

**DANA-FARBER / HARVARD CANCER CENTER
POLICIES FOR HUMAN SUBJECT RESEARCH**

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1. POLICY STATEMENT:

The research team is responsible for obtaining and documenting the informed consent of each participant who participates in research, unless the requirement for obtaining informed consent is waived by the IRB of record. Informed consent is required prior to the participants' participation in any research activities (i.e., at the point where an activity is conducted solely for the purpose of research).

2. BACKGROUND:

Obtaining legally effective informed consent of participants before involving them in research is one of the central protections provided in the regulations governing research. Informed consent in research is founded on the Belmont Principle "respect of persons."

Informed consent is a process by which a participant voluntarily expresses their willingness to participate in research, after having been informed of all aspects of the research that are relevant to the participant's decision to participate. This process is documented by means of a written, signed and dated informed consent document, where required by the Institutional Review Board (IRB). The investigator and research team are responsible for ensuring that all federal and state regulations have been adhered to and that the consent itself has been appropriately obtained from either the participant or the participant's legally authorized representative prior to initiating any research-specific procedures. It is unethical to conduct research on participants without adequately informing them of the nature of the research and obtaining their consent.

3. RESPONSIBLE PERSONNEL:

- 3.1. Principal Investigator (PI)
- 3.2. Subinvestigator
- 3.3. Research Nurse
- 3.4. Study Coordinator

4. DEFINITIONS:

- 4.1. **Assent:** A child's affirmative agreement to participate in research. If the child assents to participate in the research, this will result in the child signing the assent

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section of the Informed Consent Document or separate assent document, where required by the IRB.

- 4.2. **Interventional:** Research in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Individuals may receive diagnostic, investigational treatment, or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.
- 4.3. **Legally Authorized Representative:** An individual qualified under state law who may make medical decisions on behalf of another individual.
- 4.4. **Obtaining Informed Consent:** The act(s) of presenting information to persons enabling them to decide voluntarily whether to participate in research. If the participant decides to enter into the research, this will result in the participant or the participant's legally authorized representative signing an Informed Consent Document, where required by an IRB.
- 4.5. **Permission:** Agreement of the parent(s) or guardian to the participation of their child or ward in research.
- 4.6. **Witness:** An individual present during the entire consent discussion who can attest that the information was presented in a language the potential participant understands that they had an opportunity to ask questions, and were told that their participation is voluntary. This individual should be someone other than a research team member.
- 4.7. **Healthy Volunteer:** An individual who participates in research, which includes non-patients such as family members, visitors, staff or others.

5. POLICY:

5.1. Who May Obtain Informed Consent

- 5.1.1. The PI will prospectively identify which members of the research team will be obtaining informed consent and, unless documentation is waived by the IRB signing the informed consent document
- 5.1.2. The informed consent document must be presented by an individual who is:
(1) trained in human participant protections; (2) trained on the protocol; (3)

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when required by DF/HCC policy RCO-203, listed on the Delegation of Authority Log; and (4) for all interventional drug, biologic, radiation, surgery, or device research determined by the IRB to be more than minimal risk, must be an attending physician.

5.1.2.1. The IRB will determine which members of the research team may obtain informed consent for other types of interventional research.

5.1.2.2. Additional requirements regarding who may obtain informed consent may be determined by the IRB of record or other applicable sponsor requirements (e.g., for National Cancer Institute (NCI) sponsored or Cooperative Group protocols, the attending physician must be registered with the NCI).

5.2. Methods of Obtaining Informed Consent

5.2.1. Written Informed Consent Document(s)

5.2.1.1. Unless a different method is approved by the IRB of record, informed consent will be obtained using a written informed consent form. This method for obtaining informed consent requires a designated research team member to meet with the prospective participant (or legally authorized representative) and discuss the IRB approved informed consent document. The person is given time to consider participating in the research and an opportunity to ask questions. If the prospective participant (or legally authorized representative) chooses to participate, they will sign and date the informed consent document and the person obtaining informed consent will also sign and date the document.

5.2.1.1.1. The specific process for obtaining written informed consent will be consistent with the process outlined in the IRB approved protocol or new project application form.

5.2.1.2. For all DF/HCC research requiring the use of an informed consent form, the most current IRB approved version of the consent document must be posted in the Oncology Protocol (OncPro) system. When any other approved systems through which participants may provide informed consent are used (e.g., institutionally approved platform for

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obtaining electronic consent), the language must match the current IRB-approved version of the consent document.

5.2.1.2.1. When using a printed informed consent document, the designated research team member must access and print the most current IRB approved informed consent document from OncPro. If the document is downloaded ahead of time, the designated research team member will recheck OncPro to verify the document version and IRB status of the protocol.

5.2.2. Verbal Consent

5.2.2.1. In limited circumstances, the IRB may waive the requirement for the signature of the participant (or legally authorized representative), or the IRB may permit obtaining verbal consent where, for example, the research involves a telephone survey or other minimal risk procedures. When a PI is seeking a waiver of documentation of informed consent, an information sheet or verbal script which includes the required elements of informed consent, must be submitted by the core site for IRB review and approval prior to use.

