



SOP: Written Documentation of Consent and Assent

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1 PURPOSE

- 1.1 This procedure establishes the process to document the informed consent process in writing.
- 1.2 The process begins when a participant agrees to take part in a research study.
- 1.3 The process ends when the consent process is documented in writing and electronic format to the extent required by this procedure.

2 PREVIOUS VERSION

- 2.1 Revised from the previous version dated 07/01/2024.

3 POLICY

- 3.1 In this procedure, an “investigator” means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.
- 3.2 In this procedure, “participant/representative” means:
 - 3.2.1 The participant when the participant is an adult capable of providing consent.
 - 3.2.2 Legally authorized representative when the participant is an adult unable to give consent.
 - 3.2.3 One or both biologic or adoptive parents when the participant is a child or, in the absence of a parent, a person authorized under applicable law to consent on behalf of a child to general medical care, education, or other care.
- 3.3 In this procedure, “impartial witness” means an individual who can attest to the identity of the person so entitled. This individual may or may not be the same as the study team member who signs to document that consent was ‘obtained,’ depending on the pre-existing relationship and/or established processes in place that can confirm identity.

4 RESPONSIBILITIES

- 4.1 The principal investigator is responsible for carrying out these procedures.

5 PROCEDURE

- 5.1 If the IRB determined that the PI or designee must document the consent process in writing with the long form of consent documentation (see also the eIRB+ and IRB Electronic Signature Policy (HRP-1002) and Investigator Manual (HRP-103)):
 - 5.1.1 Verify that the consent form is in language understandable to the participant/representative.
 - 5.1.2 Have the following individuals personally date, sign, and print their names on the consent document:
 - 5.1.2.1 Participant/Legally Authorized Representative
 - 5.1.2.2 Person obtaining consent, where required
 - 5.1.2.2.1 In situations where written consent is obtained in person or remotely via electronic signature, the printed name, date, and signature from the person obtaining consent may be required on the consent document by, but not limited to, IRB determination, FDA-regulation, when using the short form process with the long consent document or a summary, ICH GCP E6(R2): Section 4.8.8, other applicable regulations, laws, or policies, or a combination thereof.
 - 5.1.3 Have the following individuals sign and date the consent document (or otherwise “make their mark” on it):
 - 5.1.3.1 Participant/Legally Authorized Representative



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- 5.1.3.1.1 If the participant /representative can only “make their mark,” document in a note to the participant’s file, the method used for communication with the prospective participant /representative, the reason for the lack of a signature and date, and the date consent was obtainedⁱ.
- 5.1.3.1.2 If the participant /representative is physically unable to sign the consent form, note this on the consent form and document in a note to the participant’s file the method used for communication with the prospective participant /representative and the specific means by which they communicated their agreementⁱⁱ.
- 5.1.3.2 Person obtaining consent, where required
 - 5.1.3.2.1 In situations where written consent is obtained in person or remotely via electronic signature, the printed name, date, and signature from the person obtaining consent may be required on the consent document by, but not limited to, IRB determination, FDA-regulation, when using the short form process with the long consent document or a summary, ICH GCP E6(R2): Section 4.8.8, other applicable regulations, laws, or policies, or a combination thereof.
- 5.1.4 If the IRB requires written documentation of assent, note in the signature block one of the following:
 - 5.1.4.1 Signature and printed name of the child or adult with impaired decision-making capacity documenting that assent was obtained.
 - 5.1.4.2 Checkbox reflecting that assent of the child or adult with impaired decision-making capacity was obtained.
 - 5.1.4.1 Checkbox reflecting that assent of the child or adult with impaired decision-making capacity was not obtained because the capability of the child or adult is so limited that the child or adult cannot reasonably be consulted.
- 5.1.5 For participants who cannot read, write, talk, or are blind [or whenever it is required by the IRB or sponsor], an impartial witness should be present during an oral presentation of the consent process for the research and documentation of the process.
- 5.1.6 If an impartial witness was part of the consent process:
 - 5.1.6.1 Have the impartial witness print their name on the consent document.
 - 5.1.6.2 Have the impartial witness personally print, sign, and date the consent document to attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the participant and that consent and assent, if applicable, were freely given.
- 5.1.7 Provide participants with the opportunity to receive copies of the signed and dated consent document to the participant/representative. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.
- 5.2 If the consent process will be documented in writing with the short form of consent documentation:
 - 5.2.1 Verify that the short consent form is in language understandable to the participant/representative.
 - 5.2.2 Print the name of the following individuals on the short form consent document:
 - 5.2.2.1 Participant/Legally authorized representative
 - 5.2.2.2 Impartial witness



