Perelman School of Medicine University of Pennsylvania Office of Clinical Research		SOP No.: 401
		Title: Clinical Research Training for PSOM Faculty and Staff
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Revised Effective Date: 12 February 2021	Next Review Date: One year after Effective Date: 12 February 2022	Page 1 of 7
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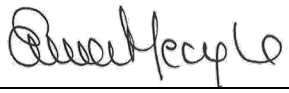
Approved By: Emma A. Meagher, M.D Vice Dean & Chief Clinical Research Officer	Signature: 	Signature Date: 19 February 21

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 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. The scope of this SOP extends only to those trainings created (Attachment 1 through 3 in this document) curated, administered, and tracked by the Office of Clinical Research (OCR). Please see Attachment 4 for reference information on non-OCR trainings. These are important as part of a clinical research employees overall onboarding, but are not managed, administered or tracked by OCR.

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. 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 privy.

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/library/SOP006_SponQualReg.pdf
Office of Clinical Research Standard Operating Procedure 400: Specifications for Use of PennCTMS
https://www.med.upenn.edu/ocrobjects/library/SOP400_Specifications_Use_PennCTMS.pdf

Attachment 1

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

Type of Training:	Training Resources:	Frequency:
Good Clinical Practice (GCP)	Select any one of the following: 1. Good Clinical Practice: An Introduction to ICH (GCP) Guidelines 2. Good Clinical Practice (GCP) for the Experienced Investigator - OCR 3. Good Clinical Practice (GCP): Test Out Challenge 4. CITI Good Clinical Practice (GCP) - OCR 5. CITI Good Clinical Practice (GCP) for Social & Behavioral Research - OCR 6. Penn CR: Full Onboarding: Good Clinical Practice: An Introduction to ICH GCP Guidelines (2HRS) This assigned course must be taken in the Penn CR: Onboarding Curriculum.	Prior to starting clinical trial and every three years thereafter Refresher training for Good Clinical Practice and Clinical Research Certification required every three years. Faculty may take GCP training geared towards social- behavioral research where applicable.
Sponsor Training**	Sponsor training relevant for the project will be specified and provided following the completion of sponsor registration via Knowledge Link: Sponsor Training	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.

The 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 Onboarding Training (includes Human Subjects Protection, Good Clinical Practice*, HIPAA** and Clinical Research Certification. Will be assigned as Penn CR: Onboarding Curriculum in Knowledge Link	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 https://www.med.upenn.edu/ocr/crc-and-crpm.html	Within 2 weeks of hire into CRC/CRPM role & prior to starting clinical research; certification should be completed within two years of hire. Refresher training for Good Clinical Practice and Clinical Research Certification required every three years and for HIPAA every year. Staff may take GCP training geared towards social-behavioral research where applicable.
PennCTMS	Designated by his or her department to serve in a role requiring PennCTMS training—e.g., registering studies or managing subjects in PennCTMS.	Knowledge Link: PennCTMS Training	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. Link: Sponsor Training	Prior to serving in sponsor representative role

* GCP Social Behavioral module for training may be taken through CITI. Staff should provide proof of complete to the Office of Clinical Research. This would be documented and would replace GCP Training requirements for Onboarding.
**This training is also required for activities beyond clinical trials or other clinical research.
As a service to PSOM research community, the Office of Clinical Research maintains links to the training resources identified above at: https://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 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:
Good Clinical Practice (GCP)	Involved in the conduct, oversight, or management of a prospective, interventional clinical trials	Select any one of the following: 1. Good Clinical Practice: An Introduction to ICH (GCP) Guidelines 2. Good Clinical Practice (GCP) for the Experienced Investigator - OCR 3. Good Clinical Practice (GCP): Test Out Challenge 4. CITI Good Clinical Practice (GCP) - OCR 5. CITI Good Clinical Practice (GCP) for Social & Behavioral Research - OCR 6. Penn CR: Full Onboarding: Good Clinical Practice: An Introduction to ICH GCP Guidelines (2HRS) This assigned course must be taken in the Penn CR: Onboarding Curriculum.	Prior to starting clinical trial and refresher every three years. Residents/ Fellows/ Others may take GCP training geared towards social- behavioral research where applicable.
Monitoring Onboarding	Designated by his or her department to serve in a clinical research monitor role.	Completion of the Penn CR: Monitoring curriculum (Staff may have already completed some modules during Onboarding training)	Preferred before assuming tasks. Or at any time as Refresher
PennCTMS	Designated by his or her department to serve in a role requiring PennCTMS training—e.g., registering studies or managing subjects in PennCTMS.	Knowledge Link: PennCTMS Training	Before system use
Sponsor	Qualified to serve and designated by a sponsor to serve as a sponsor representative	Knowledge Link: Sponsor Training	Prior to serving in sponsor representative role

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

Attachment 4

Required non-OCR Training for all staff, see breakdown by role below

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

Type of Training:	Applies to:	Training Resources:	Frequency:
Human Subjects Protections	Interacting/intervening with human subjects; obtaining identifiable data/specimens	Knowledge Link: CITI Human Subjects Protections How to assign CITI Training for Human Subject Protection: First Time Assigning	Prior to starting clinical research
HIPAA Privacy*	Faculty or staff at PSOM	Knowledge Link: HIPAA Privacy and Security Education	At start of PSOM employment and annual refresher module
Conflict of interest*	Principal Investigator, Project Director or anyone else responsible for the design, conduct or reporting of research	Knowledge Link: Financial Conflict of Interest	At start of employment at Penn; prior to engaging in research and every four years
Clinical Research Coordinators (CRCs) and Clinical Research Project Mangers (CRPMs)			
PennChart - Research Coordinator – OCR	Any CRC or CRPM working on studies in PennChart	Knowledge Link: PennChart – Research Coordinator - OCR	Before system use
PennChart - Research Biller - OCR	Any CRC or CRPM involved in research review of billable services in PennChart	Knowledge Link: PennChart - Research Biller - OCR	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: Financial Conflict of Interest	At start of employment at Penn; prior to engaging in research and every four years
PennERA	Any CRC or CRPM responsible for the administration of pre or post-award sponsored projects	Contain various modules. Contact PennERAhelp@lists.upenn.edu to identify specific training needs.	Before system use
Research Inventory System (RIS)	Any CRC or CRPM responsible for the submission and administration of agreements involving Data, Materials, Service contracts etc.	No system access training. Refer to page: https://researchservices.upenn.edu/systems/research-inventory-system/ for further guidance.	Not applicable

Residents, Fellows and others (excluding Faculty and CRCs/CRPMs)

Type of Training:	Applies to:	Training Resources:	Frequency:
Human Subjects Protections	Interacting/intervening with human subjects; obtaining identifiable data/specimens	Knowledge Link: CITI Human Subjects Protections How to assign CITI Training for Human Subject Protection: First Time Assigning	Prior to starting clinical research
HIPAA Privacy*	Faculty or staff at PSOM	Knowledge Link: HIPAA Privacy and Security Education	At start of PSOM employment and annual refresher module
Conflict of interest*	Principal Investigator, Project Director or anyone else responsible for the design, conduct or reporting of research	Knowledge Link: Financial Conflict of Interest	At start of employment at Penn; prior to engaging in research and every four years
PennChart – Coordinator - OCR*	Conducting research using hospital services	Knowledge Link: PennChart – Research Coordinator - OCR	Before system use
PennChart- Research Biller - OCR*	Any staff conducting research billing review in PennChart	Knowledge Link: PennChart - Research Biller - OCR	Before research billing review can be conducted

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