Resources for New UCLA Investigators

- New Investigators at UCLA
- CITI Training Resources
- Other Recommended Training
- Tools and Useful Links

UCLA is committed to supporting the research efforts of the UCLA investigator community through various training efforts. This section contains information on recommended and required trainings for new and experienced researchers.

We recommend that Investigators who are new to UCLA visit the following links for general institutional training guidance.

- Recommended Training-UCLA training resources for investigators
- CTSI New Investigator Programs-CTSI new investigator programs
- UCLA Environmental Health & Safety Training Schedule-Safety training requirements for research
- Responsible Conduct of Research (RCR)-Training and information

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Guidance and Resources for New Investigators - Courses & Descriptions

CITI Good Clinical Practice Modules are described below - http://www.citiprogram.org

- CITI: FDA Regulated Research and ICH for Investigators - Addresses responsibilities of investigators, IRBs, and sponsors when they participate in a study of an FDA-regulated product.
- CITI: Conducting Investigator-Initiated Studies According to FDA Regulations and GCP - Describes the role of sponsor-investigator, help determine whether an IND or IDE is required for your study, and indicate what documentation is required by the FDA.
- CITI: Investigator Obligations in FDA-Regulated Clinical Research - Describes the commitments and obligations that investigators assume when participating in clinical investigations; to subjects, IRB, sponsor organization, and the FDA
- CITI: Managing Investigational Agents According to GCP Requirements - Describes the responsibilities of investigators when using investigational products according to GCP standards.
- CITI: Overview of U.S.FDA Regulations for Medical Devices - Describes the differences of research regulatory requirements for various classes and categories of devices.
- CITI: Reporting Serious Adverse Events - Identify criteria for reporting serious adverse
events (SAEs) to regulatory agencies and defines serious and unexpected events which require immediate reporting.

- **CITI: Audits and Inspections in Clinical Trials** - Identifies different entities that can inspect or audit a clinical trial investigator and factors that determine whether an investigator will be audited.

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**Human Subjects Training**

Investigators who will work with human subjects must complete the [CITI Online Human Subjects Protection Training](https://www.citiproducts.com) before the IRB gives final approval. The IRB tracks this online training to document compliance with Federal training requirements. See the [OHRPP Education & Training Guidance & Procedure](https://www.researchgo.ucla.edu) page for more information.

**Clinical Research Training**

The [UCLA Clinical Translational Science Institute](https://www.ctsi.ucla.edu) offers a broad array of educational opportunities in the methods of clinical research to meet the diverse needs of trainees, faculty and staff at UCLA.

**US Food and Drug Administration (FDA) Training and Continuing Education**

[FDA Training and Continuing Education Resource Page](https://www.fda.gov/education/training)

Co-sponsored by FDA's CDER, Office of medical Policy and the Duke University School of Medicine.

1. Good Clinical Practice (GCP) Key Topics by Jean Toth-Allen, PhD
   - FDA Office of Good Clinical Practice- Investigator Responsibilities
   - Clinical Investigator Financial Disclosures
   - Expanded access to and charging for investigational drugs and devices

2. Investigator Responsibilities-Regulation and Clinical Trials by Cynthia F. Kleppinger, M.D.
   - Division of Good Clinical Practice Compliance
   - Federal regulations covering clinical research and clinical investigator obligations
   - Discuss specific problems seen during FDA inspections at clinical sites
   - Discuss various methods that can be used to ensure compliance with federal regulations and study protocol
3.

Safety assessment in Clinical Trials and Beyond by Yuliya Yasinskaya, MD, Medical Officer, Center for Drug Evaluation and Research

Sources of safety information
- Safety monitoring/ AE ascertainment-
- AE Coding
- Safety Reporting
- Post-marketing safety (MedWatch) reporting


Good Clinical Practice

The CITI Good Clinical Practice (GCP) Basic Course is an overview of GCP. Some departments on campus require this course, but it is optional for the HRPP. Be sure to check with your departmental GCP training requirements. See the Good Clinical Practice Training page for more information including an article on GCP training in pediatric oncology.

Responsible Conduct of Research

Federal grant proposals (all proposals to NSF, training proposals for NIH) normally include a requirement that all trainees are provided with instruction in the Responsible Conduct of Research (RCR). An RCR program normally covers these areas: ethics, conflict of interest, responsible authorship, policies for handling misconduct, data management, data sharing, and policies regarding the use of human and animal subjects.

Office of Postdoctoral Affairs

The Office of Postdoctoral Affairs offers formal instruction and support to Postdoctoral Fellows in an effort to enhance the training experience at UCLA and promote successful careers in science. It is an information warehouse providing an avenue of communication among Postdoctoral Fellows, Faculty and Administrators.

Research Conflicts of Interest

Research Conflicts of Interest training addresses the importance of ensuring financial interests do not affect, or appear to affect, the design, conduct of reporting of research or compromise the protection of human subjects.

Research Misconduct

The US Department of Health and Human Services (DHHS) Office of Research Integrity (ORI) offers web-based Research Misconduct training and resources to help researchers understand the types of misconduct and how universities handle them.

Animal Care / Environmental Health & Safety
Additional Training for Animal Care and Environmental Health & Safety in Research is available online. See the Training tab to view the courses offered and click on the course title to view the course summary. The course title link at the top of the summary will take you into the online class. Access requires a username and password, which can also be requested online.

UCLA Training & Advancement Opportunities

Browse an overview of training and advancement opportunities available primarily via CTSI programs, but with an ever-increasing inclusion of other, non-CTSI opportunities.

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New Tool

The Research Clinic, a Web-based interactive training video aimed at teaching clinical and social researchers how to better protect research subjects and avoid research misconduct, was recently released by the U.S. Department of Health and Human Services’ Office of Research Integrity (ORI) and Office for Human Research Protections (OHRP). Please visit http://www.hhs.gov/news/press/2014pres/03/20140331a.html for more information.

Other Useful Websites

- Epocrates offers a variety of health and medicine information
- Medlixicon contains medical searches, news and resources for healthcare professionals
- Medical License Printing
- Clinical Translational Science Institute
- NIH Toolkit for Clinical Researchers

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Last updated: 11 May 2016
- Group 1
  - Clinical Research Information Systems
  - Clinical Research Business Partners
- Group 2
  - Office of Research Administration
  - Jonsson Comprehensive Cancer Center
- Group 3
  - Office of Human Subjects Protection
  - CareConnect Website

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