	Office of Sponsor and Regulatory Oversight	Document #: 101-S04
	Change Control	Revision #: 3
		Effective Date: 06SEP2023

1. Purpose

To establish a procedure for controlling and documenting changes introduced into a controlled system in order to prevent changes leading to unintended consequences.

2. Scope

2.1. The procedure applies to any proposed change that is associated with a controlled computerized system managed by the Office of Sponsor and Regulatory Oversight (OSRO).

2.2. Limitation

2.2.1. Computerized systems overseen by the OSRO Sponsor and Regulatory Oversight Support (SROS) contractor are outside of scope.

3. Responsibilities

3.1. OSRO personnel shall follow this procedure.

3.2. OSRO Quality is responsible for administering the change control system.

3.2.1. The SROS Contractor assists OSRO Quality as needed.

3.3. OSRO Regulatory is responsible for determining if Regulatory approval of the change is needed and for reviewing changes that may affect regulatory submissions if the proposed change requires reporting to any regulatory authorities.

4. References

4.1. [101](#) Good Documentation Practices Policy

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. Any OSRO member can propose a change via this SOP.


6.2. The Computerized System Owner formally requests a change to the system.

6.3. The System Owner, Quality and other key stake holders assess how the change will affect the system.

6.4. The changes should be tested outside of the production system, i.e. a Sandbox or test environment, to ensure system accuracy, reliability and consistent intended performance.

6.5. The changes are introduced into the production system.

6.5.1. The changed system is released to the site and users are trained on the system changes, as needed.

	Office of Sponsor and Regulatory Oversight	Document #: 101-S04
	Change Control	Revision #: 3
		Effective Date: 06SEP2023

6.6. Temporary Change Control

6.6.1. Under rare circumstances, a temporary change control may be required.

6.6.2. A temporary change control is documented by the following information.

6.6.2.1. Date the temporary change will occur.

6.6.2.2. Duration of temporary change.

6.6.2.3. Description of temporary change, including a justification for the proposed system change.

6.7. Voiding Change Control requests

6.7.1. Change controls may be withdrawn prior to or during the approval process.

6.7.2. Approved changed controls are voided by generating a supplemental change control request to return the system to its previous configuration.

7. Associated Documents

7.1. N/A

8. Change Summary

Revision Number	Effective Date	Description of Change
1	25FEB2020	New Document
2	16NOV2021	Updated document to only include computerized systems. Added Step 3.2.1.
3	06SEP2023	Biennial review Step 2.2.1 – added Step 4.1 – added hyperlink Updated document language as required.