1 PURPOSE

1.1 This procedure establishes the process to determine that Center for Clinical Research (CCR) personnel meet minimum training requirements.

1.2 The process begins when personnel join the CCR.

1.3 The process ends when the CCR personnel's initial and/or annual training and/or study specific training is completed and documented.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 Minimum qualifications and training requirements are established by CCR job descriptions, institutional policy, and relevant regulations

3.1.1 In accordance with National Institutes of Health (NIH) policy notice NOT-OD-16-148, all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) E6(R2).

3.1.2 ICH E6(R2) states that "each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)."

3.1.3 Documentation of GCP training will be documented in the Collaborative Institutional Training Initiative (CITI) course in GCP affiliated with the University of California, San Diego.

3.1.4 UC San Diego Environmental Health and Safety (EH&S) require laboratory safety training for personnel who process and/or ship samples.

3.2 CCR personnel provide clinical operational support for research conduct in compliance with orders and direction received from principal investigators (PI) or their designees.

3.3 All CCR personnel assigned to participate in clinical activities for specific study protocols must also undergo documented study-specific training via protocol-specific in-service facilitated by PI or designee.

3.3.1 The CCR initiation meeting (in-service) with the PI and study team facilitates protocol compliance and procedures requested of CCR personnel to ensure clear understanding between the study team and the CCR personnel on how the study will be conducted and who is responsible for executing specific procedures.

3.3.2 Studies that are less complex and do not require clinical intervention or investigational products will be reviewed by clinic leadership to determine appropriate alternative training methods. Certain study-specific training materials will be distributed via email and made available on a shared drive accessible to all CCR staff for reference. For studies requiring specialized clinic resources, training may be provided only to designated clinical staff rather than to all CCR personnel.

4 RESPONSIBILITIES

4.1 All CCR personnel are responsible for following these procedures.

4.2 The CCR assistant clinical director, CCR director, or designee are responsible for verifying that training records are complete.

4.3 The CCR assistant clinical director retains administrative responsibility for all CCR personnel.

4.4 The CCR assistant clinical director will sign the DOA for study teams confirming staff have received training.

5 PROCEDURE

5.1 Determine from human resources, CCR director, CCR assistant clinical director, or designee when new personnel join the CCR.

5.1.1 Personnel use CCR-109 WORKSHEET: CCR Personnel Training Documentation, or equivalent, to document initial licensure, training, and/or other experience or qualifications commensurate with minimum training requirements. CCR-109 WORKSHEET-Personnel Training Documentation.docx

5.1.2 Personnel use CCR-109 WORKSHEET: Personnel Training Documentation, or equivalent, to update on-going licensure, training, and/or other experience or qualifications commensurate with minimum training requirements.

5.1.3 Maintain training records in accordance with CCR-004 SOP: Center for Clinical Research Records.

5.2 For each study protocol accepted by the CCR, CCR assistant clinical director or designee will determine from the PI or designee the protocol in-service schedule and special training requirements for CCR personnel. Not all study protocols will require formal training or a study in-service.

5.2.1.1 Study protocol training for non-therapeutic or non-complex studies will be done via email to CCR staff to provide overview of study, study team services and protocol for staff review.

5.2.2 Confirm the CCR in-service schedule with the PI or designee.
5.2.3 Ensure CCR personnel assigned to the study attend and/or receive relevant content from the in-service.
5.2.4 Document CCR personnel training in the CCR-104: Study-Specific Training Log, or equivalent. CCR-104 FORM Study-Specific_Training_Log.docx

6 MATERIALS

6.1 CCR-109 WORKSHEET: Personnel Training Documentation
6.2 CCR-004 SOP: Center for Clinical Research Records
6.3 CCR-104: Study-Specific Training Log

7 REFERENCES

7.1 Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects – FDA Guidance
7.2 Integrated Addendum to ICH E6(R2): Guideline for Good Clinical Practice (Part 2.8)
7.3 Integrated Addendum to ICH E6(R2): Guideline for Good Clinical Practice (Part 4.2.4)