Informed Consent for Non-English Speaking Research Participants and the Role of the CRN

Erin Ferraro, BSN, RN, OCN©, Nurse Educator
Deborah Grady, MS, BSN, CCRC, Quality Management Coordinator
Office of Education and Compliance
Center for Cancer Research

September 2024

NIH NATIONAL CANCER INSTITUTE

1

Objectives

- **Explain OHSRP policy regarding consenting non-English speaking research participants as it relates to the CRN**
- Review the process and documentation for translated ("long form") informed consent documents.
- Review the process and documentation for "short form" informed consent documents.
- Describe how translated consents are provided and when reconsenting may be needed.

2

What is Informed Consent? (IC)

- Having capacity to agree for one's self to participate in a given situation once risks and benefits are understood
- **Ongoing process** of communication and mutual understanding between the participant and investigator
- Research participant's initial agreement is evidenced by signing an informed consent document (ICD)

3

Documentation of IC Process – Research Team

- Specific statement in CRIS addressing the informed consent process
  - Required per HRPP Policy 301
- CRIS note must include a statement that:
  - A discussion occurred
  - All questions were reviewed and answered to the participant's satisfaction
  - A copy of the signed ICD was given to the participant
- CRIS has an IC process template progress note "Documentation of Research Consent Note"

4

Role of Verifying ICD - CRN

Some examples from Procedures and Standards of Practice on the Nursing Intranet…

CCND SOP Chemo/Bio	CCND SOP Cell Therapy Products Admin	CCND SOP Medication Admin
• Verify presence of a signed informed consent form or an assent form for patients under the age of 18. • i. "Protocol consent" if patient being treated on protocol. • ii. "Consent to Chemotherapy/Biotherapy" if being treated on a standard of care chemotherapy/biotherapy ynon-investigational regimen (found on iMed), per MAS Policy M112	• Verify signed protocol consent by visualizing the document in the Electronic Medical Record (EMR).	• Prior to the administration of any medication, a nurse assesses and validates the following: • A. Informed consent, if applicable.

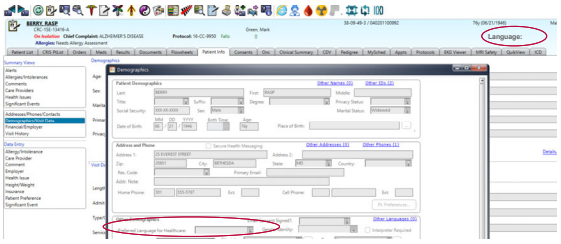
5

IC for non-English Speaking Participants

- OHSRP policy for enrolling non-English speaking participants (Effective March 2024)
- If enrollment of non-English speaking individuals is anticipated, the consent must be translated into the anticipated languages ("long form").
- Short form use acceptable in certain scenarios

6

CRIS: Preferred Language for Healthcare



7

Translation and Interpreter Services

Translation	Interpreter
• ICD translation must be done by a certified translator fluent in participant's preferred healthcare language and in English • Research team staff coordinates ICD translation through NIH Library, then submits to the IRB for approval prior to use	• Required unless the investigator obtaining consent is fluent in the participant's language • Interpreter must be someone independent of the participant. • Identity of interpreter must be listed in CRIS note • Interpreters are secured through the Social Work Department (CRIS order) or via the telephone language line

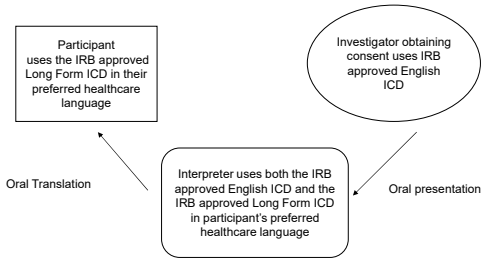
8

Objectives

- Explain OHSRP policy regarding consenting non-English speaking research participants as it relates to the CRN
- **Review the process and documentation for translated ("long form") informed consent documents.**
- Review the process and documentation for "short form" informed consent documents.
- Describe how translated consents are provided and when reconsenting may be needed.

