## 1. Purpose

To define consistent procedures for assessing the training needs of Office of Sponsor and Regulatory Oversight (OSRO) personnel and ensure a permanent, traceable record of that training.

## 2. Scope

2.1. OSRO personnel are qualified to perform tasks through education, experience and training or any combination thereof.

2.2. This SOP applies to all OSRO government and contract employees.

## 3. Responsibilities

3.1. Trainees

3.1.1. Will assure that training is completed prior to performing a task independently.

3.1.2. Will complete training courses as required by OSRO, the National Cancer Institute (NCI), Center for Cancer Research (CCR), National Institutes of Health (NIH) and the Department of Health and Human Services (HHS).

3.2. Supervisors

3.2.1. Will assure that employee has achieved the appropriate competency level prior to scheduling the employee for performing a task.

3.3. OSRO Quality

3.3.1. Will ensure that all training documents are completed prior to updating an employee's training record.

3.3.2. Will maintain employee training folders and update the training database as required.

3.3.3. Will notify employee when a training event is due.

3.3.4. Will provide periodic reports to supervisors on training compliance of their reports.

## 4. References

4.1. 103 Training Policy

## 5. Definitions

Refer to the OSRO Lexicon.

## 6. Procedure

6.1. Training Management

6.1.1. Each employee will receive initial induction training upon joining OSRO.

6.1.2. Staff members will be assigned training based on their assigned roles.

6.1.3. OSRO Quality will notify staff members when training is required.

6.1.4. Training records will be completed after each training event and filed with OSRO Quality in a timely manner.

6.1.4.1. Electronic Quality Management System (eQMS) Read and Acknowledge training records are not provided to OSRO Quality.

6.1.5. Training on new or revised documents should be completed within 5 business days of the document's effective date.

6.1.6. If an increase in corrective action training occurs for a procedure, then the current training method and/or materials will be evaluated to determine if the training is effective.

6.1.7. When training records are received by OSRO Quality, the training record will be filed in the appropriate Training Folder and the Training Database will be updated with the relevant training activity.

6.1.8. OSRO Quality will notify Functional Group Heads on a periodic basis of training gaps for staff members in their respective groups.

6.1.9. Supervisors should review their direct reports' training curriculum on an annual basis to identify any further training needs.

6.2. Training Categories

6.2.1. General Good Clinical Practices (GCP) Training

6.2.1.1. Each employee affected by this procedure will have initial induction training on GCPs (preferably US FDA focus), human subject protection (Biomedical 101) and research involving children (Vulnerable Subjects – Research Involving Children).

6.2.1.2. Training conducted within 2 years prior to onboarding is acceptable.

6.2.1.3. Employees will have GCP training at least every 3 years utilizing the Collaborative Institutional Training Initiative (CITI) training module which may be accessed through https://irbo.nih.gov/confluence/.

6.2.1.3.1. Note: Vulnerable Subjects – Research Involving Children certification is only required once, at initial induction.

6.2.2. Institutional Training

6.2.2.1. Employees shall complete mandatory training required by NCI, CCR, NIH and HHS.

6.2.2.2. Employees should consult the NIH Office of Human Resources (https://hr.nih.gov/training-center/mti/mandatory-training-inventory) to access the mandatory training listing.

