The Language of Consent:
Using the Short Form in Consenting non-English Speakers in Clinical Research

Mary A. Banks RN, BS, BSN
Director, BUMC IRB
September 17, 2008

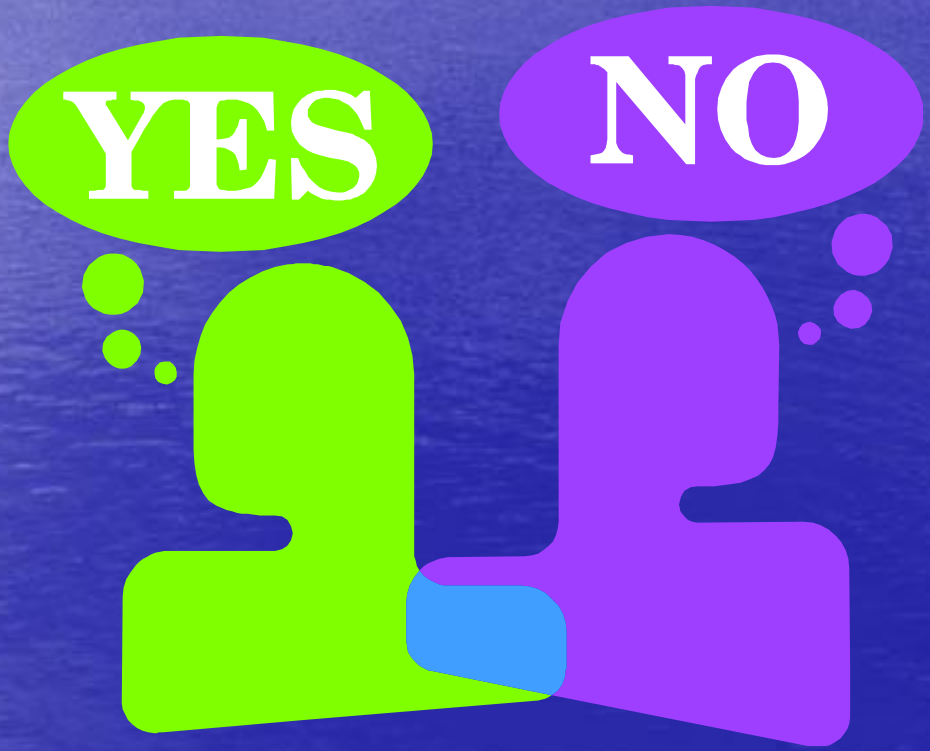
Learning Objectives

At the end of the presentation

the participants will be able to :

- Discuss the **ethical concerns** related to consenting subjects using a "short form"
- State the **federal regulations** related to consenting non-English speaking subjects
- Describe the required steps in the newly revised **BUMC policy** for consenting non-English speaking subjects using the short form.

Belmont Principle
Respect for Persons



Ethical Concern
Respect for Persons

- The Belmont report clearly articulates the desired outcome of informed consent:

- **Respect for persons** requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.

- Subjects should be given information, **understand the information** , and based on their comprehension of the information make a voluntary decision to participate in research".

FDA : The Consent Process

- Informed consent is more than just a signature on a form, it is a **process of information exchange** that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and measures of subject understanding.

- Institutional Review Boards (IRBs), clinical investigators, and research sponsors all share responsibility for **ensuring that the informed consent process is adequate**.

- Thus, rather than an endpoint, the consent document should be the basis for a **meaningful exchange** between the investigator and the subject.

The Consent Process

- Not to be confused with the **i**nformed **c**onsent **f**orm **(ICF)** document
-
- **The ICF is NOT the consent process-** it is a record of what was supposed to be communicated and a "take away" reminder of what subjects have agreed to
- The ICF is only a method for helping to assure that necessary information is communicated to potential subjects in a meaningful way and a document that tells the IRB what the investigators plan to tell the subjects
- The ICF is NOT proof that the subject understands (even if it says "by signing I agree that I understand")

Example of a consent process

(used by "other" investigators)

- Tell the potential subject that there is a study which he/she might be eligible for.
- Hand the potential subject a consent form to read. (Leave the room. Get coffee.)
- Return to the room 10 minutes later. Ask the potential subject "Are you ready to sign the consent? Do you have any questions?"
- The potential subject signs the ICF.
- **Subject consented ????**.

