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Training Overview

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COMM-QA-055
TRAINING OVERVIEW

1 PURPOSE

1.1 This procedure provides an overview of the training program for the Carolinas Cord Blood Bank (CCBB), Stem Cell Laboratory (STCL), Pediatric Blood and Marrow Transplant (PBMT), Adult Blood and Marrow Transplant (ABMT), Robertson GMP Laboratory MC3, and other designated programs to ensure that employees have the documented education, experience, and training necessary to perform their assigned functions.

2 INTRODUCTION

2.1 Personnel must have the necessary education, experience, and training to ensure competent performance of their assigned functions. All personnel must be trained to perform their assigned responsibilities competently. Personnel must perform only those activities for which they are qualified, authorized and trained. Untrained personnel must be escorted while in restricted areas, e.g., laboratory processing areas.

2.2 All personnel shall follow policies and Standard Operating Procedures related to their positions.

3 SCOPE AND RESPONSIBILITIES

3.1 An overview of training requirements is provided in this procedure. Individual programs may establish specific training requirements to supplement this procedure. The Program/Medical Director, Supervisor/Manager, Quality Systems Unit (QSU), Training Coordinator(s) and applicable program personnel are responsible for ensuring the requirements of this procedure are successfully met.

3.2 Responsibility

3.2.1 Supervisor/Manager

3.2.1.1 Ensure employees/contractors have documented education, experience and training necessary to perform assigned functions.

3.2.1.2 Ensure training records of all staff are accurate, complete and current.

3.2.1.3 Verify completion of employee training tasks in MasterControl.

3.2.1.4 Ensure yearly review of training records, job description and Curriculum Vitae (CV)/résumé is performed.

3.2.1.4.1 Activation in Master Control (MC) of new staff may be withheld until the signed and dated CV/résumé and job description are received by the System Administrator or the Training Coordinator.

3.2.1.4.2 Staff members trained to COMM-QA-083 also require a completed Signature File (COMM-QA-083 FRM1).

3.2.2 Training Coordinator

Note: This role may be performed by the Program Supervisor/Manager or designee.

3.2.2.1 Oversee the Training Program.

3.2.2.2 Develop training courses within MasterControl.

3.2.2.3 Collaborate with Supervisors/Managers as needed to satisfy additional and/or unique training requirements, e.g., annual competency assessment.

3.2.2.4 Ensure training records are readily retrievable and available for inspections.

3.2.2.5 Maintain oversight of training records.

3.2.3 Subject Matter Expert (SME)

3.2.3.1 A SME can deliver initial training, ongoing training and periodic competency assessments in the subject area.

3.2.3.2 Personnel who develop a procedure are considered a SME for the task, process and related documents covered by that procedure.

3.2.3.3 A supervisor's verification of training in MasterControl for a SME constitutes acknowledgement that competency training in that area may be waived.

3.2.4 Employee

3.2.4.1 Complete required training and achieve a full understanding prior to executing a procedure independently.

3.2.4.2 Periodically review training record to ensure accuracy and completeness. (This may be done at the time of annual performance review with the Supervisor/Manager.)

3.2.4.3 Annually, ensure CV/résumé is current, signed, and dated.

3.2.4.4 Annually, ensure Signature File Statement, if needed, is current and complete.

3.2.4.5 Provide Supervisor/Manager with applicable training documentation (e.g., external, classroom, on-the-job) for inclusion in their training record.

3.2.5 Quality Systems Unit

3.2.5.1 Initiate Good Manufacturing Practices (GMP) training as requested by Supervisor/Manager.

3.2.5.1.1 New employee GMP training is provided via classroom setting or via MasterControl, based on prior experience/training.

3.2.5.1.2 Once a year GMP training is completed via classroom setting or electronically via MasterControl.

3.2.5.1.3 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.)

3.2.5.2 Initiate training classes to promote quality improvement.

3.2.5.3 Perform training record audits as part of the internal training program.

3.2.6 Consultants

3.2.6.1 Provide appropriate documentation to show education, experience and training (e.g., CV/résumé).

3.2.7 Contractors

3.2.7.1 Provide documentation of training on appropriate Standard Operating Procedures (SOPs) prior to performing assigned task/function.

3.2.8 Trainer

3.2.8.1 Ensure the trainee has gained competency and demonstrates proficiency in each task for which he/she will be held responsible.

