



**Rowan University Guidance for Obtaining and Documenting  
Informed  
Consent of Research Subjects Who Do Not Speak  
English**

I. PURPOSE

The purpose of this guidance document is to ensure that Non-English speaking persons (or their legally authorized representative or surrogate) are provided information about proposed research in a language they understand in order to exercise autonomy to participate in research offered by and at Rowan University.

II. APPLICABILITY

This document guides all investigators and research staff conducting research involving human subjects and whose studies are subject to the oversight of Rowan University IRB's.

III. DEFINITIONS

A. **Non-English Speaking Participant:** An individual (or their legally authorized representative or surrogate) who is unable to verbally comprehend spoken English or read and comprehend documents written in English.

B. **Qualified Interpreter:** An interpreter is someone who facilitates oral communication between persons speaking different languages. A qualified interpreter is someone who possesses competency in English and a foreign, such as a certified interpreter, native speaker or possesses dual language fluency by education or training, and is able to orally communicate complex diagnostic or medical procedures. Family members may not serve as interpreters for the consent process except in emergency, life- threatening situations. Skill and impartiality are key qualities of an interpreter.

C. **Qualified Translator:** A translator is someone who converts a written text from one language to another. A qualified translator is someone who possesses competency in English and a foreign language, such as a certified translator, native speaker or provides other evidence of dual language fluency, and possesses an appropriate scientific or medical background. A qualified translator may also be an external sponsor which provides a certifiable translation, such as NIH, NSF, NCI, or private industry which provides a certified translation.

D. **Certified Interpreter/Translator and/or Services:** While no national licensing or certification program for medical research translator/interpreters exists in the United States, some universities, independent companies, and professional associations provide training and testing in translation and interpretation services. [Two notable professional associations that offer testing of trained translators/interpreters are The National Board of Certification for Medical Interpreters, <http://www.certifiedmedicalinterpreters.org>, and the American Translators Association, <http://www.atanet.org>.] For purposes of this policy, a certified interpreter or translator is a person

with professional interpreter or translator training and English and foreign language competency demonstrated successfully passing a test offered by a university, company or association. A list of Rowan University-approved local companies are available upon request. Please contact the following IRB offices with questions:

RowanSOM/Stratford IRB Office (856) 566-2712

Social and Behavioral/Glassboro IRB Office (856) 256-4078 or Jeff Lenz at (856) 256-4567

**E. Long-Form Consent Translation:** A written translation of the entire English consent document approved by the IRB into a language understandable by non-English speaking persons (or their authorized representative or surrogate) being recruited for research.

**F. Short-Form Consent Translation:** The short-form is an abbreviated consent document written in language understandable to the prospective participant recruited for research stating that the elements of informed consent, which are outlined on the long-form consent in general terms, have been presented orally and are understood by the participant (or their authorized representative or surrogate). Templates for short-form consents may be found at <http://www.rowan.edu/som/hsp/forms/index.html>

**G. Back Translation:** When a document translated from English to another language is translated back into English to confirm the accuracy of the original translation.

**H. Witness:** An adult who is fluent in both English and the language understandable to the prospective participant who witnesses the entire consent process between an English-speaking study staff member, a qualified interpreter, and the non-English speaking participant when a “short-form” translated consent is used. The witness is required to verify the adequacy of the consent process and the participant’s voluntary consent. The witness must be independent of the study and must be present for the consent discussion. An interpreter may serve as a witness if s/he is not a member of the study staff.

#### IV. BACKGROUND

The Belmont Report identifies justice and respect for persons as two fundamental ethical principles that must underlie conduct of all human subjects’ research. The principle of justice requires that the burdens and benefits of research are equitably distributed and calls for “...fair procedures and outcomes in the selection of research subjects.” The principle of respect for persons requires that “adequate standards for informed consent are satisfied” so that subjects are provided with sufficient meaningful information in order to make autonomous decisions about whether they want to enroll in research.

