TITLE: Informed Consent Process		
POLICY #: CON-100	**Page:** 1 of 11	**Effective Date:** ~~2/1/2021~~2/28/2022

1. POLICY STATEMENT:

The research team is responsible for obtaining and documenting the informed consent of each subject who participates in research. Informed consent is required 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.)

Commented [SC1]: **Key Update:**
Language added to section 5.4.4. to specify that when any additional documents are required to be given to subjects as part of the consent process, it should be documented whether they were given.

2. BACKGROUND:

Obtaining legally effective informed consent of subjects 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 subject voluntarily confirms his or her willingness to participate in research, after having been informed of all aspects of the research that are relevant to the subject'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 subject or the subject's legally authorized representative prior to initiating any research-specific procedures. It is unethical to conduct research on subjects 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

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, therapeutic, 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 or not to participate in research. If the subject decides to enter into the research, this will result in the subject or the subject'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, ideally someone other than a research team member, present during the entire consent interview who can attest to the accuracy of the oral presentation.

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 signing the informed consent document.

5.1.2. The informed consent document must be presented by an individual who is: (1) trained in human subject protections; (2) trained on the protocol; (3) listed on the Delegation of Authority Log; and (4) for all interventional drug,

biologic, 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 may be necessary as applicable (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 most current IRB approved version of the consent document must be posted in the Oncology Protocol (OncPro) system and to any other systems through which subjects may provide informed consent (e.g., electronic consent).

5.2.1.1.1. When using a printed informed consent document, the designated research team member must access and print the most current IRB approved informed consent document. 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 subject (or legally authorized representative) or the IRB may permit obtaining verbal consent where, for example, the research involves a telephone survey. 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 the 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 capabilities.

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

5.3.5.1. Clearly identify one or more non-research alternatives to the research (including palliative care, where appropriate).

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

5.3.6. Each subject (or legally authorized representative) must be told that he or she has the right to decline participation and to withdraw from the research without negatively affecting their subsequent medical care in any way at any time after the research has begun.

5.3.7. The designated research team member obtaining informed consent will strongly encourage the potential subject (or legally authorized representative) to read the consent form carefully before deciding about participation.

5.4. **Documentation Requirements**

5.4.1. All persons (including the subject or legally authorized representative, and person obtaining informed consent) must SIGN and DATE the informed consent document for him or herself.

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

5.4.2.1. Subject identification (medical record number and name or initials) is on all pages of the signed informed consent document.

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

5.4.2.3.The appropriate check boxes are completed on the last page of the informed consent document.

5.4.2.4.A copy of the signed and dated informed consent document is provided to the subject (or legally authorized representative).

5.4.3. The person obtaining informed consent will document the consenting process in the medical record for all interventional research involving a drug, device, biologic, radiation, or surgery. A description of the consenting process includes the date(s) of consent and states that the subject (or legally authorized representative) 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 an opportunity to ask questions about the research and received a signed and dated copy of the informed consent document.

~~5.4.3.~~5.4.4. If additional information (e.g., a conflict of interest information sheet) is required to be distributed or made available to potential subjects, during the consent process, the person obtaining consent must document whether this information was provided to the subject.

~~5.4.4.~~5.4.5. The signed informed consent document (e.g., original or faxed hard copy, electronic consent) must be retained. Keep all informed consent documents signed by each subject (or legally authorized representative). Do not dispose of previous signed copies. A copy of the informed consent document will be sent to Medical Records only when required by institutional policy.

5.5. **Updated Information Based on New Significant Findings**

5.5.1. The subject (or legally authorized representative) will be informed in a timely manner by a designated research team member when new information becomes available that may be relevant to the person's willingness to continue participation in the research. The Core Site will submit the new significant findings to the IRB for determination and approval of what information should be communicated to the subject (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 (e.g., Only subjects that are actively receiving treatment, or all subjects who were on the study).

5.5.2. There are four (4) acceptable methods for informing a subject (or legally authorized representative) of updated information:

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

5.5.2.1.1 The individual who obtains informed consent using the revised informed consent document and documentation requirements for informing the subject (or legally authorized representative) will be in accordance with sections 5.1 and 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.

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**

5.6.1. Persons obtaining informed consent from non-English speakers or informing them of updated information will follow the policy on consenting non-English speakers.

5.6.2. Use of an interpreter during the informed consent process for research (i.e. initial or informing them of updated information) is required.

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

5.7.1. A person who can understand and comprehend spoken English, or who is communicating through an interpreter, but is physically unable to talk, read,

or write, 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 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. The designated research team member obtaining informed consent must document in the medical record (as applicable) the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the research. The prospective subject must be consented in person. A witness must 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. **Inclusion of Children or Minors**

5.8.1. Children or minors must give assent prior to enrollment into the research as required by the IRB.

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

5.8.2. 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.

5.8.3. 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.

5.8.4. If during the course of the research the minor reaches the age of majority (18 years of age), he or she must provide informed consented with the current IRB approved version of the informed consent document, using the subject consent signature section. Studies under the DFCI IRB may use either the current IRB approved consent, or the generic 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 the Office for Human Research Studies (OHRS) website.

5.9. **Use of Healthy Volunteers**

5.9.1. 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 subjects. 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
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

7. RELATED REFERENCES:

International Conference on Harmonisation – E6
Letter from OHRS for Sponsors Outlining DF/HCC IRB Procedures
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

8. RELATED RESOURCES:

IRB approved informed consent document
DF/HCC Guidance on Documenting Informed Consent
DF/HCC Informed Consent Verification Checklist
CON-OP-1: Reconsent/Patient Notification Guidance