1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Corrective and Preventive Action (CAPA) 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. OSRO activities are within scope.

2.3. Limitations

2.3.1. 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.

2.3.2. 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 CAPA program within OSRO's Quality Management System (QMS) to achieve quality objectives and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the Corrective and Preventive Action policy.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff following OSRO procedures are responsible for understanding and using the Corrective and Preventive Action policy.

3.4. The OSRO Director is responsible for establishing and maintaining OSRO's Corrective and Preventive Action 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 Q10: Pharmaceutical Quality System, April 2009

4.3. ISO 9001:2008(E): Quality Management Systems – Requirements

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. OSRO shall establish and maintain procedures for implementing corrective and preventive action.

6.2. The procedures shall include requirements for:

6.2.1. Analyzing processes, work operations, audit reports, and other sources of quality data to identify existing and potential causes of nonconformance.

6.2.2. Investigating the root cause of a nonconformance.

6.2.3. Identifying the action(s) needed to correct and prevent recurrence of nonconformities and other quality issues.

6.2.4. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the investigational product, clinical trial, patient or quality system.

6.2.5. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality issues.

6.2.6. Ensuring that information related to quality issues or nonconforming products/systems are disseminated to those directly responsible for assuring the quality of such product or the prevention of such issues.

6.2.7. Submitting relevant information on identified quality issues, as well as corrective and preventive actions, for management review.

6.2.8. Documenting all activities and their results.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	12AUG2019	New Document
2	03JAN2022	Biennial review Step 2.2 and Step 2.3 – added Step 3.3 – added Section 4 – add hyperlinks to Steps 4.1 and 4.2 Updated document language as needed