Summary of Informed Consent Process, Non-English Speaking

March 2024

(Previous for December 2023 in green below)

An audit was conducted of all non-English speaking participants enrolled in CCR studies December 1, 2023, through February 29, 2024. A total of 58 (84) participants were reviewed. Twenty- nine (50%) [48 (57%)] participants had at least one issue identified at the time of the audit related to the informed consent process, including findings related to PRES embedded agreement answers.

The following were issues of noncompliance with NIH Policy 301 that required reporting to the IRB:
(Those issues without a green number were not found in the previous audit)

- Non-English-speaking participant was consented using only the English long form (with an interpreter) – 2 instances that were self-identified by the team and reported to the IRB
- For short form process, witness did not sign English long form – 2 (1)
- Non-English-speaking participant initialed embedded questions on English long form consent – 3
- Short form listed the incorrect protocol number, title and PI – 1
- NIH Administrative section not completed at all – 1
- Non-English-speaking participant signed English long form when short-form process was used – 1 (1)
- Documentation of research consent process note was not located in CRIS – 1 (5)

Below is a summary table of other audit findings:

Issue Found	**Number of patients**	**Percentage of total**	**Action Required**
Embedded agreements answered incorrectly in PRES	7 (25)	12% (30%)	Correct PRES
NIH Administrative Section completed only on long OR short form during the short form process	6 (4)	11% (5%)	Minor deviation
Incorrect selection made in NIH Administrative Section	4 (6)	7% (7%)	none
Informed consent documentation note contained incorrect or missing information	3 (11)	5% (14%)	Correct note, if possible
Interpreter not identified in CRIS note	3 (8)	5% (10%)	Correct note, if possible
Incorrect version of short form used	3 (2)	5% (3%)	Minor deviation

Reminders:

- Non-English-speaking participant **MUST NOT** sign or initial any English informed consent since they cannot read it.
- If an investigator is bilingual and provides interpretation for the non-English speaking patient, this must be identified in the note by selection consent type "Use of Interpeter (including staff or other parties."
- Select **ALL types** of consent used in the Documentation of Research Consent template.
- Remember to complete all NIH Administrative sections when an interpreter is used:
    - Choose the appropriate option depending on if the interpreter also served as the witness.
    - If a translated long form is used, the second option is always selected since no witness is required.