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	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
Effective Date: 01/21/2019	
Related documents: *710: Assessing risk to research participants* *720: Assessing risk in vulnerable participants* *810 Informed consent – general* *812: Informed assent and parental permission* *813: Research involving participants with questionable consent capacity and/or legally authorized representatives* *820: Waivers, alterations and exceptions to informed consent process and documentation*	

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 reading literate, the information can be presented verbally by a person who is fluent in the relevant language. The basic requirements for obtaining and documenting informed consent are stated in the federal regulations (45 CFR 46.116 and 46.117, and subparts B, C and D), but specific procedures for implementation are determined by the IRB. Based on the circumstances, 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. The investigator must provide to the IRB a copy of the materials used in the study that will be provided to the participants in the language(s) used in the study. This includes all recruitment materials, consent, assent and permission forms. If the language used is not English, an English translation of the materials also must be provided along with verification of both the linguistic accuracy and cultural appropriateness of the translation materials into the other language.

Procedures

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

    The written consent document shall be in a language understandable to the participant or to the participant's legal representative. 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,

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

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 legally authorized representative. 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. For further details about the requirements for utilizing the short-form process, see *Elements of the Short-Form Consent Process for Oral Presentation* in the **Guidance** section below.

3. Method #3—Waivers

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.***

Background

The Code of Federal Regulations at 45 CFR 46.116 states: *The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.*

Guidance

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

The short-form written consent is a method typically utilized with participants who are illiterate or otherwise unable to sufficiently understand the written long-form consent document. The following are needed to fulfill IRB requirements for this method:

i. The name of the oral presenter
ii. Written summary of consent information (elements of consent specified in 45 CFR 46.116)
iii. Written short-form of the consent information
iv. The name of the witness to the oral presentation
v. The name of the person obtaining consent

(i) Oral presenter:
The person who will orally present the information contained in the written summary (translated version of English long-form consent) to the research participant(s) and who is fluent in both of the relevant languages. The oral presenter shall not be related to, or a close associate of, the participant or the legally authorized representative. The oral presenter may also be the person obtaining consent, provided that he/she meets the IRB requirements for person obtaining consent, as described in Section (v) below. The oral presenter may not also serve as the witness.

(ii) Written summary (documentation of the elements of consent):
Translation of the information to be presented orally to the research participant(s). The translator's signed attestation statement must accompany the summary, along with a brief statement that the document was presented orally. The summary must be signed and dated by the witness, the person obtaining consent, and the oral presenter (if different from the person obtaining consent). A copy of this signed and dated document shall be provided to each participant or his/her legally authorized representative.

(iii) Written short-form consent:
A brief statement that the elements of informed consent (from section (ii) above) were presented orally in a language understandable to the participant or his/her legally authorized representative. The statement must be signed and dated by the participant or participant's legally authorized representative and the witness. A copy shall be provided to the participant or his/her legally authorized representative.

(iv) 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. The witness may not serve as the oral presenter, but may be the person obtaining consent.

(v) Person obtaining consent:

This person supervises the process of obtaining informed consent and must have enough knowledge about the research project to be able to answer questions the participant or his/her legally authorized representative may have about the study. The person obtaining consent also may serve as *either* the oral presenter or the witness (but not both) provided he/she meets all IRB requirements for those positions (specified above), which includes being fluent in both of the relevant languages. The person obtaining consent should not be related to, or a close associate of, the participant or his/her legally authorized representative.

2. OHRP Sample Short-form Consent

[Note: THIS DOCUMENT MUST BE PRINTED ON **GVSU LETTERHEAD** AND WRITTEN IN A LANGUAGE UNDERSTANDABLE TO THE SUBJECT]

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 ____name____ at ___phone number__ 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.

Signature of participant	Date
Signature of witness	Date

PRINTED NAME OF THE WITNESS: _____