Instructions for Use of the Short Form of Consent

UNC-CH Office of Human Research Ethics

A *short form* may be used when consenting non-English speakers or illiterate subjects. The short form should be used when you do not anticipate enrolling non-English speakers. If you anticipate enrolling non-English speakers, the consent form must be translated into the subject’s native language. The short form is *not* to be used when a study team has simply failed to make provisions for translated versions of the consent document in commonly spoken languages in the recruitment area/population. If the potential subject is blind, the consent form may be read to the person or the use of an audio version of the consent form (audiotape, digital audio format (e.g., MP3) should be considered.

Federal regulations (21 CFR 50.27(b)(2) and 45 CFR 46.117(b)(2) permits oral presentation of informed consent information (Use of the IRB-approved consent form is acceptable.) in conjunction with a *short form* consent document and a written summary (e.g., IRB approved consent form) of what is presented orally. A witness to the oral presentation is required and the subject must be given copies of both the short form document and the summary. In the event that the consent documents are later translated, subjects who were consented using the short form do *not* need to be re-consented.

When this method of consent is used, there are additional regulatory requirements that must be followed. These include:

* The IRB must approve the full version of the consent form documents (or summary of information to be orally presented to the subject) including stored specimens and HIPAA authorization forms.
* If the consent form includes options (e.g., video-recording, permission to re-contact for future research), the *witness* should mark the subject’s selections on the full version consent document *and* the researcher should also document the selection in the research record.
* The short forms available on the [IRB website](https://research.unc.edu/human-research-ethics/consent-forms/) are considered IRB-approved documents.Several different languages are available. The short forms *do not* need to be submitted separately to the IRB for approval however *only* the study and contact information should be edited. The English version of the HIPAA form should be signed by the subject when using the short form consent process.
* A witness must be present during the oral presentation. The witness may be the interpreter, if one is used, or an independent third party. The witness/interpreter may *not* be the subject’s family member or friend. When consenting non-English speaking subjects, a professional interpreter should be used (i.e., bilingual and fluent in the language) in order to verify the exchange and reduce the potential for undue influence.
* A description of the consent process should be well documented in your study notes.

 **REQUIRED SIGNATURES**:

**HIPAA Authorization form:**

1. Subject or subject’s representative

**Full version consent document:**

1. Witness or witness/interpreter
2. Person obtaining consent

**Short form:**

1. Subject or subject’s representative
2. Witness or Witness/interpreter

IRB Renewal: Report to the IRB, the number of times you used the short form to enroll subjects.

Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject’s consent will not truly be informed and may not be legally effective. In addition, interpreters must be available for studies in which there is ongoing contact with the subject in order to facilitate study procedures, reporting of problems, etc.

If you have questions, please contact the IRB at 919-966-3113.

**Remove instruction page. Replace yellow-highlighted fields on the next page with study-specific information and then remove highlighting.**

### University of North Carolina-Chapel Hill

**Short Form Version for Informed Consent to Participate in a Research Study**

**Study #: IRB\_ID
Study Title: [TITLE]
Principal Investigator: [PI\_NAME]**

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; (v) how confidentiality will be maintained.

When applicable, the investigator will present key information to you before presenting other information.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; (vii) how many people will be in the study, (viii) use of your biologic specimens for commercial profit, (ix) whether you will be told about your research results, (x) whether the research might include whole genome sequencing (xi) information about the research has been or will be submitted for inclusion in a clinical trial registry, and (xii) future research use of your information or biologic specimens.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact the research team at the phone number above any time you have questions about the research.

You may contact the IRB at 919-966-3113 if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

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| Your signature documents your consent to take part in this research. |
|  |  |  |
| Signature of adult subject capable of consent |  | Date |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |
| My signature below documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |