



Clinical Research Guidebook	CR-105
Clinical Research Standard Practices	Effective Date: September 2024

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

<input checked="" type="checkbox"/>	Principal Investigators	<input checked="" type="checkbox"/>	Regulatory Specialists
<input checked="" type="checkbox"/>	Sub-Investigators	<input checked="" type="checkbox"/>	Key Study Ancillary Personnel
<input checked="" type="checkbox"/>	Study Coordinators/Associates	<input checked="" type="checkbox"/>	Financial Analyst/ Contract Management Accountants
<input checked="" type="checkbox"/>	Data Specialists	<input checked="" type="checkbox"/>	Central Research Office Personnel

This standard operating procedure (SOP) describes the creation and maintenance of the central reference to support clinical research.

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

POLICY AND PROCEDURE STATEMENTS

1. The Clinical Research Guidebook is a central, web-based reference that will be maintained at <https://research.med.psu.edu/research-support/guidebook/>.
2. Research Quality Assurance will maintain primary oversight of the Clinical Research Guidebook and will coordinate collaborators to ensure references remain accurate.
3. The Clinical Research Guidebook shall be reviewed at least annually.

RELATED POLICIES AND REFERENCES

None

APPROVALS

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DATE OF ORIGIN AND REVIEWS

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CONTENT REVIEWERS AND CONTRIBUTORS

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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.”
September 2024	
Scope and Purpose	<p>Entities removed as all research at Penn State Health facilities are required to follow the policies and SOPs of College of Medicine is Updated “Financial Analyst/Contract Management Accountants”. Added “Regulatory Specialists” and “Central Research Office Personnel.”</p> <p>Notation made that this SOP may be shared with Sponsors and/or CROs upon request.</p>
Approvals	“Authorized” and “Approved” switched to align with CR-101.