (or re-consent) process that will occur.

c. Remote Consenting:

Remote consenting refers to a consent process that involves, in whole or in part, the use of phone, teleconferencing, or other audio/visual technology in lieu of (or in follow-up to) a face-to-face interaction. The following criteria at a minimum must be met in the reasonable judgment of the IRB:

- Specific rationale for the remote consenting process is presented to the IRB. The rationale may range from exceptional circumstances (such as a pandemic necessitating physical distancing) to the specific structure of the study requiring remote contact (e.g., a study involving only phone surveys or interviews with individuals not on campus).
- The identity of the research participant (or LAR) can be verified through independent means (e.g., facial recognition provided by referring physician or photo identification; verification through verbal confirmation of individually identifiable information [e.g., date of birth, medical record number or other personal information unique to the individual]).
- The research participant (or LAR) has received a copy of the informed consent form in advance, and has had an adequate opportunity to review it carefully with input from the principal investigator and/or another IRB-authorized member of the study team who is qualified to describe the research study and answer the participant's (or LAR's) questions.
- The principal investigator and/or the study team can demonstrate that the information necessary to conduct informed consent is communicated in an effective manner for the participant's (or LAR's) full comprehension.
- The research participant (or LAR) has been provided an opportunity to ask questions of the principal investigator and/or the study team about the research study and the informed consent form.
- Unless a waiver of documentation of consent has been approved by the IRB, the research participant (or LAR) must sign, date and return the informed consent form to the study team prior to the commencement of any research procedures. Methods that may be used to return the signed consent form include mail, fax, scan, secure email or web portal, or in person. The study team must document in the study file the way the consent discussion took place. The principal investigator and/or the study team must establish a process to document why the date of the research participant's signature may be sooner in time than the signature of the principal investigator and/or study team member.

The IRB's recommended remote consenting plan is as follows:

- 1) Contact potential participant to verify correct address and confirm they agree to receive the consent via mail or email. You may wish to also schedule the video/phone consent session at this time.
- 2) Mail/email the consent form to the potential participant.
- 3) Use video or phone for the consenting conference. Verify the individual's identity using date of birth or another identifier, or by visually checking a driver's license on video.
- 4) If the individual agrees to take part, they sign the form and mail, fax, or scan it back to the study team.
- 5) Upon receipt, the individual who conducted the consent discussion then also signs.
- 6) Document in the research record that consent was done via video or phone. If signatures were done on different days, document that as well.

When requesting a remote consenting plan, the submission to the IRB should include a phone script or other document clearly describing the structure of the consent plan for staff to follow.

d. Electronic Informed Consent (“e-consent”):

E-consent refers to the use of electronic systems and processes that employ some type of electronic media (including text, graphics, audio, video, passive and interactive web sites and REDCap forms, biological recognition devices, card readers, etc.) to convey consent information and/or to document informed consent. These may be used in place of, or in combination with, paper-based consent methods. It is recommended that you consult with the IRO before making any e-consent submission.

The Fred Hutch IRB recommends the **Florence e-consent tool**, the use of which has been evaluated institutionally and confirmed to be a legally valid signature method that is FDA Part 11 compliant.

If proposing the use of an e-consent tool other than Florence (including DocuSign or REDCap), the IRB generally only considers the use of an e-consent process in the Cancer Consortium for studies that are **minimal risk**. (Please note that biopsies and scans involving contrast dye are *not* considered minimal risk procedures.)

Additional points to note about e-consent requests:

- Specific rationale for an e-consent process must be presented to the IRB.
- For an e-consent tool other than Florence, you must also request a Waiver of Documentation (waiver of the ink consent signature). See section 4.b below.
- For an e-consent tool other than Florence, the request must also describe the technology proposed and all security precautions. Contact the Information Security Officer at iso@fredhutch.org to obtain a security risk assessment for the e-consent platform and include the ISO report with the IRB submission. (An ISO report is not required for the Florence e-consent tool.)
- Generally, a consent discussion should still be conducted and documented in the research record (e.g., phone or teleconference discussion).
 - An investigator could request, and the IRB could approve, a plan to omit the consent discussion, for example for a single survey study with no sensitive questions. The consent should still include contact information in case the potential participant has questions about the research.
- For FDA-regulated studies that are greater than minimal risk and requesting use of a tool other than Florence: Any e-consent platform and its accompanying procedures must be demonstrated to be fully compliant with FDA Part 11 regulations (including technological specifications and procedural controls).⁷
- Participating Sites outside the Cancer Consortium may request e-consent for greater than minimal risk studies if their institution has confirmed the electronic platform allows for a legally effective signature compliant with any state or local laws. For FDA-regulated studies, the institution must have the necessary technological and procedure controls to ensure FDA Part 11 Compliance. Include this information in the submission.

e. Review of Consent Forms

IRB review of consent forms includes all applicable content described in 45 CFR 46.116, 21 CFR 50.25, and the *IRB Member Checklist (071)*. Depending on the nature of the study (e.g., minimal risk), the IRB may decide that not all items are needed (see [Waivers](#) section).

Basic elements of informed consent:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the participant;

⁷ FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application (September 2003).

- A description of any benefits to the participant or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained (and, if FDA-regulated research, that notes the possibility that the Food and Drug Administration may inspect the records);
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.⁸

Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each participant:

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;
- Any additional costs to the participant that may result from participation in the research;
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant; and
- The approximate number of participants involved in the study.⁹

The additional elements must be disclosed whenever they apply to the research in question, but may be omitted when they do not.

For FDA-regulated applicable clinical trials and/or NIH-funded clinical trials, the consent form must also inform participants that information about the research will be posted to www.clinicaltrials.gov as outlined in 42 USC 282(j), 42 CFR 11, and/or according to NIH policy. The consent form will contain the required statements outlined in 21 CFR 50.25(c).¹⁰

If the research is covered by a federal Certificate of Confidentiality, the consent form should include a statement explaining the certificate and the additional protections that will be provided to the participant. For additional information about certificates of confidentiality, see *IRB Policy 2.12 Privacy and Confidentiality* (030).

If the study involves genetic testing, the consent form should include risks of genetic testing and information about the federal Genetic Information Nondisclosure Act (GINA).

Fred Hutch Consent Form Requirements:

Consent forms also include the following content (unless the IRB determines it is not needed), specified in the *IRB Member Checklist* (071):

⁸ HHS: 45 CFR 46.116(a)(1)-(8); FDA: 21 CFR 50.25(a)(1)-(8)

⁹ HHS: 45 CFR 46.116(b)(1)-(6); FDA: 21 CFR 50.25(b)(1)-(6)

¹⁰ FDA: 21 CFR 50.25(c); NIH: Policy on the Dissemination of NIH-Funded Clinical Trial Information

- Heading includes Fred Hutchinson Cancer Center, based on Investigator's primary appointment
- Name, affiliation and telephone number of the principal investigator (The Fred Hutch IRB only requires the PI to be listed on the consent form; however, if other investigators or research staff are listed, their affiliations and telephone numbers must also be included)
- Name and telephone number of contact(s) for participants to call in case of an emergency
- In the "Costs" section, clearly state what the participant and/or the sponsor are responsible for. For example, "Sponsor will only provide the drugs at no cost."
- A financial contact number is included in the "Costs" section
- Statement that Fred Hutch Cancer Center has access to research participants' records
- IRO Director title and contact information for participants to contact with questions about their rights as a research participant (find generic contact information in the Fred Hutch templates)
- If the study involves a cooperative group, the organization should be listed in the confidentiality of records' section as having access to records
- The attestation statement for the person obtaining consent should reference a discussion of "risks" took place

The following content, specified in the *IRB Member Checklist (071)*, is included in consent forms when research activities are occurring at UW or when the investigator's primary appointment is UW:

- Heading includes University of Washington name
- Standard University of Washington compensation for injury statement
- UW's Human Subjects Division is included in the participant's rights section

If the study may involve non-English speaking participants, the IRB recommends that the consent form refer to "study doctors" or "researchers," not "investigators." Non-English speakers may identify the word "investigators" with the police or military personnel.

