OBTAINING AND DOCUMENTING INFORMED CONSENT OF NON-ENGLISH SPEAKING RESEARCH PARTICIPANTS

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JUSTICE

The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

THE THREE BASIC ETHICAL PRINCIPALES

1. RESPECT FOR PERSONS

- INDIVIDUALS SHOULD BE TREATED AS AUTONOMOUS AGENTS
- PERSONS WITH DIMINISHED AUTONOMY ARE ENTITLED TO PROTECTION

2. BENIFICIENCE

- DO NOT HARM
- MAXIMIZE BENEFITS, MINIMIZE RISK

3. JUSTICE

- EQUAL DISTRIBUTION OF BURDENS AND BENEFITS
- TO EACH PERSON EQUAL SHARE
- TO EACH PERSON ACCORDING TO INDIVIDUAL NEED, EFFORT, SOCIETAL CONTRIBUTION , AND/OR MERIT

Governing Principle of Human Subject Research

JUSTICE

a) not exclude subjects based solely on their inability to read, speak or understand English

and

b) Researchers should find a way to communicate with subjects to ensure that consent is voluntary and informed.

AS REQUIRED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATIONS

(45 CFR 46.116 AND 45 CFR 46.117(B)(1)
AND
FDA REGULATIONS (21 CFR 50.25 AND 21 CFR 50.27)

Unless written consent has been waived as a requirement for the study, participants who do not speak English must be provided with:

- A written consent document in a language understandable to them

AND

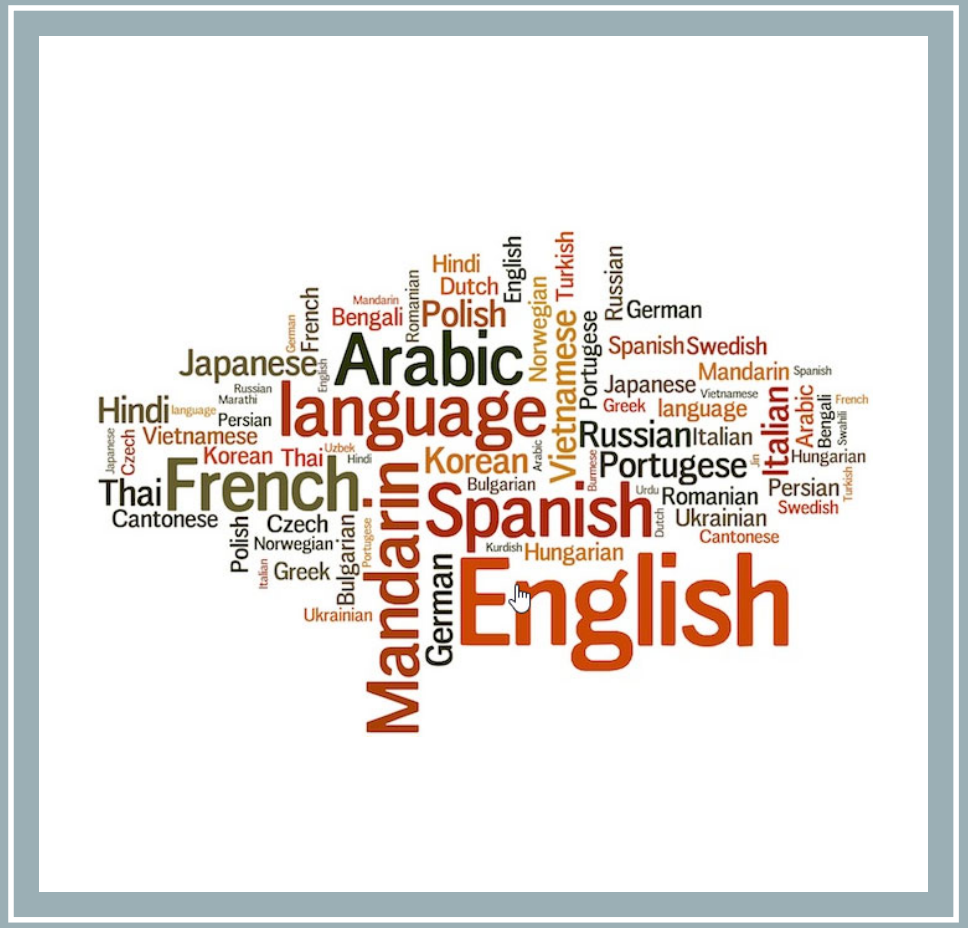
- An interpreter fluent in both English and the participant's spoken language to aid in the consent process

