1. Purpose

To describe the Office of Sponsor and Regulatory Oversight (OSRO) Operations Clinical Monitoring Plan (CMP) development and maintenance based upon standard components and consideration of protocol, research team, facility, and operational factors.

2. Scope

2.1. This SOP applies to clinical studies conducted under Center for Cancer Research (CCR) held Investigational New Drug applications (IND) or Investigational Device Exemptions (IDE), or Non-Significant Risk (NSR) Device Study under OSRO oversight.

2.1.1. These intramural studies may be conducted at the National Institutes of Health (NIH) Clinical Center or at non-NIH institutions.

3. Responsibilities

3.1. OSRO Operations oversees the process of developing and maintaining protocol-specific monitoring plans.

3.2. The OSRO Sponsor and Regulatory Oversight Support (SROS) contractor monitoring team develops and maintains protocol-specific clinical monitoring plans.

4. References

4.1. 205 Clinical Site Monitoring Policy

4.2. All applicable Codes of Federal Regulations for Human Subjects Protection (HSP), Good Clinical Practice (GCP), current Good Manufacturing Practices (cGMP) and Good Laboratory Practices (GLP)

4.3. FDA Guidance for Industry, Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring, August 2013

4.4. FDA Guidance for Industry, A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers, April 2023

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. A Clinical Monitoring Plan is prepared after a request for a Site Initiation Visit is submitted via the OSRO SROS Request for Service System.

6.2. The monitoring intensity and frequency is determined by a risk-based assessment of specific protocol and site factors which are identified in F02-205-S01 Risk-Based Assessment of Clinical Monitoring Plans (Step 7.2).

6.2.1. Studies using investigational products managed by a clinical pharmacy are subject to pharmacy monitoring per F03-205-S01 Risk-Based Assessment for Pharmacy Monitoring Plans (Step 7.3).

6.2.2. Studies using only an NSR device use a bespoke template (Step 7.5).

6.3. An assigned SROS Clinical Site Monitor drafts the protocol-specific CMP using the Institutional Review Board (IRB) approved protocol, relevant essential regulatory documents, and the completed risk-based assessments, if required.

6.4. The draft CMP is reviewed by an SROS Clinical Study Manager (CSM) and OSRO Operations.

6.5. OSRO Operations approves the CMP.

6.6. The CMP must be approved before the start of monitoring activities.

6.7. The CMP is periodically evaluated for adequacy and revised as necessary by the SROS Monitoring team and OSRO Operations.

6.7.1. Each CMP will be reviewed at least yearly.

6.7.2. Unscheduled CMP reviews may be triggered by a change in the protocol, projected enrollment rate, facility or research team, or any significant non-compliance with regulations, Human Subjects Protection (HSP), Good Clinical Practice (GCP) or Sponsor requirements.

6.8. Each approved CMP is filed in the Sponsor electronic Trial Master File (eTMF).

7. Associated Documents

7.1. 205-S01-W01 Preparation and Review of Clinical Monitoring Plans

7.2. F02-205-S01 Risk-Based Assessment of Clinical Monitoring Plans

7.3. F03-205-S01 Risk-Based Assessment for Pharmacy Monitoring Plans

7.4. SROS Clinical Monitoring Plan template

7.5. SROS NSR Device-only Monitoring Plan template

8. Change Summary

Revision Number	Effective Date	Description of Change
1	28APR2020	New Document
2	19APR2022	Biennial Review Step 3.2 – added Step 4.2 – added Step 6.6 – removed Updated language Updated process flow for addition of SROS Contractor services
3	15FEB2024	Step 4.3 – added Step 4.4 – added Step 7.2 – removed F01-205-S01 and added F02-205-S01 Steps 7.3, 7.4, and 7.5 – added Complete rewrite of process.