

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

TITLE: Informed Consent Process		
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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 a procedure diverges from the generally accepted standard of care (i.e., an activity that 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 confirms his or her 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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Commented [SC1]: Key edits

Edits throughout - Reorganization of sub-sections for clarity; removed gender-specific language.

Witness definition – updated

5.3. Edits throughout to clarify considerations in the presentation of consent information to an individual.

5.4.6 Requirement updated – A copy of the signed ICF must be uploaded to the EMR for interventional drug, device, biologic, radiation or surgery trials. The policy is silent on non-interventional studies, this would be at the discretion of the PI/study team/institutional policy if applicable.

5.5. This section has been simplified to outline the overarching DF/HCC requirements for updating subjects of new information and when applicable, obtaining reconsent in a timely manner. Because the IRB of record is responsible for determining/approving plan specifics (e.g., who may notify / obtain consent, timing, method of notification), language around these specifics has been removed from this policy. NOTE: For studies under the DFCI IRB, these specifics are now outlined and expanded upon in OHRS DFCI IRB Guidance: Reconsent and New Risk Notification: Guidance for Study Teams.

This guidance has been consolidated with DF/HCC operation CON-OP-1 to provide singular guidance for study teams under DFCI IRB in the appropriate format. Study teams using a different IRB of record should follow guidance from that IRB, keeping in mind that the base requirements outlined in DF/HCC policy (e.g. attending physician requirement) still apply.

5.6. Duplicative information that is already captured in CON-101: Consent of Non English Speaking Participants was removed.

5.7 and 5.8. reorganized and updated for clarity; DFCI IRB specific policy for use of LAR was moved to OHRS Policy.

5.9. and 5.10. Language updated to clarify requirements for seeking assent from minor participants, as well as more clearly defining requirements for when a minor participant reaches the age of majority during the course of research.

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[section of the](#) Informed Consent Document or separate assent document, where required by the IRB.

[4.1.4.2.](#) **Interventional:** Research in which individuals are assigned [prospectively](#) by an investigator based on a protocol to receive specific interventions. [Individuals](#) [Participants](#) may receive diagnostic, ~~therapeutic~~[treatment](#), [behavioral](#), or other types of interventions. The assignment of the intervention may or may not be random. The ~~individuals~~[participants](#) are ~~then~~ followed and biomedical and/or health outcomes are assessed.

[4.2.4.3.](#) **Legally Authorized Representative:** An individual qualified under state law who may make medical decisions on behalf of another individual.

[4.3.4.4.](#) **Obtaining Informed Consent:** -The act(s) of presenting information to persons enabling them to decide voluntarily whether ~~or not~~ 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.

[4.4.4.5.](#) **Permission:** Agreement of the parent(s) or guardian to the participation of their child or ward in research.

[4.5.4.6.](#) **Witness:** An individual, ~~ideally someone other than a research team member~~, present during the entire consent ~~interview~~[discussion](#) who can attest ~~to that~~ the ~~accuracy of information was presented in a language the oral~~ [presentation](#) 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.](#)

[4.6.4.7.](#) **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-

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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) 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. The IRB of record may determine any additional requirements regarding who may obtain consent as necessary.

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 ~~necessary as 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. The ~~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.

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~~5.2.1.1.~~ 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 ~~and to.~~ When any other approved systems through which participants may provide informed consent are used (e.g., institutionally approved platform for obtaining electronic consent~~), the language must match the current IRB-approved version of the consent document.~~

~~5.2.1.1.1.~~ 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.

~~5.2.1.2. The most common method for obtaining informed consent is for a designated research team member to sit with the prospective subject (or legally authorized representative) and discuss the IRB approved informed consent document. The person is given time to consider participating in the research and to ask questions. If the prospective subject (or legally authorized representative) chooses to participate, the person will sign the informed consent document and the person obtaining informed consent will also sign.~~

~~5.2.1.3. The process for obtaining written informed consent will be consistent with the process outlined in the IRB approved protocol or new project application forms.~~

~~5.2.1.4. Please note that the situation will be different when a witness must be used for the documentation of informed consent. Please see additional requirements for use of witnesses when obtaining informed consent from non-English speakers (Section 5.6) and illiterate individuals (Section 5.7).~~

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

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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 thea 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 person's ability to understand is based upon that person's level of intelligence, rationality, maturity, and language. The presentation of the information must be adapted to each person's capabilitiesabilities, the complexity of the protocol, and the disease context.

