



## STEM CELL LABORATORY (STCL)



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Training in the Stem Cell Laboratory

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## **STCL-TRN-001 TRAINING IN THE STEM CELL LABORATORY**

### **1 PURPOSE**

- 1.1 This procedure describes the system that is in place to ensure initial, on-going and remedial (as required) training is provided once a qualified individual has been hired. The system of documentation is described. Competency is assessed at specified intervals also described in this procedure.

### **2 INTRODUCTION**

- 2.1 The training program uses an electronic document management system, MasterControl, and a paper-based record system. This system allows for training tasks to be completed electronically via MasterControl and/or on paper-based forms. Each employee is required to have a training record, either via a paper-based file and/or via MasterControl. Paper-based training documents may be added to MasterControl via the System Administrator and/or Training Coordinator, as applicable.
- 2.2 New staff members are oriented to policies and procedures. They are trained for assigned job functions to ensure that they can perform required tasks competently
- 2.3 Incumbent staff must achieve competency on new tasks and maintain competency on existing tasks.

### **3 SCOPE AND RESPONSIBILITIES**

- 3.1 An overview of training requirements is provided in this procedure. The Medical Director, Laboratory Manager, Quality System Unit, Training Coordinator and laboratory personnel are responsible for ensuring the requirements of this procedure are successfully met.
- 3.2 Responsibility
  - 3.2.1 Processing Facility Director / Medical Director
    - 3.2.1.1 Shall be responsible for all Standard Operating Procedures, administrative operations, and the Quality Management Program of the Processing Facility, including compliance with all applicable standards, laws, and regulations
    - 3.2.1.2 Shall have performed or supervised a minimum of five (5) cellular therapy product processing procedures in the twelve (12) month period preceding initial accreditation and a minimum average of five (5) cellular therapy product processing procedures per year within each accreditation cycle.
    - 3.2.1.3 Shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually. Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

### 3.2.2 Laboratory Manager

- 3.2.2.1 Ensure employees/contractors have documented education, experience and training necessary to perform assigned functions.
- 3.2.2.2 Ensure training records of all staff are accurate, complete, and current.
- 3.2.2.3 Verify completion of employee training tasks in MasterControl.
- 3.2.2.4 Ensure yearly review of training records, job description, and CV/résumé performed.

### 3.2.3 Training Coordinator

- 3.2.3.1 Oversee the Training Program.
- 3.2.3.2 Develop training courses within MasterControl.
- 3.2.3.3 Collaborate with Laboratory Manager as needed to satisfy additional and/or unique training requirements, e.g. annual competency assessment.
- 3.2.3.4 Ensure training records are readily retrievable and available for inspections.
- 3.2.3.5 Maintain oversight of training records.
- 3.2.3.6 Employee
- 3.2.3.7 Complete required training and achieve a full understanding prior to executing a procedure independently.
- 3.2.3.8 Annually, ensure CV/résumé is current, signed, and dated.
- 3.2.3.9 Provide Laboratory Manager applicable training documentation (e.g., external, classroom, on-the-job), licenses or credentials for inclusion in their training record.

### 3.2.4 Quality Systems Unit

- 3.2.4.1 Initiate GMP training as requested by Supervisor/Manager.
  - 3.2.4.1.1 New employee GMP training is provided via classroom setting or via MasterControl,
  - 3.2.4.1.2 Once a year GMP training is completed via classroom setting or electronically via MasterControl.
  - 3.2.4.1.3 Documentation of GMP training is maintained in MasterControl. (If GMP training was conducted outside of MasterControl, this training documentation will be maintained in the employee's paper-based file.)
  - 3.2.4.1.4 STCL processing staff who have direct contact with cellular products (*collection or*

*processing*) that may be directly infused into a patient will be required to complete “Aseptic Technique Awareness Training” with DIDRT (*Duke Infectious Disease Response Training*) Program (*or equivalent*) on an annual basis to ensure aseptic techniques are being followed.

- 3.2.4.2 Initiate training classes to promote quality improvement.
- 3.2.4.3 Perform training record audits as part of the internal training program.

