Tools in the Consent Backpack: Unpacking how to include participants with limited English proficiency

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Objectives:

1. Understanding when studies would be expected to translate consent vs. when to it is appropriate to request the short form
2. Understanding what a short form is.
3. Using external resources to support choices and justifications.
4. Meeting IRB expectations for submitting requests to incorporate non-English speakers or participants with limited English proficiency

Case Study

Study collects data on current standard of care for a gastrointestinal surgical procedure at multiple sites across the US. The study will:

1. Assess safety of the SOC using rate of 30-day complications and adverse events
2. Assess adequate healing as determined by multiple clinical variables.

- In order to assess some measures of healing, the study includes a research-only blood draw and a research-only x-ray, in addition to the SOC follow-up at the site.

We have current IRB approval for the study with English-speaking population. My PI has asked me to request IRB approval for participants with Limited English Proficiency.

Where do I start?

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What are my study particulars?

Things I know:

- Industry-funded
- Per my IRB approval letter, approved by a Board, so this is NOT Exempt, I'm subject to federal regs

Expiration Date: 08/06/2025

Funding Source: AMGA Pharma

August 07, 2024

Dear Doctor XYZ, MD,

At the Panel Orange Institutional Review Board (IRB) meeting August 6, 2024, chaired by Dr. ABC, the Board reviewed the above-referenced submission and determined that this study now meets the stipulations set forth by the IRB and is hereby approved. This approval is valid through the expiration or status check-in due date indicated above.

This approval corresponds with the versions of the application and attachments in the electronic system most recently approved as of the date of this letter. The approved version of the attached protocol is V.1.1 dated 8/7/2024.

Protocol Specific Determinations and Findings

- Not Greater than Minimal Risk under 45 CFR 46 / 21 CFR 56
- HIPAA Authorization for research approved under 45 CFR 164.508 (a) (1)
  Waiver of HIPAA Authorization for Eligibility screening approved under 45 CFR164.512 (i) (2) (ii)
- Written consent in accordance with 45 CFR 46.117/ 21 CFR 50.27
- Inclusion of Decisionally Impaired subjects under BMC/BUMC IRB Policies and Procedures 9.5.1

What is my first point of reference?

Regulations!

45 CFR 46.116 "General requirements for informed consent."

https://www.ecfr.gov/current/title-45/section-46.116

"The information given to the subject or LAR shall be in language understandable to the subject / LAR."

45 CFR 46.117 "Documentation of informed consent."

https://www.ecfr.gov/current/title-45/section-46.117

"…consent documented by a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject / LAR. A written copy shall be given to the person signing the informed consent form. The form can be either:

- A written informed consent form that meets the requirements [in .116]…. The investigator shall give either the subject / LAR adequate opportunity **to read** the informed consent form before it is signed; alternatively, this form **may be read to** the subject / LAR."

That's the goalpost, but not helpful in how to do it.

This is already what we do for English-speaking participants

What is my first point of reference?

Regulations!

- "A short form written informed consent form stating that the elements of informed consent [in .116]…have been presented orally to the subject /LAR, and that the key information required by § 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided**. The IRB shall approve a written summary of what is to be said to the subject/LAR.** When this method is used, there shall be a **witness to the oral presentation**.
  - Only the short form itself is to be signed by the subject /LAR.
  - However, the witness shall sign both the short form and a copy of the summary,
  - and the person actually obtaining consent shall sign a copy of the summary.
  - A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form."

Oh boy. I have to figure out if the consent form needs to be translated or….this short form thing.

What other resources do I have?

A "short form" sounds good. Maybe that would save us money, or time, or….something. I need to find out more…Institutional Policies! HRPP Policies | Office of Human Research Affairs (bu.edu) "Informed Consent for Subjects with Limited English Proficiency"

