

## Summary of Audit of Embedded Agreement Information in PRES

Conducted April 2023

We recently reviewed informed consents from CCR-sponsored, industry-sponsored and CTEP-sponsored studies to assess the “Protocol Embedded Agreement” information entered into PRES, compared to content of the informed consent document. A total of 75 consents were reviewed from 56 protocols, for a selection of patients consented from January 2 – March 16, 2023.

Of the 75 consents reviewed, only 25 (34%) patients had correct embedded agreement information entered into PRES. While this is an improvement from the previous audit which only had 3 correct entries (out of 48 consents reviewed), there remains confusion about the purpose of the embedded agreement information in PRES and how to correctly answer the agreement options in PRES based on the information in the informed consent.

There were several trends noted:

- When there were no actual embedded questions in the informed consent and the future use information is part of the text, PRES is answered as “Not Applicable.” This is not correct. “Not Applicable” is only appropriate when the consent document does not address ANY future use and sharing of specimens and data beyond the research being conducted. We have not seen this yet during audits.
- When there is information in the consent for the storage and use of specimens and data with “coded identifier” only, PRES options were answered in many different ways: No, Yes, No; No, No, No; Yes, Yes, Yes, etc. The correct way to answer PRES: the first and second option in PRES should be “Yes” (unless the patient selected “No”). The third option in PRES must be “No” as the consent only indicates that coded specimens and data will be stored.
  - Important: 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.
- If a patient answers informed consent embedded questions about future use with a “No,” then all PRES options should be No as the patient has declined any future use of their specimens and data. In the one instance during the audit when the patient selected “No” for consent embedded agreements, PRES agreements were answered correctly as No, No, No.