#### 4 DEFINITIONS/ACRONYMS

- 4.1 CAF - Competency Assessment Form
- 4.2 ITP - STCL-TRN-001 FRM1 Individual Training Plan Form
- 4.3 MasterControl Course Verifier: Signs off on Training Tasks within MasterControl to indicate an employee has completed a training course. Completion of a Training Task is evident by the employee’s electronic signature on a Training Task. Verification of training is an indication the employee is now “released to task” and able to independently perform the task. This verification is completed by the employee’s supervisor/manager, or designee.
- 4.4 MasterControl (MC) Training: A validated electronic module which documents training and automates issuance of training tasks when SOPs are initially approved, revised and on an annual basis.
- 4.5 Permanent Training File: A file kept for each staff member that contains the documents which verify their initial training, annual competency assessments, and remedial training (if required). Included in the permanent training file will be the STCL-TRN-001 FRM1 Individual Training Plan Form (ITP), Grandfather Clause (if appropriate), and STCL-TRN-001 FRM2 Competency Assessment Form (CAF) to document the staffs training and competency. STCL-TRN-001 FRM3 Group Review Log Sheet is also available to use when training in groups. On-line training records for Duke-required training for the staff member are also kept in the permanent training file. Other documents as appropriate will be kept in the permanent training file. Relevant Supervisor: The individual, in management, who is responsible for releasing a trainee or staff member to task. For staff, the relevant supervisor will be the section supervisor, Laboratory Manager, or the Director.
- 4.6 QSU – Quality Systems Unit
- 4.7 Released to Task: The time when a trainee has completed training and is considered competent to independently perform a task. A trainee is released to task when his/her training has been verified and documented by their supervisor/manager, or designee.
- 4.8 Remedial Training: Retraining and/or re-education which is required when a staff member is determined by her/his supervisor/manager to no longer be competent in the performance of a specific task or process. The curriculum required for

retraining or re-education is the same as is required for initial training. The time required for successful completion of remedial training will vary.

- 4.9 SOP – Standard Operating Procedure
- 4.10 Staff: Any Duke employee who performs any of the tasks involved in the collection, transportation, testing, or processing of cellular products.
- 4.11 Subject Matter Expert (SME): An individual who is considered an expert in the particular subject area based upon their credentials and/or experience in the subject area. A SME can deliver initial and annual competency training in the subject area. A supervisor's validation of competency for a SME constitutes acknowledgement that competency training in that area may be waived. The Stem Cell Laboratory (STCL) manager and Training Coordinator, are designated SMEs. Staff members who have developed a procedure shall be considered a SME for that procedure.
- 4.12 Trainer: The trainer is a laboratory employee who meets the regulatory qualification for a technical consultant (42 CFR § 493.1413 (8)). According to these CFRs, the minimal requirements of a technical consultant are:
  - 4.12.1 An individual who 1) has earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, 2) has at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible, 3) has been trained in the procedure either by a qualified staff member or, as applicable, by the vendor, and 4) who has demonstrated competency as a trainer per this procedure, "Training in the Stem Cell Laboratory".
  - 4.12.2 A qualified manufacturing representative may be considered a trainer for his/her company's product(s) and/or technology.
  - 4.12.3 The terms trainer and instructor are used interchangeably in this document and any associated forms.
- 4.13 Training elements: The standards required by CAP to deem a technician suitable to perform analytical procedures. These standards are listed on the competency assessment form.
- 4.14 Trainee: Any staff not yet documented as competent in the independent performance of a specific procedure for which they will be responsible.
- 4.15 Non-waived test: Term used to refer collectively to moderate and high complexity testing. Laboratories or sites that perform these tests need to have a CLIA certificate, be inspected and meet the CLIA quality standards described in 42 CFR Subparts H, J, K and M.
  - 4.15.1 Moderately complex tests are usually those that are available on automated clinical laboratory equipment such as electrolyte profiles, chemistry profiles, complete blood count, urinalysis, urine drug screen, and automated immunoassays.
  - 4.15.2 High complexity tests include those that require clinical laboratory expertise beyond normal automation to perform. If the output of the

data requires some expertise, these would also be highly complex. Examples include cytology, immunohistochemistry, peripheral smears, flow cytometry, gel electrophoresis, and most molecular diagnostic tests including RT-PCR, gene chip arrays, multiplexed analyses, dot blots, viral loads, expression arrays, CGH arrays, etc.