- The PI must indicate (in INSPIR) …whether subjects are expected to be enrolled who have limited English proficiency. If so, special protections for speakers with limited English proficiency must include a plan to provide a translation of the full consent form in each language expected …or a plan to use the short form written consent….must describe the plans for conducting the consent process, communicating with subjects with limited English proficiency in emergency situations, interpreting during study visits, and obtaining translations of additional study materials.
- After the English consent forms / study materials have been approved by the IRB…submit an amendment request which includes the translated documents and a form with the qualifications of the translator. The Translator Qualification form can be found on the IRB website.
- The IRB may approve the use of a short form written consent for obtaining consent from incidental, unanticipated potential subjects with limited English proficiency.. when enrollment of subjects with LEP is anticipated, a fully translated consent should be used instead of using the short form. However, the IRB has the discretion to allow the short form if the number of anticipated subjects with LEP is few, if requiring translation of the full consent form would be unduly burdensome, and if the IRB determines the short form consent process will adequately protect the rights and welfare…
- Request approval to use the short form process in an initial submission or in an amendment request…. include an English narrative that will be translated to the subject, which may be a separate document or the entire IRB approved English consent form.
- Progress reports ask if any subjects have been enrolled using the short form consent process….so that the IRB can consider whether the pattern of short form use indicates that the PI should anticipate further enrollment of subjects with LEP.

What IS this "short form"?

Link from policies: Non-English Speaking Subjects | Institutional Review Board (bu.edu)

OOH, I love this page! **It has a link to the Short Consent form in English so I can actually see what it is!!**

It also tells me:

"If short form use is approved, the IRB will complete, attach, and stamp short form(s) in the approved language(s),

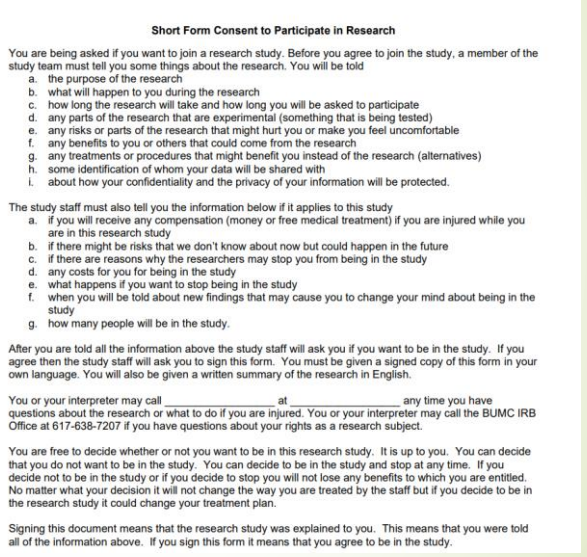
as well as a signature page that must be signed by the bilingual witness and by the person conducting the consent discussion and stapled to the English narrative.

These signature lines should be used instead of the signature lines on the approved consent form if the approved consent form is used as the English narrative.

The short form(s) and the signature page may be retrieved from the list of consent forms in the INSPIR application as follows:"

So the IRB will provide the short form to me, if I give them the right justifications and they approve it for use.

But now I know: the "short form" is NOT short!!



Short Form Consent to Participate in Research

You are being asked if you want to join a research study. Before you agree to join the study, a member of the study team must tell you some things about the research. You will be told

a. the purpose of the research
b. what will happen to you during the research
c. how long the research will take and how long you will be asked to participate
d. any parts of the research that are experimental (something that is being tested)
e. any risks or parts of the research that might hurt you or make you feel uncomfortable
f. any benefits to you or others that could come from the research
g. any treatments or procedures that might benefit you instead of the research (alternatives)
h. some identification of whom your data will be shared with
i. about how your confidentiality and the privacy of your information will be protected.

The study staff must also tell you the information below if it applies to this study

a. if you will receive any compensation (money or free medical treatment) if you are injured while you are in this research study
b. if there might be risks that we don't know about now but could happen in the future
c. if there are reasons why the researchers may stop you from being in the study
d. any costs for you for being in the study
e. what happens if you want to stop being in the study
f. when you will be told about new findings that may cause you to change your mind about being in the study
g. how many people will be in the study.

After you are told all the information above the study staff will ask you if you want to be in the study. If you agree then the study staff will ask you to sign this form. You must be given a signed copy of this form in your own language. You will also be given a written summary of the research in English.

You or your interpreter may call _____ at _____ any time you have questions about the research or what to do if you are injured. You or your interpreter may call the BUMC IRB Office at 617-638-7207 if you have questions about your rights as a research subject.

You are free to decide whether or not you want to be in this research study. It is up to you. You can decide that you do not want to be in the study. You can decide to be in the study and stop at any time. If you decide not to be in the study or if you decide to stop you will not lose any benefits to which you are entitled. No matter what your decision it will not change the way you are treated by the staff but if you decide to be in the research study it could change your treatment plan.

Signing this document means that the research study was explained to you. This means that you were told all of the information above. If you sign this form it means that you agree to be in the study.

