DUKE

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**DOCUMENT TITLE:**

Procedure Management

**DOCUMENT NOTES:**

## Document Information

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## Control Information

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| **Author:** LBM40 | **Owner:** POS-ADMIN MGR - MC |
| **Previous Number:** COMM-QA-016 Rev 15 | **Change Number:** COMM-CCR-268 |

# COMM-QA-016
# PROCEDURE MANAGEMENT

## 1 PURPOSE

1.1 To define the steps required to manage controlled documents from the point of development, review, verification, approval, implementation, and archiving.

1.2 To describe the process for document control.

## 2 INTRODUCTION

2.1 Document control procedures are established to ensure the use of current, approved, and released versions of documents.

2.2 MasterControl is a validated, 21 CFR Part 11 compliant document management system and is a primary document management system utilized by Duke Programs.

## 3 SCOPE AND RESPONSIBILITIES

3.1 The requirements of this procedure apply to all controlled documents in the MasterControl and EMMES Systems.

3.1.1 Documents residing in EMMES only apply to the following programs: CCBB, STCL, and APBMT.

3.2 Program/Medical Directors, Quality Systems Unit (QSU), and personnel utilizing controlled documents from MasterControl and EMMES are responsible for ensuring the requirements of this procedure are successfully met.

3.3 The Subject Matter Expert (SME)/document author is trained in MasterControl and is responsible for writing, reviewing collaborators comments, and approving documents in MasterControl.

3.4 The QSU is responsible for the review and approval of all new, revised, and biennially reviewed procedures in MasterControl and for establishing and verifying effectiveness of document control procedures.

3.5 The QSU Document Control Operations (DCO) is responsible for maintaining current versions of controlled documents in the EMMES System and maintains a hard copy of all released documents as a back-up to the electronic systems.

3.5.1 Documents that are initiated in the MasterControl System are maintained indefinitely in MasterControl when archived.

3.6 The Program Supervisor/Manager is responsible for ensuring personnel are trained on procedures prior to use.

## 4 DEFINITIONS/ACRONYMS

4.1 BLA – Biologic License Application

4.2 CBE 0 – Changes Being Effected immediately

4.3 CBE 30 – Changes Being Effected in 30 days

4.4 CCBB – Carolinas Cord Blood Bank

4.5 DCO – Document Control Operations

4.6 EMMES – The Carolinas Cord Blood Bank (CCBB), Duke Stem Cell Laboratory, and APBMT utilize the Advantage eClinical electronic data capture (EDC) system that can be accessed from any computer connected to the Internet and allows participating users to access their SOPs provided from MasterControl.

4.7 MasterControl – A validated, CFR 21 Part 11 compliant, document management software product that is used as the main document control agent for the automation and control of document approval, change control, and distribution processes.

4.8 ORAQ – Office of Regulatory Affairs and Quality

4.9 PAS – Prior Approval Supplement

4.10 QSU – Quality Systems Unit

4.11 SME – Subject Matter Expert

## 5 MATERIALS

5.1 NA

## 6 EQUIPMENT

6.1 Computer access to MasterControl and/or EMMES

## 7 SAFETY

7.1 NA

## 8 PROCEDURE

8.1 DCO oversees document management and is able to track the history of all documents entered into MasterControl.

8.2 The author/owner submits a Change Control Request followed by the submission of the new or revised document into MasterControl for collaboration, review, and approval. Refer to COMM-QA-019 *Change Control* or COMM-PAS-004 *Change Control*.

8.3 Procedure verification may be incorporated into the collaboration process within MasterControl or documented separately.

8.4 When satisfied, the author finalizes the document, ends collaboration, and approves the document in MasterControl.

8.5 The author's approval routes the document via MasterControl for review and approval by the Medical/Program Director, as applicable.

8.6 Final review of documents in MasterControl is completed by the Quality Systems Unit.

8.7 Training is initiated as specified by the author and documented by the Training Coordinator in MasterControl.

8.7.1 Duke Programs with access to training in MasterControl utilize MasterControl for documenting training. Those Programs without access to MasterControl or who are not yet trained in MasterControl will document completion of training outside of MasterControl and may add these documents to the individual's training file in MasterControl when applicable.

