Standard Operating Procedure (SOP)

SOP #: 401.116	Informed Consent Process and Written Documentation of Informed Consent
Executive Owner: Vice President Research Operations	Effective Date: 8/7/2020 Review Date: 8/7/2020

Scope	This Standard Operating Procedure (SOP) outlines the process that <Research Personnel> delegated the task of obtaining research informed consent should follow for obtaining and documenting informed consent of research participants. The informed consent process will follow all applicable federal regulations (including, but not limited to: FDA, DHHS/OHRP, and ICH (E6) (R2) GCP guidelines).
Purpose	This SOP describes the process to obtain informed consent and written documentation of consent when consent is obtained from a research participant in person. Other procedures may be suitable when approved by the Institutional Review Board (IRB) of record, including but not limited to processes related to the remote consenting of research participants.
Qualified Personnel	<Research Personnel> as delegated by the Principal Investigator (PI) and approved by IRB of record
Training	The investigator is responsible ensuring all <Research Personnel> are trained in accordance with 400.070 Policy, Investigator obligations in Research
Supplies & Equipment	IRBNet Access, Florence Access
Procedure	**A. Introduction** a. "Person giving consent" means: i. In the case of a cognitive intact adult, the individual being asked to take part ii. In the case of an adult unable to consent, that individual's Legally Authorized Representative (LAR) iii. In the case of a child: 1. One parent, if the other 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. 2. One parent if the IRB of record determined that permission from one parent was sufficient 3. An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care 4. Both parents b. "Consent information" means: i. Long form consent document (when the IRB of record requires the long form of consent documentation).

ii. Short form consent document and long form consent (when the IRB of record allows the short form of consent documentation).
iii. Script or information sheet (when the IRB of record has approved a waiver of written documentation of consent).

c. Communicate in the preferred language of the participant/LAR giving consent
d. Unless the IRB of record affirmatively approved a study to include the following populations, such participants may not be enrolled:

i. Adults unable to consent
ii. Children
iii. Neonates of uncertain viability
iv. Nonviable neonates
v. Pregnant women
vi. Prisoners
vii. Individuals unable to speak English

e. The short form of consent documentation may be used only if affirmatively approved by the IRB of record.
f. For the short form of consent documentation:

i. The short form is a standard template translated into the participant's language.
ii. The long consent form is the English version.

g. For waiver of written documentation of consent, the script is the long form without a signature block.
h. Interpreters are to be conversant in both English and the language understood by the participant/LAR giving consent. When allowed by institutional policy, the qualified bilingual interpreter may be a member of the research team, or a family member or friend of the participant or person giving consent.
i. If the consent process requires an <Impartial Witness>:

i. The <Impartial Witness> is to be present during the entire consent discussion and to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the participant/LAR, and that consent was freely given.
ii. The <Impartial Witness> may not be a person involved in the research.

B. Informed Consent Process

a. Obtain the IRB-approved consent document, short form consent document, or script, as applicable.

i. Verify that the <Research Personnel> obtaining consent is using the most current IRB-approved information.
ii. Verify that the consent document, is in language understandable to the person giving consent.

b. If the person giving consent cannot read or the short form of consent documentation is used, obtain an <Impartial Witness>.
c. If the person giving consent cannot speak English, obtain the services of a qualified bilingual interpreter.
d. Provide potential participant with a copy of the IRB approved consent document and go over the information in the consent document with potential participant /LAR using language understandable to them.

i. Do not provide any information to the person giving consent through which the potential participant giving consent is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
ii. When providing information about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

e. Invite and answer any questions that the potential participant may have.
f. Evaluate whether the following is true for the person giving consent. If not, take steps to correct or determine that the person giving consent is incapable of providing consent:

i. The person giving consent has been provided sufficient information.
ii. The potential participant understands the information.

1. If the person giving consent has a disease or condition that may affect cognition, assess whether the person giving consent has sufficient cognitive capacity to legally provide informed consent.
2. If the participant is pregnant, ensure the person giving consent is fully informed regarding the reasonably foreseeable effect of the research on the fetus or neonate.

iii. The person giving consent does not feel coerced or unduly influenced.

