1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) Oversight by Institutional Review Board (IRB) 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 and other departmental personnel when they are working on studies conducted under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE) or Non-Significant Risk Device (NSR) or supported by a CCR-held Master File shall follow the policy.

2.3. Limitations

2.3.1. This policy does not apply to personnel working on studies that are not under a CCR-held IND, IDE, or is an NSR device study and/or when no OSRO oversight or interdepartmental collaboration 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 the Oversight by Institutional Review Board policy and supporting its continual improvement.

3.2. Principal Investigators are responsible for communicating with the IRB.

3.3. OSRO personnel are responsible for understanding the Oversight by Institutional Review Board policy.

3.4. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding the Oversight by Institutional Review Board policy.

3.5. The OSRO Director is responsible for establishing and maintaining the Oversight by Institutional Review Board policy.

4. References

4.1. 205 Clinical Site Monitoring Policy

4.2. 206 Clinical Site Activation Policy

4.3. 21 CFR 56 Institutional Review Boards

4.4. 45 CFR 46 Protection of Human Subjects

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

4.6. NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

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. Protocols, Informed Consents and other materials provided to participants will be reviewed and approved by the IRB. These approvals will be provided to OSRO prior to the Site Initiation Visit and activation of a trial.

6.3. No amendment to the protocol or Informed Consent will be implemented prior to IRB approval and OSRO review of such approval.

6.4. It is the Investigator's responsibility to assure that the IRB reviewing the trial complies with all the requirements of 21 CFR 56, 45 CFR 46 and any other applicable local regulation.

6.5. The Investigator will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others.

6.6. The Investigator will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

6.7. For device trials, the Sponsor defers to the IRB for determination of significant risk.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	05SEP2019	New Document
2	14JAN2022	Biennial review Step 2.2 – added Non-Significant Risk Device Step 3.4 – added Section 4 – added hyperlinks to references Step 6.1 – added Updated document language as required
3	30JAN2024	Biennial review Step 2.3.1 – replaced sentence to clarify language