8.7.2 Procedures requiring training are automatically routed to the Training Coordinator, who will review the associated CCR for updates to training materials.

8.7.3 The Program Supervisor/Manager is responsible for ensuring personnel are trained on procedures prior to use.

8.8 Release of Document

8.8.1 Document workflows are configured to ensure the required review and approval is captured, before final approval to release a document.

8.8.1.1 Final approval by a trained Quality staff member is required to release controlled documents for training prior to documents becoming effective.

8.8.1.2 Documents are effective a minimum of 14 days from the date DCO releases the document for training.

8.8.1.2.1 **NOTE: –** Specific documents categories require rapid release:MSPECs, Consents, and Org Charts are made effective the same day as Document Release, unless otherwise noted.

8.8.1.2.2 Either Director and/or Executive Director of Quality - must authorize/approve requests for less than 14 days between Document Release for training and Effective Date.

8.8.1.2.3 As applicable, DCO will honor documented requests for more than 14 days between Document Release for training and Effective Date.

8.8.1.3 In the cases below, effective dates are coordinated between DCO, the Department Supervisor/Manager, Training Coordinator, QSU, and ORAQ, as applicable.

8.8.1.3.1 Release of documents designated by ORAQ as requiring prior approval (PAS), or change being effective after receipt of submission to FDA (CBE 0), or change being effective 30 days after receipt by the FDA (CBE 30), will be coordinated between QSU, ORAQ, the

Department Supervisor/Manager, and the Training Coordinator.

8.8.1.3.2 Prior to QSU approval of a document, the Quality Manager, or designee, will assess each documents' Change Control Request to identify the Regulatory Affair designation of change classification, and if PAS, CBE 0, or CBE 30, will obtain confirmation from ORAQ on the release date of the applicable document, prior to issuing QA final approval of the document.

8.8.2 Users can access released documents after they have completed training, and the document is effective. The PDF of the effective document published by the system includes a Signature Manifest, indicating who completed each document approval step and when.

8.9 Document Control

8.9.1 Released documents are effective until revised or archived.

8.9.2 Documents are printed from MasterControl, using the current, effective PDF version.

8.9.3 Staff **must** utilize working copies (PDF files) of documents, forms, and job aids (JA) printed from MasterControl.

8.9.3.1 PDF files printed from MasterControl are date and time stamped. Also, the printed PDF reflects who the document was printed by, the document number, revision number, and the effective date of the document.

8.9.3.1.1 Under the responsibility and control of the Department Supervisor/Manager, sheet labels can be printed using the Word-generated file from MasterControl if the published PDF file causes the labels to print incorrectly due to margins or printers used.

8.9.3.1.2 When an incorrectly printed document is identified, the supervisor of the affected area must confirm two points:

- That the content of the document is accurate and represents the effective revision in use at the time of printing.
- No data loss has occurred.

8.9.3.1.3 If **both** conditions are met, COMM-QA-016 FRM3 *Impact Assessment for documents printed with missing header/footer* should be issued, completed, and attached to the affected

document. In such cases, no deviation or investigation will be required, as the error is attributed to printer configuration or formatting issues rather than procedural nonconformance.

8.9.3.1.4 If either condition is not met, an investigation via COMM-QA-042 *Deviations and Investigations* may be required.

8.9.4 When computer access is not available (due to electrical outage or computer network issues for example), hard copies of current, approved versions of controlled documents are maintained by DCO and can be provided upon request.

8.9.5 DCO maintains current, approved PDF versions of documents in the EMMES System which can be downloaded by the Supervisor/Manager, or designee. The Supervisor/Manager is responsible for verifying the use of the correct document version when MasterControl is not accessible.

8.9.6 When it is not possible to print PDF documents on an as-needed basis:

8.9.6.1 The Supervisor/Manager or designee, is responsible for:

8.9.6.1.1 Providing the user copies of the accurate document version from MasterControl.

8.9.6.1.2 Completing *Weekly QC Document Control,* COMM-QA-016 FRM2.

8.9.6.2 The user receiving copies of new or revised controlled documents is responsible for verifying receipt and use of the current, released version from MasterControl and disposal of prior revisions.

