| Creation, Review, and Approval of Standard Practices for Conducting Clinical Research | CR-101 |
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| Clinical Research Standard Practices | Effective Date: May 2025 |

**SCOPE AND PURPOSE** All clinical research policies and standard operating procedure (SOPs), collectively "Standard Practices", of Penn State College of Medicine are also the Standard Practices of all Penn State Health entities.

This standard operating procedure (SOP) describes the preparation and maintenance of the written procedures that this research team follows to ensure compliance with all applicable state, federal, and local regulations and guidelines and the policies and procedures of this institution, if appropriate for all clinical trials conducted at this investigative site. This SOP also describes procedures for training on SOPs and documentation of training. This SOP applies to the written procedures followed by the research team as it conducts all clinical studies involving human subjects in research during all investigational phases of development. Attachments to each SOP serve as resources and may be utilized as applicable.

**POLICY AND PROCEDURE STATEMENTS**

1. Policies, procedures, protocols, and other documents (collectively "Standard Practices") that pertain to direct research participant care must be reviewed on an annual basis. Otherwise, documents will be reviewed every other year.
    a. A direct research participant care document is one that involves any aspect of the health care of a patient, including treatments, counseling, self-care, patient education, and administration of medication provided personally by a staff member to a research participant patient.

2. Documents will be written in the format as described in the following policies:
    a. Policy Document Control Plan (PM-100)
        i. In addition, a history of reviews and revisions will be maintained as an appendix
        ii. Approved department-specific addenda may be added
    b. How to Complete the PSH Policy Document Template and the PSH Patient Care Protocol Template GUIDELINE (PM-304)
    c. Policy document number, located in the upper right box of the header, shall be number sequentially staring with "CR-". The hundreds place will categorize the documents according to the following convention:
        i. 100s General Administration
        ii. 200s Study and Project Management
            - 201-210 Phases of the study's life cycle
            - 211-299 Other study and project management topics
        iii. 300s Participant Management
        iv. 400s Data Management, Data Integrity, and Quality Assurance
        v. 500s Clinical Research Center specific
    d. Related policies and references will be listed in the following hierarchical format:
        i. Federal laws, regulations, and guidelines

ii. International standards
iii. State laws, regulations, and guidelines
iv. National and international professional organization standards, codes of conduct, and guidelines
v. Penn State University policies and procedures
vi. Penn State Health policies and procedures
vii. College of Medicine clinical research policies and procedures

3. In ordnance with the *Policy Document Control Plan,* the following individuals and groups will perform the following responsibilities:

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| Document Owner | • Director, College of Medicine Clinical Trials Office (COM CTO) |
| Approvers | • Director, College of Medicine Clinical Trials Office<br>• Director, Office of Research Affairs, Contracts<br>• Director, Office of Research Affairs, Grants<br>• Director, Research Quality Assurance, Clinical Trials<br>• Other institutional leader responsible for reviewing and approving a Standard Practice for use. |
| Authorizers | • Associate Dean for Clinical Research<br>• Associate Dean for Research<br>• Other institutional leader responsible for reviewing and approving a Standard Practice for use. |
| Reviewer or Contributor | • Director, College of Medicine Clinical Trials Office<br>• Director, Office of Research Affairs, Contracts<br>• Director, Office of Research Affairs, Grants<br>• Director, Research Quality Assurance, Clinical Trials<br>• Other institutional leader responsible for reviewing and approving a Standard Practice for use<br>• Contributors or reviewers of the content of a document without having the authority to approve the document for use |

a. Approvers shall be listed alphabetically by the name of the work unit the individual represents.
b. Authorizers shall be listed in descending order by the position (vice dean, associate dean, etc.) then alphabetically by area of responsibility.

4. Procedure for preparing new Standard Practices or revising previously issued Standard Practices
    a. Based upon changes to all applicable state, federal, and local regulations, guidelines, or research practice in accordance with the institutional policies and procedures write a new Standard Practices or revise a previously issued Standard Practices that describes the new or revised procedures.

b. Department-specific and services line-specific addenda to Standard Practices must be submitted to the Clinical Research Oversight Committee for review and approval. Such must not addenda Departments and services lines wishing to
c. A historical archive of all previous versions of Standard Practices, including department-specific and services line-specific addenda, will be maintained in the event of an audit.

