

Summary of 04C0165 audit for appropriate use, FY 2023 (Previous for FY 2022 in green below)

An audit was conducted of a randomized sample of patients enrolled on protocol 04C0165 January 1 – February 28, 2023, with a total of 48 (61) patients reviewed. Twenty-three patients [48% (44%)] had at least one issue identified at the time of the audit related to the appropriate use of 04C0165.

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

- No documentation of informed consent process – 2 (2)
- Patient preferred language in CRIS was not English, however 04C0165 long English form was used and there was no documentation that patient preferred to use English for consent discussion – 1

Below is a summary table of audit findings:

Issue Found	Number of patients	Percentage of total
No documentation of reason for enrollment	5 (7)	10 (12)
Not taken off study when off-study criteria were met	23 (15)	48 (25)
Incorrect cohort selected in PRES	8	17

Reminders:

- Document the consent process 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.
- 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.
- 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.