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](http://research.unc.edu/offices/human-research-ethics/additional-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

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

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

Consentement à participer à la recherche

Vous êtes invité(e) à participer à une étude de recherche.

Avant que vous n'acceptiez, le médecin investigateur doit vous parler (i) des objectifs, des procédures et de la durée de la recherche ; (ii) de toute procédure expérimentale ; (iii) de tout risque, désagrément et avantage raisonnablement prévisibles en rapport avec l'étude de recherche ; (iv) de tous les autres traitements et procédures potentiellement bénéfiques ; et (v) de la façon dont la confidentialité sera respectée.

Le cas échéant, le médecin investigateur doit également vous renseigner sur : (i) toute indemnité ou traitement médical disponible en cas de lésion ; (ii) la possibilité de risques imprévisibles ; (iii) les circonstances dans lesquelles le médecin investigateur peut mettre fin à votre participation ; (iv) tous les frais supplémentaires éventuellement à votre charge ; (v) les dispositions prévues si vous décidez de vous retirer de l'étude ; (vi) le moment où vous serez informé des nouvelles découvertes susceptibles d'avoir une incidence sur votre volonté de poursuivre la participation à l'étude ; (vii) le nombre de personnes qui participeront à l'étude.

Si vous acceptez de participer, vous devez recevoir un exemplaire signé de ce document et un résumé écrit de la recherche.

Vous pouvez communiquer avec INSERT CONTACT NAME HERE (INSERT CONTACT PHONE NUMBER HERE) chaque fois que vous avez des questions sur la recherche.

Vous pouvez communiquer avec UNC IRB (919-966-3113) si vous avez des questions sur vos droits en tant que sujet de recherche ou ce qu'il convient de faire si vous êtes lésé(e).

Votre participation à cette étude de recherche est volontaire ; vous ne serez aucunement pénalisé(e) et vous ne perdrez aucun avantage si vous refusez d’y participer ou si vous décidez d'arrêter.

La signature de ce document, signifie que l'étude de recherche, y compris les renseignements ci-dessus, vous a été décrite verbalement, et que vous acceptez volontairement d'y participer.

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