5.3. Consent Presentation

5.3.1. The consent process must ensure confidentiality.

5.3.2. "The reasonable person" standard will be used. This means that enough information is given to enable a reasonable person to decide whether or not to participate in the research. The person should clearly understand the range of risks, the potential benefits, and the voluntary nature of participating in the research.

5.3.3. The manner and context in which the information is conveyed is as important as the information itself. The presentation of the information must be adapted to each person's abilities, the complexity of the protocol, and the disease context.

5.3.4. The designated research team member obtaining informed consent will emphasize the ways in which the research differs from standard of care, including:

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5.3.4.1. Clearly identifying one or more non-research alternatives to participating in the research (including palliative care, where appropriate).

5.3.4.2. Clearly identifying the potential risks and benefits of the research, compared with the non-research alternative(s).

5.3.5. Each participant (or legally authorized representative) must be told that they have the right to decline participation and to withdraw from the research at any time without negatively affecting their subsequent medical care in any way or other benefits to which they are entitled.

5.3.6. The designated research team member obtaining informed consent will encourage the potential participant (or legally authorized representative) to read the consent form carefully before deciding about participation and discuss with family or trusted advisors where appropriate.

5.4. Documentation Requirements

5.4.1. The participant (or legally authorized representative), and the person obtaining consent must sign and date the IRB-approved informed consent form, unless the IRB has waived documentation of informed consent.

5.4.2. The person obtaining informed consent, or another research team member must ensure that:

5.4.2.1. At least two participant identifiers (medical record number and name or initials) are on all pages of the signed informed consent document.

5.4.2.2. The participant (or legally authorized representative) has consented to or declined participation in any optional studies by initialing their choice, if applicable.

5.4.2.3. All sections of the informed consent document, including indication of participation in any optional studies, must be completed.

5.4.3. A copy of the signed form must be given to the individual signing the form.

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5.4.4. All signed informed consent documents (e.g., original or faxed hard copy, electronic consent) for each participant must be retained in the research file.

5.4.4.1. For interventional research involving a drug, device, biologic, radiation or surgery determined by the IRB to be greater than minimal risk, a copy of the informed consent document must be uploaded to the electronic medical record.

5.4.5. The person obtaining informed consent will document the consent process in the medical record for all interventional research involving a drug, device, biologic, radiation or surgery that is determined by the IRB to be more than minimal risk. Documentation must provide a description of the consent process, including:

5.4.5.1. The date(s) that the consent information was presented and discussed.

5.4.5.2. A statement attesting that the participant (or LAR) has received an explanation of the content of the informed consent document and an opportunity to ask questions about the research.

5.4.5.3. Whether any witnesses or others were present during the consent presentation.

5.4.5.4. A statement attesting that the participant (or LAR) received a copy of the signed and dated informed consent document.

5.4.5.5. If additional information (e.g., a conflict-of-interest information sheet) is required to be distributed or made available to potential participants, during the consent process, the person obtaining consent must document whether this information was provided to the participant.

5.5. Updated Information Based on New Significant Findings

5.5.1. The participant (or legally authorized representative) must be informed in a timely manner when new information becomes available that may be relevant to the participant's willingness to continue participation in the research.

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5.5.1.1. The IRB of record must review and approve any plan for how new information will be communicated to the participant (or legally authorized representative), including:

5.5.1.1.1. The method by which participants will be notified, including whether the use of a revised informed consent form will be required, or whether the use of a consent addendum or verbal or written notification (or a combination of these methods) will be used.

5.5.1.1.2. Timing of when participants will be informed.

5.5.1.1.3. Which participants need to be informed. (e.g., only participants that are actively receiving treatment, or all participants who were on the study).

5.5.1.1.4. Which study team members may present the updated information and when applicable obtain informed consent from the participant.

5.5.1.1.4.1. For interventional drug, device, biologic, surgery or radiation trials determined to be more than minimal risk:

5.5.1.1.4.1.1. When a signed full consent form is used, the person obtaining consent must be an attending physician.

5.5.1.1.4.1.2. When a signed consent addendum is used that includes new or increased severity of risks, the person obtaining consent must be an attending physician.

5.5.1.1.4.2. Additional requirements for who may notify participants of updated information will be determined by the IRB of record.

5.5.1.2. All instances of updating participants of new information and/or obtaining consent must be documented in accordance with section 5.4.

5.6. Participants whose Primary Language is not English

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- 5.6.1. Persons obtaining informed consent from non-English speakers, or informing them of updated information, will follow the DF/HCC policy on obtaining consent of non-English speakers, CON-101.

5.7. Inclusion of Persons with Diminished Decision-Making Capacity and Use of a Legally Authorized Representative

- 5.7.1. Federal Regulations provide for potential additional protections for participants that may be vulnerable to undue influence such as those lacking the mental capacity to consent for themselves. For persons who lack capacity to provide informed consent, the signature of a legally authorized representative (LAR) is required.

- 5.7.2. The use of a LAR in DF/HCC research requires approval by the IRB of record. When the use of a LAR is approved by the IRB:

- 5.7.2.1. The person obtaining consent will provide a copy of the signed and dated informed consent document to the LAR and present the information in accordance with section 5.3.

- 5.7.2.2. If an LAR is used, the following should be documented in the description of the consent process (in addition to the documentation requirements outlined in section 5.4.):

- 5.7.2.2.1. That decision-making capacity was assessed by the individual obtaining consent and it was determined that the use of an LAR was appropriate.

- 5.7.2.2.2. That the potential participant was included in the process of consent to the extent possible and consistent with their desires and abilities.

5.8. Inclusion of Persons with Physical Limitations or Limitations with Reading and Writing

- 5.8.1. A person who is physically unable to talk, read, or write, or may have difficulties with reading or writing, may provide informed consent for the research if; (1) they are competent and able to indicate approval or disapproval by other means and (2) the person retains the ability to

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understand the concepts of the research and evaluate the risk and benefit of being in the research when it is explained verbally.

5.8.2. The designated research team member obtaining informed consent should document in the medical record (as applicable) the method used for communication with the prospective participant and the specific means by which the prospective participant communicated agreement to participate in the research. The informed consent process must take place in person. A witness must also be present for the entire consent process and sign the informed consent document.

5.8.2.1. Participants may be permitted, due to physical limitations or limitations with reading or writing, to verbally consent if it meets the requirements of documentation of consent. In these cases, the individual will indicate their consent with a mark, such as an “x”, in the event they cannot provide a signature. A participant who is physically unable to write out a mark, and unable to speak, can be entered into a study if they are competent and able to indicate approval, or disapproval, by other means.

5.9. Inclusion of Children or Minors

5.9.1. Children or minors will be asked to provide assent prior to enrollment in the research, as required by the IRB of record.

5.9.2. The IRB of record will determine the age at which providing assent is expected.

5.9.2.1. For research conducted under the DF/HCC, children under the age of 10 are not expected to provide assent. Children aged 10-17 are expected to provide assent, unless an alternate determination is made by the IRB of record.

5.9.3. The IRB may waive the requirement for assent. If the IRB determined that the research holds out a prospect of direct benefit that is important to the health or well-being of the child or minor and is available only in the context of research, the assent of the child or minor is not a necessary condition for proceeding with the proposed research. This would be specified in the IRB minutes and the IRB approval notification.

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5.9.4. As required by the IRB, the parent(s) or legally authorized representative must sign the informed consent document to provide permission for children or minors to participate in the research.

5.9.4.1. If during the course of the research there is a change in legal guardianship of the minor, the study team should reach out to the DF/HCC Office of Human Research Studies (OHRS) for guidance.

5.10. Continued Participation for a Minor Who Reached the Age of Majority During Research

5.10.1. If a minor participant turns 18 while research activities are ongoing, the participant who has reached the age of majority must now provide informed consent and HIPAA Authorization for their continued participation in the research. The prior assent is no longer legally valid, and informed consent must now be provided on an IRB approved research consent form, unless a waiver of consent is obtained.

5.10.1.1. Informed consent must be obtained at the participant's next protocol visit, and at a minimum prior to performing any further research interventions, procedures, or activities involving this participant or their previously collected identifiable research samples or data, when applicable.

5.10.1.2. The same requirements outlined in sections 5.1. for who may obtain informed consent apply.

5.10.1.3. If the participant is no longer reachable (e.g., lost to follow-up), and it is not possible for the participant to provide informed consent, any previously collected specimens or research data must be de-identified if they will be used for future research purposes (e.g., additional research tests performed on previously collected samples.)

5.11. Use of Healthy Volunteers

5.11.1. Healthy volunteers participating in research must be recruited according to the IRB approved protocol. The informed consent requirements and processes are the same as for other research participants. The signed informed consent document is retained in the healthy volunteer's research chart.

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6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Participants
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 – Investigational Device Exemptions
45 CFR 46 – Protection of Human Participants
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811
FDA Informed Consent Guidance Document (2023)

7. RELATED REFERENCES:

International Conference on Harmonisation – E6

8. RELATED RESOURCES:

IRB approved informed consent document
CON-101: Obtaining Consent of Non-English Speakers
DF/HCC Guidance on Documenting Informed Consent
DF/HCC Informed Consent Verification Checklist

DFCI IRB Policies and Guidance (for use when DFCI IRB is the IRB of record):

OHRS Info Sheet: Policy – Use of Legally Authorized Representatives
OHRS Info Sheet: Policy – Consenting Blind and Illiterate Participants
OHRS Info Sheet: Policy – Instructions for Research Involving Non-English-Speaking Participants
OHRS Info Sheet: Guidance – Reconsent and New Risk Notification: Guidance for Study Teams
OHRS Information Sheet: Additional Protections for Children
OHRS Information Sheet: Consent for Continued Participation in a Research Study by a Young Adult Who Has Reached Age 18
OHRS Information Sheet: Use of Informed Consent Documents Posted to OncPro
Letter from OHRS for Sponsors Outlining DFCI IRB Procedures

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