Summary of Informed Consent Process, CTEP and Network-Sponsored
February 2024

An audit was conducted of all patients enrolled on CTEP or Network-sponsored protocols from June 2023 – January 2024. The audit only included English-speaking participants. A total of 28 participants were reviewed. Ten participants (36%) had at least one issue identified at the time of the audit related to the informed consent process, the majority were findings related to PRES embedded agreement answers. No issues required reporting to the IRB.

Below is a summary table of audit findings:

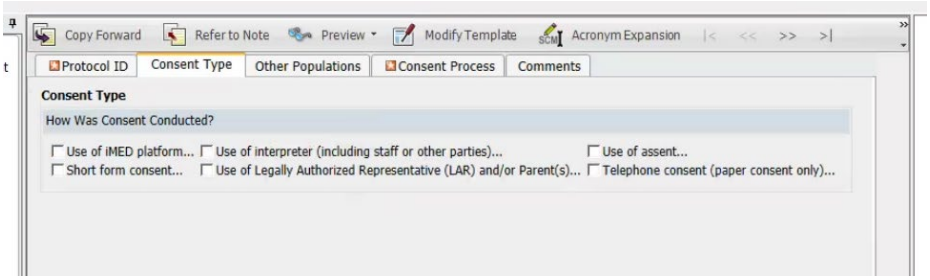
Issue Found	**Number of patients**	**Percentage of total**
Missing information in informed consent process note in CRIS	2	7%
PRES Embedded Agreements answered incorrectly	9	32%

The previous audit of CTEP and Network-sponsored studies, done in April of 2023, focused solely on embedded agreement information and not the entire informed consent process. During the previous audit, a total of 75 consents were reviewed and 50 (66%) had errors in embedded agreement information entered into PRES.

TIP: If you are unsure of how to answer the embedded agreement information in PRES compared to what is in the informed consent document, please contact the Office of Education and Compliance for assistance.

Reminders:

- When writing your Documentation of Research Consent note, please select ALL applicable types of consent that were done during the consenting process. Below is a snip of the Consent Types available:



- Before choosing options in PRES, please review the entire informed consent document to ensure there is no additional language regarding permissions for using identifiable (not coded) or de-identified (coded) specimens and data. The information about embedded agreements in PRES is not just about the embedded questions. The consent may have information about sharing of specimens and data in other areas.

- If the consent document only indicates storing and using “coded” (deidentified) specimens and data, since the study team has the “key” for the code, the first question in PRES is “yes” because the team has the key and can identify the coded specimens and data.
- The answer “Not Appliable” is rarely appropriate as this only applies when the consent document does not address the future use and sharing of specimens and data beyond the research being conducted.