1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Serious Adverse Events Reporting 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 application (IND), Investigational Device Exemption (IDE), or Non-Significant Risk Device (NSR) under OSRO oversight shall assist OSRO in following the policy.

2.3. Limitations

2.3.1. CCR 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.

2.3.2. 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 Serious Adverse Events Reporting program.

3.2. OSRO personnel are responsible for understanding and using the Serious Adverse Events Reporting policy.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Safety are responsible for understanding the Serious Adverse Events Reporting policy.

3.4. The OSRO Director is responsible for establishing and maintaining OSRO's Serious Adverse Events Reporting 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. ICH E2A Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, March 1995

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. Investigators are responsible for promptly notifying OSRO of any events that occur that have affected adversely the safety of subjects or impact the conduct of the trial. This includes at a minimum timely reporting of Serious Adverse Events (SAE), SAE follow-up and other reportable safety events according to the individual protocol.

6.3. OSRO will promptly notify all concerned investigators, regulatory authorities and collaborators of findings that could affect adversely the safety of subjects, impact the conduct of the trial, or alter the Institutional Review Board's (IRB's) approval/favorable opinion to continue the trial.

6.4. OSRO will expedite the reporting of all adverse drug reactions that are both serious and unexpected to all concerned investigators, regulatory authority(ies) and collaborators.

6.4.1. Such expedited reports will comply with the applicable regulatory requirement(s) and with Reference 4.2.

6.5. OSRO will submit to the regulatory authority(ies) all safety updates and periodic reports, as required by applicable regulatory requirement(s).

7. Change Summary

Revision Number	Effective Date	Description of Change
1	01AUG2019	New Document
2	11JAN2022	Biennial review Section 4 – Updated reference language, added hyperlinks Step 3.3 – added Step 6.1 – added Updated document language as required