Rush University Medical Center
Policies and Procedures

Policy Number:	RA-IRB-202
Category Name:	Research
Title:	Use of Translated Consent Documents for Research Subjects, Including "Short Form" Consents
Type:	Policy and Procedure
Revision Date	1/2011 (replaces 6/2009)
Applies To:	Rush Investigators/Study Staff and Rush IRB Members

Policy:

Federal regulations for the protection of human subjects require that study information be presented in language understandable to the subject. Therefore, subjects who do not speak English must receive a written consent and/or assent document in a language understandable to them <u>and</u> have an interpreter fluent in both English and the subject's spoken language be present during the consent process.

All translated documents must have IRB review and approval prior to use. These translated documents will receive the IRB approval stamp. Translation(s) of informed consent document(s) must be coordinated through the Rush Interpreter Services department, per RUMC Policy #OP-0252 "Foreign Language, Sign Language, Written Translations and Special Auxiliary Aids".

Rationale

Rush University Medical Center (RUMC) will ensure that non-English speaking individuals enrolled in research will be treated ethically, in a manner commensurate with their vulnerable status, and that their participation will conform to the federal regulations for the protection of human subjects

Provision of an interpreter and a translated consent form provides the potential subject with an explanation of the study in his/her native language, an opportunity

to discuss the study with research staff and make an informed decision to voluntarily participate in the study. Explaining study schedules, procedures and risks in the individual's native language maximizes the chances for accurate communication, and gives subjects an opportunity to express concerns and ask questions.

Procedure: Investigators who are targeting primarily non-English reading and/or speaking populations should anticipate the need for written translation(s) of study materials (such as consent and/or assent documents, the HIPAA Authorization Form, and/or any recruitment material, subject instructions, or surveys/questionnaires) prior to submission of the study to the Rush IRB. Investigators are also advised to consider the costs of this translation when preparing their study budget.

For every document submitted in a language other than English, the Principal Investigator is required to submit a letter from the translator testifying to the completeness of the translation.

The Rush IRB reserves the right to request that a translation be submitted to a translator of the IRB's choosing for a second opinion about the completeness of the translation, or to request translation by a translator with credentials more readily acceptable to the IRB.

Use of "Short Form" Consents

A written translation of the entire Rush IRB- approved English consent and/or assent document is always preferred. However, in some cases, a non-English speaking subject may be eligible for a study that has no translated consent document, as the PI could not reasonably foresee enrollment of a potential non-English speaking subject in a timely manner. Under these circumstances federal regulations allow investigators to enroll the potential subject using a "short form" consent document that has been translated into the subject's native language.

The "short form" written consent document must state that the elements of informed consent, as required by federal regulations found under 45 CFR 46.116 and 21 CFR 50, have been presented orally to the subject or the

subject's legally authorized representative. The "short form" should *only* be used for occasional and unexpected enrollment of non-English speaking subjects where the ICF has not been translated into the subject's native language.

The "short form" must be translated into the subject's native language and approved by the Rush IRB prior to use. The IRB must also approve a written summary of what is to be said to the subject or the subject's legally authorized representative. The written summary must include the basic and additional elements of disclosure (when appropriate), as outlined in the Rush Consent Template and RA-IRB-200 "Elements and Documentation of Informed Consent for Research Subjects". The IRB approved informed consent document may serve as the written summary.

When the translated "short form" is used:

- An interpreter must orally present the entire Rush IRB-approved written summary (or consent, if used as the written summary) to the subject in a language understandable to the subject, and the subject must receive a written translation of the "short form" consent document to read;
- The entire consent process must be witnessed by an individual fluent in both English and the language understandable to the subject. The interpreter may serve as the witness;
- The Rush IRB-approved written summary (or consent, if used as the written summary) must be signed by both the investigator and the witness to the consent process,
- The translated "short form" must be signed by both the subject (or the subject's legally authorized representative) and the witness to the consent process; **AND**
- The subject must be given copies of the signed Rush IRB-approved written summary (or consent, if used as the written summary) and the signed, translated version of the "short form" consent document.

The original signed written summary (or consent, if used as the written summary) with the original signed "short form" attached should be placed in the subject's research

record and a copy of both placed in his/her medical record, if appropriate.

Only in rare emergency research circumstances may a bi-lingual family member serve as an interpreter in research. Minor children should never serve as interpreters. Complex ideas and treatment regimens may demand the skills of a trained professional interpreter. Privacy considerations and potential undue influence may arise when family members serve as interpreters. Therefore, Investigators should avoid using family members as translators for research purposes. Instead, the Investigator and his/her study team should coordinate translator services through the Rush Interpreter Services Department.

Informed consent is an ongoing process throughout the life of the study. For those subjects who do not speak English, the PI should address the method for providing continued, qualified interpreter services. For those subjects who understand English but cannot read, speak or write English, the PI must provide the necessary support to ensure the subject's ongoing comprehension of new information that may become available during the study.

Reference	45 CFR 46.117(b)(2), 21 CFR 50.27 (b)(2), OHRP Guidance Document "Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English" (dated November 9, 1995), RUMC Policy #OP-0029
Related Documents	Rush Consent Template, Short Form Templates (English, Spanish, Polish, Arabic, Serbian, Russian, Simple Chinese, Korean)

Last reviewed: 12/23/2011