Three Documents – Signed Short Form + Signed Signature Page, both attached to Consent Form

RESEARCH CONSENT FORM
SIGNATURE PAGE FOR SHORT-FORM USE
ATTACHED TO APPROVED CONSENT FORM OR
ENGLISH NARRATIVE DESCRIBING THE STUDY

Subject: _____
Printed name of subject

Language of consent discussion: _____

Short form signature (check one):
- ☐ Subject personally signed the short form
- ☐ Someone other than the subject signed the short form:

_____ _____
Printed name of person signing short form — Relationship to Subject

Witness: _____
Printed name of witness

NOTE: the witness must not otherwise be associated with the study. The interpreter may sign as a witness if the interpreter is not associated with the study.

The consent form was translated for and apparently understood by the subject/parent(s) or guardian(s)/Legally Authorized Representative in my presence, and all their questions were answered.

_____ _____
Signature of witness — Date

To be completed by researcher if subject personally signs the short form
I have personally explained the research to the above-named subject and answered all questions. All

You or your interpreter may call _____ at _____ any time you have questions about the research or what to do if you are injured. You or your interpreter may call the BUMC IRB Office at 617-638-7207 if you have questions about your rights as a research subject.

You are free to decide whether or not you want to be in this research study. It is up to you. You can decide that you do not want to be in the study. You can decide to be in the study and stop at any time. If you decide not to be in the study or if you decide to stop you will not lose any benefits to which you are entitled. No matter what your decision it will not change the way you are treated by the staff but if you decide to be in the research study it could change your treatment plan.

Signing this document means that the research study was explained to you. This means that you were told all of the information above. If you sign this form it means that you agree to be in the study.

Printed name of subject _____ Signature_____ Date _____

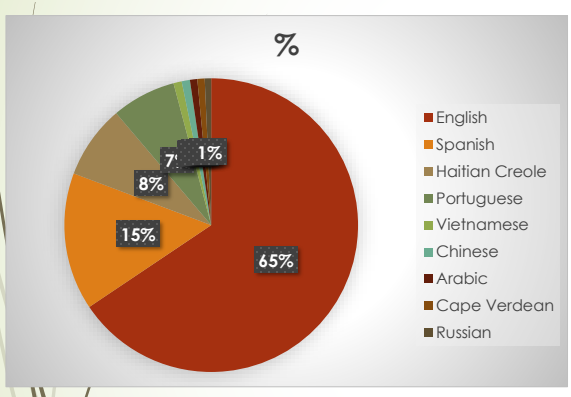
Printed name of witness _____ Signature_____ Date _____

To be completed by researcher if subject personally signs the short form
I have personally explained the research to the above-named subject and answered all questions. All required elements of informed consent were presented orally to the potential subject, the subject was first presented with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research, and this part of the informed consent was organized and presented in a way that facilitates comprehension. I believe that the subject understands what is involved in the study and freely consents to participate.

_____ _____
Signature of person conducting consent discussion — Date

To be completed by researcher if subject does not personally sign the short form
I have personally explained the research to the above-named subject's parent(s) or guardian(s)/Legally Authorized Representative and answered all questions. I believe that the parent(s) or guardian(s)/Legally Authorized Representative understands what is involved in the study and freely consents for the subject to participate. [IRB Analyst will include if some subjects are capable of providing assent; otherwise will delete sentence and two checkboxes – retaining signature line] I consider that the above-named subject

My job is the justification



- Provide the IRB information for who we can anticipate as research subjects and what the study resources are.
- Sponsor will pay to translate into top 2 languages. Not bad, but limited.
- **Patients typically seen clinically in gastro-surgical unit (chart).**
- Quick math: Our site is responsible for enrolling 60 participants. Representative proportions would give me:
  - 39 English
  - 9 Spanish
  - 5 Haitian Creole
  - 4 Portuguese.
- Policy: "anticipated subjects is few and / or unduly burdensome", we'll consider Spanish and Haitian Creole "anticipated" and I can justify "fewer than 5 subjects expected" as burdensome. However, BMC is the sponsor's most diverse site and they're counting on us for generalizability among populations. Maybe they'll budge….
- Successful amendment means:
  - submit entire Spanish and Haitian Creole translated consent forms and translator qual forms.
  - Our study doesn't use any other patient-facing information (screening info, surveys, materials, etc).
  - Request the use of the short form in Portuguese, Vietnamese, Chinese, Arabic, and Cape Verdean (Russian isn't an option from the IRB). Simultaneously, ask the sponsor for $ to translate consent into Portuguese.

