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

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

**FORMULARIO DE CONSENTIMIENTO PARA EL SUJETO DE UNA INVESTIGACIÓN**

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

Se le pide que participe en un estudio de investigación.

Antes de aceptar, el investigador debe hablarle de (i) los objetivos, los procedimientos y la duración de la investigación; (ii) cualquier procedimiento que sea experimental; (iii) cualquier riesgo, molestia y beneficio de la investigación razonablemente previsibles; (iv) cualquier procedimiento o tratamiento alternativo posiblemente beneficioso; (v) de qué manera se mantendrá la confidencialidad.

Cuando corresponda, el investigador le presentará la información clave antes de presentarle otra información.

Cuando corresponda, el investigador también debe hablarle de (i) cualquier compensación o tratamiento médico disponible en caso de que ocurra una lesión; (ii) la posibilidad de riesgos imprevistos; (iii) las circunstancias en las que el investigador puede interrumpir su participación; (iv) cualquier costo adicional que deba pagar; (v) qué ocurre si decide interrumpir su participación; (vi) cuándo se le comunicarán los descubrimientos nuevos que puedan afectar a su voluntad de participar; (vii) cuántas personas participarán en el estudio; (viii) el uso de sus muestras biológicas para obtener beneficios comerciales; (ix) si se le comunicarán sus resultados de la investigación; (x) si la investigación podría incluir la secuenciación del genoma completo; (xi) si la información sobre la investigación se ha enviado o se enviará para su inclusión en un registro de ensayos clínicos; y (xii) el uso de su información o sus muestras biológicas en futuras investigaciones.

Si acepta participar, se le entregará una copia firmada de este documento y un resumen escrito de la investigación.

Puede comunicarse con el equipo de la investigación al número de teléfono mencionado arriba en cualquier momento que tenga preguntas sobre la investigación.

Puede comunicarse con el IRB al 1-919-966-3113 si tiene preguntas sobre sus derechos como sujeto de una investigación o qué debe hacer si sufre una lesión.

Su participación en esta investigación es voluntaria y no sufrirá ningún castigo ni perderá beneficios si se niega a participar o decide interrumpir su participación.

La firma de este documento significa que se le ha explicado de manera oral el estudio de investigación, incluida la información mencionada arriba, y que acepta participar voluntariamente.

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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 |