When single IRB applies, the IRB approves a model consent form at the lead file, and each participating site then tracks site-specific language into the model form for review. Fred Hutch typically only allows the following site-specific changes to the consent form:

- Insertion of institutional name and/logo
- Institution-specific contact information
- Changes necessary for compliance with state law requirements, such as the California Bill of Rights
- Changes to the compensation for injury section
- Changes to the privacy/confidentiality section
- Changes to the signature blocks/attestations

3. Documentation

Informed consent is documented in a written consent form, properly signed and dated. A copy of the form is given to the participant or the participant's legally authorized representative.¹¹

Most of the time, the written consent form is a document containing the elements of consent and the required content listed in the *IRB Member Checklist (071)* (see [Review of Consent Forms](#) section above). Sometimes a "short form" consent process is used. The short form is a document stating that the required elements of informed consent have been presented orally to the research participant or the research participant's legally authorized representative.¹² For Fred Hutch and UW Cancer Consortium studies, the short form is used when a study unexpectedly enrolls a research participant

¹¹ HHS: 45 CFR 46.117(a); FDA: 21 CFR 50.27(a)

¹² HHS: 45 CFR 46.117(b)(2); FDA 21 CFR 50.27(b)(2)

who cannot read English. Use of the short form is described in *IRB Policy 2.13 Use of Interpreter Services and Translated Documents* (039).

When written informed consent is required, proper documentation must be obtained prior to conducting research activities.

a. Signatures

Consent forms are signed and dated by the research participant or legally authorized representative (see *IRB Policy 2.25 Identification and Use of Legally Authorized Representatives* [0177]), and a witness (if applicable, see *Witnesses* section below).¹³ A signature by the person obtaining consent is required only if the research needs to comply with International Conference on Harmonization (ICH) guidelines. When the consent form contains a signature line for the person obtaining consent, this individual signs the consent form after the participant or LAR has signed. A pre-signed consent form is not acceptable.

If circumstances prevent the person who conducted the consent discussion from signing right after the participant, the signature should be executed as soon as feasible, and, if applicable, the research staff should make a note to the study file documenting why the signature dates differ.

When children participate in the research, adequate provisions for child assent and parental permission must be made. In general, unless prescribed otherwise in the application, children aged 7-12 sign an assent form and children aged 13 through 17 sign the consent form. The parent(s) or legal guardian(s) sign the consent form. For detail about the involvement of children in the consent process, see *Vulnerable Populations* section below.¹⁴

b. Witnesses

A witness is an individual who is present during the entire consent discussion and who attests to the adequacy of the consent process and to the participant's voluntary consent. Witnesses are usually not required, but are needed in circumstances where there is a limitation on communication of information between researchers and a participant or the participant's LAR. The most common need for a witness is when the participant cannot read the consent form. The Fred Hutch IRB expects a witness to be an impartial witness.

An impartial witness is generally required in certain situations:

- when there are illiterate English-speaking participants;
- when a participant comprehends English, but is unable to speak or physically unable to sign the consent form; or
- when a short form consent process is being employed to enroll unplanned non-English speaking participants. (See *IRB Policy 2.13 Use of Interpreter Services and Translated Documents* [039] for details on the short form consent process.)

There may be other situations in which a witness is needed, such as in specific jurisdictions (e.g., if state law requires a witness), or if a sponsor requires a witness.

A witness signature may appear on the consent form itself, or on an attestation form attached to the consent form. A witness signature line does not necessarily mean a witness must sign for all participants, but rather is a place for a witness to sign when needed.

By signing the consent form, the witness is attesting to the completeness of the informed consent discussion and the participant's voluntary agreement to participate in the study. A witness signature does not vouch for the validity or contents of the document(s) signed by the research participant.

A witness is needed for the "short form" consent process when enrolling non-English speaking participants. See *IRB Policy 2.13 Use of Interpreter Services and Translated Documents* (039) for details.

c. Version Approval

Consent forms submitted for IRB review should contain a version date and version number.

¹³ HHS: 45 CFR 46.117(a); FDA: 21 CFR 50.27(a)

¹⁴ HHS: 45 CFR 46.408; FDA: 21 CFR 50.55

Approved consent forms are stamped with the Fred Hutch IRB Approval date per *IRB Policy 1.8 Approval Date Guidelines and Turnaround Times* (06) to help ensure current versions of consents are utilized.

The principal investigator should use the IRB-stamped versions to consent participants or ensure the IRB approval date appears on all documents that will be used in obtaining consent. The IRB notifies the principal investigator of this responsibility in the *HRP-103 – Investigator Manual*.

4. Waivers

Under certain circumstances, the IRB may alter or waive the requirement to obtain informed consent or waive documentation of informed consent. The IRB will document its findings justifying the waiver or alteration.

a. Waiver or Alteration of Consent

To obtain IRB approval of a waiver or alteration of consent for research, the principal investigator must demonstrate each of the following:

- the research involves no more than minimal risk to the participants;
- the waiver or alteration will not adversely affect the rights and welfare of the participants;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the participants will be provided with additional pertinent information after participation.¹⁵

In research involving minor subjects, parental consent as well as assent of the child may also be waived if the above criteria are satisfied. Reminders of these criteria are included in the *IRB Member Checklist* (071). IRB approval of the waiver or alteration is documented (with rationale) in the meeting minutes.

Though waiver or alteration of informed consent may be granted for emergency research under 21 CFR 50.24, it is Fred Hutch policy not to conduct planned emergency research. (See [Emergency](#) section below.)

b. Waiver of Documentation of Consent (waiver of the signature)

To obtain IRB approval of a waiver of the documentation of consent, the principal investigator must demonstrate one of the following:

- that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
- that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.¹⁶

For FDA-regulated studies, only the latter criterion is permitted as a reason to waive the documentation of consent.¹⁷

In evaluating the request for waiver of documentation of consent, the IRB reviews a written description of the information about the research to be provided to participants. A waiver of documentation of consent may mean that no written document is provided to the participant or LAR, or it could mean that only a participant's or LAR's signature on the consent form does not have to be obtained. The IRB may require the investigator to provide participants a written statement about the research (e.g., information sheet).

¹⁵ HHS: 45 CFR 46.116(d)(1)-(4); FDA: *FDA Guidance for Sponsors, Investigators, and Institutional Review Boards: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects*

¹⁶ HHS: 45 CFR 46.117(c)

¹⁷ FDA: 21 CFR 56.109(c)(1)

Reminders of these criteria are included in the *IRB Member Checklist* (071). IRB approval of the waiver is documented (with rationale) in the meeting minutes.

5. Vulnerable Populations

The applicant informs the IRB of any vulnerable populations planned to be included in the research. IRB approval of the process and documentation of obtaining informed consent for such populations is documented (with rationale) in the meeting minutes. For information about the inclusion of vulnerable populations in research, see *IRB Policy 2.15 Research Involving Special Populations* (033).

a. Pregnant Women

The model consent for research includes sample language informing the research participant about unforeseeable risks to an embryo or fetus if the research participant becomes pregnant. Also included is language regarding the reasonably foreseeable impact of the research on the fetus or neonate.¹⁸ The *IRB Member Checklist* (071) reminds the IRB of this criterion for consent.

b. Prisoners

The IRB approves research involving prisoners as research participants only if it finds that the information is presented in language which is understandable to the research participant population.¹⁹

The applicant attests to understandability on *HRP-265 - FORM - Prisoner Certification Checklist for Investigator*, and IRB approval is documented in the meeting minutes.

c. Children

In most states, including Washington State, children aged less than 18 years cannot consent to research. Under certain circumstances, however, they may give assent. A principal investigator wishing to include children in research informs the IRB of the age range of the children and the child research risk category, and explains the assent process in the application.

The IRB determines and documents if assent is a requirement of all children, some of the children, or none of the children. The IRB may determine that assent is not required from some or all of the children based on one or more of the following:

- The children's capability of providing assent is limited based on their age, maturity, or psychological state.
- The capability of the children is so limited that they could not reasonably be consulted about the intervention.
- The research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.
- The IRB may waive assent using the criteria for waiver of consent process.

Requirements for obtaining assent are determined per research study; however, unless the requirement for assent is waived using the same criteria as waiver of consent, the IRB will generally apply the following regarding assent:

- Children age 0-6 generally are not required to assent because they lack age or maturity to provide assent.
- Children age 7-12 generally are required to provide assent if the research has no therapeutic intent, or there are alternative treatments outside the research context.
- Children age 7-12 generally are not required to provide assent if the research holds the prospect of direct benefit and there are not alternatives outside the research context.
- Children age 13-17 are generally always required to provide assent.

The IRB will also determine how assent should be documented. In general, the form of documentation of assent depends on the age of the child:

¹⁸ HHS: 45 CFR 46.204

¹⁹ HHS: 45 CFR 46.305

- Children aged 7-12 years: document assent by signing an assent form written in language suitable for children (and the parent(s) or legal guardian(s) sign the consent form).
- Children aged 13-17 years: document assent by signing the consent form (as do the parent(s) or legal guardian(s)).

Permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; or the IRB determines that the permission of one parent is sufficient.²⁰

The concept of a second parent being “not reasonably available” is intended to encompass situations in which there really is not a possibility to obtain permission from that individual: for example, the second parent is deployed in military service abroad or is incarcerated. It is *not* intended to cover situations in which the second parent simply is working and not available the day of the scheduled consent conference. In the latter scenario, attempts must be made to schedule a second consent conference to obtain permission of the second parent; in the absence of that permission, the child should be omitted from the research.

The IRB will typically determine permission of one parent is sufficient when the research is either:

- Minimal Risk; or,
- More than minimal risk but holding the prospect of direct benefit to the individual participant.²¹

If permission is to be obtained from a guardian, the guardian will be an individual who is authorized under applicable State or local law to consent on behalf of the child to general medical care.

If optional research procedures are presented in the parental consent form, it is generally appropriate to address optional procedures in the assent form as well. In this context, the child should only undergo optional procedures if both the parent and the child have said yes. If one of the two says no, consent has not been obtained for the optional activities.

Fred Hutch does not routinely conduct studies that would qualify for a waiver of parental permission under 45 CFR 46.408(c), “not a reasonable requirement” criteria (e.g., neglected or abused children). If such a study is reviewed, the IRB requires a compelling rationale for why parental permission should not be sought and a description of the mechanism in place for protecting children as a substitute for parental consent.

The IRB determinations regarding inclusion of children in research, child assent, documentation of assent, and parental permission or waiver of parental permission are documented with rationale in the meeting minutes. If the child participant is a “research donor” or “healthy research volunteer,” the child risk category, assent requirements, and parental permission determination must be a separate determination in the IRB minutes.

An emancipated minor is legally capable of providing informed consent.

d. Impaired Decision-Making Capacity

For information about obtaining informed consent on behalf of the individuals with impaired decision-making capacity, see *IRB Policy 2.15 Research Involving Special Populations (033)*.

6. Consent of children who reach the age of majority or become emancipated:

When a child participant reaches the age where they can provide consent for procedures involved in the research, informed consent must be obtained. A waiver of consent may be approved by the IRB as described in section 4 of this policy.

7. Re-Consent

After participants initially agree to join a study, an important part of the ongoing informed consent process is sharing with participants any new information that may affect their decision to continue to

²⁰ 45 CFR 46.406, __.407; FDA: 21 CFR 50.53, __.54

²¹ 45 CFR 46.404, __.405; FDA: 21 CFR 50.51, __.52

participate. Throughout the course of a study, there may again be a need to obtain from participants their documented agreement to continue to participate. Circumstances in which re-consenting participants is necessary include, but may not be limited to:

- There are significant changes to the research procedures, risks, potential benefits, or available alternatives;
- Informed consent was not properly obtained;
- There is a desire to use information and/or biospecimens for research not previously consented to;
- A participant's legal status changes, such as a minor becoming an adult, a previously incapacitated individual regaining autonomy, or a previously autonomous individual losing capacity;
- A translated informed consent document becomes available for a participant who was previously enrolled using a short form consent process.

When submitting a Modification or Reportable New Information (RNI), the principal investigator must indicate whether re-consent will be obtained. The re-consenting plan should include details about whether participants will be asked to re-sign the consent form and whether the re-consenting will be done in-person or remotely (review section 2 above for general expectations around consent plans). The Fred Hutch IRB will determine at the time of the review of the research modification or reportable event whether re-consenting participants is required and whether the proposed plan is appropriate.

When re-consent is required, the PI may request, and the Fred Hutch IRB may allow other members of the research staff than the person who originally obtained informed consent to conduct the re-consent discussion. In general, the circumstances that necessitate re-consent and the information that must be communicated will dictate the qualifications of the individual allowed to re-consent participants. For example, a medical professional would need to discuss with the participant new drug risks or new alternative medical treatments that become available. On the other hand, the PI may not need to re-consent participants if a research modification adds another study visit to the planned schedule, or an additional research test is planned for already obtained biospecimens.

8. Withdrawal of Consent

When a research participant withdraws from a study for any reason, the data collected during the time the participant was enrolled remains in the study records, may not be removed, and must be included in any subsequent analyses. The consent document may not give the participant the option to have data removed from the study records. Researchers may not continue to access records, or other identifiable information, that would normally require consent after a participant withdraws from a study. However, researchers may continue to review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records regarding the participant, such as those establishing survival status, as approved by the IRB in the research plan.

The research team should clarify with the participant why they wish to withdraw, especially if their decision may be based on side effects they are having; however, a participant may withdraw at any time without providing a reason. For interventional studies, when appropriate, the research team may seek consent from the withdrawing participant to continue with non-interventional follow-up activities associated with the research. If the research team will seek continuation of follow-up activities, the discussion with the participant must distinguish between study-related interventions and continuing follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information. If a separate withdrawal consent is used for this purpose, IRB review and approval of the withdrawal consent is required prior to its use.

9. Observation

The IRB has the authority to observe, or have a third party observe, the consent process in order to reduce the possibility of coercion and undue influence, ensure that the approved consent process is being followed, provide additional protections to vulnerable populations, or ensure that research participants are giving informed consent.

Following are some examples of when the IRB may request the observation of the consent process:

- High risk studies;
- Studies involving highly vulnerable populations (e.g., individuals with impaired decision-making capacity);
- Corrective action in response to a serious or continuing noncompliance report;
- When the IRB has concerns that the consent process may not be conducted appropriately;
- Studies for which there is little external oversight or data safety monitoring;
- Studies involving gene therapy.

When the IRB makes such a request, the result letter will inform the investigator that the IRB recommends the consent process of his/her study will be observed. Observation of the consent process may be delegated to appropriate Fred Hutch staff. The Fred Hutch staff will inform the investigator that the next informed consent consultation will be observed. At the time of observing the consent process, the Fred Hutch staff will work with the investigator so that the investigator may inform the research participant that the consent process will be observed.

Fred Hutch Clinical Research Support selectively monitors consent documents and consent conference notes for selected research participants, and comments on the documentation of the process.

10. Emergency

a. Emergency Use of Test Article

If emergency treatment with a procedure, drug or device not IRB approved will be used to save a patient's life, prospective consent is still required unless the circumstances meet the exception to informed consent requirements under 21 CFR 50.23. Emergency treatment and related processes of IRB acknowledgment are described in *IRB Policy 2.4 Emergency Use of an Investigational Drug or Device* (014).

b. Planned Emergency Research

Fred Hutch does not conduct, or plan to conduct, planned emergency research as described in 21 CFR 50.24.