9

Long Form Consent Process (with Interpreter)



ICD = Informed Consent Document

10

Signatures on ICD: Long Form Process

- ***Full*** ICD ("long form") is translated in participant's/ LAR's preferred healthcare language
- Interpreter used to facilitate discussion
- No signatures on the English version
- Signatures on the translated long form:
  - Participant/LAR
  - Investigator (*even if they do not speak the language, because they have the full English consent to refer to)

11

Objectives

- Explain OHSRP policy regarding consenting non-English speaking research participants as it relates to the CRN
- Review the process and documentation for translated ("long form") informed consent documents.
- **Review the process and documentation for "short form" informed consent documents.**
- Describe how translated consents are provided and when reconsenting may be needed.

12

So When Can Teams Use a Short Form Consent?

- Federal regulations allow use of short form in participant's preferred healthcare language
  - Witness to the consent process is required
  - Short form states that required elements of IC document have been presented orally
- When research teams use the short form consent:
  - They must notify the NIH IRB and justify their use of the short form
  - They must promptly translate the consent into the participant's language and provide that consent to them once IRB approved (greater than minimal risk studies)

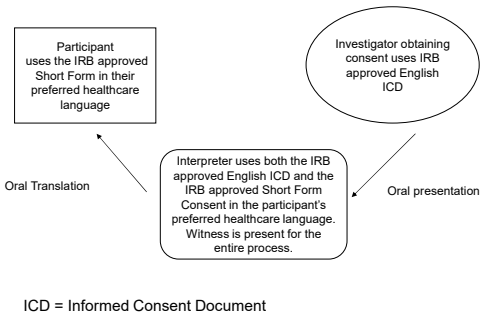
13

When is a Witness Required for IC?

- A witness is only required for the short form consent process
- Witness role is to attest, by signature, the validity of the short form consent process and the participant's agreement to participate in the research
  - Must be present for the entire oral presentation
  - Ideally speaks both languages
- If a CC interpreter facilitates the short form consent process, they are required to serve as the witness

14

Short Form Consent Process



ICD = Informed Consent Document

15

Signatures on ICD: "Short Form" Process

- "Short form," IRB approved
  - Signed by participant
  - Signed by witness
- English version, IRB approved
  - Signed by investigator
  - Signed by witness
- Participant is provided signed copies of both the short and long form consent

16

Objectives

- Explain OHSRP policy regarding consenting non-English speaking research participants as it relates to the CRN
- Review the process and documentation for translated ("long form") informed consent documents.
- Review the process and documentation for "short form" informed consent documents.
- **Describe how translated consents are provided and when reconsenting may be needed.**

17

How does the research team provide a translated consent to a participant?

- If a participant already signed the short form consent, they do not need to be reconsented.
- The participant needs to be given a copy of the translated consent (re-signing not needed) by the research team.

18

What do CRNs need to know about reconsenting?

- When a consent document is revised, the IRB may determine that some, or all, participants need to be reconsented to the new version.
  - Change in study design (e.g. new protocol test/procedure/visit)
  - New or added risk to participation
- The research teams will oversee and document all reconsents per IRB and OHSRP policies.

19

Pause and Call the Research Team When…

- There is no participant signature anywhere on a consent (short form or long form)
- There is no investigator signature anywhere on a consent (short form or long form)
- No witness signature anywhere on a consent (short form or long form) if it is a short form consent process

20

ICD Key Points…

- You will continue to see more long form translated ICDs going forward
- Investigators can sign the long form translated ICD because they have the English version to refer to
- Participants should never sign or initial any part of an English ICD if they don't speak English

21

….ICD Key Points

- If there is a long form translated ICD, a short form is NOT required
- Documentation of consent notes should explain the consent process
- If you have any questions about the consent process or documentation, please contact the research team

22

Resources

- OHSRP Consent FAQs
- OHSRP Policy 301 Guidance – Enrolling Non-English Speaking participants (6/27/24)
- MAS Policy 23-2: Language Access in Clinical Center
- An Overview of IRB Expectations When Non-English Speaking Persons Enroll in Research: The Importance of Ensuring Comprehension (2/1/24)

23

QUESTIONS?

nciccroec@mail.nih.gov

NIH NATIONAL CANCER INSTITUTE

www.cancer.gov www.cancer.gov/espanol

24