BENAROYA RESEARCH INSTITUTE Virginia Mason **STANDARD OPERATING PROCEDURE**	SOP No.	IRB SOP-001
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RESPONSIBLE DEPARTMENT: Research Protections Department (RPD)		
TITLE: Non-English Speaking Subjects in Research		
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APPROVAL SIGNATURES		
Name	Signature	Date
IRB Chair: James Bredfeldt, MD		17-May-2017
Director: Lynn M. Rose, PhD		12-MAY-2017

PURPOSE

This procedure outlines the steps taken to provide informed consent forms and other study documents to non-English speaking subjects in a language they can understand.

SCOPE

This procedure applies to IRB members, IRB staff, Principal Investigators, and other relevant study personnel who may be responsible for implementing this procedure.

DEFINITIONS

The following definitions apply to terms used in this policy:

Certified Translation: translation of a document provided by a certified individual employed at a translation service

Interpret: facilitate oral communication in more than one language; performed by an interpreter.

Interpreter: a person who translates orally for individuals conversing in different languages.

Legally Authorized Representative (LAR): an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Professional Translation: translation of a document by an individual who is not certified, but is fluent in both English and the language of translation and may hold other relevant credentials

Translation: conversion of a written document from one language to another.

Witness: an impartial third party over the age of 18 who is fluent in both languages and not a member of the study personnel. The interpreter may serve this role.

ROLES AND RESPONSIBILITIES

Investigator – Provide non-English speaking research subjects with IRB-approved translated consent form(s) and other study documents as outlined below. Must provide an interpreter and witness in consent process to ensure fully informed consent is obtained.

IRB Chair – Responsible for reviewing and approving English and non-English versions of study documents submitted with New Applications and Study Modifications. May determine whether additional study documents must be translated on a per-study basis.

IRB Member - Responsible for reviewing English and non-English versions of study documents submitted with applications for Full Review. May determine whether additional study documents must be translated on a per-study basis.

PROCEDURE

1. Investigators are strongly encouraged to recruit and include all segments of our community in research, including individuals whose primary language is not English. Participants who do not understand English must be presented with a consent document written in a language understandable to them.

2. At the initial request of inclusion of non-English speaking subjects, and subsequent Continuing Review submissions, the IRB will assess the following issues:
   2.1. Whether use of the short form consent document is permitted;
   2.2. Translation requirements of ancillary study documents;
   2.3. Subsequent translation of the long-form consent document (e.g. more than minimal risk, complex studies, use of LAR, etc.); and
   2.4. Translation requirement for studies with a partial waiver of consent.

3. Use of Interpreters
   3.1. A qualified medical interpreter fluent in both English and the subject's spoken language must be provided during the consent process to ensure the subject understands the consent document and is able to freely ask and receive answers to their questions.

4. Use of Legally-Authorized Representatives (LAR)
   4.1. A non-English speaking LAR may be used to grant consent on behalf of the subject when the subject cannot do so themselves.

5. Use of Witnesses
   5.1. An impartial witness fluent in both English and the subject's spoken language must be present during the consent process.
   5.2. The interpreter may serve as the witness.

6. Use of Translated Documents
   6.1. When non-English speaking subjects are being targeted or will otherwise make up a portion (>5%) of eligible subjects in a study, a professional or certified translation of said

materials in the appropriate language(s) is the preferred method of translation prior to IRB approval. This approval must occur in advance of use.

6.1.1. Professional Translation requirements: a BRI Translation Certificate must be completed by the person providing the translation service and submitted to the IRB with the translated document(s).

6.1.2. Certified Translation requirements: a summary of qualifications of the individual who translated the document(s) or other method of translation must be submitted to the IRB with the translated document(s). For an individual this should include any credentials, certifications, education, native language fluency, etc.

6.2. For new studies, the English and non-English version of document(s) are submitted to the IRB as part of the new application and reviewed by the full IRB committee at a convened meeting. However, the IRB suggests that translated documents be submitted after the English version(s) is/are reviewed and approved by the IRB in case changes are required. The translated document(s) must be submitted according to the Study Modification procedure.

6.3. For ongoing studies, a completed study modification form is submitted along with the IRB approved English version and the translated document(s). The IRB Chair or designee will review the modification according to the Study Modification procedure.

6.4. The following documents must be translated:

6.4.1. Consent/assent forms;

6.4.2. Recruitment materials;

6.4.3. Questionnaires/surveys;

6.4.4. Any other documents provided directly to the subject.

6.5. The fully translated written consent form must be provided to the subject during the consenting process. The following signatures are required:

6.5.1. Research subject;

6.5.2. Interpreter or witness; and

6.5.3. Person obtaining consent.

7. Use of a Short Form Written Consent Document

7.1. When the research study unexpectedly encounters a potential research subject who does not speak English, an IRB approved short form written consent document in the language of the research subject is used. The short form documents that the required elements of consent (21 CFR 50.25, 45 CFR 46.116) were presented orally to the research subject by the interpreter and the study staff member leading the consent discussion.

7.2. The consent process must include oral presentation of the entire IRB-approved English version of the consent form in language understandable to the potential subject

7.3. A witness proficient in English and in the research subject's language must be present throughout the entire consent process. When the subject is assisted by an interpreter, the interpreter may serve as the witness.

7.4. The following signatures are required:

7.4.1. The research subject signs the short form.

7.4.2. The witness signs the short form and the English long-form consent document.

7.4.3. The study staff member obtaining consent signs the English long-form consent document.

7.5. Copies of the short form and English long-form consent documents will be given to the research subject.

7.6. Study personnel must report to the IRB the use of the short form method in the next Continuing Review submission.

TRAINING REQUIREMENTS

Procedure will be posted to BRI's internal website and reviewed with BRI IRB Members, IRB staff, and BRI / VMMC researchers.

REFERENCES

21 CFR 50.20 [General Requirements for Informed Consent]

21 CFR 50.27 [Documentation of Informed Consent]

45 CFR 46.116 [General Requirements for Informed Consent]

45 CFR 46.117 [Documentation of Informed Consent]

OHRP Guidance: Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English [http://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/]

FDA Guidance: A Guide to Informed Consent [http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm]

ATTACHMENTS

None

KEYWORDS

Interpreter; Short-form consent; Translation; Witness

NEXT REVIEW DATE: **12/19/2019**

REVISION HISTORY

Revision Level	Effective Date	Description of Changes
00	12/20/2010	Initial Version of Document

01	12/19/2016	Updates to new formatting; combining and rearranging sections of previously published SOPs.