1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) Conflict of Interest 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. Clinical Investigators who are directly involved in the treatment or evaluation of research subjects 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. Safety Oversight Committee members when they are serving as part of an OSRO convened oversight committee shall follow the policy.

2.4. Limitations

2.4.1. Personnel are not bound to this policy when working on non-IND, IDE or NSR studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.

2.4.2. Nothing in this policy will supersede any NCI, National Institutes of Health (NIH), Health and Human Services (HHS) or Government-wide requirements.

3. Responsibilities

3.1. CCR Management is committed to providing resources to meet the requirements for implementing OSRO's Conflict of Interest Policy.

3.2. OSRO personnel are responsible for understanding the Conflict of Interest Policy.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding the Conflict of Interest Policy.

3.4. The OSRO Director is responsible for establishing and maintaining the OSRO Conflict of Interest Policy.

3.5. Clinical Investigators and study safety monitoring committee participants are responsible for disclosure of competing professional or personal interests that would either make it difficult to fulfill their study related duties without bias or would create an appearance of impropriety that could undermine public confidence in the study results or in the NCI CCR.

3.6. Clinical Investigators are responsible for submitting Financial Disclosure information in accordance to 21 CFR Part 54.

4. References

4.1. 21 CFR Part 54 Financial Disclosure by Clinical Investigators

4.2. 21 CFR Part 312 Investigational New Drug Application

4.3. 21 CFR Part 812 Investigational Device Exemption

4.4. Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators, February 2013

4.5. NIH Policy for Data and Safety Monitoring, June 1998

4.6. Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees, March 2006

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. Conflict of Interest

6.2.1. Clinical Investigators who are directly involved in the treatment or evaluation of research subjects in trials that OSRO has determined to have a potential to lead to registration or label change, and study safety monitoring committee participants, will disclose any clinical trial financial or personal interest.

6.2.2. For purposes of conflict of interest, the interests of the following persons or entities are treated as the Investigator's or safety committee participant's interests:

6.2.2.1. Spouses,

6.2.2.2. Minor children,

6.2.2.3. General partners,

6.2.2.4. Organizations in which the Investigator or study safety monitoring committee participant serves as an officer, director, trustee, general partner or employee, and

6.2.2.5. Any person or organization with whom the Investigator or study safety monitoring committee participant are negotiating or have any arrangement concerning prospective employment.

6.2.3. Clinical Investigators and study safety monitoring committee participants that have been determined to have a conflict of interest shall either

6.2.3.1. Recuse themselves from working on the clinical trial, or

6.2.3.2. Appropriately manage the conflict before working on the clinical trial.

6.3. OSRO Sponsor Responsibilities

6.3.1. OSRO will obtain sufficient and accurate information from Clinical Investigators and prospective safety committee participants to allow the filing of complete and accurate certification or disclosure statements or if applicable, disqualification from participation on a safety monitoring committee.

6.3.1.1. The information must be provided before the clinical trial can start.

6.3.1.2. The Clinical Investigators will update financial information promptly if any relevant changes occur during the clinical trial and for 1 year following the completion of the study.

6.3.2. OSRO will maintain complete and accurate records showing any financial interests reported by Clinical Investigators.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	27AUG2019	New Document
2	14JAN2022	Biennial Review Step 2.2 – added Non-Significant Risk Device Step 3.3 – added Section 4 – added hyperlinks Step 6.1 – added Removed Sub-Investigators Updated document language as required
3	19JAN2024	Biennial Review Section 5 – added hyperlink