1. Purpose

To define how controlled documents are managed by the Office of Sponsor and Regulatory Oversight (OSRO).

2. Scope

2.1. This procedure is used for all OSRO Quality Management System (QMS) documents including policies, standard operating procedures (SOPs), work instructions (WIs), forms and form instructions and miscellaneous documents.

2.2. Limitation

2.2.1. Only OSRO QMS documents are controlled by this procedure.

3. Responsibilities

3.1. OSRO Quality is responsible for QMS oversight and assuring that documents are kept in accordance with applicable current regulatory requirements. OSRO Quality is responsible for managing controlled QMS documents.

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

3.2. OSRO Functional Groups are responsible for ensuring that their respective documents are up-to-date with current procedures and regulatory requirements.

4. References

4.1. 101 Good Documentation Practices Policy

4.2. 21 CFR Part 11 Electronic Records; Electronic Signatures

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. Document Numbering Scheme

6.1.1. Controlled documents are assigned unique numbers. Documents are organized by Functional Group. Each Functional Group is assigned a unique hundred series, 100, 200, etc. (see Table 1). Numbers within each series begin with x01.

6.1.1.1. The single exception to this rule is 100 Quality Policy which establishes the OSRO QMS.

6.1.2. Policies use a 3-digit number, e.g., 101, 206.

Table 1. Assigned Number Series for OSRO Functional Groups.

OSRO Functional Group	Document Number Series
Quality	100
Operations	200
Safety	300
Regulatory	400
Pharmaceutical Management	500

6.1.3. SOP document numbers use the format XXX-SYY where XXX is the SOP's associated policy document and YY is a sequential number starting with 01.

6.1.3.1. For example, this SOP is assigned the number 101-S02 indicating that it is linked to Policy 101 (Good Documentation Practices Policy) and is the second SOP associated with this policy.

6.1.4. WI document numbers use the format XXX-SYY-WZZ where XXX-SYY is the WI's associated SOP and ZZ is a sequential number starting with 01.

6.1.4.1. For example, 101-S02-W01 is the first work instruction linked to SOP 101-S02.

6.1.5. Forms use the format Fnn-XXX-SYY where nn is a sequential number starting with 01 and XXX-SYY is the associated SOP.

6.1.5.1. For example, F01-101-S02 is the first form linked to SOP 101-S02.

6.1.6. Form Instructions use the format FInn-XXX-SYY where FI (Foxtrot India) replaces the F prefix in the form number.

6.1.6.1. For example, FI01-101-S02 is the form instruction linked to form F01-101-S02.

6.2. New Documents and Revision of Existing Documents

6.2.1. Document numbers, revision numbers and effective dates are assigned by OSRO Quality.

6.2.2. New documents are drafted using OSRO Quality templates.

6.2.3. Existing documents are revised using a copy of the effective document.

6.3. Document Collaborative Review

6.3.1. Documents should be reviewed by at least one subject matter expert, OSRO Quality and the OSRO Director prior to submitting the document for approval.

6.4. Document Approval Process

6.4.1. Minimum signatories shall be the author, OSRO Quality and the OSRO Director.

6.4.2. For documents belonging to an OSRO Functional Group, the head of that group should sign their approval.

6.4.3. Approval signatures must be compliant with 21 CFR Part 11 (Reference 4.2).

6.4.4. Approval signatures may be recorded in one of two ways.

6.4.4.1. Within the electronic document management system, or

6.4.4.2. Using F02-101-S02 Document Approval Form.

6.4.5. The document is effective on the date which OSRO Quality, the final signatory, signs its approval.

6.5. Issuing Controlled Documents

6.5.1. Released documents are posted in the electronic document management system.

6.5.2. Released policies and SOPs are posted on the Center for Cancer Research OSRO Wiki page.

6.5.3. Released Forms and Form Instructions to be used by clinical study staff are posted on the OSRO Wiki page.

6.6. Archiving Controlled Documents

6.6.1. OSRO Quality maintains an archive of controlled documents on the CCROSRO-QA SharePoint.

6.7. Obsolescing Documents

6.7.1. The document is made obsolete in the electronic document management system.

6.7.2. When a controlled document is made obsolete, the file is removed from the OSRO Wiki page (if posted).

6.8. Biennial Document Review

6.8.1. Each QMS document should be reviewed by the document owner or designee at least once every two years. This review will assess the document for accuracy with current practices, regulatory requirements, industry standards and applicable procedures.

6.8.1.1. The biennial review due date is 2 years from the document's effective date.

6.8.2. As a result of the review, documents may be obsolesced, revised or not revised.

6.9. Training Requirements

6.9.1. New documents will be assessed for the required training level: self-study or instructor-led.

7. Associated Documents

7.1. 101-S02-W01 Document Control Procedures

7.2. 101-S02-W02 Using Electronic Signatures in Adobe Acrobat

7.3. 101-S02-W03 Wiki Page Document Control Procedures

8. Change Summary

Revision Number	Effective Date	Description of Change
1	25FEB2020	New Document
2	16NOV2021	Updated procedure to include SROS contractor; use of electronic document management system. Updated document to match procedure.
3	06SEP2023	Biennial review Step 4.1 – added hyperlink Steps 6.4.4.1 & 6.4.4.2 – reversed order of the 2 steps Step 6.6.1 – specified location of the controlled documents archive Steps 6.7.1 & 6.7.2 – reversed order of the 2 steps Updated document language as required