



## STEM CELL LABORATORY (STCL)



**DOCUMENT NUMBER:** STCL-FORM-034

**DOCUMENT TITLE:**

Data Verification Form

**DOCUMENT NOTES:**

### Document Information

**Revision:** 02

**Vault:** STCL-Form-rel

**Status:** Release

**Document Type:** STCL FORM

### Date Information

**Creation Date:** 13 Mar 2014

**Release Date:** 14 Apr 2014

**Effective Date:** 14 Apr 2014

**Expiration Date:**

### Control Information

**Author:** WATE02

**Owner:** WATE02

**Previous Number:** STCL-FORM-034 Rev 01

**Change Number:** STCL-CCR-177

**DATA VERIFICATION FORM****SECTION 1 – DETAILS OF CHANGE(s)**

<b>MasterControl Number:</b>		<b>Document Title:</b>			
<b>CCR Number:</b>		<b>Initiator/Contact #:</b>			
<b>Proposed Date for MasterControl Release:</b>					
<input type="checkbox"/> <b>New Document</b> <input type="checkbox"/> <b>Revised Document</b>					
<b>Instructions:</b>					
<b>Mapping Required:</b>	<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>N/A</b> <input type="checkbox"/> <b>Yes</b> If yes, explain how the existing data in the released document should map to the questions in the revised document below.				
<b>MAPPING INSTRUCTIONS</b>					
<b>Current, Released Version Wording/Content</b> <input type="checkbox"/> <b>N/A</b> <small>(new document)</small>			<b>Revised/New Wording/Content</b>		
<b>DESCRIPTION OF CHANGE(S)</b>					
<b>Current, Released Version Wording/Content</b> <input type="checkbox"/> <b>N/A</b>			<b>Revised/New Wording/Content</b>		

**SECTION 2 – TRAINING / TEST SYSTEM – VERIFICATION**

2a. Changes to be verified	Initiator	2 <sup>nd</sup> Verifier	3 <sup>rd</sup> Verifier
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

2b. FORM VERIFICATION / REVERIFICATION SUMMARY					
Verification 1 Problem/Issue			Verification 2 Problem/Issue (Additional EMMES Changes Required) <input type="checkbox"/> N/A		
Initiator Name/Initials _____	Date _____	Problem/Issue: <input type="checkbox"/> None	Resolved: Yes <input type="checkbox"/> No <input type="checkbox"/> Initials: _____ Date: _____	Initiator Name/Initials _____	Date _____
2 <sup>nd</sup> Verifier Name/Initials _____	Date _____	Problem/Issue: <input type="checkbox"/> None	Resolved: Yes <input type="checkbox"/> No <input type="checkbox"/> Initials: _____ Date: _____	2 <sup>nd</sup> Verifier Name/Initials _____	Date _____
3 <sup>rd</sup> Verifier Name/Initials _____	Date _____	Problem/Issue: <input type="checkbox"/> None	Resolved: Yes <input type="checkbox"/> No <input type="checkbox"/> Initials: _____ Date: _____	3 <sup>rd</sup> Verifier Name/Initials _____	Date _____

**2c. INITIATOR'S REVIEW OF FORM VERIFICATION(S)****Verification 1**  
**Changes**  
**Satisfactory?**☐ Yes, Release to Production, Date: \_\_\_\_\_☐ No, Changes Required: \_\_\_\_\_

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**Initiator's Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_**Verification 2**  
**Changes**  
**Satisfactory?**☐ N/A☐ Yes, Release to Production, Date: \_\_\_\_\_☐ No, Changes Required: \_\_\_\_\_

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**Initiator's Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**SECTION 3 – EMMES PRODUCTION SITE – VERIFICATION**

<b>3a. Verification of EMMES Changes</b>	<b>Initiator</b>	<b>2<sup>nd</sup> Verifier</b>	<b>3<sup>rd</sup> Verifier</b>
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

3b. EMMES PRODUCTION SITE VERIFICATION SUMMARY					
Verification 1 Problem/Issue			Verification 2 Problem/Issue (Additional EMMES Changes Required) <input type="checkbox"/> N/A		
Initiator Name/Initials _____	Date _____	Problem/Issue: <input type="checkbox"/> None  Resolved: Yes <input type="checkbox"/> No <input type="checkbox"/> Initials: _____ Date: _____	Initiator Name/Initials _____	Date _____	Problem/Issue: <input type="checkbox"/> None  Resolved: Yes <input type="checkbox"/> No <input type="checkbox"/> Initials: _____ Date: _____
2 <sup>nd</sup> Verifier Name/Initials _____	Date _____	Problem/Issue: <input type="checkbox"/> None  Resolved: Yes <input type="checkbox"/> No <input type="checkbox"/> Initials: _____ Date: _____	2 <sup>nd</sup> Verifier Name/Initials _____	Date _____	Problem/Issue: <input type="checkbox"/> None  Resolved: Yes <input type="checkbox"/> No <input type="checkbox"/> Initials: _____ Date: _____
3 <sup>rd</sup> Verifier Name/Initials _____	Date _____	Problem/Issue: <input type="checkbox"/> None  Resolved: Yes <input type="checkbox"/> No <input type="checkbox"/> Initials: _____ Date: _____	3 <sup>rd</sup> Verifier Name/Initials _____	Date _____	Problem/Issue: <input type="checkbox"/> None  Resolved: Yes <input type="checkbox"/> No <input type="checkbox"/> Initials: _____ Date: _____

**3c. INITIATOR'S REVIEW OF PRODUCTION SITE VERIFICATION****Verification 1**  
**Changes**  
**Satisfactory?**☐ Yes☐ No, Changes Required: \_\_\_\_\_

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**Initiator's Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_**Verification 2**  
**Changes**  
**Satisfactory?**☐ N/A☐ Yes☐ No, Changes Required: \_\_\_\_\_

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**Initiator's Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_**QSU Reviewed:** \_\_\_\_\_ **Date:** \_\_\_\_\_



### **Verification Instructions – Extend Form as Necessary**

\*Throughout this process, it is important that the Initiator communicate updates regarding release dates with, MasterControl System Administration, QSU, and the Training Coordinator.

