Monday Morning Practice Pearls #71

What is Embedded Agreement Information in PRES?

The majority of protocol informed consents contain information about future use of and sharing of research samples and data, and the information about future use/sharing needs to be captured in PRES in the "embedded agreements" section. This information in PRES will help track and figure out if samples/data can be stored and used in future research by the team, other NIH researchers and outside researchers.

There are three types of agreements in PRES that need to be answered:

1. Identifiable (not coded) specimens and data to be stored and used by the study team for future studies
2. De-identified (coded) specimens and data to be shared with and used by other researchers for future studies
3. Identifiable (not coded) specimens and data to be shared with and used by other researchers for future studies

Many consents have actual questions within the document about future use/sharing of research samples and data both by research team, other teams within and outside of NIH that the patient answers specifically. In this case, PRES options will be answered based on the patient's response to the informed consent questions.

Other consents do not have separate questions but contain information in the text that determine future use/sharing. This text is considered an "embedded agreement" for future use / sharing and by signing the consent document the patient agrees to the future use/sharing as written. In this case, PRES options should be answered the same for all patients that sign the same informed consent version.

In very rare cases, the protocol and informed consent do not contain ANY information about future use/sharing of research samples and data with researchers outside the study team. Or the consent could have a specific statement about NOT sharing with other researchers.

Please remember to update the PRES embedded agreement information if needed when a patient is re-consented. PRES will show the history of embedded agreement answers.

How do you fill out the embedded agreements information in PRES?

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.

There are 3 response options for each agreement in PRES: Yes, No, and Not Applicable.

- The response should be "**Yes**" when the informed consent has separate question regarding the agreement in PRES, and patient's choice is "Yes". Or, when the protocol informed consent contains information in the text that allow the option in PRES agreement.
- The response should be "**No**" when the informed consent has separate question regarding the agreement in PRES, and patient's choice is "No". Or, when the protocol informed consent contains information in the text that doesn't allow the option in PRES agreement.
    - If the consent indicates that only coded/de-identified data will be shared with other researchers, then the response for agreement #2 would be "Yes" and the response for agreement #3 would be "No."

- In very rare cases, the response should be "**N/A**" when the protocol and consent do not address the storage or sharing of any type (coded or not) samples/data beyond the research being conducted. Please note, in this case the responses should be the same for all patients on the protocol.

Note: 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.

Please ensure that technology transfer agreements are executed prior to sharing any data/specimens with outside researchers. Also, the receiving institution must have an IRB approved protocol if identifiable (not coded) data/specimens from NIH are going to used (per NIH consent).

Refer to the PRES User Manual on the CCR Clinical Informatics webpage for more information.

If you have any questions about how to respond to the embedded agreements in PRES, contact your team lead or the Office of Education and Compliance.