11. HIV Testing

If HIV antibody blood testing is conducted either as part of the study or as an eligibility screening procedure, a separate consent may be required or recommended. State laws and regulations in the state in which the study participant resides may mandate specific consent provisions.

12. Training

Training in human subject's protection is mandatory for Fred Hutch faculty and staff involved in the design, conduct, or reporting of human subjects research, effective January 01, 2007. All materials approved for such training include a component explaining the ethics, regulations, and institutional policies of informed consent. In addition, training in Good Clinical Practice is mandatory for Fred Hutch faculty and staff involved in the conduct, oversight, or management of clinical trials, effective January 01, 2017. For details about training and the documentation of training, see *IRB Policy 2.20 Training* (038).

SUPPORTING DOCUMENTS

IRB Policy 1.8 Approval Date Guidelines and Turnaround Times (06)

IRB Policy 2.4 Emergency Use or Compassionate Use of an Investigational Drug or Device (014)

IRB Policy 2.12 Privacy and Confidentiality (030)

IRB Policy 2.13 Use of Interpreter Services and Translated Documents (039)

IRB Policy 2.15 Research Involving Special Populations (033)

IRB Policy 2.20 Training (038)

IRB Policy 2.25 Identification and Use of Legally Authorized Representatives (0177)

IRB Member Checklist (071)

HRP-001 - SOP - Glossary of Terms and Acronyms
HRP-103 – Investigator Manual
HRP-265 - FORM - Prisoner Certification Checklist for Investigator

REFERENCES

All references here to 45 CFR 46 are to the pre-2018 requirements of the Common Rule.

21 CFR 50.20

21 CFR 50.24

21 CFR 50.25

21 CFR 50.27

21 CFR 50.51–54

21 CFR 50.55

21 CFR 56.109

21 CFR 56.111

42 CFR 11

42 USC 282(j)

45 CFR 46.109

45 CFR 46.111

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

OHRP Guidance on Exculpatory Language in Informed Consent

OHRP Guidance on Genetic Information Nondisclosure Act (GINA)

FDA Information Sheets: FAQ Informed Consent Process

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

FDA Information Sheets: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials

FDA Guidance for Sponsors, Investigators, and Institutional Review Boards: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects

NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html>

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

APPENDIX A

Guideline: Who is presumptively qualified to obtain consent for clinical research?

Professional Role	Type of Study			
	High-risk Interventional Trials	Low-risk Interventional Trials ^A	More Than Minimal Risk Activity ^B	Only Minimal Risk Activity ^C
Principal Investigator and Study Subinvestigators with requisite health care provider credentials	X	X	X	X
MD Provider, not associated with the study (Attending physician responsible for the care of the participant)	X	X	X	X
Advanced Practice Provider (APP), associated with the study		X	X	X
Clinical Advanced Practice Provider, not associated with the study			X	X
Licensed Research Nurse, associated with the study			X	X
Licensed Clinical Nurse, not associated with the study				X
Licensed Phlebotomist, associated with the study				X
Study Coordinator, associated with the study				X

^AExamples include diet, exercise and some vaccine studies.

^BExamples include extra biologic samples obtained at a clinical procedure or phlebotomy exceeding 50 mL in an adult, not part of an interventional clinical trial intended to change an outcome in the subject.

^CExamples include phlebotomy up to 50 mL, surveys, use of data and previously collected biospecimens, not part of an interventional clinical trial intended to change an outcome in the subject.

The table indicates the professional roles that are presumed to have the qualifications necessary to obtain consent in research studies. Where the table lists specific licensure requirements (e.g., MD, RN, or APPs), this means current credentials that the individual maintains within the relevant local jurisdiction where the research is conducted. With appropriate justification, the IRB may allow other qualified individuals to obtain consent on a case-by-case basis.

The IRB's decisions may vary from these guidelines depending on the context. In particular, the IRB considers the population (healthy donors versus a patient population) and whether or not a research procedure holds the prospect for direct benefit.

The IRB application and the Delegation of Authority log should list all individuals who are authorized to obtain consent from subjects. The IRB application should explain the qualifications of these individuals and the scope of their role in the study.

Sub-study/screening consent forms: The IRB will evaluate the level of expertise required for conducting a consent discussion based on the risk level of procedures described in the form. For example, if a screening consent only covers a blood draw and does not describe the main study in detail, the consent discussion may fall into the minimal risk activity column above. The IRB application must contain a description of any such proposed break-down of consent qualifications by consent form for the IRB's consideration.

For Modifications, refer to Section 7 for re-consent considerations.

SECTION 2: 2018 REQUIREMENTS

This section applies to HHS-regulated research approved by the IRB on or after January 21, 2019.

All references in this section to 45 CFR 46 are to the 2018 requirements of the Common Rule.

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 the legally authorized representative, as required by the Fred Hutch Institutional Review Board (IRB) and by the regulations for the protection of human research subjects.²²

Informed consent documents used in studies of human subjects are approved by the IRB. Approvals and consent documents are maintained by the IRO in each protocol file.

It is the policy of Fred Hutch IRB not to review or allow the use of Broad Consent.²³

DEFINITIONS

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

2018 Requirements of the Common Rule

Assent

Broad Consent

Common Rule

Elements of Consent

Impartial Witness

Informed Consent

Legally Authorized Representative (LAR)

Legally Effective Consent

Special Population

Witness

PRINCIPLES/OVERVIEW

In its human subjects research, Fred Hutch obtains informed consent from research participants, 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.

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 informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.²⁴

²² HHS: 45 CFR 46.116(a)(1); FDA: 21 CFR 50.20

²³ HHS: 45 CFR 46.116(d)

²⁴ HHS: 45 CFR 46.116(i); FDA: 21 CFR 50.25(d)

PROCEDURES

For all research it considers, the IRB reviews the informed consent process and documentation.

1. Informed Consent Process

Informed consent is a process, not just a form. During a study, all communication (oral or written) with research participants is part of the process of informed consent. The IRB must approve not only all written documents shared with research participants, but also the plans for approach, recruitment, and other interactions during the study.

The principal investigator (PI) must state in the application who will obtain consent from research participants. This may be limited to physicians or physician's assistants, or may include other research staff. If medical judgment is needed in order to adequately explain the risks and benefits of the study, consent must be obtained by a physician or other qualified, and licensed, health care provider as appropriate. Refer to [Appendix A](#) for guidelines about who is presumptively qualified to obtain informed consent.

Consent forms must include the elements of consent described in 45 CFR 46 or in 21 CFR 50.25 when applicable.²⁵ Consent forms must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR in understanding the reasons why one might or might not want to participate in the research.²⁶

The prospective participant or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.²⁷ Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's or LAR's understanding of the reasons why one might or might not want to participate.²⁸ Consent forms should be written in language understandable to the participant or the LAR.²⁹ Consent authors are encouraged to keep scientific and medical terminology to a minimum, and to write in "plain language" at about an 8th-grade reading level.

Several consent form templates (also called model consents) are available to help investigators and research staff write plain-language forms. The substance of the templates is approved by the IRB and they are posted to the [IRO website](#). Sample language in all templates is targeted to be at or below an 8th-grade reading level. The templates are intended as guides only. Where sample language does not suit a particular study, it may be departed from, provided the resulting form meets all requirements for content and is approved by the IRB.

2. Review

The IRB must review and approve the proposed consent process described in the application as well as the content and language of all research consent forms to be used in the study.³⁰ The purpose of review is to ensure that legally effective consent is obtained. "Legally effective consent" refers to consent whose documentation contains the legally required elements; the process provides the prospective participant or LAR sufficient opportunity to consider whether to participate, and minimizes the possibility of coercion or undue influence; and the information given to the participant or the LAR is in language understandable to the participant or LAR, and free of exculpatory language.³¹

To this end the IRB review includes, but is not limited to, the considerations described below. If circumstances arise where the principal investigator or study team would like to obtain consent from participants in a way that differs from the approved consent process, the consent plan must be updated and submitted for IRB approval before that method is used.

