Grand Valley State University Institutional Review Board (IRB)	
Title*: Informed Consent for Persons Not Fluent in the Primary Language of the Study*	
Section: 814.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012 Revised: 08/01/2012 Reviewed: 10/28/2014 Revised by HRRPPC: 04/24/2018 Revised by IRBPPC: 02/03/2025	Approved by RIO/HRPA: 02/16/2012 Revisions Approved: 08/01/2012 Revisions approved by AIO/RIO: 05/23/2018 Revision approved by AIO/RIO: 3/16/2020 Revisions approved by IO: 06/15/2025
Effective Date: 06/15/2025	
Related documents: *710: Assessing Risk to Research Participants* *720: Assessing Risk to Vulnerable Participants* *810a: Informed Consent: General [Pre-Revised Common Rule Version]* *810b: Informed Consent: General [Revised Common Rule Version]* *812: Research Involving Children* *813a: Research Involving Participants with Questionable Consent Capacity and/or Legally Authorized Representatives [Pre-Revised Common Rule Version]* *813b: Research Involving Participants with Questionable Consent Capacity and/or Legally Authorized Representatives [Revised Common Rule Version]* *820a: Waivers, Alterations and Exceptions to Informed Consent Process and Documentation [Pre-Revised Common Rule Version]* *820b: Waivers, Alterations and Exceptions to Informed Consent Process and Documentation [Revised Common Rule Version]*	

Policy

1. Informed consent must be obtained using written or verbal communication in a language that is easily understandable to the participant. If the potential participant is not fluent in the primary language of the study, the information can be presented verbally by a person who is fluent in the relevant language. Researchers will use one of the following three methods for obtaining and documenting informed consent:

    a. the standard written long-form,
    b. the written short-form process with accompanying verbal presentation, or
    c. IRB-approved waiver of written documentation and use of verbal consent only.

2. This policy applies to all research involving interactions with participants. The investigator must provide both English and translated versions of all materials that will be provided to the participants in the language(s) used in the study. This includes recruitment materials, consent, assent and permission forms, surveys, questionnaires, and other written information. The investigator must provide written verification of both the linguistic accuracy and cultural appropriateness of the translated materials into the non-English language.

Procedures

1. Method #1—Long-Form (Written) Consent

    a. The written consent document shall be in a language understandable to the participant or to the participant's legally authorized representative (LAR). When documents are translated from one language to another, investigators should document the validity of whatever translation process they propose to use. Such documentation would normally include:

        i. Translation of the IRB approved consent document from one language to another by a translator who is fluent in both languages, and

        ii. A signed statement from a second translator *who is fluent in both languag*es attesting that the two documents are substantively equivalent in meaning and reflecting appropriate cultural sensitivity. The qualifications of each translator and date of translations must be documented.

2. Method #2—Short-Form Consent

    a. The short-form written consent document is a brief statement, signed by a witness, testifying that the elements of informed consent as required for the long-form have been presented orally to the participant or the participant's LAR. The short-form method may be utilized with participants who are illiterate or otherwise unable to read and/or sufficiently understand the written long-form consent document.

    b. The researcher must be prospectively approved to use the short-form consent document. A translated version of the short-form consent in the relevant language(s) must be approved by the IRB prior to use.

    c. If the research intends to focus on participants who are not fluent in the language of the study, the short-form consent document is not appropriate for use. In these cases, the long-form consent document must be translated into the relevant language(s) and approved by the IRB prior to use.

3. Method #3—Waivers

    a. In some circumstances, waivers and alterations to the standard long-form or the short-form process may be warranted. See IRB Policy 820: *Waivers, Alterations, and Exceptions to Informed Consent Process and Documentation.*

Guidance

1. Elements of the Short-Form Consent Process for Oral Presentation

a. The following are needed to fulfill IRB requirements for this method:

   i. English version of the full informed consent document
   ii. Written short form of the consent information in a language understandable to the participant
   iii. The name of the interpreter
   iv. The name of the person obtaining consent
   v. The name of the witness to the oral presentation, who must be fluent in both languages

(i) English version of the full informed consent document:
The IRB-approved informed consent document must be provided to the participant or their LAR.

(ii) Written short-form consent:
A brief statement that the elements of informed consent were presented orally in a language understandable to the participant or their LAR. The statement must be signed and dated by the participant or participant's LAR and the witness. A copy shall be provided to the participant or their LAR.

(iii) Interpreter:
The person who will orally present the information contained in the English version of the long-form consent to the research participant(s) and who is fluent in both of the relevant languages. The interpreter should not be related to, or a close associate of, the participant or the LAR. The interpreter may also be the person obtaining consent, provided they are an approved member of the research team. The interpreter may also serve as the witness, but cannot be both the person obtaining consent and the witness.

(iv) Person obtaining consent:
The person obtaining consent must be an approved member of the research team. They must have enough knowledge about the research to be able to answer questions the participant or their LAR may have about the study. The person obtaining consent may also serve as the interpreter, provided they are fluent in both of the relevant languages.

(v) Witness to the oral presentation:
A person who is fluent in both of the relevant languages must be present to witness the oral presentation of the elements of consent and the consent itself.

2. OHRP Sample Short-form Consent

   a. When printed, this document should include the GVSU logo and must be written in a language understandable to the participant or their legally authorized representative.

b. The short-form consent document must be submitted for IRB approval at the time of initial IRB review or via a modification after initial approval. It cannot be used until it has received approval.

SAMPLE SHORT FORM WRITTEN CONSENT DOCUMENT FOR PARTICIPANTS WHO ARE NOT FLUENT IN ENGLISH

Consent to Participate in Research

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact ____(researcher name)____ at ___(phone number/email)__ any time you have questions about the research.

You may contact the GVSU Office of Research Compliance and Integrity at 616-331-3197 if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

Participant Name (printed): _____

Participant Signature: _____

Date Signed:_____

Witness Name (printed): _____

Witness Signature: _____

Date Signed:_____