5.5 Use of the Short Form Consent Document

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for use of a short form written consent document for enrollment in research.

2.0 Policy

It is the policy of the Organization that:

- **2.1.** The use of a short form written consent document is permissible in accordance with HHS regulations at 45 CFR 46.117(b)(2) and FDA regulations at 21 CFR 50.27(b)(2) when:
  - **2.1.1.** A subject/LAR who cannot understand English is unexpectedly encountered.
  - **2.1.2.** There is not sufficient time to develop and obtain IRB approval for a complete ICF written in language understandable to the subject/LAR.
  - **2.1.3.** The research presents the prospect of direct therapeutic benefit to the subject.
- **2.2.** The short form is not a substitute for a complete fully translated ICF when it is anticipated that a significant number of subjects will be non-English speaking. The IRB may require that a translated CF be prepared and used for research where it is reasonable to expect that a significant number of non-English speaking persons will participate.
- **2.3.** Use of the short form is restricted to enrollment of no more than three subjects per language in a given protocol. In order to enroll more than three subjects, the PI is required to have the complete ICF translated into the appropriate language and reviewed and approved by the IRB.
- **2.4.** Use of a short form written consent document is permissible when an external IRB acts as the IRB of record for clinical trials conducted on the premises of the Organization provided the IRB of record approves the use of the short form written consent document.

3.0 Definitions

- **3.1.** Qualified Interpreter: as defined in addendum B to HRPP policy 5.7 (Obtaining Informed Consent from Non-English Speaking Persons, or Persons with Additional Needs or Vulnerabilities). Generally, it must be an individual fluent in English and in the spoken

language of the subject, and preferably who has a basic understanding of the medical or other scientific terminology related to the research.

4.0 Use of the Short Form

- **4.1.** The Short Form states that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's LAR
  - **4.1.1.** The short form will also state that a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research (as required by 45 CFR 46.116(a)(5)(i)) was presented first to the subject, before other information, if any, was provided.
  - **4.1.2.** IRB-approved short forms are available in a variety of languages on the IRB website, along with an English translation of the short form.
- **4.2.** Investigators must complete a Short Form Request within RSS, and the request must be approved by the IRB Executive Chair/designee prior to use of the requested short form.
- **4.3.** The approval to use the short form is valid for two weeks and may be used for one subject only. The approval period can be extended by the Executive Chair/designee with adequate justification.
- **4.4.** If an IRB-approved short form is not available in a language understandable to the subject/LAR, the investigator may develop an appropriate short form based upon the IRB-approved English version of the short form. The completed Short Form Request and the translated Short Form must be submitted to ORA for expedited review and approval before use.
- **4.5.** A Qualified Interpreter who is fluent in both English and the language of the subject/LAR must be identified.
  - **4.5.1.** If a prospective subject/LAR/parent wishes to designate his/her own interpreter a Qualified Interpreter must also be present to ensure the quality and accuracy of the interpretation and this must also be documented. A minor cannot be used as an interpreter.
- **4.6.** A witness who is fluent in both English and the language of the subject/LAR must be identified and must fill the same requirements as a qualified interpreter.
  - **4.6.1.** The Qualified Interpreter may also serve as the witness (with the exception that study staff may not serve as witness).
- **4.7.** The interpreter must be involved in the process of consent as follows:
  - **4.7.1.** The subject/LAR should be given a copy of the short form.
  - **4.7.2.** The person obtaining consent, with the assistance of the interpreter, should explain the use of the short form.
  - **4.7.3.** The person obtaining consent, with the assistance of the interpreter, must
    - **4.7.3.1.** Provide a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research (as required by 45 CFR 46.116(a)(5)(i)) before other information about the research.
    - **4.7.3.2.** Describe the research and the prospective subject's rights (including elements of consent required by 45 CFR 46.116), using the IRB-approved English version of the complete ICF as a guide. As long as the above

information is provided, the complete ICF need not be translated word-for-word.
    - **4.7.4.** The complete ICF, which has been approved by the IRB, will serve as the summary required by 45 CFR 46.117(b)(2).
    - **4.7.5.** Interpreters should be provided with a copy of the short form and the IRB-approved English version of the ICF. Whenever possible, these forms should be provided in advance of initiating the consent process with the subject/LAR.
- **4.8.** Upon conclusion of the consent process the subject/LAR, person obtaining consent, and the witness must sign the forms as follows:
    - **4.8.1.** The subject/LAR must sign and date the short form.
    - **4.8.2.** The person obtaining consent must sign and date the English version of the complete ICF.
    - **4.8.3.** The witness to the oral presentation of the ICF must sign both the Short Form, as well as the English version of the complete ICF.
- **4.9.** A copy of the signed and dated short form and the English version of the complete ICF must be given to the subject/LAR.
- **4.10.** Depending on the nature and duration of the research, the IRB Executive Chair/designee may determine that the English version of the complete ICF must be translated into a language understandable to the subject with a copy given to the subject as soon as possible after enrollment in the research using the short form. In general, this may be required for studies which are significant risk and of long duration.
- **4.11.** The process of consent must be documented in the medical or individual study subject record (if applicable). This documentation should include the names of the individuals involved in the process of consent, including the names and contact information of the interpreter and the witness.
- **4.12.** The enrollment of a minor under circumstances which satisfy the criteria specified above is permitted using the short form signed by the minor's parent/guardian. There is no requirement that the minor be provided with a study information sheet. However, minors, age 13 and above, must sign the short form. Minors between the ages of 7-12 must be verbally assented with documentation in the research or medical record.

DOCUMENT HISTORY:

? Written: 2/5/2016 (Approved: 2/5/2016) - original author not recorded

? Revised: 6/18/2018 - revision not documented

? Revised: 5/13/2021 - Revised to state request form available thru RSS; added BMC staff as eligible interpreter or witness; deleted list of short form available languages; deleted requirement to record time spent in the process of consent; deleted requirement that interpreter separately document the process of consent; corrected references to revised Common Rule; minor stylistic changes

? Revised 10/14/22 – added definition of "Qualified interpreter" to harmonize with HRPP 5.7; clarified that approval to use short form is only valid for 2 weeks and may only be used for one subject; stylistic changes; correction of typographic errors. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board Notified: 11/29/2022

? Revised 11/30/2022 - corrected 4.1.2 from: "IRB-approved short forms are available in a variety of languages on the IRB website in the following languages, along with an English translation of the short form.", to: "IRB-approved short forms are available in a variety of languages on the IRB website, along with an English translation of the short form." (Robert Lewis - IRB Assoc)

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