Side Note on Requirements

- Exempt Research determination: The IRB only requires discussion of a plan for who to include and how in your procedures. Translated materials are not required or reviewed for Exempt research.
  - Consent and patient-facing materials should, of course, be translated for best practice, and solid SOPs in place to incorporate people with limited English proficiency, similar to non-Exempt procedures, but there is no IRB oversight of these particulars given the low risk of the research.
- Non-Exempt (Expedited or Full Board): The IRB requires submission of all procedures and translated materials.
  - Need to think about recruitment, consent process, submission of patient-facing materials, and follow-up
  - Need to think about what "Limited English Proficiency" means for this BMC department.

What do I do now?

Amend IRB INSPIR Application

- Update Inclusion Criteria if need be
- Special populations section 11.5 and special protections 11.6.

MY JOB IS JUSTIFICATION

- Update Recruitment section if current procedures only address English speakers (ie, flyer use, need to incorporate interpreters)
- Update 16.1 Consent
- Update 16.6 Non-English consent to "yes" and fill in each section

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Study Documents

- Protocol revised / harmonized (if applicable)
- Attach Translated consent forms
- Attach Translator qualification forms for all languages where (written) translation occurs

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Submit the amendment!

The INSPIR system has been designed (and is constantly being updated) to ask the questions we need answers to AND to prompt you to think of and do certain things.
READ THE INSTRUCTIONS & USE THE HELP TEXT

INSPIR Special Protections- Vulnerable Populations language

- In the gastro-surgical unit, in order to have our research population mirror the demographics of our clinical population, we anticipate that 15% of the participant will speak Spanish, 8% will speak HC, 7% Portuguese. Other languages account for <1% of our population and we do not anticipate them as research participants.
- Therefore, we expect that 39 of them will speak English, 9 will speak Spanish, 5 will speak Haitian Creole, and 4 will speak Portuguese. The sponsor has agreed to a limited budget of translating for our top two most anticipated languages. Therefore, we will protect participants with limited English proficiency who speak/read Spanish and Haitian Creole by fully translating the approved English consent form. For Spanish, one of our study team members is a native Spanish speaker and can conduct all consent discussions and study activities. For Haitian Creole speakers, we will conduct all research activities with the use of an approved BMC interpreter.
- While we do anticipate Portuguese speakers, we currently do not have funds for this translation internally, but will request additional funds from the sponsor for this translation. Currently, however, it would be unduly burdensome for us to translate if we were to enroll 4 or fewer Portuguese speakers over a 2 year enrollment period.
- For Portuguese, Vietnamese, Chinese, and Cape Verdean speakers, we will request the use of a short form and use approved BMC interpreters for the consent process, as witnesses, and for study activities as needed to protect their rights and welfare by fully informing them of the research.

INSPIR Recruitment Procedures Update language

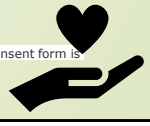
- For subjects with limited English proficiency, a BMC interpreter will already be present for the medical encounter.
- In cases of Spanish speakers, the interpreter and MD will perform ask for permission to forward information on consent directly to the Spanish-speaking team member.
- For potential participants speaking other languages, the MD will perform a warm hand-off to the study team and the interpreter will remain from the MD's study introduction through to presenting the study team and the consent process.

INSPIR Consent Procedures Update language

- For potential participants who speak Spanish, the above process will be the same and be conducted with the member of our study team who is a fluent Spanish speaker.
- For potential participants who speak Haitian Creole, the above process will also occur with a fully translated consent form and a BMC interpreter.
- For potential participants who speak Portuguese or another language using the short form, we will only conduct the consent process in person with paper documents. A BMC interpreter will be present throughout the process and will act as witness for use of the short form.

