

# Clinical Research Coordinators

- Suggested Training for Clinical Research Coordinators
- Course Descriptions and Training Checklist
- Tools and Related Guidance

This educational resource is designed for both new and experienced Clinical Research Coordinators, and other clinical research staff at UCLA who are seeking training resources, including written material, classes and computer based learning modules.

Clinical Research Coordinators (CRCs) are responsible for the organization, coordination, and overall integrity of a research project with humans. Principal and co-investigators provide the overall direction in a clinical study, but CRCs have significant roles in clinical study activities, including Clinical Trial Study Start-Up.

# **Human Research Protection Training**

Human Research Protection Training Note: These modules can take several days to complete.

# **Good Clinical Practice (GCP) Basics**

Good Clinical Practice (GCP) Information: The CITI Good Clinical Practice (GCP) Basic Course is an overview of GCP. Some units on campus require this course, but it is optional for the OHRPP. Be sure to check with your departmental GCP training requirements.

## **WebIRB**

WebIRB is the IRBs online submission and review system for research studies. The system also functions as a document repository, providing study personnel with easy access to study documents like approved consent forms. This module takes about 30 minutes to complete.

# **Clinical Research Coordinator's Group**

Clinical Research Coordinators Group; If you are interested in participating in a Professional Development and Best Practices Group for Clinical Research Coordinators, please contact ResearchGo.

## CareConnect

CareConnect training for Clinical Coordinators These modules take about 7 hours according to the APEX training staff.

# OnCore Training?

• For system security and compliance, training is required for access to OnCore. Registration for online and inperson trainings is available through the CareConnect Training Management System



#### **Clinical Research Coordinators**

Published on ResearchGo | UCLA (https://www.researchgo.ucla.edu)

- To request an account and view training requirements for the different levels of access, view the research recommended training section available from the <u>UCLA CareConnect website</u>
- For training questions, contact <u>crishelp@mednet.ucla.edu</u> or call 310-267-2273.
- Please visit ResearchGo for more information

# **Data Management Tools**

<u>Data Management Tools</u> available online include RedCap, and the Cohort Selection Tool. REDCap is a secure, web-based application for building and managing online surveys and databases.

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#### New Research Coordinator Training Checklist

## Principles of Good Clinical Practice (GCP)

Overview of the regulations that guide human subject research and what are those responsibilities.

## Study Start Up

Best practice considerations when opening a new study to avoid management problems

#### Recruitment

Review of FDA and IRB guidance on recruiting subjects for research.

Informed Consent

- Part 1 Overview of Belmont Report
- Part 2 Methods for consent compliance when enrolling subjects

#### **Documentation**

Discuss paper and electronic copies and the importance of investigator and coordinator documentation effecting audit outcomes

#### Safety of the Subject - Definitions

Defining the terminology needed for Adverse event documentation

## Reporting Adverse Events

Overview of timeliness for reporting and which agencies are involved.

## **Sponsor Responsiblities**

Describes how sponsor monitoring is regulated for quality control and quality assurance of both investigative sites whether industry or sponsor- investigator studies

#### Preparing for an Inspection

Steps to prepare for and participate in external audits and what comprises audit readiness

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#### **Tools and Guidance**



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- New Research Coordinator Training Checklist
- Sample CRC SOP
- No-Cost SOCRA Recertification
- Resources for New UCLA Coordinators-Coming Soon
- OHRPP Human Research Protection Training Opportunities
- Association of Clinical Research Professionals
- Society of Clinical Research Associates (SoCra)
- NINDS Glossary of Clinical Research Terms

# **Good Clinical Practice (GCP) Basics**

Good Clinical Practice (GCP) Information The CITI Good Clinical Practice (GCP) Basic Course is an overview of GCP. Some units on campus require this course, but it is optional for the HRPP. Be sure to check with your departmental GCP training requirements.

## webIRB

webIRB IRB's online submission and review system for research studies. The system also functions as a document repository, providing study personnel with easy access to study documents like approved consent forms.

#### CareConnect

CareConnect training for Clinical Coordinators These modules take about 5 hours according to the training staff.

## **Data Management Tools**

Data Management Tools available online including RedCap.

We recommend that Coordinators who are new to UCLA visit Resources for New Coordinators for general institutional information.

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#### Source

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