ASSURING TRULY INFORMED CONSENT

- **Certified Translator:** a professional translator who has successfully completed a certification program or exam providing them with certified translator credentials
- **Interpreter:** person who accompanies researchers, in real time, to convey verbal information to another person in their native language

TWO METHODS OF CONSENT:

LONG FORM
OR
SHORT FORM



WHEN DO I USE THE LONG FORM CONSENT PROCESS? §46.117(B)(1)

- Investigator is targeting a non-English speaking group
- Research will be done in a foreign country
- Investigator anticipates more than a few participants who speak the same non-English language will want to enroll in the study

LONG FORM CONSENT PROCESS

1. English language version of consent.

Documents should first be submitted to the IRB in English, and once approved, be sent to the translator. A modification should then be submitted to provide the translated documents.

2. The following items must be resubmitted for final approval of the translated documents:

- 1. Participants primary language version of the consent.
- 2. Documentation describing the qualifications of the translator and the date of translation.

CONSENT PROCESS, SIGNATURES AND RECORD-KEEPING REQUIREMENTS WITH TRANSLATED LONG FORM

1. Conduct the participant's informed consent process with the researcher and an **interpreter** fluent in both English and the participant's primary language.

2. The participant signs the translated informed consent.

3. The researcher or designee signs the translated informed consent

(*interpreter may interact in person, by phone or video-conferencing and does not need to sign the consent form*).

4. The participant is given a copy of the translated informed consent.

5. A copy of the signed documents is maintained in the study records.

6. A copy of the signed documents should be included in the participant's medical records *if that is the standard practice for this study.*

WHEN DO I USE THE SHORT FORM CONSENT PROCESS? §46.117(B)(2)

- When your study was approved with an English only consent and an UNEXPECTED non-English speaking participant presents for enrollment and there is ***not enough time*** to translate the English version of the approved consent document into a language the potential participant understands.
- When enrolling a non-English speaking participant who may not have a written language (Mai-Mai)

WHAT IS A SHORT FORM CONSENT?

- A consent document written in a language understandable to a non-English speaking individual [or his/her legally authorized representative (LAR)].
- It summarizes the required elements of informed consent outlined in the federal regulations, but **it does not contain specific study information.**

Consent to Participate in Research

The use of "you" throughout this document refers to the research participant. It also refers to the person authorized to give consent for the subject's participation in this research study.

You are being asked to participate in a research study. Before you agree, you must be provided with a summary of the key information to help you understand the reasons why you might or might not want to join the 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 alternate procedures of treatment;
(v) how confidentiality will be maintained; and
(vi) who to contact with questions, complaints, and injuries

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 stop your participation;
(iv) any additional 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;
(vii) how many people will be in the study; and
(viii) how you need to authorize use of you medical information for the study.

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 form means that the research study, including the above information has been described to you orally, and that you voluntarily agree to participate. If you agree to participate, you must be given a signed copy of this document and a written summary of the research in English.

If you have questions, complaints, injuries, or concerns about this study, you can contact the investigator using the phone numbers in the written study summary. If you have questions regarding your rights as a research participation, or if you have questions, complaints or concerns which you do not feel you can discussion with the study team, please contact the Human Research Protection Advocate by using the phone number in the written study summary.

