1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Quality Program.

2. Scope

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

2.2. Limitation

2.2.1. Nothing in this policy will supersede NCI, National Institutes of Health (NIH) or Health and Human Services (HHS) requirements.

3. Responsibilities

3.1. The Center for Cancer Research Management is committed to providing resources to meet the requirements for implementing a Quality Management System (QMS) within OSRO and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the Quality Management System.

3.3. OSRO Director is responsible for establishing and maintaining OSRO's QMS.

3.4. OSRO Sponsor and Regulatory Oversight Support (SROS) contractor staff assist OSRO Functional Groups as needed.

4. References

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

4.2. Applicable International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines

4.3. Applicable U.S. Code of Federal Regulations (CFR) Title 21 Food and Drugs

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. OSRO shall establish a QMS to manage quality throughout the entire clinical study process. The OSRO approach to quality will be risk-based. The QMS will help ensure that clinical trials are conducted, and data are generated, recorded, and reported, in compliance with the clinical trial protocol, Good Clinical Practices, Good Manufacturing Practices, Good Laboratory Practices, Good Documentation Practices, and other applicable regulatory requirements.

6.2. CCR Clinical Director assigns the responsibility to establish the QMS to the Director, OSRO.

6.3. OSRO shall ensure regulatory compliance of its managed clinical trials by performing the following responsibilities.

6.3.1. Serving as clinical trial Sponsor and meeting all Sponsor obligations.

6.3.2. Participating in the Protocol Development process and providing Sponsor approval for protocols prior to submission to the Food and Drug Administration (FDA).

6.3.3. Monitoring clinical trials to verify that the rights and well-being of human subjects are protected; reported trial data are accurate, complete, and verifiable from source documents, and trial conduct complies with the approved protocol or current amendment(s), with Good Clinical Practices, and with applicable regulatory requirements.

6.3.4. Tracking safety and pharmacovigilance by reviewing and approving safety reports; reporting serious adverse events (SAEs) to investigators and if required, to regulatory agencies.

6.3.5. Preparing and submitting IND applications, IDE, MF and other manufacturing information as appropriate, to the FDA. Ensuring that the trial and all documentation is in full compliance with current regulations.

6.3.6. Providing data analytics support to mine clinical databases for information on improving patient care and safety.

6.4. 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.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	19JUL2019	New Document
2	21JUL2021	1. Biennial review 2. Updated document template 3. Step 4.1 Updated language 4. Step 4.2 & 4.3 Added hyperlinks to references
3	26JUL2023	1. Biennial review 2. Step 2.2 – Removed 3. Step 2.2.1 – Replaced 4. Step 3.4 – Added 5. Steps 4 & 5 – Added and/or updated hyperlinks 6. Step 6.4 – Replaced