1. Purpose

To provide the process for the Corrective and Preventive Action (CAPA) system to promote continuous improvement of Office of Sponsor and Regulatory Oversight (OSRO) quality systems.

2. Scope

2.1. This CAPA system applies to the OSRO Quality Management System which includes the processes and procedures of the internal functional areas – Quality, Operations, Safety, Regulatory and Pharmaceutical Management.

2.2. Limitation

2.2.1. This procedure does not apply to CAPAs identified at Center for Cancer Research (CCR) clinical sites which would be governed by their own CAPA programs.

3. Responsibilities

3.1. OSRO members are responsible for reporting incidents to the OSRO Director or Quality Head.

3.2. OSRO Functional Group Heads approve CAPA documentation.

3.3. OSRO Quality oversees the CAPA system and approves CAPA documentation.

3.4. The OSRO Director approves CAPA documentation.

3.5. OSRO Sponsor and Regulatory Oversight Support (SROS) contractor staff assist OSRO Functional Groups as needed.

4. References

4.1. 104 Corrective and Preventive Action Policy

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. Sources of CAPA

6.1.1. Inputs for the CAPA program are generated from other components of the OSRO Quality Management System including processes from each OSRO functional area – Quality, Operations, Safety, Regulatory and Pharmaceutical Management.

6.1.1.1. Examples include but are not limited to the following:

6.1.1.1.1. Risk Assessments

6.1.1.1.2. Audits (internal and external)

6.1.1.1.3. Change Control

6.1.1.1.4. Deviations

6.1.1.1.5. Training

6.1.1.1.6. Serious Adverse Event (SAE) reporting

6.1.1.1.7. Clinical monitoring

6.2. CAPAs are not used for making a system change. The Change Control system justifies and approves changes.

6.3. CAPA Reports may be for corrective or preventive actions.

6.4. Any OSRO member may submit an item for evaluation for inclusion into the CAPA system.

6.5. CAPAs are documented within the Quality electronic quality management system.

6.6. CAPA Report Management

6.6.1. The CAPA Report contains descriptions of the identified issue which caused the CAPA, an analysis of cause, the proposed resolution and final actions used to correct or prevent the action from reoccurring.

6.6.2. CAPA Reports are managed using the OSRO Quality electronic document management system.

6.6.3. CAPA Reports are reviewed by the relevant OSRO Functional Group Head, Quality and the Director.

6.6.4. The OSRO Director closes CAPA Reports.

7. Associated Documents

7.1. 104-S01-W01 Completing CAPA Reports

7.2. 101-S04 Change Control

8. Change Summary

Revision Number	Effective Date	Description of Change
1	15NOV2019	New Document
2	01DEC2022	Step 3.5 – added Step 4.1 – added hyperlink Step 6.4.3 – removed; CAPA numbers will be assigned by the Quality electronic document management system Steps 6.7 and 6.8 – removed Updated language and process