1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) Clinical Site Monitoring policy.

2. Scope

2.1. OSRO in the Center for Cancer Research (CCR), National Cancer Institute (NCI) shall establish and control the policy.

2.2. Investigators, research team members, other departmental personnel and external NIH collaborators and contractors when they are working on studies conducted under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE), or a National Institutes of Health (NIH) Institutional Review Board (IRB)-approved protocol using a nonsignificant risk device (NSR) under OSRO oversight or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. Limitations

2.3.1. OSRO clinical site monitoring is not required for clinical trials that are not an IND, IDE, NSR and/or when no interdepartmental collaboration with OSRO oversight is required.

2.3.2. Nothing in this policy will supersede NCI, NIH or Health and Human Services (HHS) requirements.

3. Responsibilities

3.1. CCR Management is committed to providing resources to meet the requirements for implementing a Clinical Site Monitoring policy and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding the Clinical Site Monitoring policy.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding the Clinical Site Monitoring policy.

3.4. Clinical sites are responsible for allowing clinical site monitors access to the facility, personnel and required documents.

3.5. The OSRO Director is responsible for establishing and maintaining the OSRO Clinical Site Monitoring Policy.

4. References

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

4.2. 45 CFR Part 46 Protection of Human Subjects

4.3. 203 Clinical Trial Records Policy

4.4. 206 Site Activation Policy

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. The Office designation of OSRO shall refer both to the Office of Sponsor and Regulatory Oversight staff and the OSRO Sponsor and Regulatory Oversight Support contractor staff.

6.2. Clinical site monitors will verify that the rights and well-being of human subjects are protected; the clinical trial data collected and reported are accurate, complete, and verifiable from source documents, and the study is conducted in compliance with the approved protocol, any protocol amendments, study-specific procedural documents, Good Clinical Practice (GCP), and all applicable regulatory and Sponsor requirements. Source data verifications are not conducted for NSR device only clinical trials.

6.3. Clinical site monitors will be appropriately trained and qualified to monitor trials. At a minimum, monitors will comply with the NIH Clinical Center requirements for personnel involved in clinical research site monitoring.

6.4. A Clinical Monitoring Plan (CMP) will be developed for each protocol.

6.4.1. CMPs will be protocol-specific, risk-based and tailored to address human subject protections and integrity of the study data.

6.4.2. CMPs will include study description, monitoring activities, study subject selection criteria, and monitoring parameters to be met.

6.4.3. The intensity and frequency of monitoring will be based on several factors, including study type, phase, risk, complexity, expected enrollment rate, and any unique attributes of the study and the site.

6.5. Site monitoring contacts and visits will be conducted throughout the life cycle of each protocol such as

- Site Assessment Visit (SAV), as warranted,
- Site Initiation Visit (SIV),
- Interim/periodic Monitoring Visit(s) (IMV),
- Site Close-Out Visit (COV) and
- Ad-hoc Visits, as warranted.

6.5.1. For Site Initiation Visits, see Reference 4.4.

6.5.2. Interim and close-out monitoring visits and related activities will be conducted in accordance with CMP requirements.

6.6. On-site and remote monitoring modalities will be utilized.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	30AUG2019	New Document
2	05FEB2020	1. Added nonsignificant risk device to Section 2 Scope. 2. Added 203 Clinical Trial Records Policy and 206 Site Activation Policy to Section 4 References. 3. Removed the Site Initiation Visit prerequisites from Section 6 Policy.
3	04NOV2022	1. Step 3.3 – removed 2. Step 3.3 OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding the Clinical Site Monitoring policy. – added 3. Step 3.4 – removed 4. Section 4 – added hyperlinks 5. Step 6.1 – added 6. Step 6.10 – removed 7. Updated document language as needed