1. Purpose

To describe the system for managing deviations to procedures within the Office of Sponsor and Regulatory Oversight (OSRO).

2. Scope

2.1. This deviation system applies to the OSRO Quality Management System which includes the processes and procedures of the internal functional groups, Quality, Operations, Safety and Regulatory. This SOP applies to any deviation from an OSRO documented procedure.

2.2. Limitation

2.2.1. This procedure does not apply to deviations identified at Center for Cancer Research (CCR) clinical sites which are governed by their own deviation 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 deviation documentation.

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

3.4. The OSRO Director approves deviation documentation.

3.5. The OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor assists OSRO as needed.

4. References

4.1. 104 Corrective and Preventive Action Policy

4.2. 101-S01 Corrective and Preventive Action (CAPA) System

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. Deviations may occur in any component of the OSRO Quality Management System including processes from each OSRO functional area, Quality, Operations, Safety, Regulatory and Pharmaceutical Management.

6.2. Deviations occur when an employee does not follow an established procedure.

6.3. Deviations may be categorized as planned or unplanned.

6.3.1. Planned deviations are deviations from a procedure that are planned to occur with advanced knowledge.

6.3.2. Unplanned deviations are failures to follow a procedure that are discovered after the process is executed.

6.4. When an unplanned deviation is discovered, the person identifying the deviation informs his/her supervisor, OSRO Quality and the OSRO Director within 1 business day of the date of discovery.

6.5. The unplanned deviation is investigated for the what (happened), when (did it happen), where (did it happen), and how (did it happen) as well as the immediate actions taken.

6.5.1. A CAPA (Reference 4.2) may be required to identify corrective and/or preventive actions that are required to address the root cause of the deviation.

6.6. Deviation Report Management

6.6.1. Deviation Reports are managed using the OSRO Quality electronic document management system.

6.6.2. Deviation Reports are reviewed by OSRO Function Group Heads, Quality and the OSRO Director.

6.6.3. The OSRO Director closes Deviation Reports.

7. Associated Documents

7.1. 104-S03-W01 OSRO Deviation Management

8. Change Summary

Revision Number	Effective Date	Description of Change
1	18DEC2019	New Document
2	01DEC2022	Step 3.5 – added Step 6.1 – added Pharmaceutical Management Step 6.3.1 – removed using change control for documenting planned deviations Steps 6.9, 6.11 and 6.12 – removed Moved 101-S01 from Section 7 to Section 4 Updated document language as required