5.3.4. Whenever possible or required, the participation of a third party in the consent process will be encouraged, as it is shown to lead to improved understanding.

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

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

5.3.5.2.5.3.4.2. Clearly identifyidentifying the potential incremental-risks and benefits of the research, compared with the non-research alternative(s).

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~~5.3.6.~~5.3.5. Each participant (or legally authorized representative) must be told that ~~he or she has~~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 ~~at any time after the research has begun~~or other benefits to which they are entitled.

~~5.3.7.~~5.3.6. The designated research team member obtaining informed consent will ~~strongly~~ 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. ~~All persons (including the subject,~~ The participant (or legally authorized representative), ~~and the person obtaining consent)~~ must sign and date the IRB-approved informed consent ~~document for him or herself, 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. ~~Subject identification~~At least two participant identifiers (medical record number and name or initials) ~~is~~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 ~~his or her~~their choice, if applicable.

5.4.2.3. ~~The appropriate check boxes are completed on the last page~~ 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 ~~and dated informed consent document is provided~~form must be given to the ~~subject (or legally authorized representative);~~individual signing the form.

5.4.4. The person obtaining informed consent will document the consenting process in the ~~medical record for~~participant's research file.

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5.4.4.1. For all interventional research involving a drug, device, biologic, radiation, or surgery, ~~A~~, documentation must occur in the medical record.

5.4.5. Documentation must provide a description of the ~~consenting~~ consent process ~~includes the~~, including:

5.4.5.1. ~~The date(s) of consent and states that the subject (or legally authorized representative)~~ 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. ~~If witnesses or others were present, this is noted. When applicable, note that the subject (or legally authorized representative) had and an opportunity to ask questions about the research and received a signed and dated copy of.~~

~~5.4.3.1.~~ 5.4.5.3. Whether any witnesses or others were present during the informed consent document presentation.

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

~~5.4.3.2.~~ 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.

5.4.6. All signed informed consent document documents (e.g., original or faxed hard copy, electronic consent) for each participant must be retained. ~~Keep all informed consent documents signed by each subject (in the research file.~~

~~5.4.3.3.~~ 5.4.6.1. For interventional research involving a drug, device, biologic, radiation or legally authorized representative). Do not dispose of previous signed copies. A surgery, a copy of the informed consent

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document ~~will~~must be ~~sent~~uploaded to ~~Medical Records only when required by institutional policy.~~ the electronic medical record.

5.5. Updated Information Based on New Significant Findings

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

5.5.1.1. ~~The Core Site will submit the new significant findings to the IRB for determination and approval of what record must review and approve any plan for how new information should~~will be communicated to the participant (or legally authorized representative), ~~how the subject (or legally authorized representative) will be informed, the timeframe in which this must take place, and which subjects need to be re-consented including: (e.g., Only subjects that are actively receiving treatment, or all subjects who were on the study).~~

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., There only participants that are four (4) acceptable methods for informing a subject (or legally authorized representative) of actively receiving treatment, or all participants who were on the study).

5.5.2.—Which study team members may present the updated information:

~~5.5.2.1 Subject (or legally authorized representative) signs a revised IRB approved informed consent document.~~

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~~5.5.1.1.4. — 5.5.2.1.1 The individual who obtains informed consent using the revised and when applicable obtain informed consent document and documentation 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 informing the subject (or legally authorized representative) will be in accordance with sections 5.1 who may notify participants of updated information will be determined by the IRB of record.~~

~~5.5.2.1.5.5.1.2. All instances of updating participants of new information and 5.4, or obtaining consent must be documented in accordance with section 5.4.~~

~~5.5.2.1.2 — Unless otherwise specified by the IRB, the use of the revised inform consent document involves a review of the entire consent form, including the optional studies.~~

~~5.5.2.2 — A letter can be sent or given to the subject (or legally authorized representative) to update them on new information related to the research (written correspondence).~~

~~5.5.2.2.1 The date that the letter was sent or given to the subject (or legally authorized representative) should be documented in the subjects medical or research record.~~

~~5.5.2.3 Consent Form Addendum can be used to convey new information to subjects. This will be an abbreviated form of a consent document including only the new information relevant to the research participant, along with a signature line for the participant's continued participation.~~

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~~5.5.2.3.1 Consent Form Addendum can be presented to the subject (or legally authorized representative) by an individual who is: (1) trained in human subject protections; (2) trained on the protocol; (3) listed on the Delegation of Authority Log; (3) for all interventional drug, biologic, or device research, must be a clinical staff member (e.g. licensed physicians, dentists, NP, RN, and PA)~~