Rowan University implements these ethical principles by guiding all investigators to:

- a) Provide an ethical and scientific justification for excluding persons who cannot understand or read English from participating in research;
- b) Include non-English speaking persons in research, particularly when the research offers participants the potential for direct benefit, unless the IRB reviews and approves the investigator’s justification for exclusion;
- c) Identify and become knowledgeable about the communities from which they will be recruiting potential participants (as much as practicable); and

- d) Appropriately plan for populations that are likely to be recruited into their research by translating consent documents and related study materials (i.e., brochures, questionnaires, etc.) to allow for appropriate recruitment and consenting.

## V. REFERENCES

### Federal Regulation

Federal regulations (45 CFR 46.116 and 21 CFR 50.20) require that informed consent information be presented to a prospective participant "...in language that is understandable to the subject (or authorized representative)" and, except in infrequent situations, be documented in writing. Participants who are non-English speaking should be provided with a translation of the consent document in a language understandable to them. The federal regulations (45 CFR 46.117 and 21 CFR 50.27) permit two methods by which this requirement can be fulfilled: (1) "**Long Form Method**": a written translation in a language understandable to the participant (or their legally authorized representative or surrogate) of the IRB-approved consent document in its entirety; or (2) "**Short Form Method**": an oral presentation of the IRB-approved consent document and a written translation of an abbreviated, or "short form" consent document stating that the elements of consent have been presented orally to the participant (or their legally authorized representative). Necessary procedures to be followed for each of the two methods are outlined in Section VII below. The IRB determines which procedures are appropriate for documenting informed consent on a protocol specific basis.

A concise summary of other federal regulations, executive orders and guidance documents that direct the necessity for investigators to present consent information to participants in a language that is understandable to them may be found in the professional literature: Bustillos, Dan. 2009. "Limited English Proficiency and Disparities in Clinical Research." Journal of Law, Medicine & Ethics 37(1):28-37.

### New Jersey State Law

The process of obtaining and documenting consent to research of participants who do not speak English is also directed by a number of New Jersey State laws: (1) NJ Admin. Code Title 8, 43G-4.1 NJ Patient Bill of Rights – includes patients' right to receive, as soon as possible, the services of a translator or interpreter to facilitate communication between the patient and the hospital's health care personnel; (2) NJ Admin. Code Title 10 – All recipients of Federal financial assistance, such as any public or private individual in health or social services, must ensure that limited English speaking persons are given meaningful opportunities to participate in their programs, services and benefits. Where language differences prevent meaningful access on the basis of national origin, the Office of Civil Rights Guidance requires that recipient agencies provide oral and written language assistance at no cost to the limited English speaking person; and (3) NJ Admin. Code Title 26 14-4a – "The subject or his guardian, or authorized representative...is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's guardian or authorized representative is fluent...."

### Best Practice

The Association for the Accreditation of Human Research Protection Programs (AAHRPP), an accrediting body for research institutions, outlines best practice standards for consent processes. It states that the consent discussion must be in a language understandable to the participant or their authorized representative. Similar to federal regulation, it approves the use of either the long form or short form method (See Element II.3.F).

## VI. GUIDANCE

The inability to understand spoken English or read and comprehend documents written in English creates a practical barrier for non-English speaking persons to make an informed decision to or actually participate in research. Consistent with its mission to reflect the diversity of its communities in its services and research endeavors, Rowan University's guides investigators to provide research study information in a language potential participants understand to (1) facilitate persons' autonomy to consent to participate in research and (2) ensure equitable and fair procedures for the inclusion of diverse populations in research. The steps outlined below are intended to provide guidance to investigators on appropriate methods to ensure that non-English speaking persons (or their legally authorized representative or surrogate) are provided with sufficient information in order to exercise informed consent to participate in research and how to document that process in the research record.