- 4.16 Waived test: Simple tests with a low risk for an incorrect result. They include certain tests listed in the CLIA regulations, tests cleared by the FDA for home use, and tests approved for waiver by the FDA using the CLIA criteria. Sites performing only waived testing must have a CLIA certificate and follow the manufacturer's instructions; other CLIA requirements do not apply to these sites.

## **5 MATERIALS**

- 5.1 Standard Operating Procedures, Forms, Logs, and Templates, as applicable
- 5.2 Paper-Based Training File, as applicable

## **6 EQUIPMENT**

- 6.1 Computer Access to MasterControl

## **7 SAFETY**

- 7.1 N/A

## **8 PROCEDURE**

- 8.1 Testing Personnel –Educational Requirements for Performing Different Complexity Testing are as follows:
  - 8.1.1 Personnel performing moderate complexity testing must meet the following criteria:
    - 8.1.1.1 MD or DO with a current medical license; OR
    - 8.1.1.2 Doctoral degree in clinical laboratory science, chemical, physical or biological science; OR
    - 8.1.1.3 Master's degree in medical technology, clinical laboratory, chemical, physical, or biological science; OR
    - 8.1.1.4 Bachelor's degree in medical technology, clinical laboratory, chemical, physical or biological science; OR
    - 8.1.1.5 Associate degree in chemical, physical or biological science or medical laboratory technology; OR
    - 8.1.1.6 High school graduate or equivalent and laboratory training/experience consisting of the following:
      - 8.1.1.7 Successfully completed military training of 50 or more weeks and served as a medical laboratory specialist; OR
      - 8.1.1.8 Appropriate training/experience as specified in 42 CFR § 493.1423

- 8.1.2 Personnel performing high complexity testing must meet the following criteria:
  - 8.1.2.1 MD or DO with a current medical license<sup>1</sup>; OR
  - 8.1.2.2 Doctoral degree in clinical laboratory science, chemical, physical or biological science; OR
  - 8.1.2.3 Master's degree in medical technology, clinical laboratory, chemical, physical, or biological science; OR
  - 8.1.2.4 Bachelor's degree in medical technology, clinical laboratory, chemical, physical or biological; OR
  - 8.1.2.5 Associate degree in chemical, physical or biological science or medical laboratory or equivalent education and training (refer to 42 CFR § 493.1489(b) for details on required courses and training); OR
  - 8.1.2.6 Individuals performing high complexity testing on or before April 24, 1995 with a high school diploma or equivalent with documented training may continue to perform testing only on those tests for which training was documented prior to September 1, 1997 (refer to CLIA regulation 42 CFR § 493.1489(b) for details on required training)

## 8.2 Training Record

- 8.2.1 Each employee's paper-based training record should contain documentation of relevant education, experience, and training.
  - 8.2.1.1 Current signed and dated CV/résumé
  - 8.2.1.2 Current job description
  - 8.2.1.3 College diploma and/or transcript.
  - 8.2.1.4 Licensure from accredited agency (i.e. ASCP, NCA, etc.), as appropriate.
  - 8.2.1.5 Paper-based training documents (e.g., SOPs, computer system training, classroom training)
  - 8.2.1.6 External training records

**NOTE:** Other sections may be added to a training record to capture specific activities.
- 8.2.2 Personnel are required to be trained in the procedures they are expected to perform and in good manufacturing practices (GMPs) as applicable to those procedures.
- 8.2.3 Training must be conducted and documented on an ongoing basis. Each staff member must be documented to have been trained on any new procedure or any revised procedure implemented between routine competency assessments.

