Keck School of Medicine of USC

INVESTIGATORS' QUICK GUIDE TO GETTING STARTED IN CLINICAL RESEARCH AT USC

WHAT TRAINING DO I NEED TO COMPLETE BEFORE CONDUCTING HUMAN SUBJECTS RESEARCH AT USC?

- **CITI training**
  - Human Subjects for Investigators (HSC-Investigators, Key Personnel, and HSIRB Member/Staff)*
  - Good Clinical Practice (GCP)* Suitable for research teams involved in clinical trials of drugs, biologics, and devices. Dependent on the nature of the clinical research one or both of the GCP trainings listed below may be necessary.
    - GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
    - GCP for Clinical Trials with Investigational Medical Devices
  - Responsible Conduct of Research - Applicable if your clinical trial is funded by the National Institute of Health (NIH), National Science Foundation (NSF), or the US Department of Agriculture (USDA).

  Additional information: http://oprs.usc.edu/education/citi/

  ### Contact: USC CITI Helpdesk (UP IRB): (213) 821-5272

  *Please note USC may accept CITI training courses completed at your previous institution. Contact the USC CITI Helpdesk with such requests or questions

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- **Health Insurance Portability and Accountability Act (HIPAA)**

  Available via Trojan Learn http://trojanlearn.usc.edu/

- **IRB Submission Tracking And Review system (iStar)**

  First, obtain an iStar account via https://istar.usc.edu ("General Information"/"Obtaining an iStar Account"/ complete form to register). Once the information is verified, account information including a user name and temporary password will be sent via email. Detail instructions for CITI and iStar https://oprs.usc.edu/files/2014/07/Revised-Instructions-for-iStar-and-CITI-at-USC.pdf

  ### Contacts: Health Science IRB (Questions pertaining to obtaining an iStar Account): (323) 223-2340

  iStar Help Desk (technical issues): (323) 276-2238

- **Grants Management Training for Faculty**

  The Office of Compliance in conjunction with Department of Contracts and Grants has developed Grants Management training that must be completed by all Principal Investigators and co-Principal Investigators prior to receiving an extramurally sponsored award, and by all other faculty and staff who seek expenditure authority on a sponsored research account. This training is available via Trojan Learn: http://trojanlearn.usc.edu/

  The training course is approximately 2 hours and covers the following topics: principal investigators responsibilities, funding mechanisms, federal cost principles, USC regulatory bodies, USC internal systems, award management, effort certification, subcontracting with outside entities, and award closeout. To access the course please visit Trojan Learn and type "Grants Management Training for Faculty" in the search box or visit the following webpage for more information: https://research.usc.edu/grants-management-training-for-faculty/

- **Orientation to Clinical Research at USC (optional)**

  Provides an overview of the processes, committees and departments that clinical investigators work with throughout the submission, review, approval and conduct of human subject studies or clinical trials.

  This training is available via Trojan Learn: http://trojanlearn.usc.edu/

  The training course is approximately 7 hours and covers the following topics: planning, development & activation of a clinical trial protocol; non CICSO & non CTU studies: how they differ; coordinating a clinical trial; coordination of ancillary services; the IND and clinical trial management; IRB and human subjects protection; compliance; contracting, finance management and budgeting; and SPA. To access the course please visit Trojan Learn and type "Orientation to Clinical Research at USC" in the search box.

- **USC Healthcare Compliance Education**

  This four part training course is available via the Health Stream webpage: http://keckapps.usc.edu/healthstream

  Conflict of Interest - If you have a possible conflict of interest to disclose, please visit the following webpage to do so: https://disclose.usc.edu/ or for more information on conflict of interest please visit: http://ooc.usc.edu/conflict-interest

- **Research Training Finder**

  A comprehensive search tool for training courses that are required and suggested for University research compliance.

  webpage: https://research.usc.edu/for-investigators/training/

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WHAT KEY CLINICAL RESEARCH ENTITIES DO I NEED TO KNOW FOR STARTING CLINICAL RESEARCH AT USC?

- **Contracts, Budgeting and Billing**
  - **Department of Contracts and Grants (DCG)**
    Supports USC's investigators from proposal development to award closeout. Functions performed by this group are review, approve and submit proposal to extramural sponsors; negotiate and accept awards on behalf of the University; execute subcontracts; coordinate pre-award and post-award actions; develop and maintain positive sponsor relationships; and ensure institutional compliance with Federal and State regulations, sponsor policy and University policy. https://research.usc.edu/dcg-main-page/
    Contacts: Health Science Campus (323) 442-2396, University Park (213)740-7762

  - **Clinical Trials Office (CTO)**
    Provides budget development and negotiation services for clinical trials funded by industry as well as Medicare Coverage Analysis (MCA) for both industry and non-industry trials https://research.usc.edu/processes-resources-andreferences/
    Contact: https://research.usc.edu/clinical-trials-at-usc/

- **Sponsored Projects Accounting (SPA)**

  The mission of the SPA is to oversee post award administration of sponsored research for the University. Please visit the SPA webpage for more information, **Contact: http://fbs.usc.edu/depts/spa/**

  The training course is approximately 2 hours and covers the following topics: principal investigators responsibilities, funding mechanisms, federal cost principles, USC regulatory bodies, USC internal systems, award management, effort certification, subcontracting with outside entities, and award closeout. To access the course please visit Trojan Learn and type "Grants Management Training for Faculty" in the search box. or visit the following webpage for more information: https://research.usc.edu/grants-management-training-for-faculty/

- **Protocol Review, Approval and Study Conduct**
  - **Southern California Clinical and Translational Science Institute (SC CTSI)**
    A multi-faceted research institute created by the USC and CHLA to translate scientific discoveries into solutions for better health. Investigators are encouraged to use SC CTSI's expert resources to conceive and carry out their high-impact clinical and translational research. http://www.sc-ctsi.org/
    Contact: (323) 442-4032
  - Within SC CTSI, the **Clinical Research Support (CRS)** group provides a *single point of access* to advice and assistance for developing, activating, conducting and reporting clinical research studies and clinical trials. The CRS group helps research teams ensure that that protocols are well designed, enrollment goals are realistic and achieved, study workflows are efficient, regulatory requirements are met, and analysis and reporting of results are timely and compliant. CRS services are available to researchers at USC and CHLA. Currently, priority is given to investigator-initiated studies (i.e., studies designed and implemented by academic investigators, regardless of funding source) in fields other than cancer (For cancer-related studies, the NIH Comprehensive Cancer Centers provide analogous services for cancer studies at USC and CHLA). **The SC CTSI's CRS group contact at USC is: (323) 422-1038**

  - **Clinical Investigations Support Office (CISO)**
    Serves as a centralized unit to oversee all cancer-related clinical research infrastructure and assist investigators in their conduct of cancer-related clinical trials and translational research trials within the Norris Comprehensive Cancer Center http://uscnorriscancer.usc.edu/core/CISO/
    Contact: Co-Director, Joyce Tull (323) 865-0457 Email: Joyce.Tull@med.usc.edu

  - **Institutional Review Board (IRB)**
    An Institutional Review Board (IRB) is a committee that has been formally designed to approve, monitor, and review research involving human subjects. For more information about the IRB at USC and to read guides for Human Subjects Research information please visit the Office for the Protection of Research Subjects webpage at: http://oprs.usc.edu/review/ **Contact: Health Sciences IRB (323) 223-2340**

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