1. Purpose

To describe the process of closing out a site at the end of its participation in a clinical trial.

2. Scope

Center for Cancer Research (CCR) clinical trial protocols conducted under the Office of Sponsor and Regulatory Oversight (OSRO) oversight are within the scope.

3. Responsibilities

3.1. OSRO Operations oversees the clinical monitoring process including clinical site closure.

3.2. OSRO Sponsor and Regulatory Oversight Support (SROS) Monitoring Team is responsible for

3.2.1. Final review and determination that the investigator's obligations have been met and that all applicable study and regulatory requirements have been fulfilled.

3.2.2. Conducting the Close-Out Visit and preparing the monitoring report.

3.3. The Principal Investigator (PI) oversees the conduct of the protocol and determines when per-protocol criteria for closure have been met.

3.4. Investigators and clinical study staff are responsible for assisting OSRO and SROS by providing required information and documentation and supporting site visits.

4. References

4.1. 205 Clinical Site Monitoring Policy

4.2. 503-S02 Investigational Product Disposition

4.3. ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018

4.4. 21 CFR Part 312 Investigational New Drug Application

4.5. 21 CFR Part 812 Investigational Device Exemptions

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. The site close out process will commence once each site's Clinical Monitoring Plan (CMP) parameters are met. If a request for a Site Monitoring Close-Out Visit (COV) is submitted to the OSRO SROS Request for Service System, SROS Monitoring assesses the site to determine if it qualifies for a COV.

6.2. The SROS Clinical Monitor and the site tracks completion of all required close-out obligations prior to scheduling the COV.

6.2.1. Required close-out obligations include

- All participants are off-study and have completed all follow-up visits.
- Site data for all participants have been entered in the database and/or Case Report Form (CRF) and reconciled.
- All Adverse Events (AEs)/Serious Adverse Events (SAEs)/Unanticipated Problems (UPs) have been entered in the database, events resolved, follow-up completed, and documentation reconciled.
- All action items identified during previous monitoring visits have been addressed and resolved.
- Relevant parties have been notified by the site of the pending closure.

6.3. OSRO may allow a clinical site to close prematurely if the study is terminated early.

6.4. The SROS monitoring team conducts the COV per activities outlined in the protocol's CMP.

6.4.1. Protocol-specific CMPs are filed in the Sponsor electronic trial master file (eTMF).

6.4.2. A Pharmacy COV is performed for those protocols with investigational product (IP) held in the Clinical Center Pharmacy.

6.4.2.1. OSRO Pharmaceutical Management authorizes final disposition of remaining IP. See 503-S02 Investigational Product Disposition (Reference 4.2).

6.5. An SROS Clinical Site Monitor writes the site COV final report.

6.5.1. The site COV final report confirms that the site PI obligations have been met, future study related responsibilities have been reviewed, and confirms that site-specific monitoring activities are closed.

6.6. The COV final report is filed in the protocol-specific folder in the electronic Trial Master File (eTMF).

6.7. Clinical sites must be closed before their associated clinical protocol is closed.

7. Associated Documents

7.1. N/A

8. Change Summary

Revision Number	Effective Date	Description of Change
1	21AUG2024	New Document