Consent Process Complicated by Language Barriers

- The subject / LAR and investigator/person obtaining consent do not verbally communicate in the same language
- The subject cannot read the consent document
- The subject cannot ask questions of the investigator

- The inability to understand English makes it impossible for a prospective subject to meaningfully engage in the (standard) consent process and to make an informed decision about participation in research

- Investigators must carefully consider the ethical/legal ramifications of enrolling a subject when there is a language barrier. *

- If subjects do not clearly understand the consent document or are can not freely ask and receive answers to their questions, then their consent will not be truly informed and may not be legally effective *

FDA : Information sheet

Belmont Principle
Distributive Justice

Ethical Concern Distributive Justice

- The principle of Justice as embodied in the Belmont report calls for "… *fair procedures and outcomes in the selection of research subjects*".

- To ensure that the burdens and benefits of research are fairly distributed, Federal regulations require that IRBs consider whether selection of subjects is equitable (45CFR § 46.111)

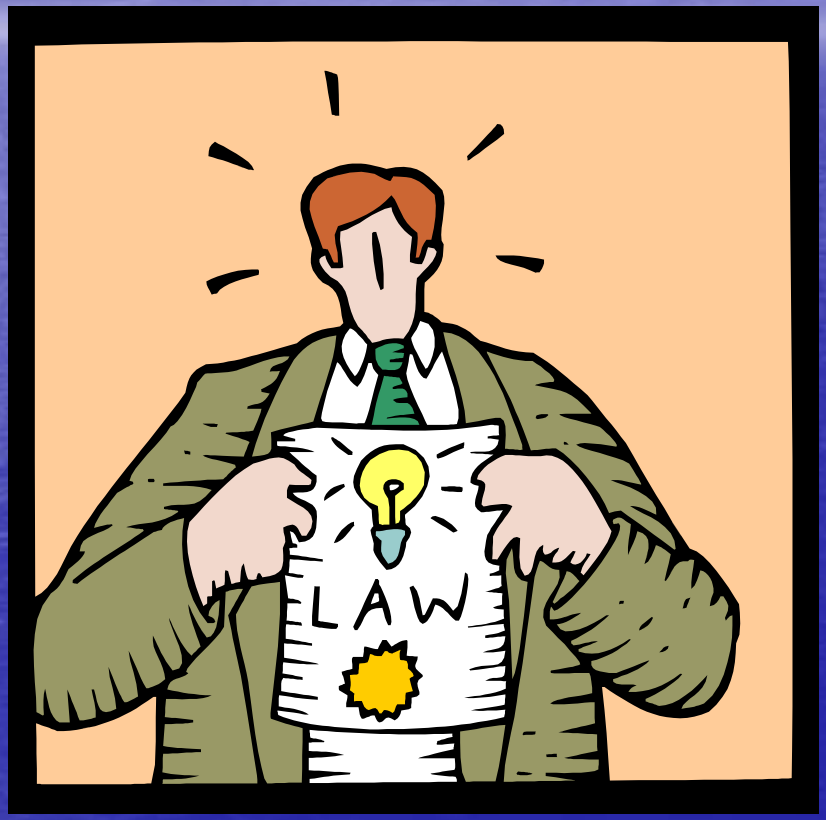
- BUMC IRB implements this principle for non-English speaking subjects by requiring that investigators:
  - Not automatically exclude subjects from research who can not understand or read English, but otherwise are eligible to participate

Not excluding subjects with prospect of direct benefit

- A related ethical principle is that the target sample for a study should be representative of the population that has the potential to benefit from participation in the research.

- IRB requires the inclusion of non-English speaking persons in research studies that have the **prospect of direct benefit** to subjects unless there is a compelling justification for their exclusion

Regulations



FDA says (21 CFR 50.20 and 50.27)

- The informed consent document should be **in language understandable to the subject/LAR.**
- When the study subject population includes non-English speaking people or the investigators/IRB anticipate that the consent interviews will be conducted in a language other than English, the IRB should require a **translated ICF** and assure that the translation is accurate.
- A copy of the translated consent document must be given to each subject.
- While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

FDA: Non-English Speaking Unexpectedly Encountered

- Translated consent are not available
- Must rely on oral translation.

- Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective.