- 8.2.4 Each staff member must be trained to perform the task or process related to his/her job function prior to independently performing the task or process.
- 8.2.5 Before training is considered complete for a given task or process, successful completion of the specific elements of assessment (e.g. quiz, checklist etc.) detailed on appropriate procedure's competency assessment form is required.
- 8.2.6 Documentation of the successful completion of the required training must be provided for every procedure on which the staff member independently works.
- 8.2.7 The trainee/staff member's supervisor, or a designated trainer, is responsible for documenting that the staff member has been trained and is competent to perform any new task or procedure.
- 8.2.8 Documentation of the reading of procedures by a staff member is maintained by MasterControl. Documentation of tasks performed to prove competency is maintained by the staff member's supervisor, or designee, in the staff member's permanent training file.
- 8.2.9 Supervisors, coordinators, managers, and other management staff who do not perform hands-on manufacturing tasks need not undergo formal training in technical procedures. They must, however, be knowledgeable with regards to any current standard operating procedure(s) in use which they have reviewed and/or signed.
- 8.2.10 If minor change(s) is/are made to a procedure, a consensus will be reached between the supervisor(s) of the area(s) involved, the training coordinator, and QSU whether staff require retraining or simple notification of the change(s).
  - 8.2.10.1 Notification may be documented using a *STCL-TRN-001 FRM3 Group Review Log Sheet* for the procedure.
  - 8.2.10.2 Each staff member is expected to read the revised procedure and raise any question(s) with his/her supervisor / trainer.
  - 8.2.10.3 Each staff member and the trainer are required to sign and date the form.
  - 8.2.10.4 A photocopy of the signed log will be placed in each staff member's permanent training file.

### 8.3 Performance Standards

- 8.3.1 Performance standards and training elements for assessing competency must be established for each procedure and can be found on the CAF for SOP. Performance standards and training elements must be communicated to the staff member/trainee at the time training is initiated.
- 8.3.2 Performance standards and training elements used in competency assessment must be consistent among staff that performs the same task(s) in the same job functions.



- 8.3.3 Task-oriented assessment of the competency of staff members to perform their assigned duties will be procedure-specific. Assessment of competency for tasks may include any, or all, of the following:
  - 8.3.3.1 Monitoring the recording and reporting of routine operations and procedures
  - 8.3.3.2 Review of worksheets, quality control records, proficiency test results, and/or preventive maintenance results
  - 8.3.3.3 Assessment of a staff member's performance in the mock-up of a procedural discrepancy situation
  - 8.3.3.4 Assessment of problem solving skills (may include written testing, review of problem reports, procedure reviews etc.)
  - 8.3.3.5 Direct observation of performance of procedure
  - 8.3.3.6 Direct observations of performance of instrument maintenance and function checks
  - 8.3.3.7 Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
- 8.3.4 While all of the competency assessment procedures may not apply to all personnel, those that do should be performed yearly as part of each employee's annual review.

#### 8.4 Individual Training Plans

- 8.4.1 An Individual Training Plan (ITP) will be prepared for new staff per STCL-TRN-001 FRM1 Individual Training Plan Form and will be maintained in the staff member's hard copy training file. The ITP will be updated as needed for an existing staff member who either assumes a new task or ceases to perform a task. The staff member's supervisor, or designee, is responsible for ensuring that the information on the ITP is accurate.
  - 8.4.1.1 The procedures/tasks the staff member is expected to perform will be listed by number and/or name on the ITP.
  - 8.4.1.2 The list of procedures may be amended by:
    - 8.4.1.2.1 Release to task for any procedure(s) for which the staff member has documented training and competency, or
    - 8.4.1.2.2 Removal from task for any procedure(s) which the staff member either does not, or is no longer considered competent to, perform
- 8.4.2 The individual training plan includes:
  - 8.4.2.1 Staff member/trainee name.
  - 8.4.2.2 Department and location.
  - 8.4.2.3 Job title of trainee/staff member.

- 8.4.2.4 Hire date.
- 8.4.2.5 If a staff member changes job responsibilities, the date the responsibilities changed should be noted in the same area of the ITP as the hire date.
- 8.4.2.6 If a staff member is terminated, the date of termination should be noted.
- 8.4.2.7 Task(s) or procedures the trainee/staff member is expected to perform listed by procedure number and/or a brief description.
- 8.4.2.8 Documentation of release to perform a task/procedure, including:
  - 8.4.2.8.1 The supervisor's signature and date on the appropriate line on the ITP in the "Release to Task" column, and
  - 8.4.2.8.2 The supervisor's signature is to be supported by a fully completed CAF for the task or procedure documenting that the trainee/staff member has:
    - Read the SOP for the task or procedure and reviewed it with the instructor
    - Achieved an understanding of each task or procedure and how it relates to his/her job function
    - Received training per SOP for the task or procedure
    - Achieved competency to perform the task or procedure independently
- 8.4.2.9 Training / Re-training frequency
  - 8.4.2.9.1 When appropriate, documentation of removal from the task or procedure by the supervisor's signature and date on the appropriate line in the "Removed from Task" column on the ITP.
  - 8.4.2.9.2 Removal from task may be due either to demonstrated incompetence, or
  - 8.4.2.9.3 Staff member no longer has responsibility for a task or procedure and the annual competency assessment for the task or procedure, if appropriate, has been suspended.
- 8.4.3 Subject matter experts may or may not have an Individual Training Plan. SMEs who currently have, or have had, responsibility for hands-on participation in the manufacturing process may have an ITP which covers that portion of their current work responsibilities or history.