~~5.5.2.4 Subject (or legally authorized representative) is verbally informed of the updated information.~~

~~5.5.2.4.1 New information can be conveyed verbally to the subject (or legally authorized representative) by an individual who is: (1) trained in human subject protections; (2) trained on the protocol; (3) listed on the Delegation of Authority Log; (4) for all interventional drug, biologic, or device research, must be a clinical staff member (e.g. licensed physicians, dentists, NP, RN, and PA)~~

~~5.5.2.4.2 The information that is verbally provided to the subject (or legally authorized representative) should be documented in either the medical or research record. The documentation should include what information was provided, by whom, and the date of the interaction.~~

~~5.5.3. The IRB will require that one of these methods or a combination of these methods be used to update the subject (or legally authorized representative). The PI and all research team members will follow the method(s) approved by the IRB.~~

~~5.6. Non-English Speaking Subject or Legally Authorized Representative~~

5.6. Participants whose Primary Language is not English

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

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5.7. Inclusion of Persons with Diminished Decision-Making Capacity and Use of an interpreter during the informed consent process

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.

~~5.6.1.1~~ 5.7.2.2. If an LAR is used, the following should be documented in the description of the consent process for research (i.e. initial or informing them of updated information) is required. (in addition to the documentation requirements outlined in section 5.4.):

5.7. ~~Illiterate English Speaking/Non-English Speaking Subject or Someone with a Physical or Cognitive Disability~~

5.7.2.2.1. A person who can understand and comprehend spoken English, or who is communicating through an interpreter, but is ~~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

~~5.7.1~~ 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

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

~~5.7.2.~~ 5.8.2. The designated research team member obtaining informed consent ~~must~~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 ~~prospective subject~~informed consent process must ~~be consented~~take place in person. A witness must also be present for the entire consent process and sign the informed consent document. ~~The illiterate or blind English speaking or non-English speaking subject will indicate his/her consent with a mark, such as an "x", in the event they cannot provide a signature.~~

~~5.7.3. For persons who lack capacity to provide informed consent, the signature of a legally authorized representative is required.~~

~~5.7.4. Provide a copy of the signed and dated informed consent document to the subject (or legally authorized representative).~~

~~5.7.5. In the event of an illiterate non-English speaking person, the use of an interpreter during the informed consent process for research as well as during the course of the trial is required.~~

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.

5.8.5.9. Inclusion of Children or Minors

~~5.8.1.~~ 5.9.1. Children or minors ~~must give~~will be asked to provide assent prior to enrollment ~~into~~in the research, as required by the IRB of record.

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5.8.1.1. Under the age of 10: Not required, but can be determined by the designated research team member obtaining informed consent

5.8.1.2. The age of 10 and older: Must sign the assent box unless the designated research team member obtaining informed consent notes that the child/minor is not capable of assenting

5.8.1.3. Waiver of assent: Determined by the IRB

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.

5.8.2.5.9.3. 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.

5.8.3.5.9.4. 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 reaches, 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 (18 years of age), he or she must now provide informed consented with the current IRB approved version of the consent and HIPAA Authorization for their continued participation in

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the research. The prior assent is no longer legally valid, and informed consent document, using the subject consent signature section. Studies under the DFCI IRB 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 use either the current IRB approved consent, or the generic obtain informed consent document entitled "Consent for Continued Participation In A Research Study By A Young Adult Who Has Reached Age 18" that is posted on apply.

5.10.1.3. If the Office for Human Research Studies (OHRS) website, 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.)

5.9.5.11. Use of Healthy Volunteers

5.9.1.5.11.1. Healthy volunteers participating in research must be recruited according to the Institutional Review Board (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.

6. APPLICABLE REGULATIONS & GUIDELINES:

- 21 CFR 50 – Protection of Human Research Subjects
- 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

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45 CFR 46 – Protection of Human Subjects
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
[Letter from OHRS for Sponsors Outlining DF/HCC IRB Procedures](#)

8. RELATED POLICIES & RESOURCES:

IRB-approved informed consent document
DF/HCC Policy - [CON-101: Obtaining Consent of Non-English Speakers](#)
DF/HCC Guidance on Documenting Informed Consent
DF/HCC Informed Consent Documentation Template

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: Legally Authorized Representatives](#)~~
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](#)

~~[CON-OP 1: Reconsent/Patient Notification Guidance](#)~~

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