

MASTERING CLINICAL RESEARCH

A Comprehensive Online Course for Clinical Research Coordinators

ADDITIONAL RESOURCES

Whether you are new to the field or looking to deepen your expertise, the resources below have been carefully selected to support your development as a Clinical Research Coordinator. They span regulatory foundations, practical operations, ethical frameworks, and professional development.

1. BOOKS

Foundational & Core References

Principles and Practice of Clinical Research (4th Ed.) — *Gallin & Ognibene (Eds.)*

Comprehensive textbook covering clinical trial design, regulatory requirements, ethics, biostatistics, and operations. Widely used in academic training programs.

Clinical Research Coordinator Handbook (4th Ed.) — *Deborrah Norris*

Practical, CRC-focused guide covering day-to-day responsibilities, informed consent, regulatory compliance, and monitoring interactions. Highly recommended for new CRCs.

Good Clinical Practice: A Question & Answer Reference Guide — *Suzanne Wood*

Q&A format covering GCP guidelines, 21 CFR regulations, and ICH E6 requirements. Excellent for CCRC/CCRA exam preparation and quick regulatory reference.

Project Management & Operations

A Guide to the Project Management Body of Knowledge (PMBOK® Guide) — *Project Management Institute*

Industry-standard project management reference applicable to clinical trial planning. Relevant for coordinators in lead study roles or pursuing PMP certification.

The CRC's Guide to Coordinating Clinical Research — *Karen E. Woodin*

The long-standing reference text on site coordination — study start-up, regulatory binders, monitoring visits, closeout. Solid foundation for the operational *what*. The Mastering Clinical Research™ course picks up where reference texts leave off, teaching coordinators *how* to evaluate their own work through the Monitoring Lens™.

Safety & Pharmacovigilance

Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk — *George Gettman*

Covers adverse event assessment, signal detection, and safety reporting obligations — key knowledge for CRCs managing safety documentation.

2. GUIDELINES, REGULATIONS & ETHICAL FRAMEWORKS

Core Regulatory Documents

ICH E6(R2) — Good Clinical Practice Guideline — *International Council for Harmonisation*

The foundational GCP guideline governing clinical trial conduct, participant protection, and data integrity. Every CRC should read and understand this document.

<https://www.ich.org/page/efficacy-guidelines>

FDA Clinical Trial Requirements, Regulations, and GCP — *U.S. Food and Drug Administration*

FDA's comprehensive resource covering 21 CFR Parts 50, 56, 312, and 314 along with guidance documents for clinical trial conduct and human subject protection.

<https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fda-clinical-trial-requirements-regulations-compliance-and-good-clinical-practice-gcp>

45 CFR Part 46 — The Common Rule — *U.S. Dept. of Health and Human Services*

Federal regulations protecting human research subjects. The 2018 Revised Common Rule governs IRB review, informed consent, and research oversight for federally funded studies.

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

ICH E8(R1) — General Considerations for Clinical Studies — *International Council for Harmonisation*

Updated guidance on clinical study design, quality by design, and risk-based approaches. Complements ICH E6(R2) and reflects modern decentralized trial considerations.

<https://www.ich.org/page/efficacy-guidelines>

Ethical Foundations

The Belmont Report — *National Commission for Protection of Human Subjects (DHHS/OHRP)*

Foundational ethical framework establishing the principles of Respect for Persons, Beneficence, and Justice. Required reading for all research professionals.

<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

Declaration of Helsinki — *World Medical Association*

Internationally recognized ethical principles for medical research involving human subjects. Particularly relevant for multi-national clinical trials and global regulatory submissions.

<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

The Nuremberg Code (1947)

Ten foundational principles governing human experimentation, established after the Nuremberg Trials. The historical basis for modern informed consent requirements.

3. ONLINE PLATFORMS & RESOURCES

Trial Registries

ClinicalTrials.gov — *U.S. National Library of Medicine*

The world's largest clinical study registry. Search by condition, intervention, phase, location, and sponsor. Critical for site feasibility and enrollment analysis.

<https://clinicaltrials.gov/>

EU Clinical Trials Register — *European Medicines Agency*

Registry of clinical trials conducted in EU member states. Useful for international and multi-regional trial research.

<https://www.clinicaltrialsregister.eu/>

Training & Certification

NIH Clinical Research Training Resources — *National Institutes of Health*



Comprehensive training materials including GCP, ethics, protocol development, and research management courses.

<https://www.nih.gov/health-information/nih-clinical-research-trials-you/training-resources>

CITI Program (Collaborative Institutional Training Initiative)

The most widely used online training platform for GCP, human subjects research, HIPAA, and research compliance. Often required by sponsors, IRBs, and academic institutions.

<https://about.citiprogram.org/>

FDA MedWatch Safety Reporting — *U.S. Food and Drug Administration*

FDA's safety information and adverse event reporting portal. CRCs should be familiar with MedWatch for SAE reporting and safety signal monitoring.

<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

Professional Organizations

Association of Clinical Research Professionals (ACRP)

Leading professional organization for CRCs and CRAs offering CCRC/CCRA certification, education, webinars, and career resources.

<https://acrpnet.org/>

Society of Clinical Research Associates (SoCRA)

Professional organization offering CCRP certification, education, and networking for clinical research professionals.

<https://www.socra.org/>

Drug Information Association (DIA)

Global association connecting life science professionals across pharmaceutical, biotech, regulatory, and clinical research disciplines.

<https://www.diaglobal.org/>

Regulatory Agency Resources

OHRP Compliance Oversight & Guidance — *Office for Human Research Protections*

Database of compliance oversight letters and guidance documents. Valuable for understanding common regulatory findings and how to avoid them.

<https://www.hhs.gov/ohrp/compliance-and-reporting/index.html>