

Summary of Audit of Embedded Agreement Information in PRES

We recently reviewed informed consents from industry-sponsored studies to assess the “Protocol Embedded Agreement” information entered into PRES, compared to content of the informed consent document. A total of 48 consents were reviewed from 11 industry-sponsored protocols, for patients consented from June 1 – September 1, 2022.

Of the 48 consents reviewed, only three had correct embedded agreement information entered into PRES. The majority of issues surround the third option in PRES “Identifiable specimens and data to be shared with and used by other researchers for future studies.” No informed consent documents reviewed during the audit had language that allowed for identifiable (not coded) specimens and data to be shared with other researchers, however there were cases when this was entered as “Yes” or “Not Applicable.” The correct response is “No” in this situation.

Please note that the answer “Not Applicable” 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.

There were no issues of noncompliance found with the informed consent process that required reporting to the IRB.