3.2.8.2 Where appropriate, demonstrate task/function for trainee.

3.2.8.3 Where appropriate, observed trainee performing task/function.

3.2.8.4 Directly supervise trainee for all activities for which he/she is not yet released to task.

3.2.9 MasterControl Course Verifier

3.2.9.1 Signs off on electronic 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 and unsupervised perform the task. This verification is completed by the employee's supervisor/manager, or designee.

4 DEFINITIONS/ACRONYMS

4.1 Classroom Training: A group or individual training that may offer hands-on instructions and a forum for employees to ask questions.

4.2 Clinical Research Support Office (CRSO)

4.3 Collaborative Institutional Training Initiative (CITI)

4.4 Computer System Training: Training on applicable computer system(s).

4.5 Consultant: Provides professional or expert advice in a particular area.

4.6 Contractor: Organization or individual that contracts with another organization or individual.

4.7 CV: Curriculum Vitae

4.8 GxP: Term used to describe Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and GTP (Good Tissue Practices).

4.9 GMP: Good Manufacturing Practices

4.10 External Training: Training offered by an outside agency, vendor, or manufacturer to a group or individual that are pertinent to an employee's job function or career development.

4.11 Group Training: Training performed when there is more than one person requiring instruction training on the same procedure, policy or topic.

4.12 Human Research Training (HRT)

4.13 Individual Training: Training performed when there is only one trainee.

4.14 MC3: Marcus Center for Cellular Cures

4.15 MasterControl (MC) Training: A validated electronic module which documents training and automates issuance of training tasks when documents are initially approved, revised and on an annual basis.

4.16 MasterControl Course Verifier: Designated person responsible for verification of training tasks.

4.17 On-the-Job Training (OJT): Training given to employees in the workplace as they perform work activities. OJT training is based on the principle of learning by doing and includes demonstration and explanation by a task trainer, supervisor/ manager, or subject matter expert as well as performance of tasks under supervision and the provision of appropriate feedback.

4.18 Qualified Trainer: An individual who has appropriate experience, education and/or training to instruct and evaluate others on the performance of a skill needed in the accomplishment of a job duty. The staff member must be approved as a qualified trainer by the department supervisor/manager and have maintained competency in the task for a minimum of six months. A supplier/vendor representative may be considered a qualified trainer for his/her company's product(s) and/or technology. The terms trainer, instructor and preceptor may be used interchangeably.

4.19 Quality Systems Unit (QSU)

4.20 Read-Only Training: Training that requires that an employee only read a document to obtain understanding of a procedure, policy or topic.

4.21 Regulatory Training: Training on applicable regulations. This training can be obtained externally or internally (e.g., classroom training).

4.22 Standard Operating Procedure (SOP)

4.23 Subject Matter Expert (SME): An individual who is considered an expert in the particular subject area based on their credentials, experience and/or training in the subject area. The Program/Medical Director, Department Directors, Managers, Supervisors and Coordinators are considered SMEs for the scope of their program/department. Qualified supplier/vendor representatives are considered SMEs for the product and/or technology of the company represented.

4.24 Trainee: An individual designated to receive training to ensure adequate skill and understanding in the performance of a job duty.

4.25 Training Job Codes: Groups or individuals used in MasterControl to coordinate training courses and users.

4.26 Training Record: Records of employee training which can include training reports, competency assessments, completed training, current CV/résumé, current job description, and signature statement file

4.27 OESO: Duke Medicine Occupational and Environmental Safety Office

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 Overview of the Training Program

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. On-the-job training and classroom training may be documented via paper or via MasterControl. External training is recorded on paper-based forms. In the event the employee does not have access to MasterControl, training may be recorded 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.

8.2 Training Record

8.2.1 Each employee's training record should contain documentation of relevant education, experience, and training.

8.2.1.1 Current signed and dated CV/résumé

8.2.1.1.1 CV/résumé does not need to be resubmitted annually if there have been no changes. Reviewer's electronic signature in MC at time of annual review constitutes documentation that the CV/résumé is current.

8.2.1.1.2 CV/résumé of non-CCBB staff collecting for the CCBB at affiliated sites do not need to be updated solely and specifically to include their collection activities for the CCBB. The document which is acceptable for their employer is acceptable to the CCBB.

8.2.1.2 Current job description

8.2.1.3 Signature File Statement, if assigned to COMM-QA-083.

8.2.1.3.1 Signature File does not need to be resubmitted annually if there have been no changes. Reviewer's electronic signature in MC at time of annual review constitutes documentation that the file is current.

