Audit of Documentation of Research Consent Note

May 2024

An audit was conducted of a random selection of patients enrolled in protocols from March 1 through April 30, 2024 to determine if the newly revised CRIS template "Documentation of Research Consent" was used appropriately. Those protocols being reviewed by ASRC for informed consent/eligibility were excluded.

A total of 107 participants were reviewed. The following issues were noted related to the use of the template:

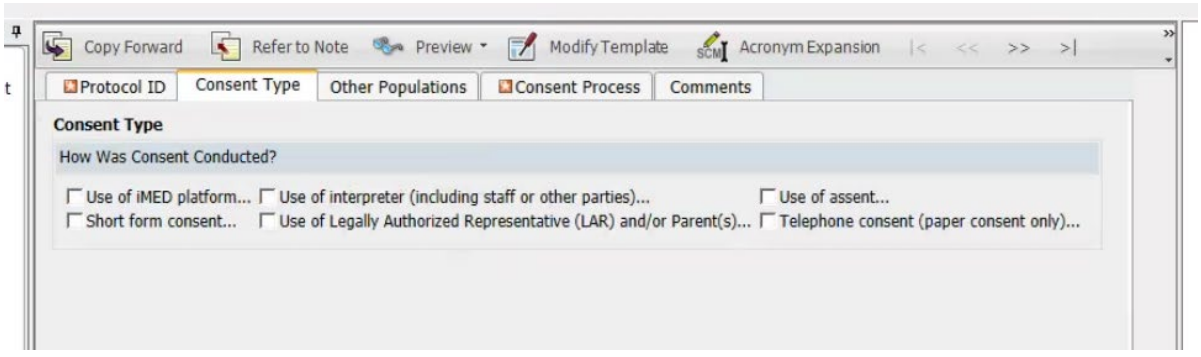
- A Documentation of Research Consent note was not found for four patients. A note is required per NIH HRPP Policy 301 so this lack of note is reportable to the IRB as noncompliance via RNI.
- Twenty-four (22%) notes did not select "Use of iMed Platform" as a consent type when the signature were captured via iMed.
- One note did not select "Use of LAR and/or parents" as a consent type when a minor was enrolled.

Several other issues were found that were not related to the use of the template:

- Error in the note
    - Incorrect informed consent version – 3
    - Incorrect investigator obtaining consent (versus who actually signed the consent) – 2
    - Note indicates LAR (son) signed consent; however, patient's name is printed on the iMed consent with a signature in that section (not the section for LAR signature)
- Incorrect/ no selection under NIH Administrative section of Informed consent when translator used – 2

<u>Reminders:</u>

- A Documentation of Research Consent note is **REQUIRED** for all informed consent processes. Lack of note is noncompliance which is required to be reported to the IRB via RNI.
- Under the Consent Type tab, select ALL types of consent that were used during the informed consent process, including use of iMed to obtain signatures.



- 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.