1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) Protocol Development 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) or Investigational Device Exemption (IDE), participating in a CCR-supported Non-Significant Risk Device Study (NSR) or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. For this policy, protocol means the protocol document and other protocol related documents.

2.4. Limitation

2.4.1. 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.

2.4.2. 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 a Protocol Development policy and supporting its continual improvement.

3.2. OSRO personnel are responsible for early and ongoing participation in protocol development, review, and revisions upon invitation of the Study Team.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO are responsible for understanding the Protocol Development policy.

3.4. The OSRO Director is responsible for establishing and maintaining the Protocol Development 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. 21 CFR 312 Investigational New Drug Application

4.3. 21 CFR 812 Investigational Device Exemptions

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. All protocols and informed consent templates will be accepted by OSRO prior to submission to the Institutional Review Board (IRB).

6.2. Any amendment to the protocol or the informed consent templates will be accepted by OSRO prior to submission to the IRB.

6.3. OSRO will determine the appropriate regulatory pathway as part of the protocol acceptance process.

6.4. It is recommended that OSRO personnel participate in early protocol development.

6.5. OSRO will provide required standard language for clinical trial protocols, informed consent forms, information sheets, case report forms and safety data reporting.

6.6. OSRO protocol reviews will be conducted with attention to compliance, consistency, clarity to maximize data integrity and subject safety.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	03SEP2020	New Document
2	03JUN2022	Step 2.2 – added NSR Step 2.3 – added Step 2.4.1 – updated Step 3.3 (Regulatory subject experts) – removed Step 3.3 (SROS contractor) – added Section 4 – added hyperlinks Section 6 – changed approval to acceptance Step 6.7 – removed
3	27MAR2024	Biennial Review