²⁵ HHS, basic elements: 45 CFR 46.116(b), additional elements: 45 CFR 46.116(c); FDA, basic elements: 21 CFR 50.25(a), additional elements: 21 CFR 50.25(b)

²⁶ HHS: 45 CFR 46.116(a)(5)(i)

²⁷ HHS: 45 CFR 46.116(a)(4)

²⁸ HHS: 45 CFR 46.116(a)(5)(ii)

²⁹ HHS: 45 CFR 46.116(a)(3); FDA: 21 CFR 50.20

³⁰ HHS: 45 CFR 46.111(a)(4)-(5); FDA: 21 CFR 56.111(a)(4)-(5)

³¹ HHS: 45 CFR 46.116(a)(1), (a)(2), (a)(3), (a)(6); FDA: 21 CFR 50.20

a. Review of Consent Process

The IRB reviews the consent process in the light of information provided in the application:

- Where will consent be obtained, and by whom?
- When will consent be obtained (relative to study procedures; the underlying question is whether participants have enough time to think about the study before consenting to join it)?
- Will consent take place in person or remotely (via phone, videoconference, etc.)?
- How is the consent process documented (e.g., chart note)?
- How will the research participant's understanding of the research be confirmed?
- How will the consent process, in particular the approach, protect the privacy of research participants?
- What is the nature of the involvement of research participants under 18 years of age, if any?
- Has a request for waiver of consent been made?

b. In Person Consenting:

The consent process generally should take place in person, especially for research studies involving more than minimal risk. All signatures are obtained in ink on a paper consent form. All appropriate signatures are completed on the consent form. Unless an alternative approach is described clearly in the submission, the IRB assumes this is the type of consent (or re-consent) process that will occur.

c. Remote Consenting:

Remote consenting refers to a consent process that involves, in whole or in part, the use of phone, teleconferencing, or other audio/visual technology in lieu of (or in follow-up to) a face-to-face interaction. The following criteria at a minimum must be met in the reasonable judgment of the IRB:

- Specific rationale for the remote consenting process is presented to the IRB. The rationale may range from exceptional circumstances (such as a pandemic necessitating physical distancing) to the specific structure of the study requiring remote contact (e.g., a study involving only phone surveys or interviews with individuals not on campus).
- The identity of the research participant (or LAR) can be verified through independent means (e.g., facial recognition provided by referring physician or photo identification; verification through verbal confirmation of individually identifiable information [e.g., date of birth, medical record number or other personal information unique to the individual]).
- The research participant (or LAR) has received a copy of the informed consent form in advance, and has had an adequate opportunity to review it carefully with input from the principal investigator and/or another IRB-authorized member of the study team who is qualified to describe the research study and answer the participant's (or LAR's) questions.
- The principal investigator and/or the study team can demonstrate that the information necessary to conduct informed consent is communicated in an effective manner for the participant's (or LAR's) full comprehension.
- The research participant (or LAR) has been provided an opportunity to ask questions of the principal investigator and/or the study team about the research study and the informed consent form.
- Unless a waiver of documentation of consent has been approved by the IRB, the research participant (or LAR) must sign, date and return the informed consent form to the study team prior to the commencement of any research procedures. Methods that may be used to return the signed consent form include mail, fax, scan, secure email or web portal, or in person. The study team must document in the study file the way the consent discussion took place. The principal investigator and/or the study team must establish a process to document why the date of the research participant's signature may be sooner in time than the signature of the principal investigator and/or study team member.

The IRB's recommended remote consenting plan is as follows:

- 1) Contact potential participant to verify correct address and confirm they agree to receive the consent via mail or email. You may wish to also schedule the video/phone consent session at this time.
- 2) Mail/email the consent form to the potential participant.
- 3) Use video or phone for the consenting conference. Verify the individual's identity using date of birth or another identifier, or by visually checking a driver's license on video.
- 4) If the individual agrees to take part, they sign the form and mail, fax, or scan it back to the study team.
- 5) Upon receipt, the individual who conducted the consent discussion then also signs.
- 6) Document in the research record that consent was done via video or phone. If signatures were done on different days, document that as well.

When requesting a remote consenting plan, the submission to the IRB should include a phone script or other document clearly describing the structure of the consent plan for staff to follow.

d. Electronic Informed Consent ("e-consent"):

E-consent refers to the use of electronic systems and processes that employ some type of electronic media (including text, graphics, audio, video, passive and interactive web sites and REDCap forms, biological recognition devices, card readers, etc.) to convey consent information and/or to document informed consent. These may be used in place of, or in combination with, paper-based consent methods. It is recommended that you consult with the IRO before making any e-consent submission.

The Fred Hutch IRB recommends the **Florence e-consent tool**, the use of which has been evaluated institutionally and confirmed to be a legally valid signature method that is FDA Part 11 compliant.

If proposing the use of an e-consent tool other than Florence (including DocuSign or REDCap), the IRB generally only considers the use of an e-consent process in the Cancer Consortium for studies that are **minimal risk**. (Please note that biopsies and scans involving contrast dye are *not* considered minimal risk procedures.)

Additional points to note about e-consent requests:

- Specific rationale for an e-consent process must be presented to the IRB.
- For an e-consent tool other than Florence, you must also request a Waiver of Documentation (waiver of the ink consent signature). See section 4.b below.
- For an e-consent tool other than Florence, the request must also describe the technology proposed and all security precautions. Contact the Information Security Officer at iso@fredhutch.org to obtain a security risk assessment for the e-consent platform and include the ISO report with the IRB submission. (An ISO report is not required for the Florence e-consent tool.)
- Generally, a consent discussion should still be conducted and documented in the research record (e.g., phone or teleconference discussion).
 - An investigator could request, and the IRB could approve, a plan to omit the consent discussion, for example for a single survey study with no sensitive questions. The consent should still include contact information in case the potential participant has questions about the research.
- For FDA-regulated studies that are greater than minimal risk and requesting use of a tool other than Florence: Any e-consent platform and its accompanying procedures must be demonstrated to be fully compliant with FDA Part 11 regulations (including technological specifications and procedural controls).³²
- Participating Sites outside the Cancer Consortium may request e-consent for greater than minimal risk studies if their institution has confirmed the electronic platform allows for a legally effective signature compliant with any state or local laws. For FDA-regulated studies, the

³² FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application (September 2003).

institution must have the necessary technological and procedural controls to ensure FDA Part 11 Compliance. Include this information in the submission.

e. Review of Consent Forms

IRB review of consent forms includes all applicable content described in 45 CFR 46.116, 21 CFR 50.25, and the *IRB Member Checklist* (071). Depending on the nature of the study (e.g., minimal risk), the IRB may decide that not all items are needed (see [Waivers](#) section).

Basic elements of informed consent:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of any benefits to the participant or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained (and, if FDA-regulated research, that notes the possibility that the Food and Drug Administration may inspect the records);
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.³³
- For any consent form that does not already request permission for storing information and/or biospecimens for future research, you must include one of the following statements if you are collecting identifiable private information or identifiable biospecimens. The first statement should generally be used, unless the PI/sponsor can *guarantee* that the identifiable data or specimens would never be de-identified and used in future research.
 - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or
 - A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.³⁴

Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each participant:

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;

³³ HHS: 45 CFR 46.116(b)(1)-(8); FDA: 21 CFR 50.25(a)(1)-(8)

³⁴ HHS: 45 CFR 46.116(b)(9)

- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's or the legally authorized representative's consent;
- Any additional costs to the participant that may result from participation in the research;
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
- A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant;
- The approximate number of participants involved in the study;³⁵
- A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).³⁶

The additional elements must be disclosed whenever they apply to the research in question, but may be omitted when they do not.

