Summary of Informed Consent Process, Industry-Sponsored
October 2023

An audit was conducted of a randomized sample of patients enrolled on industry-sponsored protocols May 2023 – September 2023. The audit only included English-speaking participants. A total of 32 participants were reviewed. Eighteen participants (56%) had at least one issue identified at the time of the audit related to the informed consent process, including findings in PRES embedded agreement answers.

The following were issues of noncompliance with NIH Policy 301 that required reporting to the IRB:

- Investigator not in PROTECT to obtain consent – 7

Below is a summary table of audit findings:

Issue Found	**Number of patients**	**Percentage of total**
Inaccurate information in informed consent process note in CRIS	2	6%
PRES Embedded Agreements answered incorrectly	16	50%

The previous audit of industry-sponsored studies, done in the fall of 2022, focused solely on embedded agreement information and not the entire informed consent process. During the previous audit, a total of 48 consents were reviewed and 45 (94%) 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:

- 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.