

Summary of 04C0165 Consult Cohort Audit August 2024

An audit was conducted of patients enrolled on protocol 04C0165, consult cohort only (per PRES), consented May 1 – May 31, 2024. In total, 54 patients were reviewed for informed consent process, including CRIS Documentation of Research Consent and Protocol Embedded Agreement information entered into PRES. Thirty-eight (72%) had at least one issue identified at the time of the audit related to the consenting/registration process.

Please note that prior audits of protocol 04C0165 were not limited to the consult cohort so previous results cannot be compared with this audit.

The following is a finding of noncompliance with NIH Policy 301 that required reporting to the IRB:

- No documentation of informed consent process – 1

Protocol 04C0165 is only for consult, treatment, and medical follow-up for patients, including genetic education and counseling as well as cell/marrow donors for NCI transplant recipients. It is **NOT** for screening purposes. However:

- Five patients had a CRIS note that indicated purpose for visit was screening
- One patient had an off study criteria of “Screen Failure”

In the future, using protocol 04C0165 for screening purposes will be considered noncompliance and reportable to the IRB via RNI.

Below is a summary table of other audit findings:

Issue Found	Number of patients	Percentage of total
Not taken off study when off-study criteria were met	29	57
PRES agreement information incorrect	27	50
CRIS note was unclear about purpose of visit	2	4
CRIS note did not indicate consent of LAR/parent when a minor was enrolled	1	2

Reminders:

- Document the consent process in CRIS AND select all types of consent used (e.g., use of LAR/parent when a minor is enrolled).
- Since there are NO embedded questions in the consent for protocol 04C0165, the PRES Embedded Agreement information should ALWAYS be Yes, Yes, No per information in informed consent section “Use of Data for Future Research.”
- 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.