- Written short form consent in a language understandable to the subjects must be used. Must contain required elements and required signatures (stated in 21 CFR 50.27(b)(2).

OHRP regulations
(45 CFR 46.116 and 46.117)

- Also require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing

- Where informed consent is documented in accordance with §46.117(b)(1), the written consent document should embody, **in language understandable to the subject**, all the elements necessary for legally effective informed consent.

Enrollment of non-English speaking subjects is expected

- When non-English speaking subjects are targeted for enrollment or when their enrollment is anticipated, they must be provided an IRB approved **translated** ICF
- Providing each subject with a consent document is his/her language is always preferable.
- Investigators should plan ahead for expected subject populations who are unable to speak or read English and should arrange for translation of the IRB approved English informed consent/assent form prior to beginning study recruitment.
- The informed consent **process** is the same for non-English speaking subjects; however, a qualified interpreter must be present to facilitate the consent conversation between the investigator and the potential subject prior to enrollment.

OHRP guidance for use of the short form

- Alternatively, §46.117(b)(2) permits **oral presentation of informed consent information** in conjunction **with a translated short form written consent document** (stating that the elements of consent have been presented orally) and **a written summary** of what is presented orally (this can be the full English version of the consent).
- A witness to the oral presentation is required
- The subject must be given copies of the short form document and the summary.

OHRP Guidance (cont.)

- When this procedure is used with subjects who do not speak English,
  - (i) the oral presentation and the short form written document should be in a language understandable to the subject;
  - (ii) the IRB-approved English language informed consent document may serve as the summary;
  - and (iii) the witness should be fluent in both English and the language of the subject.

OHRP Guidance (cont.)

- At the time of consent,
  - (i) the short form document should be signed by the subject (or the subject's legally authorized representative);
  - (ii) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and
  - (iii) the short form document and the summary should be signed by the witness.
  - When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

OHRP guidance (cont.)

- The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of §46.117(b)(2).
- Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.
- It is the responsibility of the IRB to determine which of the procedures at §46.117(b) is appropriate for documenting informed consent in protocols that it reviews.

Protection of Vulnerable Populations

- The IRB applies additional safeguards to protect the rights and welfare of vulnerable populations

- (45 CFR 46.111(b) and 21 CFR 56.111(b)).

Non-English Speaking

- Persons unable to verbally comprehend spoken English language or read and comprehend documents written in English are considered vulnerable
  - Much more difficult to meaningfully engage in the consent process
  - More vulnerable to coercion
  - More difficult to make a truly informed decision about participation in research

- Systematic selection of subjects because of easy availability, compromised position, or social, racial, sexual, economic or cultural biases results in an uneven distribution of the benefits and the burdens of research. The IRB must examine research that appears to recruit subjects based solely on their easy availability, compromised position, or susceptibility to manipulation.

Additional Safeguards

- Translation of consents when possible to a language understandable to the subject
- Witnessed consent process when the short form is used
- IRB determination as to whether or not use of the short form is appropriate

- Investigators also need to be aware of the difficulties inherent in providing accurate and effective consent to non-English speaking individuals and ensure appropriate safeguards are in place to protect the rights and welfare of these individuals
  - Allow additional time for consenting
  - Careful consideration as to who is obtaining informed consent
  - Tools or procedures to assess subjects' understanding

Institutional Policies and Procedures

BUMC Policies and Procedures

- Previously BUMC IRB only approved short form use in a very limited number of studies (mostly studies < minimal risk)
- The IRB Executive Committee recently revisited the institutional policy on the use of the short form
- Decided to expand the use of the short form to encourage enrollment of non-English speaking subjects in research

Institutional Policy

- The short form should not be used for situations where enrollment of non-English speaking subjects is anticipated or such groups are targeted for enrollment
- Ad hoc verbal translation of the English consent for non-English speaking subjects is **NOT** allowed.
- The preferred method is still to provide subjects with **fully translated consent documents**.
- The IRB will approve on a protocol by protocol basis the use of the short form consent process for use with incidental, unanticipated non-English speaking subjects

Institutional Policy (cont.)

- The IRB Executive Committee has reviewed and approved a **BUMC English version** of an short form. It will be posted on the IRB website. (www.bumc.bu.edu/irb)

- This short form utilizes the recommended language in the OHRP sample but has been simplified to 6-7th grade language.

