Document Controls of Medical Device

14.1 INTRODUCTION

As per the ISO 13485 a relevant procedure that outlines the process of control of internal and external origin documents needs to be put in place covering all aspects of adequacy, approval, re-approval, issue, availability, revision and legibility in accordance to the international standards and regulatory bodies in your Quality Management system for Medical Devices.

The procedure should cover the below elements:

1. **Approval of documents matrix-** A list of approving/Preparing authorities who can sign off/Prepare the documents needs to be given.
2. **Controlled and uncontrolled copies**- The company needs to put in place a system to identify controlled and uncontrolled copies and storage.
3. **Revision:** The revision status is included in the master copies by the MR and any revision requests need to be appropriately signed off and made note of in the revision history.
4. **Legibility**
5. **Obsolete documents:** Collection and destruction of obsolete documents and retention of one copy till the lifetime of the device
6. **External Origin:** An index with all the external documents and its relevant details needs to be maintained

ISO 13485 section 4.2, describes the requirements which must be adhered to when producing **documentation**. Such **documentation** includes quality **management** manuals, procedures for approval, distribution, and change of a **document** and the designation of a person or persons who should implement those procedures.

Documentation control is the first task that most people would prepare for before an upcoming audit. Prior to an audit, we would ensure that any changes made to the work procedures are updated, review the Quality Manual and Quality Management System documents, and ensure that each process owner is aware of their roles and responsibilities. This is an ecosystem that forms the fundamentals of good documentation control.

According to Section 4.2.4 (Control of documentation) of **ISO 13485:2016**, documents required by the Quality Management System (QMS) should be maintained and controlled to ensure their usability, effectiveness, and adequacy for operation. The organization should archive the documents, based on the projected useful life of the medical device or according to national regulatory requirements – whichever is the longest. ISO 13485:2016 requires that documentation related to the manufacture or testing of a medical device must be retained for the lifetime of the device, but not less than two years after distribution of the device. The retention period must also meet the requirements of the regulatory authorities of the countries in which the device is distributed. It is important to adopt a risk-based approach when you make changes to the work procedures, the Quality Manual, and other related documents that might affect the Quality Management System.

14.2 What are the common mistakes when implementing Section 4.2.4?

1) Documents are used without prior approval and review –

The consequence is that people do not follow the correct procedures to perform their daily work. For example, people make changes to the prescribed procedure when they perform a task. As a result, they use a procedure that is not updated in the approved work instructions. To avoid the above scenario, it is recommended to perform a routine check on the status of procedures as documented in the system, as compared to the actual procedure that is carried out. In addition, instead of using paper copies, each work

station could have a computer screen that is tied into the document control center so that only the current work instruction could be called up. This needs to be done so that there is no discrepancy between what is executed and what is written. It can also help in identifying gaps and improvement opportunities within the existing procedures in the Quality Management System.

2) No defined controls to prevent unintended use of outdated documents –

If the organization does not perform archiving on a regular basis, that will lead to the unintended use of incorrect procedures to execute the task. We can take simple steps, such as creating a folder in the common drive to store the outdated documents on a regular basis, and restricting the access only to the process owner or administrator. Alternatively, we can rename each document so that the title includes the version number and the date of our changes. That way, it would be much easier to identify the current document for use.

3) No tracking of revision status and changes of documents –

In companies where there is a central documentation control department, individual departments tend to take less responsibility over their own processes. They depend on the document controller to update the changes for them. However, in such a scenario, during an audit, the process owners are not able to explain the changes. The recommendation would be to keep a Master Control List with details about the current version of the document, effective date, changes that have been made, and validity of the documents. This is important to provide an overview for tracking purposes. In addition, it is also recommended to conduct a monthly meeting with the Central Documentation Department. This should be done to review the current version of the documents with the Master Control List to avoid discrepancies. That way, the company will be a step closer to being in compliance with the standard.

14. 3 What are the benefits from good documentation practice?

