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**DOCUMENT TITLE:**
Procedure Management

**DOCUMENT NOTES:**

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| Author: BS76 | Owner: BJ42 |
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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 EDC\textsuperscript{SM} electronic data capture 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 The MasterControl System Administrator 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.
8.6 Final review of documents in MasterControl is completed by the Quality Manager, or designee.
8.7 Training is initiated as specified by the author and documented by the Department Supervisor/Manager or Training Coordinator.

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Office of Regulatory Affairs and Quality, DUMC
Durham, NC

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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 collaborates with the Supervisor/Manager to establish a feasible release/effective date, allowing sufficient time to coordinate and complete training.

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

8.8 Release of Documents

8.8.1 Review and approval by the Medical/Program Director and final approval release by the Quality Manager, or designee, is required on controlled documents.

8.8.2 Release/effective dates are coordinated between the MasterControl Systems Administrator, the Department Supervisor/Manager, Training Coordinator, QSU, and ORAQ, as applicable.

8.8.2.1 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.

8.8.2.2 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.

8.8.3 The agreed upon document release and effective dates are noted on the MasterControl Signature Manifest at which time the document will be made available for access by trained MasterControl users and a controlled copy placed/replaced in the EMMES System by DCO.

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, released 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.

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.


8.9.6.2 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 CORD:USE

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

8.11.2 The CORD:USE 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

10 REFERENCES


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

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<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
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| 12           | B. Shen | • Clarified programs using EMMES in Scope and Responsibilities section.  
               |        | • Clarified EMMES definition.  
               |        | • Section 8.2 Added COMM-PAS-004 Change Control as reference.  
               |        | • DTMI was replaced by ORAQ.  
               |        | • Footer changed from QSU to ORAQ. |
**Signature Manifest**

**Document Number:** COMM-QA-016  
**Title:** Procedure Management

*All dates and times are in Eastern Time.*

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## COMM-QA-016 Procedure Management

### Author

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### Medical Director

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### Quality

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