1. Initiator completes the following prior to performing verification:

#### **SECTION 1 - Details of Change(s) -**

1. MasterControl Number
2. Document Title
3. CCR (Change Control Request) Number
4. Initiator name/Contact #
5. Proposed Date for MasterControl Release
6. Select if New Document or Revised Document
7. Mapping Required - Select No, N/A, or Yes. If yes, describe/compare how the existing data in the released document should map to the questions in the revised document.

Mapping Instructions section:

- Two columns (Current, Released Version Wording/Content and Revised/New Version Wording/Content) are provided to list changes, reflect Mapping Instructions, and to specific Description of Changes.
  - Current, Released Version Wording/Content – Select N/A if new document
- 8. Add details to the appropriate columns (content may be copied and pasted from applicable MasterControl documents).
- 9. Mapping may be color coded in each column or a written in narrative.

#### **SECTION 2 – FORM Verification training site**

1. (2a) List the exact specifications/requirements that verifiers must confirm to be correct and present in the new or revised form.
  - The form and cells will expand as needed. Unnecessary space may be deleted as necessary.
2. Initiator collaborates with MasterControl System Administration, QSU, and the Training Coordinator to determine/communicate when the CCR is approved.
3. When the document's CCR is approved, the Initiator will begin the verification process as follows:
  - a. Initiator identifies 2 qualified personnel, associated with the use of the FORM being verified to perform verification steps.
4. Verification:
  - a. Initiator, 2<sup>nd</sup> and 3<sup>rd</sup> verifiers complete verification of new FORM changes and documents verification in, Section 2:
    - i. Section 2a, Answer all FORM changes required for verification. Select YES if acceptable. Select NO if problems/issues and record on Section 2b.
    - ii. Go to Section 2b. Add name, initials, and date verification completed.
    - iii. List any Problems/Issues or select NONE in the designated verifier's section.
  - b. Initiator reviews Section 2b and completes Section 2c, Verification 1.
    - i. Select YES, if FORM changes are satisfactory. Add proposed implementation date.
    - ii. If changes are not satisfactory, select NO and document the required changes.

5. When additional changes are required, the Initiator, 2nd and 3rd Verifiers return to Section 2b, Verification 1, and circles Yes or No if the Problem/Issues are resolved, and adds initials and date.
6. If Problems/Issues continue, the verifier(s) document additional changes required, the process continues as above and verification and resolution of problems/issues is documented under the appropriated Verification (1 or 2) Section.
7. When satisfied with all changes, the Initiator completes Section 2c., FORM Verification Satisfactory by selecting Yes, Release to Production, and adds Date, or selects No and lists all changes required.
8. If additional space is required, applicable sections of this form may printed and used to document.

### **SECTION 3 – FORM Verification - production site**

1. (3a) List the exact specifications/requirements that verifiers must confirm to be correct and present in the new or revised.
  - o The form and cells will expand as needed. Unnecessary space may be deleted as necessary.
2. Initiator collaborates with MasterControl System Administration, QSU, and the Training Coordinator to determine/communicate when the CCR is approved.
3. When the document's CCR is approved, the Initiator will begin the verification process as follows:
4. Initiator identifies 2 qualified personnel, associated with the use of the FORM being verified to perform verification steps.
5. Verification:
  - c. Initiator, 2<sup>nd</sup> and 3<sup>rd</sup> verifiers complete verification of new FORM changes and documents verification in, Section 3:
    - i. Section 3a, Answer all FORM changes required for verification. Select YES if acceptable. Select NO if problems/issues and record on Section 3b.
    - ii. Go to Section 3b. Add name, initials, and date verification completed.
    - iii. List any Problems/Issues or select NONE in the designated verifier's section.
  - d. Initiator reviews Section 3b and completes Section 3c, Verification 1.
    - i. Select YES, if FORM changes are satisfactory. Add proposed implementation date.
    - ii. If changes are not satisfactory, select NO and document the required changes.
6. When additional changes are required, the Initiator, 2nd and 3rd Verifiers return to Section 3b, Verification 1, and circles Yes or No if the Problem/Issues are resolved, and adds initials and date.
7. If Problems/Issues continue, the verifier(s) document additional changes required, the process continues as above and verification and resolution of problems/issues is documented under the appropriated Verification (1 or 2) Section.
8. When satisfied with all changes, the Initiator completes Section 3c., FORM Verification Satisfactory by selecting Yes, Release to Production, and adds Date, or selects No and lists all changes required.
9. Provide completed Verification Form and supporting documents to QSU. QSU will review, add signature and date to Verification Form. This form and supporting documents will be scanned and attached to the designated Change Control Request Form in MasterControl.
10. If additional space is required, applicable sections of this form may printed and used to document.

**Signature Manifest****Document Number:** STCL-FORM-034**Revision:** 02**Title:** Data Verification Form

All dates and times are in Eastern Time.

**STCL-FORM-034 Data Verification Form****Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		19 Mar 2014, 04:49:53 PM	Approved

**Manager**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		19 Mar 2014, 04:50:46 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		19 Mar 2014, 09:05:30 PM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
John Carpenter (JPC27)		20 Mar 2014, 03:05:11 PM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		01 Apr 2014, 05:08:58 PM	Approved