8.2.1.4 Paper-based training documents (e.g., SOPs, computer system training, classroom training)

8.2.1.5 External training records

Note: Other sections may be added to a training record to capture specific activities.

8.2.2 Storage/Retrieval of Training Records

8.2.2.1 Employee safety records are maintained by Duke University and Duke Medicine Occupational and Environmental Safety Office (OESO) at http://www.safety.duke.edu/. Duke Medicine currently uses the web-based modules available at the Collaborative Institutional Training Initiative (CITI) website https://www.citiprogram.org and the Duke Learning Management System (DLMS) https://hr.duke.edu/training/learning-management-system for certification in Human Research Training (HRT) Training. HRT training documentation is available through the Duke Office of Clinical Research (DOCR) docr.help@dm.duke.edu.or (919)681-6665.

8.2.2.1.1 Supervisor/Managers will designate the HRT training requirements for personnel engaged in or who support human subject research. (e.g., all personnel listed in eIRB as key

personnel are required to meet both CITI and DLMS HRT training requirements. Personnel not listed in eIRB as key personnel but support human subject research are required to meet DLMS requirements.)

8.2.2.1.2 A list of required CITI training for applicable personnel can be found at: https://ors.duke.edu/researcher/initial-certification .

8.2.2.2 Paper-based training records are maintained by the Supervisor/Manager or Training Coordinator and stored in designated, secure cabinets. Paper-based training records may be incorporated into the MasterControl Document Management System, as applicable.

8.2.2.3 Electronic read-only training records are maintained within MasterControl.

8.2.2.3.1 Quizzes and other documented training items in paper form can be scanned and downloaded to an individual trainee's Trainee InfoCard in MasterControl.

8.2.3 Employee Training Record Review

Note: May be done at the time of annual performance review.

8.2.3.1 The employee will review their training record once a year, to ensure the content reflects current and applicable education, experience, and training.

8.2.3.1.1 Verification that the CV/résumé is current may be accomplished by the employee signing and dating the CV/résumé or as noted by the CV/résumé version date.

8.2.3.1.2 Annual review of the job description, CV/résumé, training records, and Signature File can be documented in MC for employees.

8.2.3.2 Each employee will verify that documentation is present for required and completed training. It is the responsibility of the employee in conjunction with the Supervisor/Manager to address discrepancies and update their training records.

8.3 Training Reports

8.3.1 Individual training reports reflecting completed and pending training tasks within MasterControl may be generated by the employee, Supervisor/Manager and/or MasterControl System Administrator.

8.4 Types of Training

8.4.1 Read-Only Training (may include quizzes)

8.4.1.1 Read-Only training for SOPs and other controlled documents is completed via MasterControl unless the individual is a non-MasterControl user, e.g., consultant or contractor.

8.4.1.1.1 A non-MasterControl user will train on an issued copy of the procedure and document the training outside of MasterControl.

8.4.2 Classroom Training

8.4.2.1 Classroom training is conducted by a SME.

8.4.2.2 Documentation of attendance is to be provided to attendees.

8.4.2.3 Employees will provide documentation of completed classroom training to their Supervisor/Manager for inclusion in their training record.

8.4.3 On-the-Job Training

8.4.3.1 The Supervisor/Manager will determine training requirements based on a trainee's experience, job description, and specific procedure/task. Concurrent documentation of training will occur.

8.4.3.2 The Supervisor/Manager will verify that all records related to the training have been reviewed and approved and are added to the employee's training record.

Note: Employees, in collaboration with their Supervisor/Manager, are responsible for ensuring they complete all required on-the-job training before independently executing a task without supervision.

8.4.4 External Training

8.4.4.1 If external training is required to satisfy a specific training need, the Supervisor/Manager must ensure that the training meets the specific training requirement.

8.4.4.2 Employees attending external seminars or courses pertinent to their job function, for career development or to satisfy a specific training requirement should forward documentation of attendance to their Supervisor/Manager for inclusion in their training record.

8.5 Training Requirements

Note: Based on individual job responsibilities, Program Management, the Supervisor/Manager and/or the Training Coordinator designate training requirements for each employee. Training for MasterControl users is assigned, documented and verified within MasterControl. The supervisor/manager is responsible for verifying completed training tasks within MasterControl. Annual training on documents is triggered automatically within MasterControl. MasterControl has the capability of generating reports documenting completed

and pending document training for individual employees as well as by all employees trained on a specific document.

