Summary of Audit of Embedded Agreement Information in PRES and Use of the Revised CRIS Template

Conducted July 2024

We recently reviewed informed consents from CCR-sponsored studies to assess the "Protocol Embedded Agreement" information entered into PRES, compared to content of the informed consent document. In addition, we reviewed the CRIS Documentation of Research Consent note to determine if the template was used appropriately and the information was accurate. A total of 71 consents were reviewed from 45 protocols, for a selection of patients consented from March – June 2024.

PRES Embedded Information

Of the 71 consents reviewed, only 11 (15%) had incorrect information about embedded agreements entered into PRES. During the last audit in April 2023, 66% of the consents had incorrect information so this is a great improvement

There were several trends noted:

- When there are three separate questions in the consent about storage of future use of samples and data, the selection in PRES is not consistent with how the patient answered the question in the consent document. Please enter the PRES response to be consistent with the patient's answer to the question in the consent
- When there are questions in the consent for the storage and use of specimens and data with "coded identifier" only, PRES options were answered in many different ways. The correct way to answer PRES: the first and second option in PRES should be selected per the patient choice, the third option in PRES must always be "No" as the consent only indicates that coded specimens and data will be stored.
- When there were no actual embedded questions in the informed consent and the future use information is part of the text, just by signing the consent the patient has agreed to storage and future use as indicated in the text. The correct way to answer PRES: the first and second option in PRES should be "Yes" and the third option in PRES must always be "No" as the consent only indicates that coded specimens and data will be stored.

Please note that the language in the consent may be slightly different which can affect how PRES sections are made. Please consult with your team lead or OEC if you have any questions.

CRIS Documentation of Research Consent note

The Documentation of Research Consent note could not be located for one consent process. This has been reported to the IRB for non-compliance with Policy 301.

Of the remaining 70 consent notes, there were 10 (14%) that did not include all types of consent. Most commonly, the Use of iMed consent platform was not selected when iMed was used. Please ensure that ALL types of consent are selected in the template that are actually USED during the consent process.