For FDA-regulated applicable clinical trials and/or NIH-funded clinical trials, the consent form must also inform participants that information about the research will be posted to www.clinicaltrials.gov as outlined in 42 USC 282(j), 42 CFR 11, and/or according to NIH policy. The consent form will contain the required statements outlined in 21 CFR 50.25(c).³⁷

If the research is covered by a federal Certificate of Confidentiality, the consent form should include a statement explaining the certificate and the additional protections that will be provided to the participant. For additional information about certificates of confidentiality, see *IRB Policy 2.12 Privacy and Confidentiality* (030).

If the study involves genetic testing, the consent form should include risks of genetic testing and information about the federal Genetic Information Nondisclosure Act (GINA).

Fred Hutch Consent Form Requirements:

Consent forms also include the following content (unless the IRB determines it is not needed), specified in the *IRB Member Checklist* (071):

- Heading includes Fred Hutchinson Cancer Center, based on Investigator's primary appointment
- Name, affiliation and telephone number of the principal investigator (The Fred Hutch IRB only requires the PI to be listed on the consent form; however, if other investigators or research staff are listed, their affiliations and telephone numbers must also be included)
- Name and telephone number of contact(s) for participants to call in case of an emergency
- In the "Costs" section, clearly state what the participant and/or the sponsor are responsible for. For example, "Sponsor will only provide the drugs at no cost."
- A financial contact number is included in the "Costs" section
- Statement that Fred Hutch Cancer Center has access to research participants' records

³⁵ HHS: 45 CFR 46.116(c)(1)-(6); FDA: 21 CFR 50.25(b)(1)-(6)

³⁶ HHS: 45 CFR 46.116(c)(7)-(9)

³⁷ FDA: 21 CFR 50.25(c); NIH: Policy on the Dissemination of NIH-Funded Clinical Trial Information

- IRO Director title and contact information for participants to contact with questions about their rights as a research participant (find generic contact information in the Fred Hutch templates)
- If the study involves a cooperative group, the organization should be listed in the confidentiality of records' section as having access to records.
- The attestation statement for the person obtaining consent should reference a discussion of "risks" took place

The following content, specified in the *IRB Member Checklist (071)*, is included in consent forms when research activities are occurring at UW or when the investigator's primary appointment is UW:

- Heading includes University of Washington name
- Standard University of Washington compensation for injury statement
- UW's Human Subjects Division is included in the participant's rights section

If the study may involve non-English speaking participants, the IRB recommends that the consent form refer to "study doctors" or "researchers," not "investigators." Non-English speakers may identify the word "investigators" with the police or military personnel.

When single IRB applies, the IRB approves a model consent form at the lead file, and each participating site then tracks site-specific language into the model form for review. Fred Hutch typically only allows the following site-specific changes to the consent form:

- Insertion of institutional name and/logo
- Institution-specific contact information
- Changes necessary for compliance with state law requirements, such as the California Bill of Rights
- Changes to the compensation for injury section
- Changes to the privacy/confidentiality section
- Changes to the signature blocks/attestations

3. Documentation

Informed consent is documented in a written consent form, properly signed and dated. A copy of the form is given to the participant or the participant's legally authorized representative.³⁸

Most of the time, the written consent form is a document containing the elements of consent and the required content listed in the *IRB Member Checklist (071)* (see [Review of Consent Forms](#) above). Sometimes a "short form" consent process is used. The short form is a document stating that the required elements of informed consent have been presented orally to the research participant or the research participant's legally authorized representative.³⁹ For Fred Hutch and UW Cancer Consortium studies, the short form is used when a study unexpectedly enrolls a research participant who cannot read English. Use of the short form is described in *IRB Policy 2.13 Use of Interpreter Services and Translated Documents (039)*.

When written informed consent is required, proper documentation must be obtained prior to conducting research activities.

a. Signatures

Consent forms are signed and dated by the research participant or legally authorized representative (see *IRB Policy 2.25 Identification and Use of Legally Authorized Representatives [0177]*), and a witness (if applicable, see [Witnesses](#) section below).⁴⁰ A signature by the person obtaining consent is required only if the research needs to comply with International Conference on Harmonization (ICH) guidelines. When the consent form contains a signature line for the person obtaining consent, this individual signs the consent form after the participant or LAR has signed. A pre-signed consent form is not acceptable.

³⁸ HHS: 45 CFR 46.117(a); FDA: 21 CFR 50.27(a)

³⁹ HHS: 45 CFR 46.117(b)(2); FDA: 21 CFR 50.27(b)(2)

⁴⁰ HHS: 45 CFR 46.117(a); FDA 21 CFR 50.27(a)

If circumstances prevent the person who conducted the consent discussion from signing right after the participant, the signature should be executed as soon as feasible, and, if applicable, the research staff should make a note to the study file documenting why the signature dates differ. When children participate in the research, adequate provisions for child assent and parental permission must be made. In general, unless prescribed otherwise in the application, children aged 7-12 sign an assent form and children aged 13 through 17 sign the consent form. The parent(s) or legal guardian(s) sign the consent form. For detail about the involvement of children in the consent process, see [Special Populations](#) below.⁴¹

b. Witnesses

A witness is an individual who is present during the entire consent discussion and who attests to the adequacy of the consent process and to the participant's voluntary consent. Witnesses are usually not required, but are needed in circumstances where there is a limitation on communication of information between researchers and a participant or the participant's LAR. The most common need for a witness is when the participant cannot read the consent form. The Fred Hutch IRB expects a witness to be an impartial witness.

An impartial witness is generally required in certain situations:

- when there are illiterate English-speaking participants;
- when a participant comprehends English, but is unable to speak or physically unable to sign the consent form; or
- when a short form consent process is being employed to enroll unplanned non-English speaking participants. (See *IRB Policy 2.13 Use of Interpreter Services and Translated Documents* [039] for details on the short form consent process.)

There may be other situations in which a witness is needed, such as in specific jurisdictions (e.g., if state law requires a witness), or if a sponsor requires a witness.

A witness signature may appear on the consent form itself, or on an attestation form attached to the consent form. A witness signature line does not necessarily mean a witness must sign for all participants, but rather is a place for a witness to sign when needed.

By signing the consent form, the witness is attesting to the completeness of the informed consent discussion and the participant's voluntary agreement to participate in the study. A witness signature does not vouch for the validity or contents of the document(s) signed by the research participant.

c. Version Approval

Consent forms submitted for IRB review should contain a version date and version number.

Approved consent forms are stamped with the Fred Hutch IRB Approval date per *IRB Policy 1.8 Approval Date Guidelines and Turnaround Times* (06) to help ensure current versions of consents are utilized.

The principal investigator should use the IRB-stamped versions to consent participants or ensure the IRB approval date appears on all documents that will be used in obtaining consent. The IRB notifies the principal investigator of this responsibility in *HRP-103 - Investigator Manual*.

d. Posting Requirements

For federally funded studies, one IRB-approved informed consent form used to enroll participants must be posted to www.ClinicalTrials.gov or www.Regulations.gov (Docket ID: HHS-OPHS-2018-0021) after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any participant.⁴²

4. Eligibility Activities without Consent

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective

⁴¹ HHS: 45 CFR 46.408; FDA: 21 CFR 50.55

⁴² HHS: 45 CFR 46.116(h)

participants without the informed consent of the prospective participant or the LAR, if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective participant or LAR, or
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.⁴³

Note: A researcher may still need to obtain a HIPAA waiver to access protected health information. Refer to *IRB Policy 2.12 Privacy and Confidentiality* (030) for more information.

5. Waivers

Under certain circumstances, the IRB may alter or waive the requirement to obtain informed consent or waive documentation of informed consent. The IRB will document its findings justifying the waiver or alteration.

a. Waiver or Alteration of Consent

To obtain IRB approval of a waiver or alteration of consent for research, the principal investigator must demonstrate each of the following:

- the research involves no more than minimal risk to the participants;
- the waiver or alteration will not adversely affect the rights and welfare of the participants;
- the research could not practicably be carried out without the waiver or alteration;
- whenever appropriate, the participants will be provided with additional pertinent information after participation; and
- if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.⁴⁴

In research involving minor subjects, parental consent as well as assent of the child may also be waived if the above criteria are satisfied. Reminders of these criteria are included in the *IRB Member Checklist* (071). IRB approval of the waiver or alteration is documented (with rationale) in the meeting minutes.

