

	Office of Sponsor and Regulatory Oversight	Document #: 202
	Protocol Development Policy	Revision #: 1
		Effective Date: 03SEP2020

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), Investigational Device Exemption (IDE), or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. Limitation

2.3.1. Personnel are not bound to this policy when working on non-IND or IDE 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 a Protocol Development policy and supporting its continual improvement.

3.2. OSRO personnel are responsible for early and ongoing participation in document development, review, and revisions.

3.3. OSRO Regulatory subject matter experts are responsible for assessment and collaboration with investigators in responding to regulatory agency comments.

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.

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6. Policy

- 6.1. All protocols and informed consent templates will be approved 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 approved by OSRO prior to submission to the IRB.
- 6.3. OSRO will determine the appropriate regulatory pathway as part of the approval 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 reviews will be conducted with attention to compliance, consistency, clarity to maximize data integrity and subject safety.
- 6.7. This Policy shall be reviewed periodically and updated as necessary.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	03SEP2020	New Document