1. Ensure there is no threat of harm or adverse consequences for a decision to not participate.

2. Ensure that outside parties (family or caretakers) do not coerce or unduly influence the person giving consent, especially if that person is vulnerable to coercion or undue influence.
3. Ensure that the amount of payment does not coerce or unduly influence economically disadvantaged individuals.
4. For persons giving consent who are in a subordinate position to a member of the research team (e.g., employee or student), ensure that there is no threat of harm or adverse consequences to the participant's position for a decision to not participate.

iv. The person giving consent has sufficient time to make a decision.

1. Provide the person giving consent with sufficient time to understand the information. Spend as much time as needed.
2. Provide the person giving consent with sufficient time to ask questions.

v. The individual giving consent understands the consequences of a decision.

vi. The individual giving consent can communicate a choice.

g. If the potential participant or LAR indicates that he or she does not want to consent to participate in the research study, stop.

h. If the participant is a child or adult unable to consent:

i. Explain the research to the extent compatible with the participant's understanding.

1. Ensure that parents or guardians do not coerce or unduly influence children.
2. Ensure that outside parties (family or caretakers) do not coerce or unduly influence adults unable to consent.

ii. If the IRB of record determined that assent was a requirement and the participant is capable of being consulted, request the assent (affirmative agreement) of the participant.

1. If the participant indicates that he or she does not want to take part, stop.

i. In the event that a non-English speaking participant needs to be enrolled on a study, but an up to date long form consent in their language is not available:

i. A short form in the language of the potential participant or LAR should be used in conjunction with the newly approved English long consent form to enroll that subject provided the following are true:

1. The IRB of record has approved the use of the short form for that study
2. The fully translated long consent form with the new information is provided to the potential participant/LAR when available and either they are re-consented on that version or the discussion is documented that they understand the new information.

ii. If the use of a short form is not approved for that study, the IRB of record and study sponsor should provide further guidance on whether the non-English speaking participant may be enrolled before proceeding.

iii. For treatment only protocols or minimal risk studies, the IRB of record reserves the right to make an exception to this process weighing factors including but not limited to risk, benefit and situational feasibility.

1. In this case, the participant/LAR can be consented on the currently approved fully translated long consent form however they should be notified of any changes made to the English version of the consent form and this should be source documented in the consent note.
2. If feasible, the participant/LAR should be provided with the fully translated long consent form with the new information when translated and IRB approved.

C. Written Documentation of Informed Consent

a. If the consent process will be documented with the long form in the language of the potential participant or LAR:

i. Verify that the document is in language understandable to the person giving consent.

ii. If the IRB of record required written documentation of assent, note one of the following:

1. Assent was obtained.
2. Assent was not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.

iii. Have the following individuals personally sign and date the consent document:

1. Person giving consent
2. Person obtaining consent

3. <Impartial Witness>, if any

b. If the consent process will be documented with the short form in the language of the potential participant or LAR:

   i. Verify that the document is in language understandable to the person giving consent.
   ii. If the IRB of record required written documentation of assent, note one of the following:

      1. Assent was obtained.
      2. Assent was not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.

   iii. Have the following individuals personally sign and date the short form:

      1. Potential participant or LAR giving consent
      2. <Impartial Witness>
      3. Interpreter, or document the interpreter information if not physically present

   iv. Have the following individuals personally sign and date the long form English consent:

      1. Person obtaining consent
      2. <Impartial Witness>
      3. Person obtaining consent to write name of participant on the long form

   v. If the IRB of record includes additional requirements, then these requirements must be followed.

c. Provide the person giving consent with copies of the signed and dated documents.

   i. This may be accomplished either by making a photocopy or by having individuals sign and date two copies.

d. File a copy of the consent document in the electronic medical record when required by institutional policy.
e. Retain the signed and dated documents in the study records for the greater of:

   i. Seven years after completion of the research.
   ii. For drug studies conducted under an Investigational New Drug (IND), two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication,

until two years after the investigation is discontinued and FDA is notified.

iii. For device studies conducted under an Investigational Device Exemption (IDE) or abbreviated IDE, two years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

iv. The retention period requested by the sponsor.

v. The retention period required by local, state, or international law.

vi. The retention period required by a site that is not part of AdventHealth Orlando.