5. Procedure for reviewing Standard Practices
    a. Standard Practices will be reviewed on a five-year cycle, with exception for High-Risk Area policies and SOPs. High-Risk Area policies and SOPs will be annually or biennially. High-Risk Area policies and SOPs are those that relate to following:
        i. Good Clinical Practices
        ii. Research billing compliance
        iii. Informed consent
        iv. Regulatory compliance.
        v. Direct research participant care
            - A direct research participant care document is one that involves any aspect of the health care of a patient, including treatments, counseling, self-care, patient education, and administration of medication provided personally by a staff member to a research participant.
    b. The review cycle of each Standard Practice will be noted in the **Date of Origin and Reviews** section.
    c. Review cycles will run on the following schedule:
        i. Standard Practices with an annual or biennial reviews will have expiration dates of March and September.
        ii. Standard Practices with five-year reviews will have expiration dates of June and December.
    d. Standard Practices may be reviewed more frequently for regulatory or organizational changes, following audit or inspection findings, or process or technology changes if needed.
    e. If revisions or additions are required, follow the procedure described above.
        i. Administrative and clerical changes may be reviewed and approved by the listed Standard Practice Approvers.
    f. If no changes are required, the date of review will be documented and file appropriately.

6. Final versions of new or revised Standard Practices will be presented to the Clinical Research Oversight Committee, consisting of the Approvers listed above, for review and approval. Upon approval of the committee, the standard will be sent to the respective Authorizers for review and approval. With final approval, the revisions will be communicated to all affected parties.

7. Procedure for Providing Training on Implementing Standard Practices
    a. Once approved by the Associate Dean for Clinical Research and the Associate Dean for Research, the College of Medicine Clinical Trials Office will distribute any new or revised Standard Practices within 60 days of becoming effective.

b. Each operational group will ensure that each employee documents the training of the Standard Practices reviewed. Sample documents to record training will be made available.
c. New employees must review all applicable Standard Practices prior to undertaking any responsibilities at the site for which Standard Practices apply.
d. All current Standard Practices will be maintained electronically to permit access to all employees at this site.

8. All Standard Practices should be considered appropriate for sharing with outside parties
    a. Any Standard Practice deemed to be proprietary or of a nature that it should be considered confidential shall contain a statement in the Scope and Purpose section indicating that sharing of the document should be limited.
        i. The Approvers of the Standard Practice may issue a waiver to permit an otherwise sharing-restricted document to be shared. The Document Owner will transmit the Standard Practice to the intended recipient and notify the intended recipient that the Standard Practice should not be shared outside of the recipient's organization. A copy of the waiver and the intended recipient will be recorded by the Document Owner.

## RELATED POLICIES AND REFERENCES

Policy Document Control Plan (PM-100)

PSH Policy Document Template and the PSH Patient Care Protocol Template GUIDELINE (PM-304)

## APPROVALS

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| Approved: | Kevin Gardner, Jr., MS, BSN, RN, CCRC<br>Director, College of Medicine Clinical Trials Office<br><br>Adam McDowell, BA, JD, CRA<br>Director, Office of Research Affairs, Contracts<br><br>Thomas Brydebell<br>Director, Office of Research Affairs, Grants<br><br>Elizabeth Galgocy, MEd, RN, CIP<br>Director, Research Quality Assurance, Human Research Trials |
| Authorized: | Neal Thomas, MD, MSc<br>Associate Dean of Clinical Research<br><br>Sheila Vrana, PhD<br>Associate Dean of Research |

**DATE OF ORIGIN AND REVIEWS**
Date of origin: February 2010

Review Date(s): July 2006, February 2010, April 2022, December 2022, March 2025

Review Cycle: 5 years

**CONTENT REVIEWERS AND CONTRIBUTORS**
Director, College of Medicine Clinical Trials Office

Director, Office of Research Affairs, Contracts

Director, Office of Research Affairs, Grants

Director, Research Quality Assurance, Human Research Trials

## HISTORY OF REVIEWS AND REVISIONS

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| **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. |
| **July 2024** | |
| Scope and Purpose | Entities removed as all research at Penn State Health facilities are required to follow the policies and SOPs of College of Medicine. |
| Policy and Procedure Statements | Administrative and clerical changes may be reviewed and approved by Approvers. |
| Approvals | "Authorized" and "Approved" switched to align with CR-101. |
| **March 2025** | |
| Scope and Purpose | Entities removed as all research at Penn State Health facilities are required to follow the policies and SOPs of College of Medicine.<br>Roles removed. |
| Policy and Procedure Statements | Review cycles changed. |
| Date of Origin and Reviews | Review cycle listed. |
| Throughout document | Removed erroneous content |