## VII. PROCEDURE(S)

### A. Long Form Method- Written Translation of an IRB-Approved English Language Consent Document

#### ***When must I use the Long Form Method?***

Rowan University requires investigators to use the **Long Form Method**, a written translation of the entire English language consent document approved by the IRB, assent document and any accompanying study materials

(i.e., brochures, questionnaires, etc., unless the documents have not been validated for use in non-English speaking populations) into a language understandable by potential participants in research when:

- The research targets a specific population that is non-English speaking;
- A significant proportion of participants are anticipated to be non-English speaking; or
- However unanticipated, when five or more persons enrolled in the research do not speak English, but share another language in common.
- **NOTE:** Investigators who request a waiver of necessity for translated consents when conducting **pilot studies** in environments where non-English speaking participants are anticipated must demonstrate how exclusion of non-English speaking participants in the pilot study will not later negatively impact equitable access, participant comprehensibility or research tool applicability to diverse populations that may be solicited for participation in the full research.

#### ***What steps should I follow to ensure an accurate translation?***

After obtaining IRB-approval of the English language consent document to be used in your research study, have a qualified translator translate the IRB-approved document in its entirety. The translation from English to another language may be completed by a person who is a member of the research team, providing they possess the necessary qualifying language competency. If the study is deemed greater than minimal risk, or is otherwise required by the IRB, a back translation must be completed by a qualified person who is independent of the research. Back translations are not required if the original translation is provided by a certified translator. **[Please note:** To conserve resources, it is strongly recommended that investigators first obtain approval for the English version of the consent document before translating it.]

If paragraphs within a proposed consent document were translated by different sources (e.g., some paragraphs were translated by NIH, NSF or NCI, while other paragraphs were provided by department personnel within Rowan University), a back translation of the consent document must be conducted to ensure the pieced together consent maintains the integrity and meaning of the original sources.

### ***How do I obtain IRB approval?***

Translations of the consent documents must be reviewed and approved by the IRB before their use. It is recommended that investigators first obtain approval for the English version of the consent document, and then submit translation(s) of other language(s) and back translations, if applicable, as a modification to the approved protocol. The following items should be submitted for IRB review and approval of the foreign language translation of the full consent document:

- IRB-approved English language consent document;
- Consent document translated into the desired language;
- A letter or other written documentation confirming that the translation (and back translation, as applicable) is accurate and consistent in content, style, and level of readability with the IRB-approved document and, for non-certified translators, an explanation of the translator(s)' qualifications (See Exhibit A). The letter or other written documentation should reference the study title and IRB approval number, as well as document identifier(s) (i.e., title and IRB-approved version date) that is unique to each IRB-approved item being translated (and back-translated, as applicable); and
- A plan to ensure an adequate consent process and an outline of how communication between the non- English speaking person (or their legally authorized representative or surrogate) will be facilitated throughout the course of the research.

The accuracy of documents translated must be confirmed by a qualified translator whose credentials are acceptable to the IRB. The IRB will use its discretion in determining whether the credentials of the translator are acceptable, based on the nature and level of risk involved in the proposed research study:

- Consent and supporting documents must be translated by a qualified translator for minimal risk studies;
- Consent and supporting documents must be translated by a qualified translator **and** then back-translated by another qualified translator for greater than minimal risk studies. However, if the research is a minor increment over minimal risk, the IRB may waive the requirement of the back translation into English;
- Certified translated consent and supporting documents do not require back-translation, regardless of risk determination; and
- The IRB may require a certified translation depending on the complexities of the proposed research.

### ***What consent process must I follow when using the Long Form Method?***

The following consent process should be followed when using the Long Form Method to ensure that non-English speaking participants can provide meaningful informed consent:

- If a member of the study staff obtaining consent is not fluent in the potential participant's language, a qualified interpreter fluent in English and the participant's language must orally interpret the consent conversation, ask if the participant has any questions and then be available to answer their questions. Interactive 3-way communication is essential to ensure informed consent; and
- The person, if agreeing to participate, and a member of the research team obtaining consent must sign and date the IRB-approved non-English language version of the consent document. If a qualified interpreter is present, they should also sign the consent. If a qualified telephone interpreter

is used, their participation should be appropriately documented on the consent document and the research record by the research staff (document the date, time, language, interpreter ID#, and interpreting company used) (See Exhibit B for recommended documenting format)

## **B. Short Form Method – Oral Presentation of the IRB-Approved Consent Document and a Written Translation of an Abbreviated, or Short Form, Consent Document**

### ***When may I use the Short Form Method?***

The short form method—the use of an oral presentation of the IRB-approved consent document and a written translation of an abbreviated, or short form, consent document stating that the elements have been presented orally to the potential participant (or their legally authorized representative) in a language understandable to the participant—may be used when all of the following apply:

- The research does not target a non-English speaking population;
- The research is classified as minimal risk or greater than minimal risk but with prospect for direct benefit;
- The participant (or legally authorized representative) speaks only a language(s) that was not anticipated in the potential study population. **Please note:** the Short Form Method may not be used when the potential participant is represented by a surrogate—only use the Long Form Method in these instances;
- An appropriately translated consent document in the participant’s language has not been approved by the IRB; and
- Fewer than 5 participants enrolled in the research do not speak English but do share another language in common.

***What steps should I follow to ensure an adequate oral presentation and short-form written translation?*** Templates for the short form consent in English and a number of other languages are available at the IRB website (<http://www.rowan.edu/som/hsp/forms/index.html>). Choose the short form consent written in the language the subject is fluent. Have a qualified translator translate the study title and insert it at the top of the short form. If the study is greater than minimal risk, a back-translation of the title by a second qualified translator is recommended. If the translator is certified, a back translation is not necessary.

### **How do I obtain IRB approval?**

When you wish to enroll a non-English speaking person in IRB-approved research but do not have a written translation of the entire English language consent document approved by the IRB, you must notify the IRB and request use of a non-English language abbreviated short form consent. Investigators should contact and then submit to the IRB (1) a modification request; (2) the translated short form consent; and (3) documentation of translator(s) qualifications (Exhibit A). The IRB will respond to the request within 48-

72 hours. **Please note:** IRB approval of the non-English language short form consent document and process is required prior to their use, even when using the Rowan University IRB downloadable templates.

When five or more persons enrolled in the research do not speak English, but share another language in common, the investigator must obtain an IRB-approved translation of the IRB-approved consent document and follow the long form method outlined above.

### **What consent process must I follow when using the Short Form Method?**

The following consent process should be followed when using the Short Form Method to ensure that non-English speaking persons can provide meaningful informed consent:

- A qualified interpreter fluent in English and the potential participant's language must orally present the entire English language IRB-approved consent form in a language understandable to the participant (or his/her legally authorized representative). The interpreter must also ask if the participant (or his/her legally authorized representative) has any questions and then be available to answer their questions. Interactive 3-way communication is essential to ensure informed consent. The interpreter may be a member of the research team. If a bilingual investigator serves as the qualified interpreter, there must also be a witness to the presentation who is fluent in English and the language understood by the potential participant (or his/her legally authorized representative). The witness may not be a member of the study staff.
- The potential participant (or his/her legally authorized representative) is provided a copy of the abbreviated short form consent written in the language they are fluent in to review;
- A witness to the oral presentation fluent in English and the participant's (or their legally authorized representative) language is required to attest to the adequacy of the consent process and to the participant's (or their legally authorized representative's) voluntary consent. An interpreter may serve in the dual role as interpreter and witness, if s/he is not a member of the study staff.

