Summary of 04C0165 Audit for Appropriate Use

(Numbers in green are from FY21 audit)

An audit was conducted of a randomized sample of patients enrolled on protocol 04C0165 January 25 – March 8, 2022, with a total of 61 (25) patients reviewed. Twenty-seven (8) patients (44%/32%) had at least one issue identified at the time of the audit.

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

- No documentation of informed consent process – 2 (0)

In addition, three patients did not have signed informed consent documents uploaded in CRIS at the time of the audit. The signed informed consents were later found and uploaded into CRIS.

Below is a summary table of audit findings:

Issue Found	**Number of patients**	**Percentage of total**
No documentation of reason for enrollment	7 (2)	12(8)
Not taken off study when off-study criteria were met.	15 (0)	25 (0)
Investigator signature was obtained in IMED consent prior to the patient signature	1 (n/a)	2% (n/a)

Reminders:

- When using paper informed consent document, please ensure that the signed version is uploaded into CRIS.
- The patient's signature should be obtained first, prior to the investigator obtaining consent and witness if needed. The iMED consent process will populate the exact time, to the second, that signatures were obtained.
- Document the consent process in CRIS within 1 business day of obtaining consent.
- CRIS documentation should clearly indicate the reason patient is being enrolled on 04C0165.
- 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.