Perelman School of Medicine University of Pennsylvania Office of Clinical Research		SOP 203 Title: Clinical Research Training for PSOM Faculty and Staff Effective Date: July 10, 2017
Revised Effective Date: Not applicable	Next Review Date: July 1, 2018	Page 1 of 6
Process Owner: Office of Clinical Research Operations Unit	Signature:	Signature Date: 12/22/17
Approved By: Emma A. Meagher, M.D Vice Dean & Chief Clinical Research Officer	Signature:	Signature Date: 12.22.17

1. Purpose:

This standard operating procedure (SOP) describes the clinical research training requirements for principal investigators, investigators, sponsors, sponsor representatives, clinical research coordinators (CRCs), clinical research project managers (CRPMs) and other staff (Other Staff) engaged or otherwise involved in clinical trials or other clinical research at the Perelman School of Medicine. These training requirements help enable Faculty, CRCs, CRPMs and Other Staff to demonstrate the knowledge needed to conduct and/or sponsor a clinical trial or other clinical research at PSOM, including the requisite understanding of the principles, regulations and best practices that constitute key ethical and scientific standards relevant to clinical research.

2. Scope:

This SOP applies to all PSOM Faculty, CRCs, CRPMs, and Other Staff (including but not limited to, residents, fellows, research assistants, student workers, temporary hires, etc.)

3. Instructions:

a. Faculty: All Faculty who are engaging or otherwise involved in clinical trials or other clinical research must complete the training set forth on Attachment 1.

b. Clinical Research Coordinators and Clinical Research Project Managers: All CRCs, CRPMs or other staff engaging in or otherwise involved in clinical trials or other clinical research and functioning in a CRC or CRPM role must complete the training set forth on Attachment 2.

c. Other Staff: Any other staff member who is engaging or otherwise involved in clinical trials or other clinical research and is not covered by 3.a or 3.b above must complete the training specified in Attachment 3 when his or her role is described in the "Applies to" column.

4. Procedures

Faculty, CRCs, CRPMs and Other Staff are required to complete the training specified in the relevant Attachment prior to engaging, sponsoring or otherwise becoming involved in clinical trials or other clinical research.

5. Roles and Responsibilities

Faculty:

Ensure completion and maintenance of required training for him or herself. If a faculty member is serving as Sponsor or Principal Investigator, he/she must ensure completion and maintenance of required training for others involved in the research.

Clinical Coordinators, Clinical Research Project Managers and Other Staff:

Complete required training.

OCR Compliance Unit:

Assess completion and maintenance of required training as part of the annual compliance review process.

Penn IRB:

Withhold approval or include notification in IRB correspondence related to any outstanding training requirements to which the IRB personnel are privacy.

6. References:

NIH Policy on Good Clinical Practice Training: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

NIH Policy on Required Education in the Protection of Human Subjects: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

University of Pennsylvania IRB Guidance re Human Subjects Research Training Requirement: http://www.upenn.edu/IRB/mission-institutional-review-board-irb/guidance/citi-training

University of Pennsylvania Policy on Conflicts of Interest Related to Research:
http://www.upenn.edu/almanac/volumes/v59/n02/pdf_n02/090412-Supplement-ConflictsInterest.pdf

Office of Clinical Research Standard Operating Procedure 006: Sponsor, Qualification, Registration, and Training
https://www.med.upenn.edu/ocrobjects/secure//library/SOPs/SOP006_SponQualReg.pdf

Office of Clinical Research Standard Operating Procedure 400: Specifications for Use of Penn CTMS
https://www.med.upenn.edu/ocrobjects/secure/PennCTMS/SOP.pdf

Attachment 1

Required Training for Faculty engaging or otherwise involved in clinical trials or other clinical research

Type of Training:	Training Resources:	Frequency:
Human Subjects Protections	CITI Human Subjects Protection in Knowledge Link	Prior to starting clinical research & every three years
Good Clinical Practice	Select any one of the following: 1. Completion of on-line, interactive ACRP GCP eLearning Module: GCP: An Introduction to ICH GCP Guidelines; Knowledge Link 2. Completion of CITI's GCP module 3. GCP Opt-Out Exam: GCP Test-Out Challenge: Demonstrate Your Mastery of GCP; Knowledge Link 4. Providing documentation of approved, sponsor-required GCP training	Prior to starting clinical trial and every three years
HIPAA Privacy*	HIPAA Privacy and Security in Knowledge Link	At start of PSOM employment and every year
Conflict of Interest*	Financial Conflicts of Interest in Research Investigator Training Course in Knowledge Link	At start of employment at Penn; prior to engaging in research and every 4 years
Sponsor Training**	Sponsor training relevant for the project will be specified and provided following the completion of sponsor registration	Prior to assuming sponsor responsibilities

*This training is also required for activities beyond clinical trials or other clinical research.
**This training required only for Faculty who serve in the role of regulatory sponsors of research—i.e., hold an IND, IDE or comparable international regulatory filing.

