

Summary of 04C0165 audit for appropriate use, January 2024
(Previous for August 2023 in green below)

An informed consent and appropriate use audit was conducted of a randomized sample of patients enrolled on protocol 04C0165 October 1 – December 31, 2023, with a total of 58 (48) patients reviewed. Thirty-five patients [60% (52%)] had no issues identified at the time of the audit.

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

- No signed informed consent document in CRIS, without documentation of informed consent process - 1
- Patient preferred language in CRIS is Spanish, however 04C0165 long English form was used and there is no documentation that patient preferred to use English for consent discussion – 1
- No documentation of informed consent process – 6 (2)

Below is a summary table of audit findings:

Issue Found	Number of patients	Percentage of total
No documentation of reason for enrollment or notes are not clearly documented	13 (5)	22 (10)
When consult cohort, no plan of care documented in CRIS	3	5
Not taken off study when off-study criteria were met	1 (23)	2 (48)
No further CRIS documentation after informed consent note and/or first registration note (why is patient still on study?)	4	7
Incorrect cohort selected in PRES	6 (8)	10 (17)

Reminders:

- **Document the consent process in CRIS.** NH Policy 301 requires a note documenting the informed consent process and lack of note is reportable noncompliance.
- CRIS documentation should clearly indicate the reason patient is being enrolled on 04C0165. Please ensure that the cohort in PRES is consistent with the documentation in CRIS.
- After the enrollment on study 04C0165, any further communication/consult with the patient must be documented in CRIS. There were several instances when no further notes were entered into CRIS after consent documentation.
- Remove the patient from the protocol when the patient meets off-study criteria. In particular, when there is documentation in CRIS that the patient is going to continue treatment/management at an outside facility, that patient meets off-study criteria for 04C0165.