


DukeMedicine


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

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Procedure Development

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COMM-PAS-027

Procedure Development

1 PURPOSE

- 1.1 This procedure defines the sections or elements required in a Standard Operating Procedure (SOP) and outlines the specific information that should be provided in each section.
- 1.2 Procedures are written in an approved standardized format to provide continuity and uniformity in writing and presenting work instructions to the staff.

2 INTRODUCTION

- 2.1 Documents and records are the core of a quality system. Procedures are best established through the use of an SOP. SOPs serve as a useful tool for assuring that a procedure is applicable for a specific requirement. SOPs should be written with sufficient detail so that someone with general knowledge/experience with a procedure can understand and duplicate the requirements.
- 2.2 The need for a new or changed procedure may be identified from a variety of sources such as:
 - 2.2.1 New or changing regulatory standards
 - 2.2.2 Event management
 - 2.2.3 Process improvement activities including suggestions from staff
 - 2.2.4 Customer service or business needs

3 SCOPE AND RESPONSIBILITIES

- 3.1 This procedure covers the required elements of an SOP for programs using MasterControl.
- 3.2 The Adult and Pediatric Blood and Marrow Transplant (APBMT) Program and Stem Cell Laboratory (STCL) utilizing MasterControl are responsible for ensuring the requirements of this procedure are met successfully.

4 DEFINITIONS/ACRONYMS

- 4.1 APBMT – Adult and Pediatric Blood and Marrow Transplant
- 4.2 CCR (Change Control Request) – A form used to document changes to controlled documents, processes, equipment, operations, designs, and other changes to ensure compliance with applicable regulatory requirements.
- 4.3 CFR – Code of Federal Regulations
- 4.4 CQP – Clinical Quality Program
- 4.5 DCS – Document Control System
- 4.6 FACT – Foundation for the Accreditation of Cellular Therapy
- 4.7 FACT-JACIE – Foundation for the Accreditation of Cellular Therapy- Joint Accreditation Committee

- 4.8 FDA – Food and Drug Administration
- 4.9 FRM (Form) – A printed or typed document with blank spaces for insertion of required or requested information.
- 4.10 JA (Job Aid) – JA is a “how-to” guide that provides guidance for performing a task.
- 4.11 MC (MasterControl) – A validated, CFR 21 Part 11 compliant, document management software product that is used as the main document control system for the automation and control of document approval, change control, distribution and training processes. MC manages critical information throughout the entire document lifecycle.
- 4.12 SOP (Standard Operating Procedure) – An approved document describing a procedure, which establishes a particular course of action or way of performing an activity.
- 4.13 STCL – Stem Cell Laboratory

5 MATERIALS

- 5.1 Manufacturer’s instructions, if applicable
- 5.2 Computer instructions, if applicable
- 5.3 Current reference materials, where indicated
- 5.4 Quick Reference Cards and Training Modules, as applicable

6 EQUIPMENT

- 6.1 Access to MasterControl

7 SAFETY

- 7.1 NA

8 PROCEDURE

- 8.1 General Information

NOTE: A Change Control Request (CCR) form is required for ALL documents (new, revised, or archived). Refer to COMM-PAS-004 *Change Control*.

- 8.1.1 **A Standard Operating Procedure** must have a documented review by at least the Medical Director, Management, and Clinical Quality Program (CQP).

- 8.1.1.1 **Forms and Job Aids** – FRMs and JAs are used to record actions that trace processes in the operational systems, provide quick reference information, or provide instructions related to business needs.

- 8.1.1.1.1 These documents must have a documented review by at least the assigned Medical Directors, Management, and CQP, as applicable.

- 8.2 Writing a Standard Operating Procedure

NOTE: The following elements in Section 8.3 outline the specific information that is required in the procedure.

- The format outlined in COMM-PAS-027 JA1 *SOP Template* is required for all procedures.
- Do not delete any section headings. Sections of the template that do not apply to the procedure should remain in the document. **Write NA for *Not Applicable* in any section that does not apply.**
- Do not use heading levels beyond Heading Level 5.
NOTE: In MSWord, heading levels are used by creating Styles. See Section 8.4.8 for information about **Styles**.

8.3 Elements of an SOP (see Procedure Development SOP Template JA1)

- 8.3.1 **PURPOSE (section 1)** – The purpose statement should be a concise description of what the procedure is about.
- 8.3.2 **INTRODUCTION (section 2)** – The introduction may provide background information or expound on aspects of the purpose.
- 8.3.3 **SCOPE AND RESPONSIBILITIES (section 3)**
- 8.3.3.1 The **Scope** should provide limits to the use of the procedure. State to what areas, situations, or age-specific issues, where relevant, the procedure applies; and identify who needs to follow the procedure.
- 8.3.3.2 **Responsibilities** should be assigned for various aspects of the procedure. The responsible party must be knowledgeable of the subject to ensure compliance with regulations and related guidelines.
- 8.3.4 **DEFINITIONS/ACRONYMS (section 4)** – List and define any key terms or acronyms referenced in the procedure.
- 8.3.5 **MATERIALS (section 5)** – List all materials needed to perform the procedure (supplies, reagents, etc.). It is not necessary to list common office supplies such as pens, paper clips, etc.
- 8.3.6 **EQUIPMENT (section 6)** – List all pieces of equipment that will be used in the procedure.
- 8.3.7 **SAFETY (section 7)** – This section is intended to provide the person(s) performing the procedure with information on potential human health hazards and potential hazards to the facility, equipment, or process.
- 8.3.7.1 List any specific clothing requirements for personal protection; for example: laboratory coats, safety glasses, and gloves required when performing specific operations. This section may refer the reader to a document that describes safety procedures in general.
- 8.3.7.2 List designated personnel and methods of communication for safety incidents.

