**COMIRB Policy on the Use of Short Forms** (2 pages)

Non-English speaking subjects may not be enrolled with a short form process of consent documentation unless the use of short forms has been reviewed and approved by the COMIRB. If your protocol is not currently approved for the use of the short forms, there is insufficient time to obtain such approval prior to enrolling the subject, and there is appropriate justification for using the short form without approval, you must submit an [Unanticipated Problem form](http://gcrc.ucdenver.edu/comirb/Unanticipated-Problem-Form.doc) to report the use of the short form without COMIRB approval, along with a [Change form](http://gcrc.ucdenver.edu/comirb/Change-Form.doc) to request approval for any future uses.

A study is permitted to utilize the short form up to three times in the same language. If a fourth subject is to be enrolled, then a translation of the entire consent form should be submitted to COMIRB for approval, along with a [Change form](http://gcrc.ucdenver.edu/comirb/Change-Form.doc) and translator’s credentials.

When a short form is used and the elements of informed consent have been presented orally to the subject or subject’s legally authorized representative (LAR), there should be a witness to the oral presentation. The role of the witness in this situation is to verify that the oral consent process took place in the subject’s (or LAR’s) preferred language and the subject or the subject’s LAR signed the short form. The witness will sign both the short form and the COMIRB-approved English consent form.

For studies utilizing a combined consent and HIPAA authorization form, the HIPAA section must also be translated by the interpreter as part of the consent process. In order to document HIPAA Authorization from the subject or subject’s LAR, the subject or the subject’s LAR (and the witness) will also sign the consent form.

For studies utilizing a consent form and a separate HIPAA B form, the English HIPAA B form must also be translated by the interpreter as part of the consent process. The subject (or the subject’s LAR) and the witness must also sign the HIPAA B form.

A statement in the research records (and on the English consent form) should indicate that the translation took place and identify the translator. If the subject is a patient, a note about the translation should be made in the patient‘s medical records as well. Researchers should try to provide a written translation of the vital emergency contact information.

The following are required for the use of the short form:

Witness

* Witnesses the consent process and the subject's signature
* Must be impartial and independent of the study; Cannot be the potential subject or the person who obtained consent from the subject, but may be the interpreter, or a family member
* Signs both the short form and the English consent form
* Signs the HIPAA B form, if applicable

Interpreter

* Interprets the consent form and facilitate the consent process between the subject and the person obtaining consent

Person obtaining consent

* Person authorized to obtain consent per the protocol
* Conducts the consent process with the assistance of the interpreter
* Signs the English consent form only

Subject

* Signs the short form (for consent) and HIPAA authorization form (combined or separate, for HIPAA authorization)
* Receives a copy of both the short form and the English consent form