8.9.7 Staff are instructed **not to save** any controlled documents from MasterControl on their personal computers.

8.9.7.1 As an internal control and safety measure, MasterControl PDF documents saved to a personal computer or alternate storage device expire and become unusable and inaccessible after 48 hours.

8.9.8 A fillable, electronic, PDF version of a controlled document may be prepared by DCO and provided to sites by the Program Supervisor/Manager.

8.9.9 The QSU will perform periodic verification of document control via onsite assessments.

8.10 EMMES Document Control

8.10.1 PDF versions of approved documents in MasterControl will be printed, scanned, and sent to EMMES for upload by DCO as documents become effective.

8.10.2 The EMMES database will be reviewed and verified by DCO for accuracy and consistency with MasterControl as documents are updated.

8.10.3 EMMES will be notified by DCO to remove documents from the EMMES database when documents require archival in MasterControl.

8.10.3.1 For documents requiring archival, DCO emails impacted users that the *document has been archived*; and the users are requested to *remove all copies from their work area*.

8.11 Notification of Release to CryoCell

8.11.1 At the time of release in MasterControl, CryoCell Quality Management is notified by the applicable Program Supervisor/Manager of the impending implementation and/or archival of a document.

8.11.2 The CryoCell Quality Management staff release the effective document and training to their sites and verify disposal of prior revisions.

8.12 Procedure Document Retention

8.12.1 MasterControl retains all entered versions of controlled documents.

8.12.2 All archived procedures are maintained indefinitely.

8.12.3 Documents are retained according to regulatory requirements and the Program's *Records Management* or *Records Retention* procedures.

## 9 RELATED DOCUMENTS/FORMS

9.1 COMM-QA-057 – Procedure Development

9.2 COMM-QA-019 – Change Control

9.3 COMM-PAS-004 Change Control

9.4 CCBB-QA-018 – CCBB Records Management

9.5 STCL-GEN-015 – Records Management

9.6 APBMT-COMM-033 – Records Management

9.7 COMM-QA-016 FRM2 – Weekly QC Document Control

9.8 COMM-QA-016 FRM3 – Impact Assessment for documents printed with missing header/footer

9.9 COMM-QA-042 Deviations and Investigations

## 10 REFERENCES

10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.

10.2 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and Netcord. International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release Current edition.

10.3 21 CFR 606.100 SOPs

10.4 21 CFR 211.100 Written procedures

10.5 21 CFR 1271.270 Records

10.6 21 CFR 1271.250 Process Changes

10.7 21 CFR 1271.220 Processing & Process Controls

10.8 21 CFR 1271.180 Procedures

10.9 21 CFR Part 11 Electronic Records; Electronic Signatures

## 11 REVISION HISTORY

| Revision No. | Author | Description of Change(s) |
|---|---|---|
| 16 | Linda Morton | • Added 8.9.3.1.2 When an incorrectly printed document is identified, the supervisor of the affected area must confirm two points:<br>That the content of the document is accurate and represents the effective revision in use at the time of printing.<br>No data loss has occurred.<br>• Added 8.9.3.1.3 If both conditions are met, COMM-QA-016 FRM3 should be issued, completed, and attached to the affected document. In such cases, no deviation or investigation will be required, as the error is attributed to printer configuration or formatting issues rather than procedural nonconformance.<br>• Added 8.9.3.1.4 If either condition is not met, an investigation via COMM-QA-042 *Deviations and Investigations* may be required.<br>• Added reference to COMM-QA-042 *Deviations and Investigations* and COMM-QA-016 FRM3 *Impact Assessment for documents printed with missing header/footer* |

## Signature Manifest

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### COMM-QA-016 Procedure Management

### Author

| Name/Signature | Title | Date | Meaning/Reason |
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| Linda Morton (LBM40) | GMP, Quality Control Associate I | 18 Sep 2025, 10:17:25 AM | Approved |

### Medical Director

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Joanne Kurtzberg (KURTZ001) | | 18 Sep 2025, 11:04:22 AM | Approved |

### Quality

| Name/Signature | Title | Date | Meaning/Reason |
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| Austin Rudisill (ADR35) | Associate Director, Quality Assurance | 18 Sep 2025, 11:10:36 AM | Approved |

### Document Release

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Amy McKoy (ACM93) | Document Control Specialist | 18 Sep 2025, 01:37:12 PM | Approved |