INSPIR Non-English Consent Procedures Update language

- The sponsor will translate the entire consent form into Spanish and Haitian Creole. We have an RA who is fluent in Spanish (native speaker) to conduct the consent process in accordance with consent as described above. For Haitian Creole, we will use a BMC approved interpreter for all consent discussion and study activities (during the blood draw/x-ray process). We do not anticipate any emergency situations due to the research, as the study is deemed not greater than minimal risk, but if they occur we would rely on our Spanish-speaking RA or use BMC interpreters (phone line/in-person) to communicate with the participants post-consent. We don't anticipate any other translation needed besides the consent form as there are no other participant-facing materials (flyers, surveys, etc).
- For potential participants who speak Haitian Creole, the above process will also occur with a fully translated consent form and a BMC interpreter.
- For potential participants who speak Portuguese or another language using the short form, we will only conduct the consent process in person with paper documents. A BMC interpreter will be present throughout the process and will act as witness for use of the short form.
- (If an LIP is needed, Spanish-speaking RA would need to be BMC-certified interpreter to interpret consent between patient and LIP, or BMC interpreters could be used.)
- For Spanish consent forms, we will have the participant and RA conducting consent (fluent in Spanish) sign as they normally would for and English consent form.
- For Haitian Creole consent forms, we will have the participant, person conducting consent, and BMC interpreter sign the translated consent form.
- We would like to request use of the short form for the following languages: Portuguese, Vietnamese, Chinese, Arabic, and Cape Verdean due to the numbers presented in section 11.6.
- We consider any number of participants fewer than 5 as potentially burdensome on our team to translate materials. However, given that the sponsor is relying on us to diversify the participant portfolio, we will continue to ask for additional funds for translation, particularly for Portuguese.
- For languages where the short form is used, we will have the participant and BMC-approved interpreter (used as witness) sign the short form in the person's native language. Then the participant, the person conducting consent, and the witness will sign the signature page provided by the IRB. Finally, the witness and the person conducting the consent discussion will sign the English consent form. Last, we will attach the English consent form as the full "written summary" or narrative used as the basis of the verbal presentation.
- none needed; no other participant-facing materials are used in English, either.
- We will use the entire approved English consent form as the basis of our verbal summary for the short form. This ensures that if the English consent form is updated, we will also know to provide an update and what the update is to participants consented using the short form.



Translator Qualifications

Who is a qualified translator | Institutional Review Board (bu.edu)

- "Translated by a translator who is considered by the Principal Investigator to be qualified to perform the translation."
- "Provide enough detail about the "qualifications" for the IRB to make a determination that the translator has appropriate qualifications. The IRB review will consider what medical background, if any, would be appropriate based on the risks and complexities of study interventions, and based on whether any of the study procedures are procedures that require additional consent when performed for clinical care."

Boston Medical Center and Boston University Medical Campus
Human Research Protection Program
Translator Qualifications Form

Instructions: The Principal Investigator retains the overall responsibility for ensuring that each subject provides legally-effective informed consent for participation in research and that the rights and welfare of all subjects are protected. When it is anticipated that subjects who do not speak English will be enrolled, the Principal Investigator must arrange for the translation of the consent form(s) and other study documents into appropriate language(s) by a qualified translator after the English versions have received IRB approval. This form must be completed and attached to the modification request accompanying the translated documents.

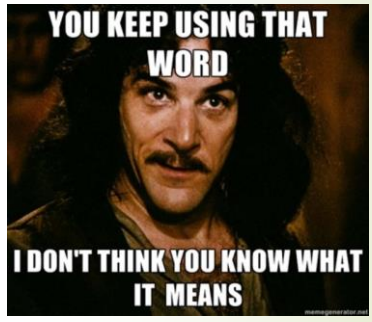
IRB Number:
Principal Investigator:
List of materials translated:
Approval date on English consent form(s):
Translation from English to (language):

Translation by	
Name:	**Position:**
Qualifications of translator:	

By attaching this form to the IRB submission, the Principal Investigator acknowledges his or her responsibility to ensure that consent forms and other study documents are accurately translated into language understandable to study subjects.

WORDS MATTER: Translator vs. Interpreter vs. Speak-to-Speaker

- Translators: take written English and create the same words in another written language (usually ahead of time). There are not necessarily strict rules about who can translate, as long as one's background provides reasonable evidence of medical / study terms in the target language.
- Interpreters: take in-the-moment English speech and provide an oral delivery in a person's native language. Difficult skill, BMC has policies on who can interpret.
- Speaker-to-speaker: For our study, we have an RA who is a native Spanish speaker. In this case, they are simply people having a conversation and consent discussion with the participant in their native language and no "medical advice" is being transmitted. They are neither translator nor interpreter.
- **NOTE:** For studies where LIPs are required, if the LIP only speak English, the RA could act as an "interpreter" between the LIP and the potential participant if they are BMC-Certified. Otherwise, BMC interpreters would be required. In this case, the information transmitted between the clinician and the participant is being interpreted, and it's not a conversation between two people, even if the RA and participant speak the same language.



