Training of Clinical Research Personnel	CR-109
Clinical Research Standard Practices	**Effective Date:** September 2024

SCOPE AND PURPOSE The document is applicable to the following people and processes of the Penn State College of Medicine and all Penn State Health entities specified below engaged in clinical research:

X	Principal Investigators	X	Regulatory Specialists
X	Sub-Investigators	X	Key Study Ancillary Personnel
X	Study Coordinators/Associates	X	Financial Analyst/Research Accountants
X	Data Specialists	X	Central Research Office Personnel

This policy describes the methods by with personnel engaged in clinical research are trained and documentation of said training.

This policy may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. Documentation of training records
    a. Records will be managed and maintained according to the institutional SOPs *Regulatory Files and Participant Records* (CR-211) and *Use of Florence eBinders for Electronic Records* (CR-406), respectively.
    b. Training logs are to be completed for all training where a separate training certificate is not issued or expected to be issued.
        i. For paper-based logs, either Sponsor's training log template or the investigative site's training log template can be used. The template to be used should be decided by the primary study coordinator and the monitor prior to the Site Initiation Visit.
        ii. For electronic training logs, an eLog is the preferred method for studies using Florence eBinders. If Florence eBinders is not being used but electronic signatures will be collected using DocuSign, the investigative site's training log template designed for electronic signatures is the preferred method.
            - There are multiple eLog template designs to cater to Sponsor's preference for training logs to a single, ongoing list of all training or to be specific to 1) training event, 2) training topic, or 3) study team member. The template to be used should be decided by the primary study coordinator and the monitor prior to the Site Initiation Visit.
            - Due to character limitations of eLogs in Florence eBinders, multiple log lines may need to be created to document all training properly and thoroughly.

- If Sponsor is adamant that their training log template be used for electronic signatures, they must modify the document to ensure that the space for the signature is at least 0.6 inches in height and 4.5 inches in width.

iii. If a study has a combination of electronic and wet ink signatures, there must not be a comingling of the signatures on the same log pages. Copies of the wet ink signatures can be uploaded into Florence eTMF/eISF to have a complete record in one place. Log pages of electronic signatures should not be routinely printed out.

2. Training materials
    a. When documenting training materials used, all materials used should be recorded to be able to recreate what was used to train those in attendance. Such materials can include protocols, IBs, manuals, webinars, newsletters, etc. Furthermore, version dates, version identifications (e.g., v1, v2, Rev A, Rev B, etc.), and/or document control numbers should be included.
        i. A copy of all materials used for should maintained as supporting documentation.
    b. As the ultimate authority on the study, the party serving as Sponsor, whether an external entity or an institutional investigator, is responsible for the training materials used for the study.
    c. If supplemental training materials are needed to train ancillary group (e.g., inpatient nurses, clinic staff, etc.), Sponsor must approve site-developed training materials prior to use. If Sponsor has engaged an CRO for managing study operations, the investigative site may send site-developed training materials to the CRO for review and approval. It is the responsibility of the CRO to determine if it is within its scope to approve such materials. **Note:** site-developed job aids, checklists, internal requisition forms, etc. are not considered supplemental training materials within the context of this policy.

3. Methods of training
    a. Except for Site Initiation Visits, Investigator Meetings, device training, and surgical/procedure training, it is expected that self-guide training is an acceptable method training.
    b. If Sponsor/CRO expects the PI or Sponsor/CRO staff to conduct all training, Sponsor/CRO must provide appropriate remuneration for investigative site personnel time.

4. Signatures on training log
    a. The signature of the trainee is to confirm understanding of the material presented and affirm that all questions have been answered.
    b. The signature of the trainer is to confirm attendance of the trainee, that the material was presented wholly and accurately, and affirm that all questions have been answered.
        i. If multiple individuals served as the trainer during a larger training event (i.e., Site Initiation Visit, etc.), then one of the following options should be selected:
            - Individual log lines should be generated for each topic and the appropriate trainer sign for the topic(s) on which they trained.

- Each trainee creates one log line and one of the trainers is designated as the primary trainer to sign on behalf of all the trainers. The other trainers document the topic(s) on which they trained in a Note to File, which is included with the training log.
- The trainers indicate at the top of the log on what topic(s) they provided training and sign. **Note**: this option is not available for use with eLogs in Florence eBinders.

ii. If one individual served as the primary trainer and one or more other individuals provided support or supplemented the information provided, then only the individual serving as the primary trainer needs to sign as the trainer. However, it is acceptable for the other individual(s) to document their involvement in the training as noted in section 4.b.i. above.

RELATED POLICIES AND REFERENCES

Clinical Research Guidebook (https://research.med.psu.edu/research-support/guidebook/)

Code of Federal Regulations: Institutional Review Boards (21 CFR 56.109 & 111)

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.21 & 23)

International Conference on Harmonization Good Clinical Practice E6(R2)

Responsibilities of the Research Team (CR-103)

Regulatory Files and Participant Records (CR-211)

Electronic Signatures (CR-402)

Use of Florence eBinders for Electronic Records (CR-406)

APPROVALS

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HISTORY OF REVIEWS AND REVISIONS

December 2022	
Scope and Purpose, Roles	Updated "Financial Analyst/**Research Accountants**". Added "Regulatory Specialists" and "Central Research Office Personnel."
Policy and Procedure Statements, Bullet 2.a.i.	Add statement that a history of reviews and will be maintained as an appendix to each Standard Practices.

FOR REVISIONS:

- [X] Principal Investigators
- [X] Sub-Investigators
- [X] Study Coordinators/Associates
- [X] Data Specialists
- [X] Regulatory Specialists
- [X] Key Study Ancillary Personnel
- [X] Financial Analyst/Research Accountants
- [X] Central Research Office Personnel

HISTORY OF REVIEWS AND REVISIONS

June 2023	
Scope and Purpose, Entities	Added Lancaster Medical Center.
Scope and Purpose, Roles	Updated "Financial Analyst/**Research Accountants**". Added "Regulatory Specialists" and "Central Research Office Personnel."
Policy and Procedure Statements	Subsection "Collecting, filing and storing study-related documents and records" renamed to "General standards" Subsection "Electronic" renamed to include "maintenance of files" Subsection "Sponsor/CRO-provided electronic Trial Management File (eTMF)" added.
History of Reviews and Revisions	Section added.