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

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

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

**研究受试者同意表**

您受邀参加一项试验研究。

在您同意参加之前，研究员必须告诉您 (i) 研究的目的、程序和持续时间；(ii) 任何试验性程序；(iii) 任何可合理预测的研究风险、不适和益处；(iv) 任何可能有益的替代手术或治疗方案；以及 (v) 将如何进行保密。

在适用的情况下，研究员将在展示其他信息之前，先展示关键信息。

如适用，研究员还必须告诉您 (i) 如果出现损伤，您可以获得的任何补偿或治疗；(ii) 出现意外风险的可能性；(iii) 研究员在什么情况下可能让您停止参与研究；(iv) 研究给您带来的任何额外费用；(v) 如果您决定停止参与研究会怎样；(vi) 您何时会被告知可能影响您的参与意愿的新发现；以及 (vii) 将有多少人参与研究；(viii) 出于商业利益使用您的生物标本；(ix) 是否将向您告知您的研究结果；(x) 研究是否可能包括全基因体测序；(xi) 已经或将要提交关于研究的信息供纳入临床试验注册表；(xii) 未来研究将使用您的信息或生物标本。

如果您同意参与，您必须获得此文件的一份签名副本以及本研究的一份书面摘要。

如果您对研究存有任何疑问，则可随时拨打上述电话号码联系研究团队。

如果您对于作为研究受试者的权利或如果受到损伤应该怎么办存在疑问，则可拨打（电话号码）联系 IRB。

您参与本次研究纯属自愿，如果您拒绝参与或决定停止参与本次研究，均不会遭到处罚或失去权益。

签署本文件表明已经有人向您口头描述试验研究的情况（包括上述信息），并且您自愿同意参与研究。

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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 |