- 8.3.8 **PROCEDURE (section 8)** – Describe the procedure in a step-by-step, chronological manner. Provide enough information to allow the procedure to be performed in a reliable and consistent manner.
- 8.3.8.1 Calculations, range of expected results, endpoints, etc., may be included in the associated form(s) and/or in the body of the procedure.
- 8.3.8.2 Diagrams or pictures may be included to illustrate a piece of equipment or how to perform an activity.
- 8.3.9 **RELATED DOCUMENTS/FORMS (section 9)** – List other documents and forms that pertain to the procedure. The MasterControl document number can be included with the document title to assist in readily locating the file.
- 8.3.10 **REFERENCES (section 10)** – A list of relevant documents used to develop the procedure. The list of references should include documents that are specifically cited in the procedure as well as documents that were used as source materials; e.g., FDA guidance documents, CFR citations.
- 8.3.11 **REVISION HISTORY (section 11)** – Use this section to document changes that have been made to the procedure. Identify the changes by listing the affected section number(s); and briefly describe the changes.
- NOTE:** The use of a **Revision History** section may be included at the end of a FRM or JA. This is optional and is left at the discretion of the author/owner of the document. However, once it starts, it must be maintained.
- 8.3.11.1 **Revision No.:** If the SOP is a new procedure, start with revision number 01.
- 8.3.11.2 **Author:** Indicate the name of the person writing/revising the procedure.
- 8.3.11.3 **Description of Change(s):** Describe the changes made to the procedure; e.g., editorial, process, or equipment changes.
- 8.3.11.3.1 Only the current revision changes will be included in the Revision History table (Section 11). The complete history of changes for each revised document is maintained in MasterControl.
- 8.3.11.3.2 If the changes made to the SOP are extensive and require rewriting, a more general all-inclusive statement about the modifications will be acceptable.
- 8.3.11.3.3 If the SOP is a new procedure, indicate “New Procedure” in this section.

8.3.11.3.4 Only the current revision history information is to be entered. As in the example below, Rev 01 information is not displayed.

NOTE: It is not necessary to include the specific section number in the Description of Change; for example: Section 8.3.4.2; just list the heading section number as illustrated in the example below.

EXAMPLE:

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
02	B. Jordan	<ul style="list-style-type: none"> Section 3 added re: Ex Utero cord blood collection will be performed by CMC-NE. Added definition for ISBT Barcode. Section 8 added new “Open Pinch Clamp” picture. Section 8 added new step instructing operator to remove samples for testing.

8.4 Recommended Elements for Formatting an SOP, Form or JA

8.4.1 Suggested Page Setup Margins

Top 0.75” Bottom 0.75”
Left 1.25” Right 1.0”

8.4.2 Suggested Page Setup Layout

Header 0.5”
Footer 0.5”

NOTE: 0.5” Header/Footer layout is desirable to allow for header/footer in MasterControl when document is converted to PDF through the PDF Publisher.

8.4.3 Suggested Font

12 pt Times New Roman

8.4.4 All acronyms are spelled out the first time used: example Stem Cell Laboratory (STCL).

8.4.5 The document number and title will appear as the title at the top of the first page.

8.4.6 Numbering System – A unique numbering scheme based on document type and vaults in MasterControl (MC) will be assigned by Document Control System (DCS) staff for all procedures for ease of tracking. The document number will be assigned when a procedure is entered into MC via auto-numbering. Some examples of numbering patterns include: STCL--GEN--XXX or APBMT-COMM-XXX.

