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

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

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

**연구 피험자 동의서**

귀하께서는 본 연구 조사에 참여하도록 요청 받으셨습니다.

귀하께서 동의하시기 전에, 연구원이 (i) 연구 조사의 목적, 절차 및 기간; (ii) 임상 시험인 절차; (iii) 연구 조사에 있어서 예측 가능한 위험성, 불편함 및 혜택; (iv) 잠재적으로 도움이 될 수 있는 대체 절차 또는 치료; (v) 비밀 유지 방법 등에 대해 귀하께 알려드려야 합니다.

해당되는 경우, 연구원은 다른 정보보다 중요한 정보를 먼저 제시할 것입니다.

해당되는 경우, 연구원은 (i) 상해가 발생하는 경우에 사용 가능한 보상이나 의학적 치료, (ii) 예측하지 못한 위험의 가능성, (iii) 연구원이 귀하의 참여를 중단시키는 상황, (iv) 귀하께 발생하는 추가적인 비용, (v) 참여를 중단하기로 결정하신 경우에 발생하는 사항, (vi) 귀하의 참여 의사에 영향을 미칠 새로운 사항이 발견되는 경우에 이것을 귀하께 알려드리는 시기, (vii) 연구에 참여하는 피험자 수, (viii) 상업적 이익을 위해 귀하의 생물학적 표본 사용 여부, (ix) 연구 결과에 관한 정보의 제공 여부, (x) 연구에 전체 게놈 서열 분석을 포함할 것인지 여부, (xi) 연구에 대한 정보를 임상 시험 등록부에 포함하도록 제출했는지 또는 제출할 것인지 여부, (xii) 향후 연구에 귀하의 정보 또는 생물학적 표본을 사용할 것인지 여부 등에 대해서도 알려드려야 합니다.

참여에 동의하시는 경우, 본 문서의 서명된 사본과 연구 조사에 대한 요약서가 귀하께 제공되어야 합니다.

연구 조사에 대한 질문이 있는 경우 언제든지 상기에 명시된 전화 번호로 연구 팀에 문의하실 수 있습니다.

연구 피험자로서의 권리나 상해를 입은 경우에 해야 할 일에 대해서는 IRB 전화(전화 번호)로 문의하실 수 있습니다.

본 연구 조사에 대한 귀하의 참여는 자발적이며 귀하께서 연구 참여를 중단하시기로 결정하시더라도 귀하께서 불이익을 받으시거나 귀하에 대한 혜택이 손실되지 않습니다.

본 동의서에 서명하시는 것은 상기의 정보를 포함하여 연구 조사에 대한 사항을 귀하께 구두로 설명해 드렸고 귀하께서는 자발적으로 참여하시기로 동의하셨음을 의미합니다.

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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 |