1. Purpose

To define the process by which Office of Sponsor and Regulatory Oversight (OSRO) documentation is provided to collaborators.

2. Scope

2.1. OSRO will provide its controlled documents to collaborators who have justification to possess them.

2.2. Limitation

2.2.1. OSRO's control over its documentation terminates upon collaborator receipt of the document.

3. Responsibilities

3.1. OSRO Operations manages requests related to clinical trial oversight.

3.2. OSRO Safety manages requests related to Serious Adverse Event (SAE) reporting.

3.3. OSRO Regulatory manages requests related to regulatory authorities.

3.4. OSRO Pharmaceutical Management manages request related to investigational products.

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

3.6. The OSRO Director has final authority on the release of an OSRO-controlled document to a collaborator.

4. References

4.1. 101 Good Documentation Practices Policy

5. Definitions

5.1. Refer to the OSRO Lexicon.

6. Procedure

6.1. Personally identifiable information (PII) should not be in OSRO possession and will not be shared with a collaborator.

6.2. Quality Management System Documents

6.2.1. Policies, SOPs, select Forms and Form Instructions are posted on the OSRO Wiki Page.

6.2.1.1. Only those Forms which are used by non-OSRO personnel are posted on the OSRO Wiki Page.

6.2.1.2. Documents related to internal OSRO procedures are not posted on the OSRO Wiki Page.

6.2.2. Information to which the collaborator is not authorized to view will be redacted prior to releasing the document.

6.3. Operations Documents

6.3.1. Documents will be shared with non-OSRO personnel according to established agreements.

6.3.2. The OSRO Director or the OSRO Operations Head approves the collaborator's request.

6.3.3. Information to which the collaborator is not authorized to view will be redacted prior to releasing the document.

6.4. Safety Documents

6.4.1. MedWatch and CIOMS reports will be shared with non-OSRO personnel according to established agreements.

6.4.2. The OSRO Director or the OSRO Safety Oversight Coordinator approves the collaborator's request for additional information.

6.4.3. Information to which the collaborator is not authorized to view will be redacted prior to releasing the document.

6.5. Regulatory Documents

6.5.1. Documents filed with regulatory agencies will be shared with non-OSRO personnel according to established agreements.

6.5.2. The OSRO Director or the OSRO Regulatory Head approves the collaborator's request for additional documents.

6.5.3. Information to which the collaborator is not authorized to view will be redacted prior to releasing the document.

6.6. Pharmaceutical Management Documents

6.6.1. Documents regarding investigational products will be shared with non-OSRO personnel according to established agreements.

6.6.2. The OSRO Director or the OSRO Pharmaceutical Management Head approves the collaborator's request for additional documents.

6.6.3. Information to which the collaborator is not authorized to view will be redacted prior to releasing the document.

6.7. Other documentation not identified in this procedure will be provided to collaborators on a case-by-case basis.

7. Associated Documents

7.1. N/A

8. Change Summary

Revision Number	Effective Date	Description of Change
1	26NOV2019	New Document
2	16NOV2021	Added Steps 3.1, 3.4, 3.5, and 6.3.1. Added Section 6.6. General updates to document.
3	06SEP2023	Biennial review Step 4.1 – added hyperlink Step 6.2.2 – added Updated document language as required