Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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DOCUMENT TITLE:
Procedure Management

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COMM-PAS-028
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 for the Adult and Pediatric Blood and Marrow Transplant Program (APBMT) and the Stem Cell Laboratory (STCL).

2 INTRODUCTION

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

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

2.2.1 Documents that are initiated in the MC System are maintained indefinitely in MC when archived.

2.3 A separate, secured Duke Health SharePoint site is utilized and can be accessed from any computer connected to the Internet for those who do not have access to MC and need to review documents related to their job function provided by MC.

2.3.1 The Duke University Health Systems (DUHS) Cell Therapy SharePoint Online (CT-SPO) site requires access approval provided by the site owners. Additionally, the site requires Duke's multi-factor authentication (MFA) to access outside of the registered computers within the program.

3 SCOPE AND RESPONSIBILITIES

3.1 The requirements of this procedure apply to all controlled documents in the MasterControl (MC).

3.2 Division Chiefs, Program/Facility Medical Directors, APBMT Clinical Quality Program (CQP), and personnel utilizing controlled documents from MC are responsible for ensuring the requirements of this procedure are successfully met.

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

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

3.5 The Document Control System (DCS) staff is responsible for:

3.5.1 Maintaining current versions of controlled documents in MasterControl (MC) and the secured CT-SPO site.

3.5.2 Maintaining a hard copy of all released documents as a backup to the electronic systems.

3.6 The Program and/or Facility's Manager is responsible for ensuring personnel are trained on procedures before use.

4 DEFINITIONS/ACRONYMS

4.1	APBMT	Adult and Pediatric Blood and Marrow Transplant Program
4.2	CCR	Change Control Request
4.3	CQP	APBMT Clinical Quality Program
4.4	DCS	Document Control System
4.5	DUHS	Duke University Health System
4.6	MC	MasterControl
4.7	MFA	Multi-factor Authentication
4.8	SME	Subject Matter Expert
4.9	CT-SPO	DUHS Cell Therapy SharePoint Online

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 Computer Access

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 The DCS staff's MasterControl Administrator oversees document management and can track the history of all documents entered in MC.

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

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

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

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

8.6 Final review of documents in MC is completed by the APBMT Clinical Quality Program (CQP).

8.7 Training is initiated as specified by the author and documented by a DCS staff member in MC.

8.7.1 Those within APBMT and STCL with access to training in MC utilize MC for documenting training.

8.7.2 Those without access to MC or who are not yet trained in MC will document completion of training outside of MC. This documentation may be added to the individual's personnel file held by their manager and/or training file in MC when applicable.

8.7.3 Procedures requiring training are automatically routed to a DCS staff member, who will review the associated CCR for updates to training materials.

8.8 Release of Document

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

8.8.1.1 Final approval by a trained CQP staff member is required to release controlled documents for training before the documents become effective.

8.8.1.2 Documents are generally assigned to become effective 14 days from the date DCS staff releases the document for training.

8.8.1.2.1 Note – Specific document categories may require rapid release. If that is the case, they are made effective the same day as the Document Release, unless otherwise noted.

8.8.1.2.2 Either the CQP Manager and/or the Administrative Director of Quality and Safety must authorize and/or approve requests for less than 14 days between the Document Release for training and the Effective Date.

8.8.1.3 Effective dates are coordinated between the DCS staff's MC Administrator, the Program and/or Facility Manager, and CQP, as applicable.

8.8.2 MC Users can access released documents after they have completed training, and the document is effective. The PDF of the effective document published by the MC includes a Signature Manifest, indicating who completed each document's 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 MC, using the current, effective PDF version.

8.9.3 APBMT and/or STCL staff **must** utilize working copies (PDF files) of documents, forms, and job aids (JA) printed from MC.

8.9.3.1 PDF files printed from MC 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 Occasionally, under the responsibility and control of the Program and/or Facility's Manager and in coordination with CQP, documents can be printed using the Word-generated file from MC if the published PDF file causes the document to print incorrectly due to margins or printers used.

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 DCS staff and can be provided upon request.

8.9.5 The DCS staff maintains current, approved PDF versions of documents in the CT-SPO site, which can be downloaded by the Program and/or Facility's Manager or designee. The Program and/or Facility's Manager or designee is responsible for verifying the use of the correct document version when MC is not accessible.

8.9.6 When it is not possible to print PDF documents on an as-needed basis, such as in Section(s) 8.9.3.1.1:

8.9.6.1 The Program and/or Facility's Manager or designee is responsible for:

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

8.9.6.1.2 Completing COMM-PAS-028 FRM1 *Weekly QC Document Control* and submitting the completed document to CQP for review and sign-off.

8.9.6.2 The user receiving copies of new or revised controlled documents is responsible for verifying receipt.

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

8.9.7.1 As an internal control and safety measure, MC 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 the DCS staff and provided to sites by the Program and/or Facility's Manager.

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

8.10 CT-SPO Site Document Control

8.10.1 PDF versions of approved documents in MC will be printed, scanned, and uploaded to the CT-SPO site by DCS staff as documents become effective.

8.10.2 The CT-SPO site will be reviewed and verified by DCS staff for accuracy and consistency with MC as documents are updated.

8.10.3 When a document is archived in MC, DCS staff will remove the document from the CT-SPO site.

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

8.11 Procedure Document Retention

8.11.1 MC retains all entered versions of controlled documents.

8.11.2 All archived procedures are maintained indefinitely.

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

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-027 Procedure Development

9.2 COMM-PAS-004 Change Control

9.3 STCL-GEN-015 Records Management

9.4 APBMT-COMM-033 Records Management

9.5 COMM-PAS-028 FRM1 Weekly QC Document Control

10 REFERENCES

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

10.2 21 CFR 606.100 SOPs

10.3 21 CFR 1271.270 Records

10.4 21 CFR 1271.250 Process Changes

10.5 21 CFR 1271.220 Processing & Process Controls

10.6 21 CFR Part 11 Electronic Records; Electronic Signatures

11 REVISION HISTORY

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