Rush University Medical Center
Policies and Procedures

Policy Number:	RA-IRB-202
Category Name:	Research
Title:	Enrollment of Subjects Who Do Not Read, Speak, or Understand Written or Spoken English
Type:	Policy and Procedure
Revision Date	2/2014 (replaces 1/2011 version)
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, the consent and assent process for subjects who are limited-English speaking (including subjects who are illiterate, mute, or deaf/hard-of-hearing) or non-English speaking must be conducted in a language or manner understandable to that subject. A Qualified Interpreter fluent in both English and the subject's understood language must 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) by a Qualified Interpreter/Qualified Translator must be completed by Rush Translation Services or a company approved by Rush Translation Services, consistent with RUMC Policy #OP-0252 "Foreign Language, Sign Language, Written Translations and Special Auxiliary Aids".

Rationale

Rush University Medical Center (RUMC) will ensure that limited-English proficient 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 a Qualified 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.

Definitions

Limited English Proficient (LEP): Individuals that are unable to speak, read, write or understand the English language at a level that allows them to have meaningful and effective communication with health care providers.

Qualified Interpreter: A person who provides **sign or foreign** language services and who has received Medical Center approved training in the skill of interpreting; abides by a professional code of ethics and is knowledgeable in medical terminology.

Qualified Translator: A person who provides **written** language services and who has received Medical Center approved training in the skill of translation; and is knowledgeable in medical terminology.

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 expense 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 qualifications of the translator are subject to approval by Rush Translation Services. 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. When being submitted for review and approval by the Rush IRB, translation of study materials that require validation (such as surveys or rating scales) should be

accompanied by certification that the translated version has also been validated.

Use of Translated "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:

- A Qualified Interpreter must orally present the entire Rush IRB-approved written summary (or consent, if used as the written summary) and HIPAA Authorization 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 function of the witness is to attest to the following facts to the best of their knowledge: (a) they were present during the consent process; (b) the person signing the consent form is the subject or the subject's legally authorized representative (when applicable) and; (c) the person signing the form has done so voluntarily. 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" and HIPAA Authorization 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), the signed HIPAA Authorization, and the signed, translated version of the "short form" consent document.

The original signed written summary (or consent, if used as the written summary), original signed HIPAA Authorization, and original signed "short form" should be placed in the subject's research record and a copy of of each document placed in the subject's medical record, if appropriate.

In general, use of a subject-selected interpreter (such as a bi-lingual family member) to interpret communications between a subject and RUMC personnel is not recommended for reasons of confidentiality and accuracy. 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.. Accordingly, RUMC will not use a subject-selected interpreter unless requested by the subject, provided, however, that a family member, friend, or companion may be used to interpret in limited time-sensitive, life-threatening situations.

If a subject desires to use a subject-selected interpreter to interpret communications with RUMC personnel, an interpreter provided by Rush Translation Services ("RUMC-provided interpreter") must provide interpretation

services to explain the availability of interpreter services free of charge to the subject and confirm the subject's request to use the subject-selected interpreter. If a subject confirms his or her desire to use a subject-selected interpreter, then (a) a RUMC-provided interpreter should monitor the encounter to ensure accurate interpretation of clinical information, (b) the offer and declination, including the name of the individual interpreting the offer and declination, should be recorded in the subject's medical and research record by the individual obtaining consent, and (c) the Office of Interpreter Services should be notified. No compensation will be provided to any subject-selected interpreter. A subject will never be asked to provide his or her own interpreter. **Minors may never serve as interpreters.**

Subject safety is always a primary consideration, thus in limited time-sensitive, life-threatening situations a family member, friend, or companion may be used to interpret until a RUMC-provided interpreter is available.

Modification of the Consent Process for Subjects Who Understand English, But Cannot Read, Speak, or Write in English

For subjects who are illiterate or incapable of speaking or writing English due to physical limitations, the consent discussion must follow much of the same processes as outlined above.

A written summary of what is to be orally presented to the subject or the subject's legally authorized representative must be approved by the Rush IRB. The written summary must include the basic and additional elements of disclosure, 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.

The Rush IRB-approved written summary (or consent, if used as the written summary) must be signed by the investigator and a witness who can attest to the following: (a) they were present during the consent process; (b) the person signing the consent form is the subject or the subject's legally authorized representative (when applicable) and; (c) the person signing the form has done so voluntarily. If possible, the subject must also sign the summary.

	For subjects who cannot read or write in English, the subject may sign the written summary (or consent, if used as the written summary) with an “X”. If physical limitations prevent the subject from making their mark, the investigator and witness must sign the written summary and HIPAA Authorization under the subject signature lines, noting the document was presented orally to the subject and that illiteracy or physical limitations that prevented the subject from physically signing the consent. The study team must document in the study records that the entire consent process was conducted under the terms of this policy. Informed consent and participation in a research study is more than a signature on a consent document. For those subjects enrolled who are limited-English proficient, the Investigator should consider methods for providing support for those subjects in order to ensure the subject’s ongoing comprehension of study interventions and new information that may become available during the study. Coordination with both Rush Translation Services and the study Sponsor will be necessary to ensure subjects are able to safely participate in the research.
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: 5/13/2014