D. Re-consenting

a. Re-consent Determination

i. The research participant/LAR should be re-consented when changes to the research study are directly applicable to the participant's involvement and may impact their willingness to continue in the clinical trial, as determined by the study sponsor and/or PI.

ii. The IRB of record makes the final decision on whether re-consenting a research participant is required.

b. Re-consent Timeline

i. All effort is made to complete the re-consenting process at the next scheduled study visit after IRB approval of the updated/revised consent.

ii. If the IRB of record does not clearly outline the re-consenting plan, the PI will determine timeframe for consenting depending on risk changes.

iii. If initial consent was not completed in a fully compliant manner, re-consent is required as soon as possible when the research staff is made aware of the deviation.

iv. Any extenuating circumstances causing delay in re-consent should be addressed with the PI and sponsor for further guidance.

c. If a non-English speaking participant/LAR previously signed a translated Non-English long consent form, they should be re-consented on the translated long consent form in their language once it has been translated and IRB approved.

d. Documentation of re-consent should follow the same process as documentation of initial consent.

e. Refusal of study participant/LAR to sign revised consent
   i. Discuss with the participant/LAR that refusal to sign a revised consent document when reconsent is required will result in their withdrawal from the research study.
   ii. If applicable based on changes to consent, confirm whether the participant/LAR intends to withdrawal participation in the study in part or fully. This decision must be documented in the research records.

E. Participants Transferring in from Another site

When a participant transfers to AdventHealth Orlando from another site, the subject must be consented on the AdventHealth Orlando Informed Consent Form (ICF) even though they already signed the study level ICF at their previous institution.

F. Withdrawal of Consent

a. Participant removal by PI
   i. A research participant may be removed from some or all study components at any time by the PI at his or her discretion. Circumstances for removal can include when a participant's safety may be compromised or to maintain the integrity of the study data when the participant is not compliant with study procedures.
   ii. The treating investigator and/or study coordinator should document the date and reasons for discontinuing a participant's participation in the research record and explain the reasons for this action.

b. Participant voluntary withdrawal
   i. Participants may withdraw their participation from a research study at any time.
   ii. Regardless of the reasons for the withdrawal, the PI should consider:
      1. Procedures for safe discontinuation of participation;
      2. Retention and use of the data already collected about the participant; and
      3. The conditions under which the study sponsor may collect additional data about the participant after his/her withdrawal from the study.

c. Documentation of participant withdrawal
   i. For studies involving more than minimal risk, the date and decision by a study participant to stop their participation, along with documentation of any correspondence and/or conversations regarding their withdrawal, should be captured in the participant's research record.

ii. The participant/LAR should only sign a withdrawal of consent form if it has been approved by the IRB of record for the study.

G. Consent for Pediatric Patients who Reach the Age of Majority

Pediatric participants that reach the age of majority while on study must be consented at the next study visit.

Definition(s)

Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the entire consent process and reads the consent document and any other written information supplied to the subject as part of the consent process. (ICH-GCP definition)

Research Personnel: Individuals involved in designing, conducting, or reporting of research.

Reference(s)

21 CFR §50.20, §50.25
45 CFR §46.116
AHO SOP 010.024
AHO POLICY 400.001 - HRP-001 Definitions in Research
AHO POLICY 405.002 Billing Compliance in Clinical Research
HRP-804 INVESTIGATOR GUIDANCE: Short Form Consent Process in Research
Interpreter Services Guide for Researchers V.21NOV2019

21 CFR §50.27, 56.115(b), §312.62(c), §812.140(d)
45 CFR §46.115(b), §46.117

Related Documents

HRP-831 INVESTIGATOR GUIDANCE - Remote Consent Guidance

Keywords

Informed Consent, IRB, Research, ICF