8.4.7 Footers shall appear on each page in procedures, forms, and JAs, with the exception of the native PDF files.

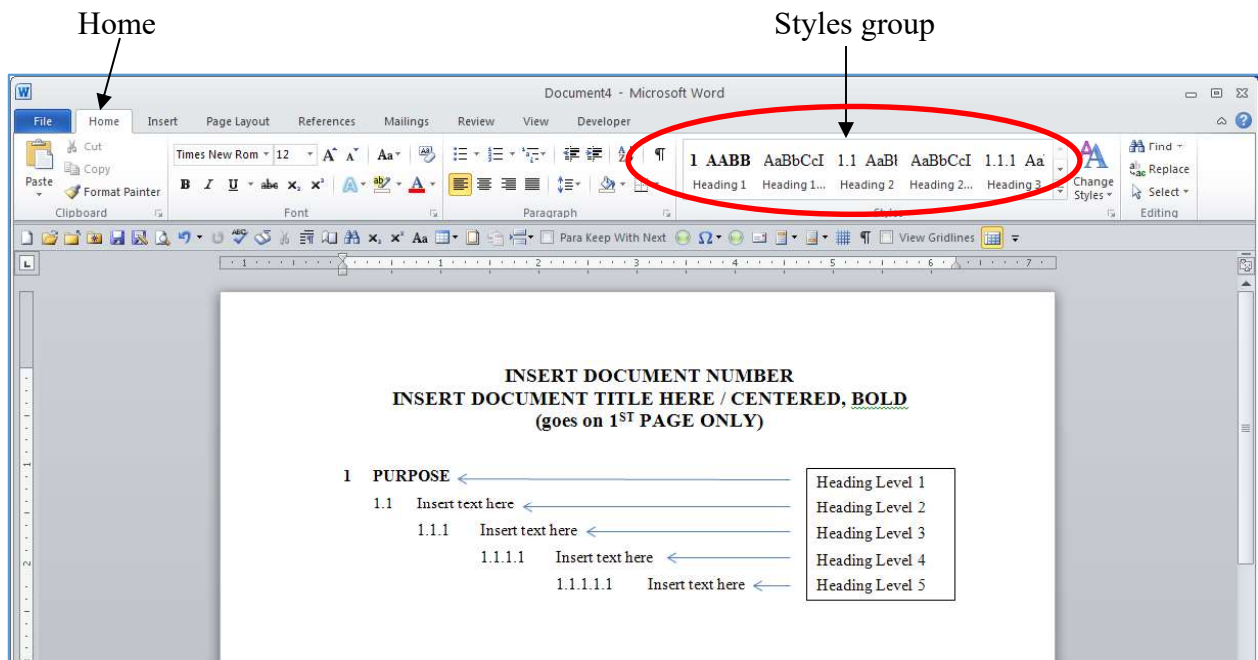
8.4.7.1 Footers shall contain the document number, document title, department name, department direct report, city/state, and page number (Page 1 of x).

8.4.7.2 It is recommended to have the Footer placement flushed left using 10-point Times New Roman. Page numbering is set to the right margin.

8.4.8 Suggested Styles

NOTE: COMM-PAS-027 JA1 *SOP Template* must be used as the template for creating a new document.

NOTE: Styles allow you to quickly format major elements in your document, such as titles, headings, and subheadings. Highlight the information in your document that you want to change and pause your pointer over any style in the Styles group to see a preview of that style. To apply a specific style, just click it. Styles are located on the **Home** tab in the **Styles** group.



Repeat Styles for each section of the SOP.

8.5 Forms and JAs

NOTE: Margins and font sizes can be adjusted accordingly to fit Forms and JAs on a page.

8.5.1 Forms and JAs will be numbered as a “sister document” to the associated SOP. For example:

COMM-PAS-005
 COMM-PAS-005 FRM1
 COMM-PAS-005 FRM2
 COMM-PAS-005 JA1

- 8.5.2 Forms and JAs must identify at least the department name and city/state.
- 8.5.3 Forms should be used to collect data required as part of the procedure.
- 8.5.4 Forms should be designed for ease of use and to provide evidence that processes are functioning in a state of control.
- 8.5.5 Calculations, ranges of expected results, and endpoints should be included on forms as appropriate.
- 8.5.6 Forms should include a space to document the review as appropriate.
- 8.5.7 Depending on the complexity of the form, an instruction page and/or an example of a properly completed form may be provided as a guide for completing the form or task.
- 8.5.8 Forms may include procedural steps, if appropriate.
- 8.5.9 Form in use will be Page 1 of 1, Page 1 of 2, etc. If Instructions and/or Examples of Forms are used, the page numbering will be numbered Page 1 of 8, etc.
- 8.5.10 JAs are intended to provide reference or supplemental information related to a procedure (e.g., a table defining health history exclusion criteria or a diagram depicting the proper way to package samples). JAs may also take the form of a flow chart, process chart, or abbreviated list of steps.
 - 8.5.10.1 JAs should not conflict with or supersede procedure instructions.

9 RELATED DOCUMENTS/FORMS

- 9.1 COMM-PAS-004 Change Control
- 9.2 COMM-PAS-004 FRM1 Change Control Request (Effectiveness Check)
- 9.3 COMM-PAS-004 FRM2 Change Control Request (No Effectiveness Check)
- 9.4 COMM-PAS-027 JA1 SOP Template

10 REFERENCES

- 10.1 FACT International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration. Current edition.
- 10.2 FACT Common Standards for Cellular Therapies. Current edition.
- 10.3 21 CFR Part 1270, Human Tissue Intended for Transplant.
- 10.4 21 CFR Part 1271, Human Cells, Tissue and Cellular and Tissue-based Products.
- 10.5 21 CFR Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	M. Christen	<ul style="list-style-type: none">• New document

Signature Manifest**Document Number:** COMM-PAS-027**Revision:** 01**Title:** Procedure Development**Effective Date:** 01 Jul 2025

All dates and times are in Eastern Time.

COMM-PAS-022 -- COMM-PAS-027 JA1**Author**

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Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		26 Jun 2025, 05:14:55 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	30 Jun 2025, 05:51:48 PM	Approved