Do remember that everything discussed in this article could also extend to the maintenance of records. It's always a good practice to track changes using a Master Control List, and conduct regular reviews of existing procedures for compliance and improvement opportunities with the process owners. Also, regular meetings will help you to discuss the effectiveness of the current Quality Management System. By doing so, you can enhance your documentation system and improve operational workflow. This could also be a good way to identify any potential improvements or feedback during the internal audit or management review.

14.4 PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to ensure that controlled documents related to clinical research are appropriately managed at the CRC. The purpose of "control" is to assure that documents used in more than one location are

a) properly situated where needed, and

b) can be withdrawn and re-issued when changed, assuring that only current, non-obsolete versions of the documents are in place.

14.5 SCOPE:

This SOP encompasses all documents used to control the management and processes associated with clinical research studies at the CRC.

14.6 RESPONSIBILITY:

The **Principal Investigator** is responsible for determining which documents need to be controlled. The **Research or Regulatory Coordinator** is responsible for implementing and maintaining document control system that includes the following:

- Coordinates reviews and revisions of quality system documents

- Maintains Master File to ensure active and revised documents are provided to staff that must contain Document Number, Title, Revision Level and Review date
- Archives superseded or obsolete documents
- Reviews SOP prior to use
- Ensures that all routine operations and activities are documented by SOPs
- Creates or delegates creation of documents

Other Designated Research Personnel are responsible for the following:

- Verifying that the official version of the document is used
- Review and determine need for new procedures or its revision and to convey that need to their immediate supervisor

14.7 DEFINITIONS:

Controlled Document: A document is considered "controlled" when its distribution is identified by means of a written list or log that gives the document a title and the identity of the location where it is situated (which may be a list of names or physical locations).

14.8 PROCEDURE:

1. Research staff will be knowledgeable of various types of controlled documents used for clinical research. Examples of controlled documents include the following:
   - Clinical protocol (including monitoring plan)
   - Protocol amendments
   - Case report forms (CRFs)
   - Informed consent form (ICF)
   - Investigator Brochure

- Equivalent medical device study documents (Investigational Plan, Report of Prior Investigations)
- Adverse event (AE) reporting form
- Certain other FDA documents: All other documents that are developed for clinical study purposes are considered non-controlled.

2. Version Control and Naming Convention:

2.1. All controlled documents need to be dated and/or versioned in sequential order and systematically named, especially if they belong to a series or set of documents e.g. protocol, informed consent form.

2.2. The first draft of the protocol should be labelled with a version number and dated, for example 'Draft version 0.1 and dated. Further draft versions should be labelled 'Draft version 0.2, 0.3' etc. and dated.

2.3. The final original version of the protocol may be labelled 'Final Version 1.0' and dated before being submitted for the appropriate approvals.

2.4. If amendments are necessary following review of the protocol then subsequent versions of the protocol may be labelled 'Draft Version 1.1, 1.2' while still being drafted and reviewed and the version re-submitted for approval should be labelled 'Final Version 2.0' and dated.

2.5. If the protocol is then amended again during the study then the version submitted for approval of the amendment will be labelled 'Final Version 3.0' and so on.

2.6. Other considerations that should be on the document when appropriate:

- Effective date and expiry date or next review dates if applicable. It may be necessary to also include date issued and date printed.
- Page numbers – It is recommended that pages are numbered as "Page X of Y"
- Confidential – If the document is confidential, mark "Confidential"
- Document identification- e.g. a title, department name

- Approvals - It may be necessary to include signature and date of Author, Reviewer and Authorizer with titles of signatories e.g. for SOPs, protocols.
- Copyright as appropriate – Insert copyright information if necessary.
- Reason for Change – If it is a revision of the control document, state reason for change and list changes.
- Referencing - When reference is made to another controlled document, you may use the instruction "see/refer to *Document Title*". The version number may be excluded.

3. Document Initiation and Approval Procedures:

3.1. The PI or designated research personnel will use the procedures below for the drafting, review, approval and revision of controlled documents.

3.2. Determine which documents are needed for developing regulatory submissions, collecting data or other study information, and/or performing any other study-related function.

3.3. Determine who will draft the first version of a given document (the author) and any related appendices (list of attachments) to be included with the document.

