CTSC Human Subject Research Courses 2019-2020

CITI Training

This training is mandatory for anyone participating in human subjects research. UC Davis employs the Collaborative Institutional Training Initiative (CITI) program—a web based training program to satisfy the training requirements for all personnel conducting human subject research at UC Davis. CITI offers two versions of the Basic Human Research Training course: one for Biomedical Investigators and one for Social & Behavioral Investigators. However, IRB recommends Social & Behavioral Module offered via lms.ucdavis.edu. An additional module on Good Clinical Practice (GCP) is required for individuals conducting clinical trials with the FDA-regulated drugs or devices. Certification is valid for 3 years.

Clinical Epidemiology and Study Design Course

This intensive 34-hour course in clinical research methods will cover issues related to developing a research question, synthesizing the literature, study design, questionnaire design, data collection, data management, sample size planning, data analysis, presentation and publication. It is designed to meet the requirements for research methods training in most ACGME-accredited fellowship training programs.

The principal instructors are Drs. Patrick Romano, Eleanor Bimla Schwarz, and Laurel Beckett. The course is designed for new faculty, fellows, nurses, and interested persons beginning or considering a career in conducting or interpreting clinical research.

Short Syllabus for 2017

IRB Training and Investigator Manual

New Submitter Training is conducted by the IRB Administrations Outreach, Training and Education team. This orientation provides detailed training on the ethical principles of human research, an explanation of the researcher’s primary responsibility for protecting research subjects and for complying with all applicable provisions of institutional, state and federal laws. It provides an explanation of the different levels of IRB review and describes the processes for IRB submissions.

In addition, the UC Davis Investigator Manual, and IRB Standard Operating Procedures are available as guides related to the conduct of Human Research that are specific to UC Davis. The Investigator Manual discusses the mechanics of working with the IRB and Human Research Protection Program.

Contact: Nicole Walters, IRB Education
ACRP eLearning

This excellent additional educational resource is available at no charge to all UC Davis employees. These webinars match the CTSA Clinical Research Competency domains. Self-paced study modules and webinar replays - use them for self-study continuous education units towards your ACRP or SoCRA certification. Variety of topics

Contact Dannelle Jimenez, Education Program Manager, Clinical Trials Office, Clinical Trials Office, to be added to the eLearning system

Clinical Trials Education and Training Program

The UC Davis Clinical Trials Office (CTO) administers the CTSC Education and Training Program, CTSA Consortium is working towards achieving a standardized training platform in Good Clinical Practices and the necessary means to disseminate it across all consortium sites. UC Davis CTSC aligns the educational offerings to match Competency Domains adopted by the CTSA Consortium and outlined in the COAPCR publication "Moving from Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional," by S.A. Sonstein et al. The UC Davis curriculum delivers practical knowledge for implementation of clinical research regulations specifically at UC Davis and is supplemental to the IRB Training.

- Human Subject Research Courses, three tracks:
  - EMR
  - Regulatory
  - Operations
- Yearly Leadership and Professionalism Conference and Award Ceremony.
- SoCRA Northern California Brown bags deliver bi-monthly web-based seminars on a variety of global topics in clinical research.

Contact Dannelle Jimenez, Education Program Manager, Clinical Trials Office, to be added to the listserv.

CRC Mentoring Program

The CTO one-on-one CRC Mentoring Program supplements the Department/Center-based training for the new staff. Participation is voluntary and is at the discretion of the mentee's home Departments/ORUs. The program's goal is to provide individual personalized mentoring based on the mentee's level of skills, knowledge and experience. Selection of staff for the program is given to those participating in FDA-regulated clinical trials with drugs, devices or dietary supplements. The program is provided for a maximum of 10 hours of face-to-face training with a CTSC mentor. Department funding is required for the trainee to enter the program. More details can be found in C TSC Clinical Research SOP#3.

Contact: Virina De Jesus, Clinical Research Supervisor, CTO

Financial Conflict of Interest (FCoI) training

On August 24, 2012, new and more stringent rules for the disclosure of financial interests took effect for all research sponsored by the Public Health Service (PHS), including the National Institutes of Health (NIH). The new rules also apply to several non-federal sponsors, including the American Cancer Society and the American Heart Association. Click here for the list of agencies and entities ("covered entity") that have adopted the PHS financial conflict of interest (FCOI) and disclosure rules.