Signature of Participant	Name of Participant	Date/Time (if required)

Witness

By signing this form, you are indicating that:

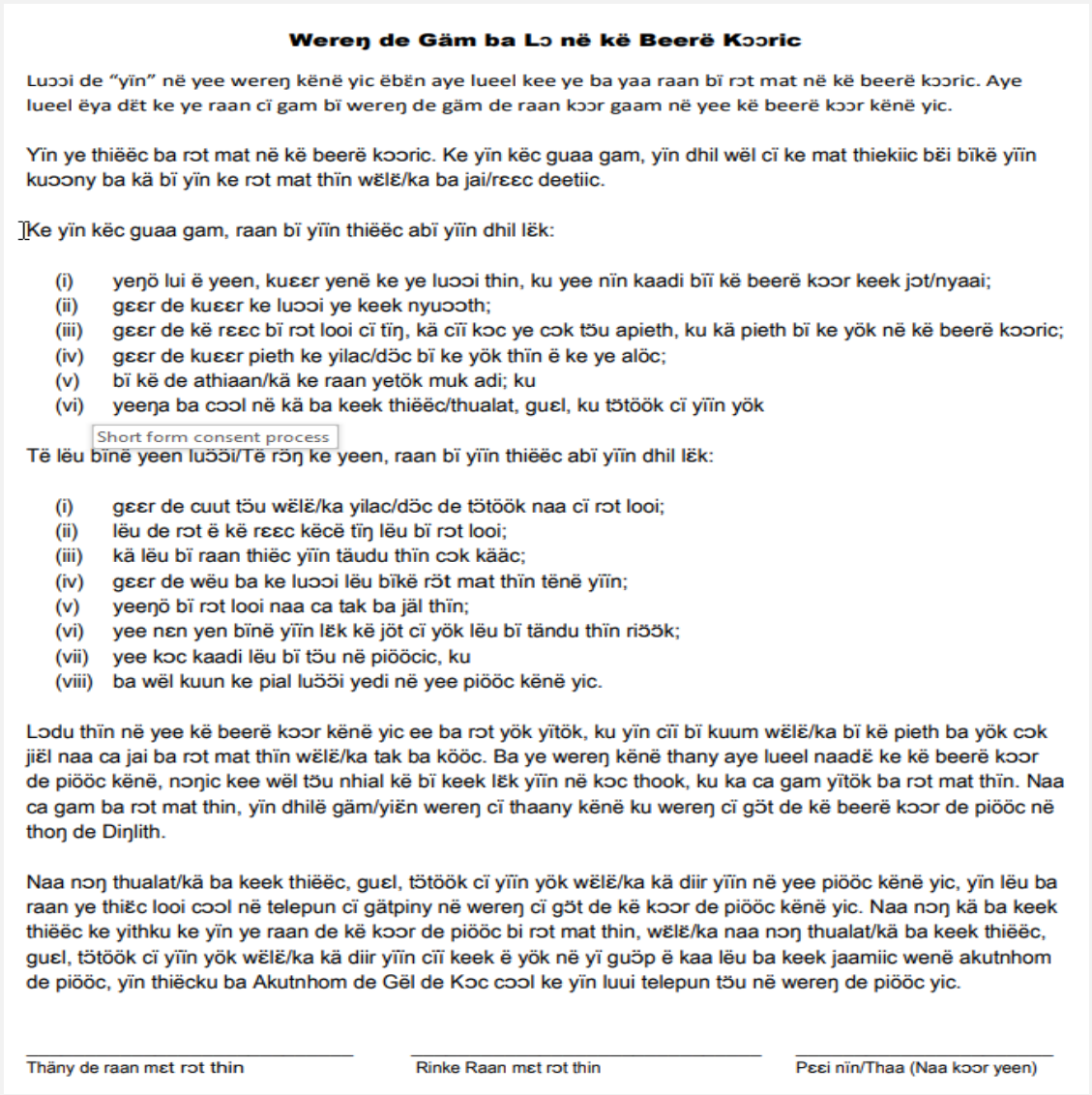
- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

Signature of Witness	Name of Witness	Date/Time

Interpreter Attestation:

I affirm that I interpreted the summary as presented, as well as the patient's questions and the researcher's responses to the best of my ability.

Signature of Interpreter	Name of Interpreter	Date/Time



Wereŋ de Gäm ba Lɔ në kë Beerë Kɔɔric

Luɔɔi de "yïn" në yee wereŋ kënë yic ëbën aye lueel kee ye ba yaa raan bï rɔt mat në kë beerë kɔɔric. Aye lueel ëya dët ke ye raan cï gam bï wereŋ de gäm de raan kɔɔr gaam në yee kë beerë kɔɔr kënë yic.

