



Clinical Research Definitions	CR-104
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/Research Accountants
<input checked="" type="checkbox"/> Data Specialists	<input checked="" type="checkbox"/> Central Research Office Personnel

This policy describes how a list of clinical research terms, definitions, and applicable abbreviations will be curated.

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

POLICY AND PROCEDURE STATEMENTS

The Clinical Trials Office will maintain a list of terms, definitions, and applicable abbreviations on its website.

RELATED POLICIES AND REFERENCES

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

APPROVALS

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DATE OF ORIGIN AND REVIEWS

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Review Date(s): October 2021, May 2022, December 2022, November 2023, August 2024

CONTENT REVIEWERS AND CONTRIBUTORS

Director, College of Medicine Clinical Trials Office

Director, Office of Research Affairs, Contracts

Director, Office of Research Affairs, Grants

HISTORY OF REVIEWS AND REVISIONS

December 2022	
Scope and Purpose, Roles	Updated “Financial Analyst/ Research Accountants ”. Added “Regulatory Specialists” and “Central Research Office Personnel.”
Clinical Trial/Study	Updated to reflect 2016 NIH definition of a clinical trial (https://grants.nih.gov/policy/clinical-trials/definition.htm)
August 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 policy may be shared with Sponsors and/or CROs upon request.</p>
Policy and Procedure Statements	Policy statement revised to indicate that terms, definitions, and applicable abbreviations are located on the CTO website.
Approvals	“Authorized” and “Approved” switched to align with CR-101.
Appendix	Definitions deleted from policy and located to CTO website.