- 8.4.4 Incumbent staff trained prior to the implementation of the current training documentation system have in their permanent training file a “Grandfather Clause” statement. This statement was used to bring existing personnel’s training records up to date and establish a point from which to move forward.
- 8.4.5 The Grandfather Clause was a one-time documentation for incumbent staff. Documentation of competency has been required subsequently.
- 8.5 Competency Assessment: Competency assessments must be performed upon initial training, after 6 months and annually thereafter. The trainee/staff member’s supervisor, or the trainer, must assess competency of each individual to perform the procedures listed on his/her ITP.
  - 8.5.1 Competency will be assessed per the procedures and training frequency noted on the ITP.
  - 8.5.2 Documentation of assessments, per STCL-TRN-001 FRM2 Competency Assessment Form, is filed in the staff member/trainee’s permanent training file.
  - 8.5.3 STCL-TRN-001 FRM2 Competency Assessment Form may be altered to give more detail in the method used to determine competency.
  - 8.5.4 In cases where a procedure is administrative or does not require hands-on performance of a technical procedure, an abbreviated form of training documentation (e.g. the STCL-TRN-001 FRM3 Group Review Log Sheet for the procedure) is acceptable.
- 8.6 Failure of Competency
  - 8.6.1 If a staff member is found not to be competent to independently perform a procedure for which they have been released to task, he/she must not be allowed to independently perform the procedure or task. Removal of the staff member from the task must be documented by the staff member’s supervisor on the staff member’s ITP.
  - 8.6.2 Corrective action in the form of remedial training must be initiated, completed and documented per each procedure’s training document.
  - 8.6.3 Documentation of satisfactory completion of remedial training must be completed before the staff member is once again released to task and allowed to independently perform the procedure or task.
- 8.7 Periodic Assessment of Competency
  - 8.7.1 Laboratory Staff: For the required procedures as indicated on each staff member’s ITP, competency assessment will be performed on an annual basis per a schedule determined by the laboratory manager.
  - 8.7.2 Administrative Staff: For the required procedures as indicated on each staff member’s ITP, competency assessment for administrative staff will be performed on an annual basis per a schedule determined by the relevant supervisor.

8.8 Scope of Annual Competency Assessment

- 8.8.1 The annual competency assessment must include an evaluation of the performance of each task listed on the staff member's ITP which has a direct impact on a product.
- 8.8.2 Annual competency assessment is not required but may be done for tasks which do not have a direct impact on a product.
- 8.8.3 Staff members will receive an annual review of good manufacturing practices.

8.9 Documentation of Annual Competency Assessment

- 8.9.1 As part of the annual competency assessment, the staff member's supervisor, or designee, shall review the procedure(s) listed on the staff member's ITP to ensure that the ITP is complete, accurate.
  - 8.9.1.1 If the list of procedures on the ITP is found to be incomplete, inaccurate or not current the list must be amended.
  - 8.9.1.2 The ITP should reflect that the staff member is released to task on only those procedures for which he/she has documented current training and competency.
- 8.9.2 Documentation must include a completed and signed annual Competency Assessment Form for all procedures for which annual competency is required.

8.10 Each member of the training team has unique responsibilities which must be met to ensure successful training.

- 8.10.1 Responsibilities of the trainee/staff member's supervisor:
  - 8.10.1.1 Inform the Master Control System Administrator and the Training Coordinator, or designee, when a new staff member has been hired.
  - 8.10.1.2 Provide the trainee with job orientation and orientation to the training process.
  - 8.10.1.3 Ensure that for each day the trainee/staff member is in training there is an assigned trainer.
  - 8.10.1.4 Ensure that the trainee/staff member is trained on the current version of all procedures for which they are responsible.
  - 8.10.1.5 After successful completion of all required training elements, review any documents supporting competency (quizzes, checklists, lab results etc.) as detailed on the completed STCL-TRN-001 FRM2 Competency Assessment Form (CAF) for the procedure.
  - 8.10.1.6 When satisfied that all supporting documentation meets expectations and that the CAF has been completed accurately, release the trainee/staff member to task for that procedure. Once the competency of the trainee/staff

member has been documented by the completion of the CAF and the trainee/staff member has been released to task on his/her ITP, supporting documents (quizzes, checklists, lab results etc.) need not be retained.