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Problems with the short form

No one likes it – not ethicists, not study team, not even the people who wrote it

Equity Issues:

- Why don't we just present a one-pager to English speakers?
- What happens when we need to do reconsent? What written documentation can a non-English speaker point to for the updates/differences?

Our population is increasingly multi-lingual and diverse.

AI is making translation easier – is a 'qualified translator' a moot point?

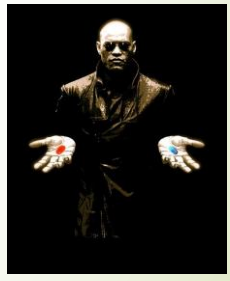
It's burdensome to implement and document

**NIH-funded studies: 3014-301 - Informed Consent (nih.gov)

#7 and #8: If you do use the short form, the NIH limits use to 3 participants, after which the PI must translate into that language anyway and have your retroactively provide the translation to the people consented using the short form.

What we haven't talked about

- Operationalizing processes for participants with L.E.P. Who can serve as a witness and/or interpreter? Section 8.5.4.3
  - HRPP Policies | Office of Human Research Affairs (bu.edu)
    - Minors may not serve as witnesses
  - Contrast this with who can be witness for limited and non-readers Section 8.4.6:
  - HRPP Policies | Office of Human Research Affairs (bu.edu)
    - Neither minors nor family members
- If I have more people enroll via short who speak a certain language, what do I do?
  - Continuing Review information must be given each year on use of the short form



Take a swing:

- Your study is approved with English, Spanish, and Haitian Creole speakers. A potential participant is present in clinic who speaks Albanian. The IRB has short forms for Albanian. Your study isn't approved to use it but a similar study in your department is. Could you use their approved short form in this scenario to enroll this person and submit an amendment later?

A. Yes, the short form is basically the same for all studies.
B. Yes, you'd still have an interpreter work from your English consent form.
C. No, you haven't yet come up with a separate English narrative.
D. No, approval is study-specific and will be detailed on the outcome letter.

Take a swing:

- You are submitting an amendment to the IRB to use the short form in Albanian. Your clinic sees Albanian participants every other week, on average, and you have 25 Albanian speakers who pre-screen as eligible for the study. Is it appropriate to petition the IRB for the use of the short form?

A. Yes, it can't hurt and will save you time.
B. No, they are not an unanticipated population.
C. Yes, the IRB can make exceptions.
D. No, your Albanian speakers should not be approached for research.

Take a swing:

- You are setting up an internally funded cancer registry. You plan for this to be a long-term (at least 20 year) registry enrolling as diverse a population as possible. You begin by translating the consent form into the top 3 languages the center sees, as they all make up more than 5% of your population. When you get to Cambodian, Arabic, and Greek, you think these might be good candidates for the short form. What is your justification to the IRB?

A. You don't have time to translate into every language.
B. Interpreters for those languages are hard to come by.
C. You don't see anyone on your pre-screening list who speakers those languages, and a search of BMC interpretation calls reveals no calls in the past year for those languages.
D. You don't anticipate these speakers being non-readers.

Take a swing:

- You have a native Haitian Creole speaker on your team as a research assistant, who also writes the language. Can this person serve as the official translator for the consent form?

A. Yes, if the person has the education to show reasonable knowledge of medical and other terms used in the study.
B. No, they're not a BMC-approved interpreter.
C. Yes, they can just translate it orally while in the room.
D. No, the research assistants has not been in Haiti for over 2 years.

Take a swing:

- A Greek-speaking family comes in and the mother qualifies for your study. The BMC interpretation line has been backed up all day and a BMC-approved Greek interpreter is a 30-minute wait. The child is fluent in English and has been interpreting casual discussion during the encounter so far. Your study has a Greek short form approved. While you wait, could you enroll the mother into the study through the child?

A. No, it is against policy for minors to interpret the consent form.
B. Why not? The child's English is excellent.
C. No, it alters the dynamic of authority in the family.
D. Yes, the father says it's ok.

Questions? AND

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- Khaled Khattar (IT specialist)
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  - kkhattar@bu.edu
- Main IRB number: 358-5372
- Resources:
  - https://www.bu.edu/crtimes/
  - https://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/
  - http://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/