



## STEM CELL LABORATORY (STCL)



**DOCUMENT NUMBER:** STCL-TRN-001 FRM2

**DOCUMENT TITLE:**

Competency Assessment Form FRM2

**DOCUMENT NOTES:**

4B.600 FRM3.  
Document required for the BLA.

### Document Information

**Revision:** 02

**Vault:** STCL-TRN-rel

**Status:** Release

**Document Type:** STCL-TRN

### Date Information

**Creation Date:** 26 Feb 2015

**Release Date:** 18 Mar 2015

**Effective Date:** 18 Mar 2015

**Expiration Date:**

### Control Information

**Author:** WATE02

**Owner:** WATE02

**Previous Number:** STCL-TRN-001 FRM2 Rev 01 **Change Number:** STCL-CCR-270

**STCL-TRN-001 (FRM 2)**  
**Competency Assessment Form (CAF) for the STCL**

**Staff Name:** \_\_\_\_\_ **Job Title:** \_\_\_\_\_

**Facility Name:** Stem Cell Laboratory

**Facility Address:** 2400 Pratt Street, Suite 1300, Durham, NC 27705

**Procedure Name and Number:**

**Verification of Procedure List on Individual Training Plan**

The procedure designated above is present on the staff member's Individual Training Plan (ITP). The ITP has been reviewed and determined to be complete, accurate, and current as of this date.

**Instructor's Initials:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Assessment of Competency (check ONE):**

- ☐ Initial
- ☐ Annual Recertification [Review Period: From \_\_\_\_\_ To \_\_\_\_\_]
- ☐ Remedial
- ☐ Procedure Change

**Method of Assessment (check ALL that apply):**

- |  |  |
|--|--|
| <input type="checkbox"/> Direct Observation                      | <input type="checkbox"/> Written Test                  |
| <input type="checkbox"/> Checklist                               | <input type="checkbox"/> Records Review                |
| <input type="checkbox"/> Review of Problem Log / Troubleshooting | <input type="checkbox"/> Review of Maintenance Records |
| <input type="checkbox"/> Proficiency/Blind Sample Testing        | <input type="checkbox"/> Other:                        |

**Outcome:**    ☐ Satisfactory    ☐ Unsatisfactory

**Competency Assessment Statement:**

I, \_\_\_\_\_, (print name of instructor) conclude that \_\_\_\_\_  
(print name of staff member) is competent to satisfactorily perform the procedure designated on this document.

**Instructor's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

I, \_\_\_\_\_, (print name of staff member) acknowledge that I am competent to perform all of the tasks listed as satisfactory. I also acknowledge my continuing responsibility to inform my supervisor if I am not trained or if I do not feel competent to independently perform any task to which I have been assigned.

**Staff Member's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**STCL-TRN-001 (FRM 2)****Competency Assessment Form (CAF) for the STCL****Instructions for Completing the Competency Assessment Form (CAF) for the STCL**

**Note:** For ease of use, all portions of this form may be completed electronically except for any space that requires a signature.

<b>In the field...</b>	<b>Record...</b>
Staff Name	<i>The name of the staff member whose competency is being assessed</i>
Job Title	<i>The job title of the staff member whose competency is being assessed</i>
Facility Name	<i>The Stem Cell Laboratory is the facility employing the staff member whose competency is being assessed</i>
Facility Address	<i>The address (including street address, city, state and zip code) of the facility employing the staff member whose competency is being assessed</i>
Procedure Name and Number	<i>The name and number of the procedure as it appears on the Individual Training Plan (ITP)</i>
Verification of Procedure List on Individual Training Plan	<ul style="list-style-type: none"> <li>- Confirm with the staff member that the procedure listed on this form is included in the procedure list on his/her Individual Training Plan (ITP).</li> <li>- Confirm that the ITP lists all procedures for which the staff member is responsible.</li> <li>- If the list on the ITP is not complete, update the ITP as required.</li> <li>- Place initials and date on designated lines <u>only</u> if the designated procedure is included on the ITP and the ITP list is complete, accurate, and current.</li> </ul>
Assessment of Competency	<ul style="list-style-type: none"> <li>- Check the box indicating the specific type of competency that is being assessed with this form (<u>check only one box</u>).</li> <li>- If this is an Annual Recertification, note the calendar period (start date to finish date) covered under this recertification.</li> </ul>
Method of Assessment	<ul style="list-style-type: none"> <li>- Check <u>all</u> appropriate boxes.</li> <li>- If "Other" is selected, record the specific method of assessment used to measure competency for this procedure (ie. Read and Review, etc)</li> </ul>
Outcome	<ul style="list-style-type: none"> <li>- Check the most appropriate box.</li> <li>- If "unsatisfactory" is selected, the employee must be restricted from performing the task.</li> </ul>
Competency Assessment Statement	<i>The printed name of the instructor and the printed (or typed) name of the staff member whose competency is being assessed, as indicated.</i>
Staff Member's Signature/Date	<i>The signature of the person whose competency was assessed for the indicated procedure and the date the assessment was completed.</i>
Instructor's Signature/Date	<i>The signature of the person who assessed the employee's competence for the indicated procedure and the date the assessment was completed.</i>

**Signature Manifest****Document Number:** STCL-TRN-001 FRM2**Revision:** 02**Title:** Competency Assessment Form FRM2

All dates and times are in Eastern Time.

**STCL-TRN-001 FRM2 Competency Assessment Form****Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		02 Mar 2015, 06:37:14 PM	Approved

**Manager**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		02 Mar 2015, 06:37:25 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		03 Mar 2015, 02:29:01 PM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
John Carpenter (JPC27)		04 Mar 2015, 12:03:38 PM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		11 Mar 2015, 08:48:02 PM	Approved