Yïn ye thiëëc ba rɔt mat në kë beerë kɔɔric. Ke yïn këc guaa gam, yïn dhil wël cï ke mat thiekiic bɛ̈i bïkë yïïn kuɔɔny ba kä bï yïn ke rɔt mat thïn wɛ̈lɛ̈/ka ba jai/rɛɛc deetiic.

Ke yïn këc guaa gam, raan bï yïïn thiëëc abï yïïn dhil lɛ̈k:

(i) yeŋö lui ë yeen, kuɛɛr yenë ke ye luɔɔi thin, ku yee nïn kaadi bïï kë beerë kɔɔr keek jɔt/nyaai;
(ii) gɛɛr de kuɛɛr ke luɔɔi ye keek nyuɔɔth;
(iii) gɛɛr de kë rɛɛc bï rɔt looi cï tïŋ, kä cïï kɔc ye cɔk tɔ̈u apieth, ku kä pieth bï ke yök në kë beerë kɔɔric;
(iv) gɛɛr de kuɛɛr pieth ke yilac/dɔ̈c bï ke yök thïn ë ke ye alöc;
(v) bï kë de athiaan/kä ke raan yetök muk adi; ku
(vi) yeeŋa ba cɔɔl në kä ba keek thiëëc/thualat, guɛl, ku tɔ̈tɔ̈ök cï yïïn yök

Short form consent process

Të lëu bïnë yeen luɔ̈ɔ̈i/Të rɔ̈ŋ ke yeen, raan bï yïïn thiëëc abï yïïn dhil lɛ̈k:

(i) gɛɛr de cuut tɔ̈u wɛ̈lɛ̈/ka yilac/dɔ̈c de tɔ̈tɔ̈ök naa cï rɔt looi;
(ii) lëu de rɔt ë kë rɛɛc këcë tïŋ lëu bï rɔt looi;
(iii) kä lëu bï raan thiëc yïïn täudu thïn cɔk kääc;
(iv) gɛɛr de wëu ba ke luɔɔi lëu bïkë rɔ̈t mat thïn tënë yïïn;
(v) yeeŋö bï rɔt looi naa ca tak ba jäl thïn;
(vi) yee nɛn yen bïnë yïïn lɛ̈k kë jöt cï yök lëu bï tändu thïn riɔ̈ɔ̈k;
(vii) yee kɔc kaadi lëu bï tɔ̈u në piööcic, ku
(viii) ba wël kuun ke pial luɔ̈ɔ̈i yedi në yee piööc kënë yic.

Lɔdu thïn në yee kë beerë kɔɔr kënë yic ee ba rɔt yök yïtök, ku yïn cïï bï kuum wɛ̈lɛ̈/ka bï kë pieth ba yök cɔk jiël naa ca jai ba rɔt mat thïn wɛ̈lɛ̈/ka tak ba kööc. Ba ye wereŋ kënë thany aye lueel naadë ke kë beerë kɔɔr de piööc kënë, nɔŋic kee wël tɔ̈u nhial kë bï keek lɛ̈k yïïn në kɔc thook, ku ka ca gam yïtök ba rɔt mat thïn. Naa ca gam ba rɔt mat thin, yïn dhilë gäm/yiɛ̈n wereŋ cï thaany kënë ku wereŋ cï gɔ̈t de kë beerë kɔɔr de piööc në thoŋ de Diŋlith.

Naa nɔŋ thualat/kä ba keek thiëëc, guɛl, tɔ̈tɔ̈ök cï yïïn yök wɛ̈lɛ̈/ka kä diir yïïn në yee piööc kënë yic, yïn lëu ba raan ye thiɛ̈c looi cɔɔl në telepun cï gätpiny në wereŋ cï gɔ̈t de kë kɔɔr de piööc kënë yic. Naa nɔŋ kä ba keek thiëëc ke yithku ke yïn ye raan de kë kɔɔr de piööc bi rɔt mat thin, wɛ̈lɛ̈/ka naa nɔŋ thualat/kä ba keek thiëëc, guɛl, tɔ̈tɔ̈ök cï yïïn yök wɛ̈lɛ̈/ka kä diir yïïn cïï keek ë yök në yï guɔ̈p ë kaa lëu ba keek jaamiic wenë akutnhom de piööc, yïn thiëcku ba Akutnhom de Gël de Kɔc cɔɔl ke yïn luui telepun tɔ̈u në wereŋ de piööc yic.

