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. Office of Sponsor and Regulatory Oversight (OSRO) personnel shall follow this procedure.

   3.2. OSRO Regulatory manages all requests related to regulatory authorities.

   3.3. OSRO Safety manages all requests related to SAE reporting and protocol amendments.

   3.4. 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**

   Refer to the OSRO Lexicon.

6. **Procedure**

   6.1. Personal Identified Information 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, [https://ccrod.cancer.gov/confluence/display/CCRCRO/Office+of+Sponsor+and+Regulatory+Oversight](https://ccrod.cancer.gov/confluence/display/CCRCRO/Office+of+Sponsor+and+Regulatory+Oversight).

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

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

   6.3. **Operations Documents**

       6.3.1. The OSRO Director or the OSRO Operations Head approves the collaborator’s request.

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

6.7. This document shall be reviewed periodically and updated as necessary.

7. Associated Documents

7.1. N/A

8. Change Summary

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<th>Revision Number</th>
<th>Effective Date</th>
<th>Description of Change</th>
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