

Summary of 01C0129 Audit for Appropriate Use

An audit was conducted of a randomized sample of patients enrolled on protocol 01C0129 January 25 – March 8, 2022, with a total of 67 patients reviewed. Forty-six patients (69%) 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:

- Research procedure done prior to informed consent being signed – 1
- No documentation of informed consent process – 1
- Treatment protocol does not specify use of screening protocol - 3
- Incorrect version of informed consent used - 17

In addition, 2 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.

Eleven patients (16%) were not taken off the screening protocol when enrolled onto a treatment protocol.

Below is a summary table of other audit findings:

Issue Found	Number of patients	Percentage of total
No documentation of specific treatment protocol for which patient is being screening	30	45
Documentation does not indicate appropriate reason for enrollment onto 01C0129	22	33
No documentation that patient is being evaluated for treatment protocol	18	27

Reminders:

- When obtaining consent via remote process, the signed informed consent MUST be returned prior to any research procedures being performed.
- Ensure that the current IRB-approved informed consent is used. Utilizing the iMED remote signature capture system in CRIS can help ensure the current informed consent document is used and that the signed informed consent is uploaded in CRIS.
- Document the consent process in CRIS.
- CRIS documentation should indicate the treatment protocol(s) for which the patient is being screened.
- If a patient is being seen for a “second option” or “consult,” it not appropriate to enroll them on protocol 01C0129; use 04C0165 instead.
- Remove the patient from the screening protocol when the patient is enrolled on a treatment protocol. is found to be eligible for a treatment protocol or otherwise meets off-study criteria for 01C0129.