1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) Audit 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), Non-Significant Risk Device (NSR) study or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. Limitations

2.3.1. Personnel are not bound to this policy when working on non-IND, IDE or NSR studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.

2.3.2. Nothing in this policy will supersede NCI, National Institutes of Health (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 an Audit policy and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the Audit policy.

3.3. The OSRO Director is responsible for establishing and maintaining OSRO's Audit policy.

3.4. Investigators, research team members, other departmental personnel, and external NIH collaborators and contractors will allow site access to OSRO auditors.

4. References

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

4.2. ISO 19011(2018): Guidelines for auditing management systems

4.3. Applicable Code of Federal Regulations (CFR) based on audit scope

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. Sponsor Quality Management System Audits

6.1.1. OSRO will conduct periodic audits to assure that the Quality Management System (QMS) and ancillary programs comply with requirements and are following established procedures, and to determine the effectiveness of the Sponsor quality system.

6.2. Sponsor Vendor Audits

6.2.1. OSRO will establish a vendor audit plan for each product for which OSRO is considered the manufacturer.

6.2.1.1. OSRO is considered the manufacturer for those products that are:

6.2.1.1.1. Included in an OSRO Master File, or

6.2.1.1.2. In an IND submission including the complete Chemistry, Manufacturing and Controls (CMC) sections (not reliant on a letter of cross reference, or available commercial product), or

6.2.1.1.3. In an IDE submission including the complete manufacturing information (not reliant on a letter of cross reference, or available commercial product), or

6.2.1.1.4. In an NSR study including the complete manufacturing information (not reliant on a letter of cross reference, or available commercial product).

6.2.2. Audits of product manufacturing vendors may be deferred to the NIH Clinical Center Office of Research Support and Compliance (ORSC), or other NIH entities at the discretion of the OSRO Director.

6.2.3. OSRO will audit contract research organizations, pharmaceutical companies, institutions, service providers and other collaborators, as necessary, to assure that they are following required Quality System requirements.

6.3. Clinical Trial Audits

6.3.1. OSRO will audit the main and ancillary clinical research facilities utilized for clinical trials, investigational product storage or preparation, human subject specimen storage or testing, and endpoint data generation or collection to evaluate compliance with the protocol, OSRO Policy and institutional Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and applicable regulatory requirements.

6.3.1.1. A clinical site audit may be triggered by a significant and/or pervasive clinical site monitoring finding, but the justification and execution of an audit would be independent of and separate from routine clinical site monitoring.

6.3.2. The audit plan, procedures and prioritization will be guided by the importance of the trial to submissions to regulatory authorities, the type and complexity of the trial, the level of risks to the trial subjects, and any identified problem(s).

6.4. Audits will be conducted in accordance with the written audit plan on what to audit, how to audit, the frequency of audits, and the form and content of audit reports.

6.5. Observations and findings of the auditor will be documented.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	30AUG2019	New Document
2	03JAN2022	Biennial review Step 2.2 – added NSR language Step 4.1 – added hyperlink Step 4.2 – added reference Step 4.3 – added general CFR reference to support Step 6.3.1 Updated document language as needed
3	05JAN2024	Biennial review