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 groups, Quality, Operations, Safety and Regulatory.

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. OSRO Director approves CAPA documentation.

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 group, Quality, Operations, Safety, and Regulatory.

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

- Risk Assessments
- Audits (internal and external)
- Change Control
- Deviations
- Training
- Serious Adverse Event (SAE) reporting
- Clinical monitoring
6.2. CAPAs are not used for making a system change. The Change Control system justifies and approves changes.

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

6.4. CAPA Reports
   6.4.1. CAPA Reports may be for corrective or preventive actions.
   6.4.2. 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.
   6.4.3. The CAPA is issued a unique number using the format CAPAYY-XX where YY is the last two digits of the current year and XX is a sequential number starting with 01.
   6.4.4. CAPA Reports are reviewed by OSRO Function Group Heads, Quality and the Director.
   6.4.5. The OSRO Director closes CAPA Reports.

6.5. OSRO Quality maintains tracking logs for CAPA Reports.

6.6. Closed CAPA Reports are archived by OSRO Quality.

6.7. Metrics
   6.7.1. Metrics of the CAPA System will be presented to OSRO Management on a periodic basis.

6.8. This SOP shall be reviewed periodically and updated as necessary.

7. Associated Documents
   7.1. 104-S01-W01 Completing CAPA Reports
   7.2. 101-S04 Change Control

8. Change Summary

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