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- 5.2.3 Print the name of the following individuals on the summary:
 - 5.2.3.1 Person obtaining consent
 - 5.2.3.2 Impartial witness
- 5.2.4 Have the following individuals personally sign and date the short form consent document:
 - 5.2.4.1 Participant/Legally authorized representative
 - 5.2.4.2 Impartial witness
- 5.2.5 Have the following individuals personally sign and date the summary:
 - 5.2.5.1 Person obtaining consent
 - 5.2.5.2 Impartial witness
- 5.2.6 If the IRB requires written documentation of assent, note on the signature block on the short consent document one of the following:
 - 5.2.6.1 Assent of the child was obtained.
 - 5.2.6.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
- 5.2.7 Provide a copy of the signed and dated short consent document and a copy of the signed and dated summary to the participant/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.
- 5.3 If the IRB waived the requirement for written documentation of the consent and the IRB determined that the participant/representative had to be offered the opportunity to document their consent in writing, offer the participant/representative the option to document their consent in writing.
 - 5.3.1 If the participant/representative declines, take no further action.
 - 5.3.2 If the participant/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation.
- 5.4 Place the signed and dated documents in the participant's binder.
- 5.5 The person obtaining consent will date and sign when applicable.
 - 5.5.1 In situations where written consent is obtained in person or remotely via electronic signature, the printed name, date, and signature from the person obtaining consent may be required on the consent document by, but not limited to, IRB determination, FDA-regulation, when using the short form process with the long consent document or a summary, ICH GCP E6(R2): Section 4.8.8, other applicable regulations, laws, or policies, or a combination thereof.
 - 5.5.2 Document within the participant's binder/research record when and with whom the consent process occurred and if there were any issues.

Note: Documentation of the informed consent process occurs after explaining the research study to a potential participant and ensuring the participant understands what's required should they choose to enroll. The informed consent process, including any alterations from the guidance outlined in this SOP, should be described in the protocol and documented in the participant's research record.

6 MATERIALS

- 6.1 TEMPLATE: Long Form Consent Form Documents:
 - 6.1.1 Social Behavioral Consent (HRP-582)
 - 6.1.2 Biomedical Consent (HRP-592)
 - 6.1.3 Written Assent (for minors) (HRP-1707)
 - 6.1.4 Assent to Participate in Research (HRP-1708)



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- 6.1.5 Parent Consent and Permission with Child Assent (HRP-1711)
- 6.1.6 Parent Permission with Child Assent (HRP-1712)
- 6.1.7 IRB website: <https://www.irb.northwestern.edu/informed-consent/>
- 6.1.8 IRB website: <https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html>
- 6.2 CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- 6.3 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- 6.4 CHECKLIST: Children (HRP-416)
- 6.5 SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)
- 6.6 SOP: Informed Consent Process for Research (HRP-090)
- 6.7 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 6.8 POLICY: Electronic signature policy (HRP-1002)
- 6.9 POLICY: Investigator Manual (HRP-103)

7 REFERENCES

- 7.1 21 CFR §50.27
- 7.2 45 CFR §46.117
- 7.3 <https://www.fda.gov/media/88915/download>

¹ FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)
<https://www.fda.gov/media/88915/download>

ⁱⁱ FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)
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