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

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

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

 **調査研究被験者の同意書**

あなたに調査研究への参加を願いしております。

あなたが同意する前に、治験責任医師は (i) 研究の目的、手順、および継続期間、(ii) 試験的なあらゆる手順、(iii) 合理的に予測可能な研究のリスク、不快感、および便益、(iv) 可能性のあるあらゆる有益な代替的手順または治療、および (v) 守るべき機密性の程度についてあなたに告知しなければなりません。

必要に応じて、治験責任医師は、主要な情報を提供した後にその他の情報を提供します。

必要に応じて、治験責任医師は、(i) 損傷が発生した場合に提供できるあらゆる補償または治療、(ii) 予測不能なリスクの可能性、(iii) 治験責任医師があなたの参加を停止する可能性のある状況 (iv) あなたに対するあらゆる追加的費用、(v) あなたが参加を取りやめることを決めた場合に発生すること、(vi) 参加しようとするあなたの積極的意思に影響を及ぼす可能性のある新しい知見についてあなたに通知される時期、 (vii)研究に組み込まれる人の数、（viii）商用上の利点のためにあなたの生物標本の使用、（ix）研究結果について知らせてもらえるか否か、（x）研究には全ゲノム解読が含まれているか、（xi）研究は臨床試験のレジストリに記載されるために提出済みあるいは提出される予定があるかどうかに関する情報、および（xii）あなたの情報または生物標本の将来の研究利用について、治験責任医師はあなたに通知しなければなりません。

あなたが参加に同意した場合は、署名された本文書の写しと書面による研究の概要があなたに提供される必要があります。

あなたは研究について質問があるときはいつでも研究チームに上述の電話番号からお問い合わせください。

あなたは、研究の被験者としてのあなたの権利または負傷した場合に行うべきことについて質問がある場合は、IRBにお問い合わせください。。

あなたの本研究への参加は自発的なものであり、参加を拒否したり停止することに決めた場合でも、罰則を受けたり利益を喪失することはありません。

本文書に署名することは、調査研究が上記の情報を含めて口頭であなたに説明されていること、およびあなたが参加することに自発的に同意することを意味します。

|  |
| --- |
| 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 |