Institutional Policy (cont.)

- The IRB has had the short form translated into 5 of the most common languages used at this institution. These short forms have been validated. They will be posted on the IRB website. Only the BUMC short form may be used.
  - Spanish
  - French
  - Haitian Creole
  - Brazilian Portuguese
  - Vietnamese

Obtaining IRB Approval to use the short form consent process

- Complete the **short form request** (on the IRB website) and **attach to Section S of INSPIR**
  - Indicate which languages you wish to use
  - Indicate on the form the plan for who will serve as translators/interpreters
  - Indicate the plan for emergency on call, how you will communicate with subjects during follow-up visits, how you will answer subjects' questions, etc.
- Download the IRB approved **English version** of the short form and attach to Section S of the INSPIR protocol
- Download the IRB approved **translated short forms** from the IRB website and attach to the protocol in Section S

Obtaining IRB Approval for use of the short form

- Submit to the IRB **via INSPIR** with a new protocol, as an amendment, or with the next progress report. Do NOT email these requests separately to the IRB (outside INSPIR).
- Approval for use of the short form (with any stipulations) will be noted in the IRB approval letter
- The English version of the short form and the translated short forms will NOT need to be stamped by the IRB as they will already be validated.
- (The **English version of the full consent** will still need to be validated per the usual INSPIR process).

Process for Obtaining Consent Using the Short Form

- The protocol is approved for use of the short form process
- A non-English speaking person presents
- Investigator secures an interpreter (if he/she does not speak the language of the potential subject.)
- Investigator, via the interpreter, conducts the consent process with the subject
  - Reviews the contents of the short form
  - Using the full English version of the consent as a script, reviews the entire full consent which is then translated by the interpreter into the subject's language
- Investigator answers questions (via interpreter)

Witness to the Consent Process

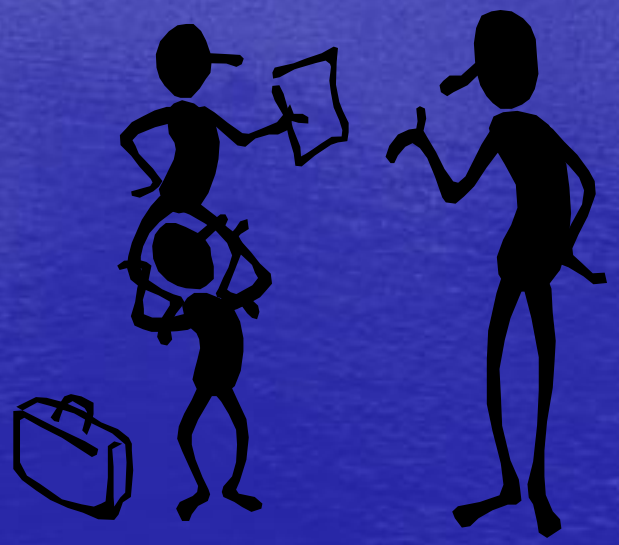
- Witness- a witness to the consent process is required
  - If the person obtaining consent does the verbal translation then a witness (who understands both languages) is required
  - The witness must be fluent in both languages
  - If an interpreter is used- the interpreter can serve as the witness

Signatures

- **Short form**
  - Signed by the subject or the LAR
  - Signed by the witness
  - Signed by the person obtaining consent
- **English version of the consent**
  - Signed by the person obtaining consent
  - Signed by the witness

Give to the subject

- A copy of the translated short form
- A copy of the English version of the full consent



Additional Considerations

- Informed consent is a process that requires investigators to continuously re-assess the subject's understanding of the nature of the research, its risks and benefits.
- Adequate communication between the research staff and subject must occur throughout the research to ensure the safety and welfare of the subject and the integrity of the research data.
- As part of the short form request the IRB will ask for the plan for how non-English speaking subjects will be managed, who will interpret for all study visits, the plan for translation of additional study materials, etc.

Summary

- The BUMC IRB has approved the expanded use of the short form as part of the consent process for non-English speaking subjects
- It is the responsibility of the person obtaining consent, and ultimately the responsibility of the PI, to ensure that a truly informed, legally effective, consent process takes place (not just signatures on the documents).
- Investigators must be committed to the **consent process** and recognize that obtaining consent from non-English speaking subjects will take additional effort and time


Thank
You!