3.4. Determine who must review and approve the first and succeeding draft

3.5. Use templates or other available guidelines for developing new documents where available, and initiate the document drafting process.

3.6. Complete the document control noting version date in the document number section and in the footer of the document.

3.7. Circulate the draft if it needs continued review securing signature/review date, comments and suggestions from all specified reviewers.

3.8. Revise the document per initial review process, and if any revisions are not incorporated, he/she will notify the affected reviewer(s) of the reason(s) for not

including the revision(s), and negotiate a resolution, documenting any significant differences in the space provided on the Document Control Form.

3.9. Continue to circulate the revised document to all signatories until the review process is complete. The document will have a version date for each review and then a final version date.

3.10. Ensure all required reviewer approvals are indicated by entries in the Signature and Approval Date boxes on the controlled document.

3.11. Upon final signature of the last reviewer, the authorized person should sign and date the controlled document in the space provided to indicate responsibility for that document.

4. Following final approval, the research designee will assign all newly approved documents a version number and effective date.

5. The original approved document and Document Control Form(s) will be retained in the appropriate archive file or section of the Regulatory Master File.

6. For new, non-controlled documents, there are no specific required procedures to follow for development, but department administration must approve the development of new documents and their final version.

7. Document Review/ Change Procedures:

7.1. Each respective department will review controlled documents periodically or as needed by circumstances (e.g., new federal or state regulation, new University or institutional policy or procedure, or need for update of Investigational Brochure, etc).

7.2. If revisions are needed in a controlled document, the research designee will do the following:

- Have the author of the change(s) circulate the revised draft with a copy of the original, clearly noting the changes, using the Document Control Form as its cover
- Continue to give updated and revised controlled documents a new version number (01, 02, etc.) and a current effective date
- Document periodic review and updating by maintaining an accurate Table of Modifications Form for each controlled document
- Watermark prior version of the controlled document "Obsolete" and save copy for the appropriate archive file or section of the Regulatory Master File
- Update any related tables or indices, as appropriate (refer to the current OHR policy for details).

8. Revision of Non-Controlled Documents:

8.1. When revisions are needed in a non-controlled document, the author of the non-controlled document or a designee will do the following:

- Make the change(s) and circulate the revised draft with a copy of the original, clearly noting the changes and why they are needed.
- Continue to give updated and revised non-controlled documents a new version number (01, 02, etc.) and current effective date. .
- Mark prior version of the document "Obsolete" and save copy for the appropriate archive file (see specific SOP for location).
- Update any related tables or appendices, as appropriate

9. Document Implementation Procedures:

9.1. The Investigator will ensure that all appropriate staff is trained in the proper use of the new or revised document.

9.2. The Investigator will make a list of all affected parties and appropriate regulatory authorities (IRB, FDA) who must be notified of changes to applicable and notify

them in writing when the changes are implemented (or prior to implementing, if appropriate).

9.3. The research designee will provide the updated version of appropriate documents to affected parties.

9.4. documents

10.Storage and Archiving:

10.1. Controlled documents should be stored in an area or room restricted to authorized individuals only. If the controlled documents are part of essential documents, they should be part of the Research Master/Regulatory File (see SOP 201: Regulatory Documentation) and archived appropriately (see SOP: 504 Archiving Study Records).

10.2. Old versions of controlled documents must be archived in a separate file.

- Obsolete documents that are retained for reference or legal obligations are water marked "OBSOLETE" and kept separate from active documents. Obsolete electronic documents are removed from the network and stored in media that are only accessible to authorized personnel. Any obsolete documents that need to be reactivated must be reviewed, approved and released in the same manner as newly established documents.
- At least one copy of all obsolete documents must be archived.

10.3. The OCR will maintain a master list of all SOPs specific to the CRC. This file or database will indicate the SOP number, version number, effective date, title, author, status, and any historical information regarding past versions.

10.4. Documents will be archived in electronic storage to:

- Prevent their continued use
- Facilitate easier access for retrieval purposes
- Limit documents to a read-only format to protect them against unauthorized changes made to the document as well as to be available for historical data review