The IRB may not approve an alteration or omission of the general requirements for informed consent (though an IRB may still waive informed consent as normal). See section [Review](#) for general requirements for informed consent.⁴⁵

Though waiver or alteration of informed consent may be granted for emergency research under 21 CFR 50.24, it is Fred Hutch policy not to conduct planned emergency research. (See [Emergency](#) section below.)

b. Waiver of Documentation of Consent (waiver of the signature)

To obtain IRB approval of a waiver of the documentation of consent, the principal investigator must demonstrate one of the following:

- that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant or LAR will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
- that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or

⁴³ HHS: 45 CFR 46.116(g)

⁴⁴ HHS: 45 CFR 46.116(f)(3)(i)-(v); FDA: *FDA Guidance for Sponsors, Investigators, and Institutional Review Boards: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects*

⁴⁵ HHS: 46.116(a)

- if the participants or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.⁴⁶

For FDA-regulated studies, only the second criterion is permitted as a reason to waive the documentation of consent.⁴⁷

In evaluating the request for waiver of documentation of consent, the IRB reviews a written description of the information about the research to be provided to participants. A waiver of documentation of consent may mean that no written document is provided to the participant or LAR, or it could mean that only a participant's or LAR's signature on the consent form does not have to be obtained. The IRB may require the investigator to provide participants a written statement about the research (e.g., information sheet).

Reminders of these criteria are included in the *IRB Member Checklist* (071). IRB approval of the waiver is documented (with rationale) in the meeting minutes.

6. Special Populations

The applicant informs the IRB of any special populations planned to be included in the research, including populations of participants that are vulnerable to coercion or undue influence. IRB approval of the process and documentation of obtaining informed consent for such populations is documented (with rationale) in the meeting minutes. For information about the inclusion of special populations in research, see *IRB Policy 2.15 Research Involving Special Populations* (033).

a. Pregnant Women

The model consent for research includes sample language informing the research participant about unforeseeable risks to an embryo or fetus if the research participant becomes pregnant. Also included is language regarding the reasonably foreseeable impact of the research on the fetus or neonate.⁴⁸ The *IRB Member Checklist* (071) reminds the IRB of this criterion for consent.

b. Prisoners

The IRB approves research involving prisoners as research participants only if it finds that the information is presented in language which is understandable to the research participant population.⁴⁹

The applicant attests to understandability on the *HRP-265 - FORM - Prisoner Certification Checklist for Investigator*, and IRB approval is documented in the meeting minutes.

c. Children

In most states, including Washington State, children aged less than 18 years cannot consent to research. Under certain circumstances, however, they may give assent. A principal investigator wishing to include children in research informs the IRB of the age range of the children and the child research risk category, and explains the assent process in the application.

The IRB determines and documents if assent is a requirement of all children, some of the children, or none of the children. The IRB may determine that assent is not required from some or all of the children based on one or more of the following:

- The children's capability of providing assent is limited based on their age, maturity, or psychological state.
- The capability of the children is so limited that they could not reasonably be consulted about the intervention.
- The research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.
- The IRB may waive assent using the criteria for waiver of consent process.

⁴⁶ HHS: 45 CFR 46.117(c)(1)(i)-(iii)

⁴⁷ FDA: 21 CFR 56.109(c)(1)

⁴⁸ HHS: 45 CFR 46.204

⁴⁹ HHS: 45 CFR 46.305

Requirements for obtaining assent are determined per research study; however, unless the requirement for assent is waived using the same criteria as waiver of consent, the IRB will generally apply the following regarding assent:

- Children age 0-6 generally are not required to assent because they lack age or maturity to provide assent.
- Children age 7-12 generally are required to provide assent if the research has no therapeutic intent, or there are alternative treatments outside the research context.
- Children age 7-12 generally are not required to provide assent if the research holds the prospect of direct benefit and there are not alternatives outside the research context.
- Children age 13-17 are generally always required to provide assent.

The IRB will also determine how assent should be documented. In general, the form of documentation of assent depends on the age of the child:

- Children aged 7-12 years: document assent by signing an assent form written in language suitable for children (and the parent(s) or legal guardian(s) sign the consent form).
- Children aged 13-17 years: document assent by signing the consent form (as do the parent(s) or legal guardian(s)).

Permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; or the IRB determines that the permission of one parent is sufficient.⁵⁰

The concept of a second parent being “not reasonably available” is intended to encompass situations in which there really is not a possibility to obtain permission from that individual: for example, the second parent is deployed in military service abroad or is incarcerated. It is *not* intended to cover situations in which the second parent simply is working and not available the day of the scheduled consent conference. In the latter scenario, attempts must be made to schedule a second consent conference to obtain permission of the second parent; in the absence of that permission, the child should be omitted from the research.

The IRB will typically determine permission of one parent is sufficient when the research is either:

- Minimal Risk; or,
- More than minimal risk but holding the prospect of direct benefit to the individual participant.⁵¹

If permission is to be obtained from a guardian, the guardian will be an individual who is authorized under applicable State or local law to consent on behalf of the child to general medical care.

If optional research procedures are presented in the parental consent form, it is generally appropriate to address optional procedures in the assent form as well. In this context, the child should only undergo optional procedures if both the parent and the child have said yes. If one of the two says no, consent has not been obtained for the optional activities.

Fred Hutch does not routinely conduct studies that would qualify for a waiver of parental permission under 45 CFR 46.408(c), “not a reasonable requirement” criteria (e.g., neglected or abused children). If such a study is reviewed, the IRB requires a compelling rationale for why parental permission should not be sought and a description of the mechanism in place for protecting children as a substitute for parental consent.

The IRB determinations regarding inclusion of children in research, child assent, documentation of assent, and parental permission or waiver of parental permission are documented with rationale in the meeting minutes. If the child participant is a “research donor” or “healthy research volunteer,” the child risk category, assent requirements, and parental permission determination must be a separate determination in the IRB minutes.

An emancipated minor is legally capable of providing informed consent.

⁵⁰ 45 CFR 46.406, __.407; FDA: 21 CFR 50.53, __.54

⁵¹ 45 CFR 46.404, __.405; FDA: 21 CFR 50.51, __.52

d. Impaired Decision-Making Capacity

For information about obtaining informed consent on behalf of individuals with impaired decision-making capacity, see *IRB Policy 2.15 Research Involving Special Populations* (033).

7. **Consent of children who reach the age of majority or become emancipated:**

When a child participant reaches the age where they can provide consent for procedures involved in the research, informed consent must be obtained. A waiver of consent may be approved by the IRB as described in section 4 of this policy.

8. **Re-Consent**

After participants initially agree to join a study, an important part of the ongoing informed consent process is sharing with participants any new information that may affect their decision to continue to participate. Throughout the course of a study, there may again be a need to obtain from participants their documented agreement to continue to participate. Circumstances in which re-consenting participants is necessary include, but may not be limited to:

- There are significant changes to the research procedures, risks, potential benefits, or available alternatives;
- Informed consent was not properly obtained;
- There is a desire to use information and/or biospecimens for research not previously consented to;
- A participant's legal status changes, such as a minor becoming an adult, a previously incapacitated individual regaining autonomy, or a previously autonomous individual losing capacity;
- A translated informed consent document becomes available for a participant who was previously enrolled using a short form consent process.

When submitting a research modification or reportable event, the principal investigator must indicate whether re-consent will be obtained. The re-consenting plan should include details about whether participants will be asked to re-sign the consent form and whether the re-consenting will be done in-person or remotely (review section 2.a. above for general expectations around consent plans). The Fred Hutch IRB will determine at the time of the review of the research modification or reportable event whether re-consenting participants is required and whether the proposed plan is appropriate.