As a service to PSOM research community, Office of Clinical Research maintains links to the training resources identified above at: http://www.med.upenn.edu/ocr/faculty.html. The above training menu includes training typically required for members of the Penn research community involved in clinical research and does not include training required based on the specifics of project (e.g., funding sponsor requirements).

Attachment 2

Required Training for Clinical Research Coordinators (CRCs) and Clinical Research Project Mangers (CRPMs)

Type of Training:	Applies To:	Training Resources:	Frequency:
Clinical Research On Boarding Training (includes Human Subjects Protection, Good Clinical Practice, HIPAA* and Clinical Research Certification)	All CRCs and CRPMs	Complete information regarding the Penn Clinical Research Onboarding and Certification Program may be found on the Office of Clinical Research website	Within 2 weeks of hire into CRC/CRPM role & prior to starting clinical research; certification should be completed within one year of hire. Refresher training for Human Subjects Protection, Good Clinical Practice and Clinical Research Certification required every three years and for HIPAA every year
PennChart - Coordinator	Any CRC or CRPM working on studies in PennChart	PennChart Coordinator in Knowledge Link	Before system use
PennChart- Research Biller	Any CRC or CRPM involved in research review of billable services in PennChart	PennChart Research Biller in Knowledge Link	Before conducting research billing review in PennChart
Conflict of interest*	If a PI determines that a CRC or CRPM is responsible for the design, conduct or reporting of research, conflict of interest training is required	Financial Conflicts of Interest in Research Investigator Training Course in Knowledge Link	At start of employment at Penn; prior to engaging in research and every four years
Penn CTMS	Designated by his or her department to serve in a role requiring Penn CTMS training—e.g., registering studies or managing subjects in Penn CTMS.	PennCTMS training in Knowledge Link	Before system use
Sponsor	Qualified to serve and designated by a sponsor to serve as a sponsor representative	Sponsor training relevant for the project will be specified and provided following the completion of sponsor registration	Prior to serving in sponsor representative role

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Attachment 3

Required Training for Residents, Fellows and others (excluding Faculty and CRCs/CRPMs) in the "Applies to" category below

Type of Training:	Applies to anyone who is:	Training Resources:	Frequency:
Human Subjects Protections	Interacting/intervening with human subjects; obtaining identifiable data/specimens	CITI Human Subjects Protection in Knowledge Link	Prior to starting clinical research and every three years
Good Clinical Practice	Involved in the conduct, oversight, or management of a prospective, interventional clinical trials	Select any one of the following: 1. Completion of on-line, interactive ACRP GCP eLearning Module: GCP: An Introduction to ICH GCP Guidelines; Knowledge Link 2. Completion of CITI's GCP module 3. GCP Opt-Out Exam: GCP Test-Out Challenge: Demonstrate Your Mastery of GCP; Knowledge Link 4. Providing documentation of approved, sponsor-required GCP training	Prior to starting clinical trial and every three years
HIPAA Privacy*	Faculty or staff at PSOM	HIPAA Privacy and Security in Knowledge Link	At start of PSOM employment and every year
Conflict of interest*	Principal Investigator, Project Director or anyone else responsible for the design, conduct or reporting of research	Financial Conflicts of Interest in Research Investigator Training Course in Knowledge Link	At start of employment at Penn; prior to engaging in research and every four years
PennChart - Coordinator	Conducting research using hospital services	PennChart Coordinator in Knowledge Link	Before system use
PennChart- Research Biller	Any staff conducting research billing review in PennChart	PennChart Research Biller in Knowledge Link	Before research billing review can be conducted
PennCTMS	Designated by his or her department to serve in a role requiring Penn CTMS training—e.g., registering studies or managing subjects in Penn CTMS.	PennCTMS training in Knowledge Link	Before system use
Sponsor	Qualified to serve and designated by a sponsor to serve as a sponsor representative	Sponsor training relevant for the project will be specified and provided following the completion of sponsor registration	Prior to serving in sponsor or sponsor representative role

*This training is also required for activities beyond clinical trials or other clinical research.

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