### **Requirements for documenting the consent process when using the short form:**

- The participant (or their authorized representative) must sign and date the short form written in the appropriate language, if agreeing to participate;
- The witness, who may not be a member of the research team, must sign and date the foreign language short form and the orally presented IRB-approved English language consent form;
- The principal investigator or research team member obtaining consent must sign and date a written copy of the orally presented IRB-approved English language consent form;
- A copy of the signed short form in the participant's language and the orally presented IRB-approved English language consent form must be given to the participant (or their authorized representative); and
- The consent process, including the language used and presence of interpreters and witnesses,

should be appropriately documented on the consent form and in the research record (by study staff (document the date, time, language, interpreter ID#, and interpreting company used). (See Exhibit Informed consent is a process that requires investigators to continuously reassess the participant's understanding of the nature of the research, its risks of harm and potential for benefit. Adequate communication between the research staff and participant must occur throughout the research to ensure the participant's willingness to continue participation in the research, the safety and welfare of the participant and the integrity of the research data. To avoid delay in participant recruitment and enrollment, investigators are urged to anticipate the presentation and language requirements of potential non-English speaking persons.

## VIII. EXHIBIT

- Exhibit A. Statement of Translator Qualifications and Confirmation of Translation Form (see page 7)
- Exhibit B. Recommended Signature Page Format for Persons Who Do Not Speak English (see page 8)

**Exhibit A: Statement of Translator Qualification & Confirmation of Translation Form**

**Statement of Translator/Interpreter Qualifications**

To Be Completed by Translator or Interpreter:

I confirm that I am a qualified translator or interpreter: I am a certified translator or interpreter, native speaker **OR** have professional education and training in the foreign language I am translating or interpreting **AND** possess an appropriate scientific or medical background. I possess competency in English and \_\_\_\_\_ (specify language). My qualifications are as follows:

A. Foreign Language Proficiency

\_\_\_\_\_ I am certified by \_\_\_\_\_ (name of institution/company providing certification). My certificate number is \_\_\_\_\_. **OR**

\_\_\_\_\_ I am not certified. However, I possess the following qualifications to serve as a qualified translator or interpreter (e.g., it is my native language, I have X number of years of education and training in this foreign language, or I have other evidence of dual language fluency.) Please explain or attach resume as applicable.

\_\_\_\_\_

Translator/Interpreter Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(please print)

**Exhibit B: Recommended Signature Page Format for Persons Who Do Not Speak English**

**AGREEMENT TO PARTICIPATE**

**Consent for Myself:**

I have read this form, or it has been read to me, and I understand what has been discussed. My questions about the research and this consent form have been answered to my satisfaction. I give my consent to take part in this research.

Participant's Name: \_\_\_\_\_

(please print your name)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_

**Consent for My Child, or as the Legally Authorized Representative or Surrogate of the Participant:**

I give my consent for my child, for a child for whom I am a guardian, as the legally authorized representative or as a surrogate of the participant to take part in this research and agree to allow him or her to participate in the research as described above.

Participant's Name: \_\_\_\_\_

(please print their name)

Parent/Guardian/Representative/Surrogate: \_\_\_\_\_

(please print your name)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Signature of Investigator or Person Authorized to Obtain Participant's Consent:**

To the best of my ability, I have explained and discussed the research study including all of the information contained in this consent document. All questions of the participant and/or of the participant's parent/guardian/representative/surrogate have been accurately answered and the participant has been given a copy of the consent.

Investigator/Person Obtaining Consent: \_\_\_\_\_

(please print your name)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Signature of Witness (as applicable—when using "Short Form Consent")**

Witness Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Signature of Qualified Interpreter (as applicable):**

The person, who has signed above, \_\_\_\_\_, does not read or speak English well. I read English well and am fluent in \_\_\_\_\_, a language the participant (or his/her representative) understands well. I understand the content of this consent document and confirm that, to the best of my knowledge and belief, I have accurately interpreted the entire content of this document. The participant (or his representative) has had an opportunity to ask questions about the research and this consent document, and these questions have been answered.

Qualified Interpreter (if present): \_\_\_\_\_

(please print your name)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Qualified Interpreter (if service provided by telephone):

ID# \_\_\_\_\_ Time: \_\_\_\_\_ Date: \_\_\_\_\_ Interpretation Co Name (If applicable): \_\_\_\_\_

