UC San Diego Senior Associate Vice Chancellor for Health Sciences Office of Clinical Research	SOP Number	OCR:014 Page 1 of 4
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	Author:	T. Graham
	Approved by:	S. Little
SOP TITLE: TRAINING REQUIREMENTS		

1 PURPOSE

1.1 This procedure describes the minimum requirements for Principal Investigators (PIs) and key personnel training before a clinical study commences at UC San Diego Health. Training will include, but is not limited to:

1.1.1 Protection of human subjects training

1.1.2 Protection of protected health information (PHI) training

1.1.3 Regulatory training

1.1.4 Protocol-specific training

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 Prior to conducting clinical research, the PI and key personnel, including sub-investigators and study personnel, are required to undergo and document training to ensure the rights, safety, and welfare of study participants are protected. It is generally expected that all personnel involved in the conduct of the trial are appropriately trained to perform their duties in compliance with Good Clinical Practice (GCP) guidelines. This includes training in human subjects protection and GCP principles.

3.2 The Office of IRB Administration (OIA) specifies the minimum human subjects protection training requirements in OIA-103: IRB Handbook "What training do I and my staff need to conduct human subjects research?" The required training must be taken through the Collaborative Institutional Training Initiative (CITI) program. This training is a condition of IRB approval.

3.3 On January 1, 2017, the National Institutes of Health (NIH) issued a policy that requires Good Clinical Practice (GCP) training for all NIH funded clinical trials. For research involving certain patient populations or conditions and drugs, devices, or agents, GCP training is strongly recommended as a foundation for clinical research and it may be required by study sponsors. GCP training is available through the CITI program.

3.4 The Research Compliance and Integrity Office (RCI) and Office of Compliance and Privacy (OCP) specify training requirements for researchers who potentially use protected health information (PHI) or related data. Training is available through the CITI program and UC Learning, e.g., 1) Health Privacy Issues for Researchers, and 2) Basics for Health Privacy.

3.5 The PI, sub-investigators, and research personnel should receive study-specific training on the study protocol to ensure compliance with the protocol, protection of human subjects, and the validity and integrity of study results.

3.5.1 Protocol training is required for interventional trials.

3.5.1.1 For industry sponsored studies, a representative of the study sponsor generally provides the protocol training in a site initiation visit (SIV) or other protocol training session.

3.5.1.2 For institutional- or investigator-initiated studies, the PI, protocol author, or other individual familiar with the study intervention and the study design should provide protocol specific training.

3.6 All protocol-specific training records for the PI, sub-investigators, and other study personnel should be maintained with the study records in the study regulatory file.

3.7 Individual training records that are not protocol-specific (e.g., CITI certificates) may be maintained separately from the study records but must be available for review by study sponsor or a regulatory inspector upon request.

4 RESPONSIBILITIES

4.1 The PI is responsible for ensuring that all study personnel have received appropriate training before the study commences and for ensuring that on-going or remedial training is provided as needed during the conduct of the study.

4.2 Sub-investigators and study personnel are responsible for completing all required training promptly and for maintaining current training certification during the course of the study.

5 PROCEDURE

5.1 Prior to conducting any study-specific procedures:

5.1.1 All study personnel must complete the required trainings per OIA and sponsor requirements and ensure that training documentation is on file.

5.1.2 The sponsor designee, for sponsored research, or the PI or designee, for investigator-initiated research, should conduct the SIV or initial training meeting.

5.1.2.1 The training typically includes, but is not limited to:

5.1.2.1.1 Purpose of the research

5.1.2.1.2 Protocol design

5.1.2.1.3 Investigational product attributes and administration requirements

5.1.2.1.4 Skills needed to perform assigned study tasks

5.1.2.1.5 Regulatory requirements

5.1.2.1.6 Standards for the conduct of research and for protection of human subjects

5.1.2.2 The following personnel should attend the training:

5.1.2.2.1 PI and sub-investigators

5.1.2.2.2 Research coordinators and other key team members

5.1.2.2.3 Data managers

5.1.2.2.4 Investigational drug service pharmacist or designee

5.1.2.2.5 Clinical, technical, laboratory, or imaging personnel, as indicated[1]

5.1.2.2.6 Nurse manager or nurse educator, as indicated, for studies that may be conducted on nursing units[1]

5.1.2.3 Personnel who were unable to attend the SIV or initial training session must complete and document their training prior to performing any study-related research procedures.

5.1.2.3.1 Training should be conducted by the PI or another qualified individual who attended the SIV or is otherwise appropriately trained.

5.2 During the study:

5.2.1 Personnel who are added to the study after the SIV or initial protocol training should complete and document training prior to engaging in any study-related research procedures.

5.2.1.1 Training should be conducted by the PI or another qualified individual who attended the SIV or is otherwise appropriately trained.

5.2.2 The PI or designee should meet with the study team throughout the study to provide updated training information as necessary.

5.2.3 When a substantive protocol amendment is initiated, all study personnel should receive training on the amendment.

5.2.4 Meetings at which any training is provided should be documented on a training log, and all personnel in attendance should sign the log.

5.3 Document the training

5.3.1 All study personnel who participated in the SIV or other protocol training session should sign the study training log, or equivalent, such as OCR-108 Sample Training Log, to document the training.

5.3.2 The study training records should be maintained in the study file and must be retained for the applicable record retention period.

6 MATERIALS

6.1 OCR-108 Training Log

7 REFERENCES

7.1 OIA-103: IRB Handbook

7.2 NIH NOT-OD-16-148

7.3 Collaborative Institutional Training Initiative

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[1] Individuals performing routine job procedures who are not delegated by the PI with a specific or permanent role on the study are not required to have study specific training documented.

7.4 Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice