ADIRONDACK HEALTH

TITLE:	Informed Consent Document (ICD) and Assent Document (AD) Requirements and Processes	POLICY #: SOP-3
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 2
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1. The following elements are generally required for Informed Consent Documents:
    a. A statement that the study involves research, an explanation of the purpose(s) of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and specific identification of which procedures are experimental.
    b. A description of any reasonably foreseeable risks or discomforts to the subject.
    c. A description of any benefits to the subject or to others, which may reasonably be expected from the research.
    d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
    e. A statement describing the extent to which confidentiality of records identifying the subject will be maintained and that notes that the US Food and Drug Administration, representatives from the sponsor, the sponsor's designees or the IRB may inspect all study records.
    f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatment are available if any injury occurs, and if so, of what they consist or where further information can be obtained.
    g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of research-related injury to a research subject.
    h. A statement that participation is voluntary and that refusing to participate or discontinuing participation will involve no penalty or loss of benefits to which the subject might otherwise be entitled.
2. The following elements may be required for Informed Consent Documents:
    a. A statement that the particular treatment or procedure may involve risks that are currently unforeseeable to the subject, the embryo or the fetus, if the subject should be or become pregnant.
    b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
    c. Any additional costs to the subject which may result from participation in the research.
    d. The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation, will be provided to the subject.
f. The approximate number of subjects involved in the study.

3. All informed consents must be written at the sixth-grade level and all technical terms should be reduced to lay-terms as nearly as possible.
4. There must be signature and date lines for the subject, (or the subject's legally authorized representative) which must be signed and dated by that individual, before any study-related procedure can be performed. .
5. There must be signature and date lines for the person obtaining informed consent, which must be signed and dated at the time the informed consent is obtained.
6. There may a be a signature line for a witness, if one was required because of incompetence or incapacitation of the subject or a translation of the consent was made by a third party. Generally, a witness is not required in New York except in extenuating circumstance, so if there is a witness line and none of the extenuating circumstances apply, then the witness line may be left blank. No other blank lines are allowed.
7. The informed consent process must also be documented in the subject's medical record and the original consent must be part of that record, either a hard copy or a scanned-in copy must be present in the patient's chart.
8. A copy of the completed (meaning signed and dated by each party, as above) informed consent must be given to the subject and that delivery needs to be included in the process reported in the subject's medical record.
9. The assent document (AD) is meant to be a simplified version of the ICD and must be presented to minors who have the capacity to read and understand it. A parent or guardian or the investigator may help them to understand it but may not coerce the subject in any way. The IRB may waive the assent requirement if:
    a. The is no more than minimal risk to the subject;
    b. If the waiver will not adversely affect the rights or welfare of the subject;
    c. The clinical investigation could not practically be carried out without the waiver; or
    d. Whenever appropriate, the subject will be provided with additional pertinent information after their participation is complete.
10. When a parent signs the ICD for the minor, both parents must sign unless one parent is deceased, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the minor if consistent with State law. The reason for one signature-only must be documented in the patient's chart.

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 50.25, 21 CFR 50.27, 21 CFR 50.50-56
NYCRR: N/A
HFAP: N/A