

	Office of Sponsor and Regulatory Oversight	Document #: 403
	Oversight by Institutional Review Board Policy	Revision #: 1
		Effective Date: 05SEP2019

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 (IND) or Investigational Device Exemption (IDE), or supported by a CCR-held Master File, shall follow the policy.
- 2.3. Limitation
 - 2.3.1. Personnel are not bound to this policy when working on non-IND/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 the Oversight by Institutional Review Board policy and supporting its continual improvement.
- 3.2. Principal Investigators are responsible for communication with the IRB.
- 3.3. OSRO personnel are responsible for understanding and using the Oversight by Institutional Review Board policy.
- 3.4. The OSRO Director is responsible for establishing and maintaining the Oversight by Institutional Review Board policy.

4. References

- 4.1. OSRO 205 Clinical Site Monitoring Policy
- 4.2. OSRO 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

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4.6. NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
(https://osp.od.nih.gov/wp-content/uploads/2016/06/NIH_sIRB_Policy_Multi_site_Research_UPDATED2016.pdf)

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

- 6.1. Protocols, Informed Consents and other materials provided to participants will be IRB reviewed and approved by the IRB. These approvals will be provided to OSRO prior to the Site Initiation Visit and activation of a trial.
- 6.2. No amendment to the protocol or informed consent will be implemented prior to IRB approval, and OSRO review of such approval.
- 6.3. 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.
- 6.4. 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.
- 6.5. The Investigator will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
- 6.6. For device trials, the Sponsor defers to the IRB for determination of significant risk.
- 6.7. This Policy shall be reviewed periodically and updated as necessary.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	05SEP2019	New Document