Thäny de raan mɛt rɔt thin | Rinke Raan mɛt rɔt thin | Pɛɛi nïn/Thaa (Naa kɔɔr yeen)

SHORT FORM CONSENT

- The UVM IRB has translated the short form consent into 11 of the most interpreted languages at the hospital and UVM.
  - Arabic
  - Bosnian
  - Dinka
  - French
  - Khmer
  - Kirundi
  - Lingala
  - Nepali
  - Russian
  - Spanish
  - Swahili

CONSENT PROCESS WHEN USING A SHORT FORM CONSENT DOCUMENT

1. The participant reads the translated short form consent document in their native language

2. Interpreter presents the oral version of the IRB-approved English consent form (or written summary of study-specific details if the Investigator has decided not to use the IRB-approved English consent form to meet the oral presentation requirement)

- A study team member, who is approved to obtain consent, must be present for this presentation.
- If the Interpreter is not also acting as the Witness, the Witness must be present during this presentation as well
- The Interpreter facilitates participants asking questions and study team members providing answers, to ensure participant understanding

SIGNATURES AND RECORD KEEPING REQUIREMENTS WHEN USING A SHORT FORM CONSENT DOCUMENT

- When all the Participant's questions and concerns have been addressed, the Participant signs and dates the translated "Short Form" consent document
- The researcher signs the IRB-approved English version of the informed consent document
- The witness *(fluent in both languages)* signs BOTH the translated short form and the written English consent version. *(Note, when the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness.)*

SHORT FORM CONSENT PROCESS WHEN ENROLLING A NON-ENGLISH SPEAKING PARTICIPANT WHO MAY NOT HAVE A WRITTEN LANGUAGE

- An interpreter will read the oral summary of consent procedures, risks, objectives to the participant but there will be no translated short form to sign.
- All parties taking part in the consent process will sign the English version consent form.
- It is imperative that the research team has good consent process documentation to ensure legally effective consent in this rare case.

CAN FAMILY MEMBERS SERVE AS THE INTERPRETER FOR THE SHORT FORM CONSENT PROCESS?

- Use of a family member for interpretation is not permitted unless a professional medical translator cannot be located
- Family members may not translate verbatim and skip over parts they deem to be not important or not fully understand themselves.
- Minors interpreting for parents is strongly discouraged

INTERPRETING & TRANSLATION SERVICES

- Language Access Services at the University of Vermont Medical Center offers interpreting and translation services for patients with hearing loss and patients with limited English proficiency.
- These services should be used when interacting with participants involved in clinical research.
- Researchers can access on-site interpreters in many languages. They have telephone and video remote interpreters available 24 hours a day.
- Researchers can also request translation of research documents. Language Access Services can be reached at UVMMC Language Access Services.