6.2.3. Outside Training and Seminars

6.2.3.1. Training and seminars attended outside of OSRO.

6.2.4. Group Training

6.2.4.1. Group training may be held for annual and other department training events.

6.2.5. Individual OSRO Competency Training

6.2.5.1. Individual training on documents and procedures.

6.2.5.2. Training may be by read and understand, task training or instructional training with a trainer.

6.3. Training Folders

6.3.1. The employee Training Folder will contain the following:

6.3.1.1. Resume / Curriculum Vitae (CV)

6.3.1.1.1. A summary resume detailing the employee's qualifications, experience and training.

6.3.1.2. Training Curriculum

6.3.1.2.1. A set of training requirements for specific functional roles within OSRO.

6.3.1.3. Training Records

6.3.1.3.1. Signed forms stating the procedure trained upon and the date of training.

6.3.1.3.2. Training certificates from group or individual training.

6.3.1.4. Record of GCP training defined in Step 6.2.1.

6.3.1.5. Certificates attained though NIH and external training courses.

6.3.2. OSRO Quality will maintain Training Folders in a secure location.

6.4. Training Database

6.4.1. A Training Database will be maintained to track the status of employee training.

6.4.2. Employee training events which occur outside the eQMS will be recorded in the database.

6.4.3. Reports will be generated to provide training events due, training events past due and training events performed.

6.4.4. OSRO Quality will maintain the Training Database in a secure location.

6.5. Training curricula will be reviewed on a periodic basis by the Functional Group Head to determine if documents and procedures need to be added or deleted from them.

6.5.1. Changes to training curricula will be managed via Change Control.

6.6. Training Methods and Evaluation

6.6.1. The types of training are:

6.6.1.1. Read and Acknowledge

6.6.1.1.1. May be applicable to non-complex operations when the procedure provides detailed instruction for completion of the task, revision training for complex operations where the procedure changes are minor, where only limited knowledge of the procedure is required, or when the trainee will not need to perform the procedure unsupervised, e.g., for review function only.

6.6.1.1.2. Employees who sign as having read and understood the procedure and will comply with it will be considered trained when read and understand training is required.

6.6.1.1.3. All OSRO Quality Management System (QMS) documents require read and understand training.

6.6.1.2. Task Training

6.6.1.2.1. For procedures where a certain level of complexity is involved and where the trainee must physically demonstrate understanding of the procedure.

6.6.1.2.2. Task training is a 3-step process: 1.) watching the procedure, 2.) performing it successfully under supervision and then 3.) performing it successfully independently, before being approved as trained to perform the task independently.

6.6.1.2.3. Only qualified trainers may conduct task training.

6.6.1.3. Instructional Training

6.6.1.3.1. For training that requires specific directions or instructions on a training subject.

6.6.1.3.2. May be performed for an individual or a class.

6.6.1.3.3. Only qualified trainers may conduct instructional training.

6.6.1.3.4. Trainers are qualified based on their experience in performing a procedure.

6.6.1.4. Commercial or other training provided by outside parties

6.6.1.4.1. Will be documented by a completion certificate, or proof of attendance.

6.6.2. The level of competence for a procedure will be assigned as follows:

6.6.2.1. Read and Acknowledge – Trainees are required to confirm that they have read, understood and will comply with the procedure.

6.6.2.2. Retrain – Trainees who fail training and/or competence assessment will need to retrain on the procedure.

6.6.2.3. Supervised – Trainees who will either perform procedures under supervision or will only perform a review function.

6.6.2.4. Unsupervised – Trainees may carry out the procedure unsupervised.

6.7. Training Materials

6.7.1. Training materials may be on electronic media or paper.

6.7.2. As a procedure is revised, the training material will also be reviewed and updated to reflect the changes to the procedure.

6.7.3. Training materials may include a test or quiz.

6.8. Terminated Employees

6.8.1. Training records for terminated employees will be retained by OSRO Quality.

6.8.2. Terminated employees who return to OSRO within 3 months will not have to retrain on procedures if training documentation on the current revision of a procedure exists.

## 7. Associated Documents

7.1. 103-S01-W01 Staff Training Procedures

7.2. F06-103-S01 Training Curricula

7.3. F07-103-S01 Training Database

## 8. Change Summary

| Revision Number | Effective Date | Description of Change |
|---|---|---|
| 1 | 17SEP2019 | New Document |
| 2 | 18DEC2020 | Updated document to clarify language.<br>Added disclaimers to steps where use of the eQMS impacts the process. |
| 3 | 01DEC2022 | Step 4.1 – added hyperlink<br>Step 6.1.7.1 – removed<br>Step 6.4.1.1 – removed<br>Step 6.9 – removed<br>Changed “Read and Understand” to “Read and Acknowledge” |