	Office of Sponsor and Regulatory Oversight	Document #: 202
	Protocol Development Policy	Revision #: 2
		Effective Date: 03JUN2022

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

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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