When re-consent is required, the PI may request, and the Fred Hutch IRB may allow other members of the research staff than the person who originally obtained informed consent to conduct the re-consent discussion. In general, the circumstances that necessitate re-consent and the information that must be communicated will dictate the qualifications of the individual allowed to re-consent participants. For example, a medical professional would need to discuss with the participant new drug risks or new alternative medical treatments that become available. On the other hand, the PI may not need to re-consent participants if a research modification adds another study visit to the planned schedule, or an additional research test is planned for already obtained biospecimens.

9. **Withdrawal of Consent**

When a research participant withdraws from a study for any reason, the data collected during the time the participant was enrolled remains in the study records, may not be removed, and must be included in any subsequent analyses. The consent document may not give the participant the option to have data removed from the study records. Researchers may not continue to access records, or other identifiable information, that would normally require consent after a participant withdraws from a study. However, researchers may continue to review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records regarding the participant, such as those establishing survival status, as approved by the IRB in the research plan.

The research team should clarify with the participant why they wish to withdraw, especially if their decision may be based on side effects they are having; however, a participant may withdraw at any time without providing a reason. For interventional studies, when appropriate, the research team may seek consent from the withdrawing participant to continue with non-interventional follow-up activities associated with the research. If the research team will seek continuation of follow-up activities the

discussion with the participant must distinguish between study-related interventions and continuing follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information. If a separate withdrawal consent is used for this purpose, IRB review and approval of the withdrawal consent is required prior to its use.

10. Observation

The IRB has the authority to observe, or have a third party observe, the consent process in order to reduce the possibility of coercion and undue influence, ensure that the approved consent process is being followed, provide additional protections to vulnerable populations, or ensure that research participants are giving informed consent.⁵²

Following are some examples of when the IRB may request the observation of the consent process:

- High-risk studies;
- Studies involving highly vulnerable populations (e.g., individuals with impaired decision-making capacity);
- Corrective action in response to a serious or continuing noncompliance report;
- When the IRB has concerns that the consent process may not be conducted appropriately;
- Studies for which there is little external oversight or data safety monitoring;
- Studies involving gene therapy.

When the IRB makes such a request, the result letter will inform the investigator that the IRB recommends the consent process of his/her study will be observed. Observation of the consent process may be delegated to appropriate Fred Hutch staff. The Fred Hutch staff will inform the investigator that the next informed consent consultation will be observed. At the time of observing the consent process, the Fred Hutch staff will work with the investigator so that the investigator may inform the research participant that the consent process will be observed.

Fred Hutch Clinical Research Support selectively monitors consent documents and consent conference notes for selected research participants, and comments on the documentation of the process.

11. Emergency

a. Emergency Use of Test Article

If emergency treatment with a procedure, drug or device not IRB approved will be used to save a patient's life, prospective consent is still required unless the circumstances meet the exception to informed consent requirements under 21 CFR 50.23. Emergency treatment and related processes of IRB acknowledgment are described in *IRB Policy 2.4 Emergency Use or Compassionate Use of an Investigational Drug or Device* (014).

b. Planned Emergency Research

Fred Hutch does not conduct, or plan to conduct, planned emergency research as described in 21 CFR 50.24.

12. HIV Testing

If HIV antibody blood testing is conducted either as part of the study or as an eligibility screening procedure, a separate consent may be required or recommended. State laws and regulations in the state in which the study participant resides may mandate specific consent provisions.

13. Training

Training in human subject's protection is mandatory for Fred Hutch faculty and staff involved in the design, conduct, or reporting of human subjects research, effective January 01, 2007. All materials approved for such training include a component explaining the ethics, regulations, and institutional policies of informed consent. In addition, training in Good Clinical Practice is mandatory for Fred

⁵² HHS: 45 CFR 46.109(g); FDA: 21 CFR 56.109(f)

Hutch faculty and staff involved in the conduct, oversight, or management of clinical trials, effective January 01, 2017. For details about training and the documentation of training, see *IRB Policy 2.20 Training* (038).

SUPPORTING DOCUMENTS

IRB Policy 1.8 Approval Date Guidelines and Turnaround Times (06)
IRB Policy 2.4 Emergency Use or Compassionate Use of an Investigational Drug or Device (014)
IRB Policy 2.12 Privacy and Confidentiality (030)
IRB Policy 2.13 Use of Interpreter Services and Translated Documents (039)
IRB Policy 2.15 Research Involving Special Populations (033)
IRB Policy 2.20 Training (038)
IRB Policy 2.25 Identification and Use of Legally Authorized Representatives (0177)
IRB Member Checklist (071)
HRP-001 - SOP - Glossary of Terms and Acronyms
HRP-103 - Investigator Manual
HRP-265 - FORM - Prisoner Certification Checklist for Investigator

REFERENCES

All references here to 45 CFR 46 are to the 2018 requirements of the Common Rule.

21 CFR 50.20
21 CFR 50.24
21 CFR 50.25
21 CFR 50.27
21 CFR 50.51–54
21 CFR 50.55
21 CFR 56.109
21 CFR 56.111
42 CFR 11
42 USC 282(j)
45 CFR 46.109
45 CFR 46.111
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
OHRP Guidance on Exculpatory Language in Informed Consent
OHRP Guidance on Genetic Information Nondisclosure Act (GINA)
FDA Information Sheets: FAQ Informed Consent Process
FDA Information Sheets: A Guide to Informed Consent & FAQ: Informed Consent Document Content
FDA Information Sheets: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials
FDA Guidance for Sponsors, Investigators, and Institutional Review Boards: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects
NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html>
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

APPENDIX A

Guideline: Who is presumptively qualified to obtain consent for clinical research?

Professional Role	Type of Study			
	High-risk Interventional Trials	Low-risk Interventional Trials ^A	More Than Minimal Risk Activity ^B	Only Minimal Risk Activity ^C
Principal Investigator and Study Subinvestigators with requisite health care provider credentials	X	X	X	X
MD Provider, not associated with the study (Attending physician responsible for the care of the participant)	X	X	X	X
Advanced Practice Provider (APP), associated with the study		X	X	X
Clinical Advanced Practice Provider, not associated with the study			X	X
Licensed Research Nurse, associated with the study			X	X
Licensed Clinical Nurse, not associated with the study				X
Licensed Phlebotomist, associated with the study				X
Study Coordinator, associated with the study				X

^AExamples include diet, exercise and some vaccine studies.

^BExamples include extra biologic samples obtained at a clinical procedure or phlebotomy exceeding 50 mL in an adult, not part of an interventional clinical trial intended to change an outcome in the subject.

^CExamples include phlebotomy up to 50 mL, surveys, use of data and previously collected biospecimens, not part of an interventional clinical trial intended to change an outcome in the subject.

The table indicates the professional roles that are presumed to have the qualifications necessary to obtain consent in research studies. Where the table lists specific licensure requirements (e.g., MD, RN, or APPs), this means current credentials that the individual maintains within the relevant local jurisdiction where the research is conducted. With appropriate justification, the IRB may allow other qualified individuals to obtain consent on a case-by-case basis.

The IRB's decisions may vary from these guidelines depending on the context. In particular, the IRB considers the population (healthy donors versus a patient population) and whether or not a research procedure holds the prospect for direct benefit.

The IRB application and the Delegation of Authority log should list all individuals who are authorized to obtain consent from subjects. The IRB application should explain the qualifications of these individuals and the scope of their role in the study.

Sub-study/screening consent forms: The IRB will evaluate the level of expertise required for conducting a consent discussion based on the risk level of procedures described in the form. For example, if a screening consent only covers a blood draw and does not describe the main study in detail, the consent discussion may fall into the minimal risk activity column above. The IRB application must contain a description of any such proposed break-down of consent qualifications by consent form for the IRB's consideration.

For Modifications, refer to Section 8 for re-consent considerations.