The FCOI rules apply to all "investigators" who engage in any research funded by a covered agency. "Investigators" are defined by PHS to include principal investigators and any other individual who, regardless of title or position, have responsibility for the design, conduct, or reporting of such covered research. This includes, for example, any graduate student or post-doctoral fellow who meets the definition of investigator. Each investigator must separately submit a financial disclosure statement to the UC Davis' Research Compliance and Integrity. The Disclosure must identify financial interests of the investigator, spouses/registered domestic partners, and dependent children that exceed the thresholds set by PHS and that relate to any of the investigator's institutional responsibilities. Disclosures must be made at the time of application for funding from a covered agency; annually; and within 30 days after acquiring or discovering a financial interest that must be disclosed as defined by PHS.

All investigators who are engaged in any research funded by a covered entity must complete mandatory "UC Compliance and Conflict of Interest for Researchers" eLearning training (COIR-DA-ECO).

Laboratory Training
Dangerous Goods Shipping (IATA DG registration instructions*)

Four Modules (chose what applies):

- Training for all Shippers (must be completed for all)
- Dry Ice and Overpack Training
- Category B, GMO/GMMO, and Exempt Patient Specimen Training
- Category A Training

VMTH IIPP and EAP Training (Course Code: DAC-VMTH-IIPP)

UC Davis Bloodborne Pathogen Awareness (Course Code: DACS-UCDBBP-SAFSVC)

UC Davis Medical Waste Management (Course Code: DACS-MEDWASTE-SAFSVC)

NIH Guidelines Training (Course Code: DACS-G-NIH-112311-SAFSVC) (Only required if working with recombinant or synthetic nucleic acids)

Safe Use of Biological Safety Cabinets (Course Code: DACS-LBSC001-SAFSVC) (Only required if using biological safety cabinets)

*Registration instructions:

USE CHROME FOR THE ONLINE CLASS FOR EACH REQUEST. Register at the following website: [http://ccm-safety.ucdavis.edu](http://ccm-safety.ucdavis.edu). You have to hit the register button twice. When you hit register once it takes you to the log-in screen of which you aren't an authorized user yet so you have to hit register again. Use your UCD e-mail address and indicate you are a DGR user. The website will e-mail you a password, which could take up to 24 hours. When you get your password, you can change it if you want under the "MY ACCOUNT" tab. After that please review the appropriate training modules under the IATA DGR Training and take the associated quizzes. Please notify Niki Drazenovich at ndraz@ucdavis.edu (530) 752-1561 when you are done and she will issue you a certificate of completion.

Epic® EMR Clinical Research Management

UC Davis Health Compliance requires all Principal Investigators and Coordinators to complete the mandatory Epic Research Management eLearning courses in LMS. These courses describe the basics of maintaining the study in Electronic Medical Records, linking patients, their visits and procedures with research studies, and performing reviews of research-related charges.

- Billing Review Process #09234
- Research Study Management #08074
- Investigator Research Management Requirements #08084

Clinical Research Budgeting and Billing Course

The course (LMS# 09155) builds on the principles for clinical research billing provided by the ACRP eLearning Module "Managing Billing Compliance Risk: Navigating Medicare in Clinical Trials." The regulatory environment related to clinical research billing is complex and compliance with guidelines is a key part of every research study. This training program provides an orientation to the financial and administrative infrastructure that supports clinical research billing across UC Davis Health.

Topics covered in the course:

- Correctly routing charges for hospital and clinic procedures and services
- Coverage Analysis in the Bridge
- EMR Research Study File (RSH) in Epic
- Association of the patient to the study
- Association of Orders and Encounters to the study
- Completion of Billing Review
- Verification of charges using Reports2Web billing statements

All study team members are encouraged to take this orientation program to prepare for this important process.

Contact: Suzan Bruce, Research Coder, Clinical trials Office

Investigational Drugs
This eLearning Course (DAHS-PSID16) provides basic background knowledge of Investigational Drug Services. Highlights key requirements for dispensing investigational substances on a UCDMC IRB Approved Protocol.

Begin with the UC Davis IRB Website
- IRB Education and Training Calendar
- CTSC Clinical Trials Education and Training Calendar
- UC Davis Learning Management System

Related articles
- Training and Education
- Internal Budget in Unified Budget Template (UBT)