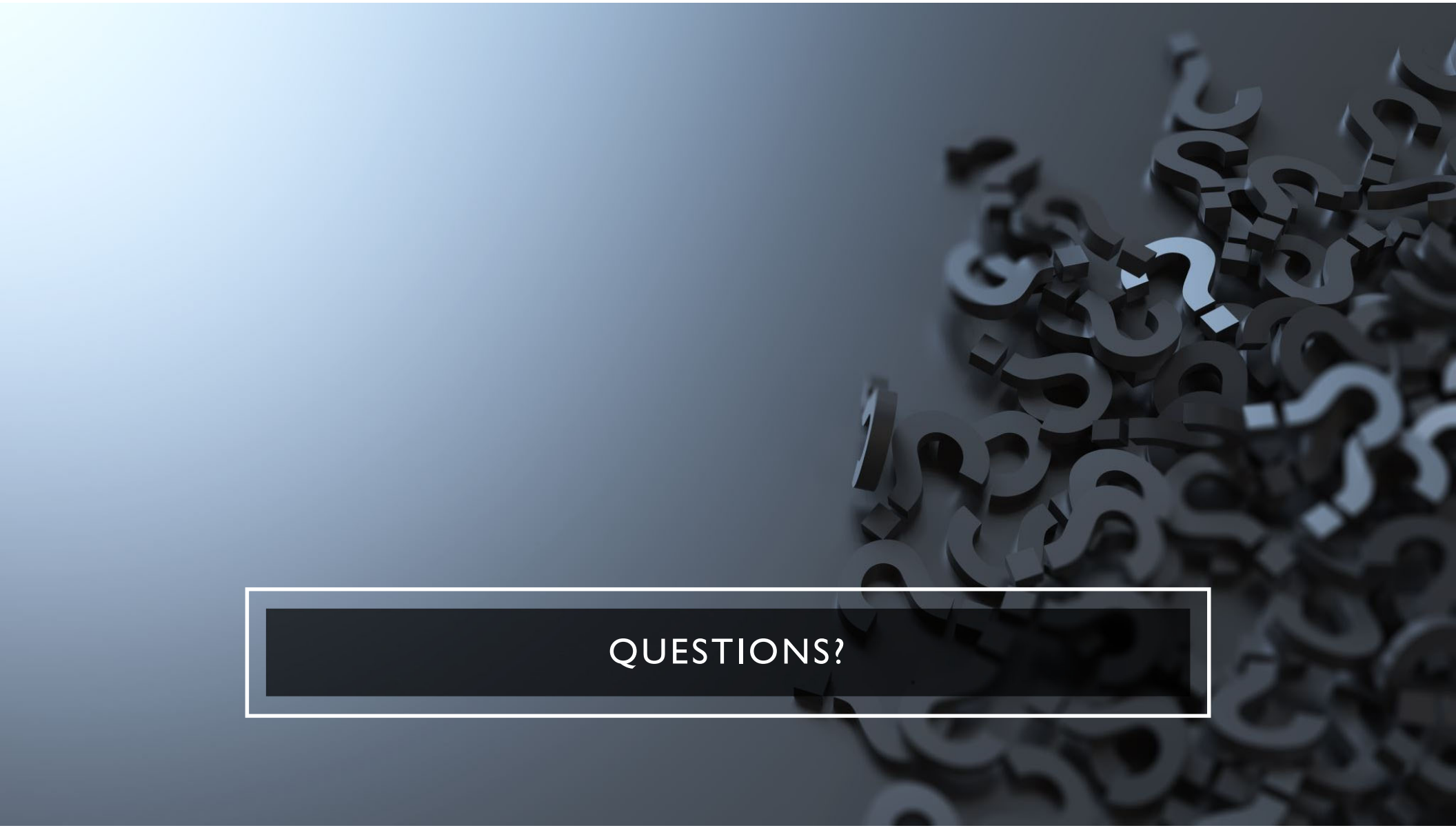
OTHER CONSIDERATIONS

Recruitment materials such as flyers must be translated in order to accommodate expected non-English speaking participants *(i.e., a significant number of participants who are not fluent in English)*. All translations of recruitment materials must be completed by a certified translator and approved by the IRB prior to their use.

Study instruments may be in English and translated orally by an interpreter or a member of the research team who is fluent in the language spoken by the non-English speaking participant. If an investigator prefers to have study instruments translated, the translations must be completed by a certified translator and approved by the IRB

POSSIBLE REASONS TO EXCLUDE NON-ENGLISH SPEAKING PARTICIPANTS

- Early phase clinical trials without a prospect for direct benefit, that will enroll only a limited number of subjects
- Studies without a prospect for direct benefit and with procedures that are greater than minimal risk
- Assessment tools, surveys, questionnaires or psychological tests that are only available in English
- Enrollment required in situations where translators will not be readily available (satellite clinics, after regular working hours, emergencies, etc.)
- Expectation based on experience that non-English speakers will rarely present to the clinic where enrollment will take place



QUESTIONS?