- 8.10.1.7 Ensure that the required documentation of successful completion of training is placed in the trainee/staff member's permanent training file.

8.10.2 Responsibilities of the trainer:

- 8.10.2.1 Review the procedures with the trainee/staff member in a clear and understandable manner. The review should include an explanation of the purpose of the procedure, the principal behind the method(s) used in the procedure, and the expected outcome.
- 8.10.2.2 Discuss the critical steps in the procedure.
- 8.10.2.3 Discuss the potential impact of errors and how to respond to problems or errors that may occur during the procedure.
- 8.10.2.4 If appropriate, demonstrate procedures to the trainee/staff member.
- 8.10.2.5 If appropriate, observe the trainee/staff member performing the procedures.
- 8.10.2.6 Directly supervise the trainee/staff member's work for all procedures on which he/she is not yet released to task.
- 8.10.2.7 Respond effectively to the trainee/staff member's questions.
- 8.10.2.8 Assess the trainee/staff member's competency. Suggest appropriate corrections and/or improvements of the trainee/staff member's performance in a supportive manner.
- 8.10.2.9 Determine the need for additional training, when appropriate.
- 8.10.2.10 Ensure training requirements are met and properly documented
  - 8.10.2.10.1 Administer any test required and ensure that the trainee/staff member has achieved the required passing score.
  - 8.10.2.10.2 Open-book tests require a score of 100%.
  - 8.10.2.10.3 Closed-book tests require a score of 80% or greater.
  - 8.10.2.10.4 Document competency on all required performance and training unit checklists as well as any other required activity (e.g. blind samples, etc.).

8.10.2.10.5 When the trainee/staff member has successfully completed all required elements of assessment for a procedure, document the competency of the trainee/staff member on the Competency Assessment Form (CAF) for that procedure. Ensure that the CAF has been completed with all required information and signatures.

8.10.3 Responsibilities of a trainee/staff member:

- 8.10.3.1 Read the procedures and review with the trainer.
- 8.10.3.2 Do not independently perform procedures until released to task by his/her supervisor. Until released to task, perform only under the trainer's direct supervision.
- 8.10.3.3 If appropriate, observe the trainer perform the procedures and practice the procedures under supervision until proficient.
- 8.10.3.4 If uncertain about any aspect of a procedure, ask the trainer for additional explanation or demonstration.
- 8.10.3.5 Successfully complete all required elements of assessment for the procedure (e.g. quizzes, checklists etc.).
- 8.10.3.6 Complete all required documentation, including signing and dating the 'Competency Assessment Statement' on the CAF after the instructor has signed.

## 9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-TRN-001 FRM1 Individual Training Plan Form
- 9.2 STCL-TRN-001 FRM2 Competency Assessment Form
- 9.3 STCL-TRN-001 FRM3 Group Review Log Sheet
- 9.4 STCL-TRN-001 FRM4 STCL Medical Director Competency Checklist
- 9.5 COMM-QA-057 Procedure Development
- 9.6 Grandfather Clause

## 10 REFERENCES

- 10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.
- 10.2 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and Netcord. International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release Current edition.

## 11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
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STCL-TRN-001 Training in the Stem Cell Laboratory  
Stem Cell Laboratory, DUMC  
Durham, NC

Revision No.	Author	Description of Change(s)
04	B. Waters-Pick	<ul style="list-style-type: none"> <li>• Add Responsibilities of Processing Facility Director / Medical Director in Section 3.2 to meet new FACT standards, 7<sup>th</sup> Edition, effective March 2018.</li> <li>• Added STCL-TRN-001 FRM4 STCL Medical Director Competency Checklist to Section 9.</li> </ul>

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**Document Release**

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Sandy Mulligan (MULLI026)		20 Aug 2018, 11:48:27 AM	Approved