8.5.1 Employees

8.5.1.1 New Hire

8.5.1.1.1 Program Management, Supervisor/Manager, and/or Training Coordinator designate initial training requirements.

8.5.1.1.2 Supervisor/Manager and/or Training Coordinator may create a training file.

8.5.1.1.3 QSU Document Control Operations provides MasterControl access/training as requested by the Supervisor/Manager.

8.5.1.1.4 The new hire is responsible for ensuring successful completion of all required training assigned by their Supervisor/Manager before independent execution of a procedure/task. A new hire cannot review work or execute any task independently and without supervision for which they do not have completed and documented training.

8.5.1.1.5 The new hire must provide a CV/résumé that identifies their current position.

8.5.1.1.6 New hires who will be assigned to COMM-QA-083 must provide a completed Signature File Statement.

8.5.1.1.7 The new hire will complete required training tasks in MasterControl and will provide relevant training documents to their Supervisor/Manager for inclusion in their training record.

8.5.1.1.8 QSU will initiate GMP training as requested by the Supervisor/Manager for all new employees performing regulated functions.

8.5.1.2 Existing Employee

8.5.1.2.1 Employees performing GMP functions will be required to attend or complete on-line GMP training via MasterControl once a year.

8.5.1.2.2 Annual training on documents, as designated by the Supervisor/Manager, will be initiated via MasterControl.

8.5.1.2.3 Additional training requirements (e.g., classroom, on-the-job) of new and existing

documents will be designated by the Supervisor/Manager.

8.5.1.2.4 If necessary, an employee may complete training on a document after the effective date of that document as long as the employee does not perform the task before training has been completed and documented.

8.5.1.2.5 Remedial training will be specified as needed and documented by the Supervisor/Manager.

8.5.1.3 Retraining

8.5.1.3.1 If staff member(s) discontinue collection and/or processing functions for greater than 6 months, the staff member(s) must be retrained and have their competency assessed in accordance with each department's training requirements upon resumption of activities.

8.5.1.3.2 The curriculum for retraining is the same as is required for initial training.

8.5.1.3.3 Documentation of satisfactory completion of retraining must be completed before staff are once again allowed to independently perform procedures or tasks from which they have been absent for greater than 6 months.

8.5.2 Employee – Temporary or Intern / Contractor

8.5.2.1 The Supervisor/Manager maintains a training record on all temporary employees and contractors. Training will be initiated as necessary to correspond with job requirements.

8.5.2.2 Temporary employees and contractors may or may not be users of MasterControl. Training may be documented via MasterControl or paper.

8.5.3 Consultants

8.5.3.1 Programs utilizing a consultant should collect a current CV/résumé from the consultant to document proof of their education, experience, and training in the area for which they are providing consulting services or acting as a SME.

8.6 Documentation

8.6.1 Paper-based training records for employees are maintained by the Supervisor/Manager or Training Coordinator. All documentation of training completed in MasterControl is maintained within the MasterControl document management system.

8.6.2 Former employee training records may be sent off-site for storage per CCBB-QA-018 *CCBB Records Management.*

9 RELATED DOCUMENTS/FORMS

9.1 COMM-TRN-001 Training

9.2 CCBB-TRN-004 Cord Blood Collection Training Overview

9.3 CCBB-TRN-006 CCBB Processing Laboratory Training Overview

9.4 STCL-TRN-001 Training

9.5 CT2-TRN-001 Training

9.6 COMM-QA-016 Procedure Management

9.7 CCBB-QA-018 CCBB Records Management

9.8 COMM-QA-066 Review of Documents in MasterControl

9.9 COMM-QA-068 Good Manufacturing Practices – GMP

9.10 COMM-QA-083, Personnel Signature and Initial Verification

9.11 COMM-QA-083 FRM1, Signature File Statement

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. 21 CFR Part 58.29 (a), (b) and 58.195.

10.3 21 CFR Part 211.25; 600.10 and 1271.170 Personnel Qualifications

10.4 21 CFR Part 11.10 (i) Electronic Records; Electronic Signatures

10.5 ICH Guideline for Good Clinical Practice (E6)

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	C. Curtis	• Updated procedure to include details about personnel signature files. See attachment on COMM-CCR-218 for more information.

Signature Manifest

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