



SOP: Written Documentation of Consent			
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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 previous version dated 05/14/2019

**3 POLICY**

- 3.1 In this procedure “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.

**4 RESPONSIBILITIES**

- 4.1 The principal investigator is responsible to ensure these procedures are carried out.

**5 PROCEDURE**

- 5.1 If the consent process will be documented in writing with the long form of consent documentation (see also the eIRB+ and IRB Electronic Signature Policy):
  - 5.1.1 Verify that the consent form is in language understandable to the participant/representative.
  - 5.1.2 5.1.3 Have the following individuals personally print their name on the consent document:
    - 5.1.2.1 Participant/Legally authorized representative
    - 5.1.2.2 Person obtaining consent
  - 5.1.3 Have the following individuals personally sign and date the consent document:
    - 5.1.3.1 Participant/Legally authorized representative
    - 5.1.3.2 Person obtaining consent
  - 5.1.4 If the IRB required written documentation of assent, note on the signature block one of the following:
    - 5.1.4.1 Assent of the child was obtained.
    - 5.1.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
  - 5.1.5 Have the person obtaining consent personally sign and date the consent document.
  - 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 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



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- understood by, the participant, and that consent and assent, if applicable was 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 and the summary:
      - 5.2.2.1 Participant/Legally authorized representative
      - 5.2.2.2 Person obtaining consent
      - 5.2.2.3 Impartial witness
    - 5.2.3 Have the following individuals personally sign and date the short form consent document and the summary:
      - 5.2.3.1 Participant/Legally authorized representative
      - 5.2.3.2 Person obtaining consent
      - 5.2.3.3 Impartial witness
    - 5.2.4 If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:
      - 5.2.4.1 Assent of the child was obtained.
      - 5.2.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
    - 5.2.5 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 requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the participant/representative had to be offered the opportunity to document his or her consent in writing, offer the participant/representative the option to document his or her 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.

## 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 Verbal Assent Script (HRP-1708)
  - 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.ird.northwestern.edu/informed-consent/>

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- 6.1.8 IRB website: <https://sites.northwestern.edu/irb2/files/2020/01/eIRB-and-IRB-Electronic-Signature-Policy-GENERAL-1002.pdf>
- 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 Electronic signature policy.

**7 REFERENCES**

- 7.1 21 CFR §50.27
- 7.2 45 CFR §46.117