**DOCUMENT NUMBER:** COMM-QA-057

**DOCUMENT TITLE:**
Procedure Development

**DOCUMENT NOTES:**

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### Document Information

**Revision:** 10  
**Vault:** COMM-QA-rel

**Status:** Release  
**Document Type:** COMM-QA

### Date Information

**Creation Date:** 06 Aug 2018  
**Release Date:** 21 Aug 2018

**Effective Date:** 21 Aug 2018  
**Expiration Date:**

### Control Information

**Author:** BS76  
**Owner:** BJ42

**Previous Number:** COMM-QA-057 Rev 09  
**Change Number:** COMM-CCR-070
COMM-QA-057
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 CCBB/PBMT and ABMT Medical Directors, CCBB Collections management, MC3, CCBB and STCL Laboratory management, and other programs utilizing MasterControl are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS
4.1 SOP (Standard Operating Procedure) – An approved document describing a procedure, which establishes a particular course of action or way of performing an activity.
4.2 JAs (Job Aids) – JAs are “how-to” guides that provide guidance for performing a task.
4.3 FRM (Form) – A printed or typed document with blank spaces for insertion of required or requested information.
4.4 CCBB – Carolinas Cord Blood Bank
4.5 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.

4.6 ABMT – Adult Blood and Marrow Transplant

4.7 PBMT – Pediatric Blood and Marrow Transplant

4.8 STCL – Stem Cell Laboratory

4.9 FACT – Foundation for the Accreditation of Cellular Therapy

4.10 FACT-JACIE – Foundation for the Accreditation of Cellular Therapy-Joint Accreditation Committee

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 QSU – Quality Systems Unit

4.13 FDA – Food and Drug Administration

4.14 CFR – Code of Federal Regulations

4.15 MC3 – Marcus Center for Cellular Cures

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 or COMM-QA-019 Change Control.

8.1.1 A Standard Operating Procedure must have a documented review by the CCBB/PBMT and/or ABMT Medical Director, CCBB and STCL Laboratory management, CCBB Collections management, MC3 management and QSU, as applicable.
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 the CCBB/PBMT and ABMT Medical Directors, CCBB and STCL Laboratory Management, CCBB Collection Site Coordinator, MC3 Management, and QSU, as applicable.

8.1.1.2 Documents related to the Biological Licensed Product will also be reviewed by Regulatory Affairs.

8.1.2 Other controlled documents/policies that describe the intent to implement regulations defined in the Code of Federal Regulations (CFR), and the core standards FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration, FACT Common Standards for Cellular Therapies, and Netcord-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release must have a documented review by the CCBB/PBMT and ABMT Medical Directors, CCBB and STCL Laboratory Management, CCBB Collection Sites Coordinator, MC3 Management, and QSU, 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 Procedure Development JA1 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 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 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, paperclips, 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 are required when performing operations. This section may refer the reader to a document that describes safety procedures in general.

8.3.7.2 List designated personnel and method of communications 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 on 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.

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 the document will be 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: 8.3.4.2; just list the heading section number as illustrated in the example below.

### EXAMPLE:

#### 11 REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
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<tbody>
<tr>
<td>02</td>
<td>B. Jordan</td>
<td>• Section 3 added re: Ex Utero cord blood collection will be performed by CMC-NE.</td>
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<tr>
<td></td>
<td></td>
<td>• Added definition for ISBT Barcode.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Section 8 added new “Open Pinch Clamp” picture.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Section 8 added new step instructing operator to remove samples for testing.</td>
</tr>
</tbody>
</table>

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" – No Headers in SOP, but can be used on Forms
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 CCBB
(Carolinas Cord Blood Bank).

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 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: CCBB-ADMIN-
xxx, PBMT-COLL-xxx, GMP-FAC-xxx, STCL-GEN-xxx, MPACT-
QA-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,
program name, address and page number (Page 1 of x).

8.4.7.2 Footer placement is flush left using 10 point Times New
Roman. Page numbering is set to right margin.

8.4.8 Suggested Styles

**NOTE:** COMM-QA-057 JA1 Procedure Development SOP Template
JA1 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.
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.

8.5.1.1 Example: CCBB-COL-005, CCBB-COL-005 JA1, CCBB-COL-005 FRM1

8.5.2 Forms and JAs must identify the facility 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 Change Control, COMM-PAS-004
9.2 Change Control Request, COMM-QA-019
9.3 Procedure Development SOP Template JA1, COMM-QA-057 JA1

10 REFERENCES

10.4 21 CFR Part 1270, Human Tissue Intended for Transplant.
10.6 21 CFR Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals.

11 REVISION HISTORY

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<tr>
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<th>Description of Change(s)</th>
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<tr>
<td>10</td>
<td>B. Shen</td>
<td>• Added verbiage to Section 4 to reflect that MC manages critical information throughout the entire document lifecycle.</td>
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<td>• Section 8 added COMM-PAS-004 as reference.</td>
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<td>• Added Note to Description of Change section regarding section numbering.</td>
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<td>• Edited Numbering System section for clarity.</td>
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# COMM-QA-057 Procedure Development

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<td>20 Aug 2018, 07:28:54 AM</td>
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**Document Release**

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**Quick Approval**

**Approve Now**

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