STEM CELL LABORATORY (STCL)

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Procedure Verification for STCL

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Author: WATE02	**Owner:** WATE02
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STCL-GEN-013
PROCEDURE VERIFICATION FOR STCL

1 PURPOSE

1.1 Verification is to assure that the procedure presents clear and understandable work instructions to staff, and that following the procedure as written, results in the desired outcome.

1.2 Verification will be performed by collaborators in Master Control or manually using Verification Form for those who are not considered Power Users in Master Control (as appropriate).

1.3 Discard of Verification form once changes have been made in MC.

2 INTRODUCTION

2.1 All new procedures to be developed for the Stem Cell Laboratory require a Procedure Verification Protocol. Existing active procedures will not have verification performed until revisions are required.

3 SCOPE AND RESPONSIBILITIES

3.1 The procedure developer is responsible for ensuring the completion and documentation of the procedure verification. Procedural steps are evaluated by the user, prior to implementation of a procedure, to assure that the procedure is accurate, clearly understood, and relevant to the function.

NOTE: The procedure verification process is not intended to measure the success of a significant new or changed process.

4 DEFINITIONS/ACRONYMS

4.1 **Procedure Verification Document** - A listing of the steps required to be performed by the user, prior to implementation of a Procedure, to assure that the Procedure is accurate, clearly understood, and relevant to the function. The Verification Document contains "Pass" or "Fail" results of each Verification step, the signature and date of the observer.

4.2 **Verification Procedure Kit** - The collection of the document copies required for the verification of the procedure: Procedure Document and Verification Document. This kit is printed from Master Control prior to the verification process for each procedure.

4.3 **MC** – Master Control

5 MATERIALS

5.1 Verification Procedure Kit for the specific procedure to be verified.

5.2 Procedure Verification Document for the specific procedure to be validated.

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 Verification process for new or changed procedures

8.1.1 The goal of verification is to test the accuracy of the procedure to cover all steps in a clear manner, grammatically correct, and logically formatted.

8.1.2 The procedure developer is responsible for ensuring the completion and documentation of the procedure verification. Use STCL-GEN-013 FRM1 "Procedure Verification for STCL".

8.1.3 The procedure author shall assign staff to review, and if applicable, perform the procedure to evaluate for clarity, completeness, and accuracy. Ideally, staff who reviews the procedure will be familiar with the process, and not part of the development of the procedure.

8.1.4 If any problems are discovered, the procedure author will make the necessary corrections and document actions on the Procedure Verification Form.

8.1.5 The form will be reviewed and signed by the author and the laboratory manager.

8.2 The procedure author must perform the following.

8.2.1 Assemble Verification Procedure Kit(s).

8.2.2 Consult with the laboratory manager for designated staff names for verification

8.2.3 Forward the applicable Verification Procedure Kit(s) to the designated persons responsible for the verification activity.

8.2.4 Conspicuously mark the documents as "Verification Document."

8.3 Designated validator(s) responsibilities:

8.3.1 Personnel receiving the Procedure Verification Document are responsible for performing the Procedure Verification steps, but are encouraged to consult with others.

8.3.2 Indicate "pass" or "fail" for each step. Has the procedure met the requirements of the verification document? If fail, document in D (Observations)

8.3.3 Initial and date each step.

8.3.4 Review the Procedure Verification Document to assure that all steps have been completed and documented appropriately.

8.3.5 Sign and date that the Verification has been performed (after Observation Section).

8.3.6 Forward the Verification Procedure Kit containing the completed Procedure Verification Document to the procedure author, within the assigned time limit.

8.4 Procedure author must

8.4.1 Receive the completed verification documents, review and revise if required by comments.

8.4.2 If one or more Procedure Verification steps have not been successful, ("Failed") the Procedure may not be implemented.

8.4.3 Repeat the verification process, if required.

8.4.4 In the event of verification failure, assess the Procedure Verification Process and recommend further action.

8.4.5 Until a successful Procedure Verification has been achieved, the Procedure shall not be implemented.

9 RELATED DOCUMENTS/FORMS

9.1 STCL-GEN-013 FRM1 Procedure Verification for STCL

10 REFERENCES

10.1 American Association of Blood Banks. Standards for Blood Banks and Transfusion Services. Arlington, VA. Current edition.

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

10.3 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT). Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation current edition.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
02	B. Waters-Pick	Formatted to current SOP template. <u>DELETED the following sections</u>: 4.1 Master Procedure Kit - The collection of the original Document Control Page, Procedure Process Overview, Procedure Document, Training Document, and Verification Document which is assembled at the outset of development and implementation of each procedure. The Master Procedure Kit contains all the original documents and all signatures relevant to the process. This is the Procedure Kit of record for the process. 8.4.6 When verification is completely successful, then assemble the procedure kit for signature.

		8.4.7 Assemble the Master Procedure Kit as directed by 5B.310 , Procedure Management. 8.5 Document author must forward the Master Procedure Kit as directed by 5B.310, Procedure Management. 8.6.2 Determine if the Procedure Verification has been successful. 8.6.3 Document the approval of the Procedure Verification Process on the Procedure Verification Document. 8.6 Medical Director(s) must 8.6.1 Evaluate the accuracy, clarity, completeness and relevance of the Procedure in Master Control.

Signature Manifest

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STCL-GEN-013 Procedure Verification

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Document Release

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Sandy Mulligan (MULLI026)		01 Apr 2014, 05:18:59 PM	Approved