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   - LA County + USC Hospital
   - Clinical Trials Office (CTO)
   - Clinical Investigations Support Office (CISO)
   - Office for the Protection of Research Subjects (OPRS)
   - Institutional Review Board (IRB)
   - USC Investigational Drug Services Pharmacy
   - Southern California Clinical And Translational Science Institute (SC-CTSI)
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3. Other Entities & Resources
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   - Research Facilities & Core Laboratories at USC
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UNIVERSITY ENTITIES & RESOURCES

UNIVERSITY OFFICES AND ENTITIES

This chapter provides an overview of the offices, entities and ancillary committees at USC associated with Human Subject Research (HSR). The scope of activities encompassed by HSR is very broad and includes scientific, investigatory and research activities involving human subjects, clinical data, or any materials (including tissues, serum, cells, and DNA) from any human source, whether specimens are from a known, specified individual or are "de-identified."

KECK SCHOOL OF MEDICINE (KSOM)

Established in 1885 and located at the Heath Science Campus (HSC), the Keck School of Medicine is the oldest medical school in Southern California and is home to the Keck Medical Center, which is composed of three USC-owned hospitals:

- **Keck Hospital of USC** (formerly USC University Hospital) is a private research and teaching hospital staffed by more than 500 physicians who are also faculty of USC's Keck School of Medicine. The hospital’s 18 departments, individual clinical programs and integrated clinical and business services provide support to USC's academic physicians.

- **USC Norris Cancer Hospital**, a 60-bed inpatient facility, features a bone marrow transplantation unit and a surgical unit exclusively designated to cancer research and patient acute and critical care.

- **USC Verdugo Hills Hospital** is a 158-bed hospital in Glendale staffed by USC faculty physicians. Services include a 24-hour emergency room; a primary stroke center; bariatric and minimally invasive surgery; OB-GYN and infant services; orthopedic surgery; occupational, physical and speech therapy; cardiac rehabilitation; and imaging and diagnostic services including mammograms, magnetic resonance imaging (MRI), CT scans and angiograms.

In addition, the Department of Pediatrics of Children’s Hospital, Los Angeles (CHLA) is the largest department within the USC Keck School of Medicine. CHLA has been affiliated with KSOM since 1932; its Department of Pediatrics is comprised of 20 divisions, including bone marrow transplant and a pediatric intensive care unit, and the Department of Surgery is one of the country’s most comprehensive, encompassing nine divisions, including five solid organ transplant programs (heart, lung, liver, intestine, and kidney). In 1992, the CHLA Research Institute became the Saban Research Institute, which houses over 150,000 sq. ft. of research space and provides investigators with core facilities which include: genomics, gene targeting and pathology, proteomics, biostatistics, Good Manufacturing Practice (GMP) in cell therapy, cellular imaging, fluorescence activation cell sorting (FACS), stem cell, vector and research imaging. The hospital’s The Clinical Investigation Center and the Clinical Trials Unit support clinical research while the Office of Research Advancement and Administration provides centralized support for all aspects of our research.

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Additional KSOM research affiliates and medical centers include:

- House Ear Institute
- Healthcare Consultation Center (HCC) I and II
- Outpatient Surgery Center
- Keck Medical Center of USC Downtown
- Keck Medical Center of USC Beverly Hills
- Keck Medical Center La Canada
- Keck Medical Center of USC Pasadena
- USC Norris Westside Cancer Center
- Westside Center for Diabetes
- USC Engemann Student Health Center

LA COUNTY + USC HOSPITAL

A partner institution of the Keck School of Medicine of USC, the LAC + USC Medical Center is the nation’s largest academic institution and one of the largest acute care hospitals in America, recording nearly 39,000 inpatient discharges, 150,000 emergency department visits, and 1 million ambulatory care visits each year.

LAC+USC provides a full spectrum of emergency, inpatient and outpatient services. These include medical, surgical and emergency/trauma services in the General Hospital. The Women's and Children's Hospital provides obstetrical, gynecological, pediatric and specialized neonatal intensive care services as well as psychiatric services for adults, adolescents and children. Staffed by USC faculty physicians, LAC+USC also operates one of only three burn centers in the county and is home to one of only a few Level III Neonatal Intensive Care Units in Southern California.

CLINICAL TRIALS OFFICE (CTO)

The Clinical Trials Office supports USC’s investigators through budgeting, conducting Medicare Coverage Analysis (MCA), contracting, and general sponsor relations for clinical trials sponsored by industry, government, and non-profit entities. CTO teams are composed of a Senior Contract Manager (reviews, negotiates, and executes the Clinical Trial Agreements, CTAs), an MCA Administrator (conducts MCA and helps with clinical trial budget development), and a Budget Specialist (develops a budget based on the MCA and in a collaboration with the Principal Investigator).

CTO Contact Information:
Phone: (323) 442-2396
E-mail: ctoffice@usc.edu
CLINICAL INVESTIGATIONS SUPPORT OFFICE (CISO), USC NORRIS COMPREHENSIVE CANCER CENTER

CISO serves as a centralized unit to oversee the clinical research infrastructure and assist investigators in their conduct of clinical trials and translational research projects. CISO has three main operational units:

- **The Protocol Administration Unit** provides the centralized consultation and regulatory services necessary for the design, initiation, and conduct of clinical trials.
- **The Protocol Implementation Unit** provides and manages staff for study conduct as well as oversight for quality assurance and data control.
- **The Administrative/Business Management Unit** fulfills administrative functions necessary for efficiency and coordination of CISO with sponsors, investigators and others.

OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS (OPRS):

The OPRS is responsible for the university Human Subjects Protections Program (HSPP) and oversees the Institutional Review Boards (IRBs) on the HSC and UPC campuses. The office is also responsible for updating USC Human Subjects Research Policies and Procedures to ensure compliance with local, state and federal regulations, keeping the USC human subjects research community apprised of evolving practices and expectations. OPRS develops and implements education policies to ensure all USC human subjects researchers complete training in Human Subjects Protection and offers human subjects educational training sessions covering a variety of topics, including federal regulations, human subjects ethics and history. The USC Human Subjects Protection Program was accredited by the Association for Accreditation of Human Research Protection Programs in 2007.

INSTITUTIONAL REVIEW BOARD (IRB)

The FDA defines IRB as any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

USC has IRBs at both the Health Science Campus (Health Sciences Review Board – HSIRB) and the University Park Campus (University Park Institutional Review Board – UPIRB). The former is charged with reviewing and overseeing primarily biomedical research projects submitted by students, faculty, or staff at HSC while the focus of UPIRB review is primarily

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socio-behavioral research projects submitted by students, faculty, or staff at UPC. No human subject research can be conducted at USC without prior review and approval of the study protocol by the IRB.

**USC INVESTIGATIONAL DRUG SERVICES PHARMACY**

The Investigational Drug Services integrates its activities with the clinical, safety, informatics, administrative, and drug distribution systems of USC Hospitals and Clinics to optimize study drug therapy for patients. These services include: regulatory compliance integrity of blinding; prevention of errors involving study drugs; dispensing of investigational products in a timely manner; contributing to study design and data integrity randomization; and providing drug and supply procurement, as needed, as well as study drug accountability, sterile preparation and distribution, of both hazardous and non-hazardous study medications in a USP 797-compliant environment. Research pharmacists also work with clinical investigators during clinical protocol develop, providing input on work flow processes, feasibility and budget.

**SOUTHERN CALIFORNIA CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE (SC-CTSI)**

The SC-CTSI is one of 60 NIH-funded research institutes nationwide that aim to move discoveries through the research pipeline and into sustainable public health solutions. The institute provides USC clinical trial investigators with a range of research resources, from funding opportunities to mentorship and career development, including support with pre-clinical translation of discoveries; resources for community-engaged research; training and education; research team building activities, as well as expert advice/support in: biostatistics and bioinformatics, regulatory knowledge, study design and feasibility, data management and research ethics.

**Clinical Trials Unit (CTU):** The CTU, part of the SC-CTSI, is an important resource for studies that require intensive pharmacokinetic (PK) and/or pharmacodynamic (PD) blood draws, as well as studies that may require intensive monitoring (such as serial EKGs, etc.). The CTU is also equipped with a core laboratory that can perform complex specimen handling. It is suggested that investigators contact the CTU for all studies involving: (1) serial and frequent blood draws (beyond 2 or 3 draws that could be done in the day hospital or clinic); (2) serial blood draws for PD markers with complex specimen handling and/or (3) intensive monitoring with EKGs, vitals, etc.
OFFICE OF COMPLIANCE

The Office of Compliance ensures USC investigators implement and adhere to a broad range of university policies and state and federal regulations related to the conduct of sponsored research, including clinical trials by (1) helping USC faculty and staff employees understand and comply with applicable laws, rules, regulations; (2) preventing and detecting violations of law, regulations and university policy; and (3) promoting ethical conduct as articulated in the USC Code of Ethics. For clinical trials, the Office of Compliance ensures that guidelines issued by payers (Medicare, Medical, etc.) delineating requirements for billing in an academic medical center are an integral part of the business practice of all faculty, staff, employees and billing agents. Additionally, the office maintains oversight of issues related to Privacy and Security, Conflicts of Interest and Ethics at USC.

Within the Office of Compliance, the Scientific Conduct Committee hears evidence and determines, after preliminary analysis, if allegations have merit. Committee membership is comprised of senior faculty members with significant achievement in research and with administrative experience pertinent to committee function. The committee meets on an ad hoc basis, only when formal investigations are necessary. The determinations of the committee are transmitted to the faculty under question, the department chairs and the provost.

SPONSORED PROJECTS ACCOUNTING (SPA)

Sponsored Projects Accounting (SPA) is charged with oversight of post award administration of sponsored research for the University, including: (1) managing awards for compliance with Federal, State, and Private agency fiscal and reporting guidelines, University policy and procedures, and with Generally Accepted Accounting Principles; (2) ensuring the payment of obligations and the collection of funds with an efficient cash management system and (3) encouraging and facilitating proper management of sponsored funds through training and development, streamlined financial systems, and high professional standards.

ANCILLARY COMMITTEES

As you develop and conduct a clinical or translational study, you will interact with several oversight committees at USC, some of which are specific to the Cancer Center for cancer-related studies.

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The Institutional Biosafety Committee (IBC) reviews research use of all potentially hazardous biological agents including infectious agents, human and non-human primate materials (including established cell lines), known regulated toxins and carcinogens, select agents, recombinant DNA and studies involving...
human gene transfer. The Committee is responsible for ensuring that research involving these agents is conducted in a manner that does not endanger the researcher, laboratory workers, human research subjects, the public or the environment. As an institution that receives NIH funding, the IBC must ensure that all research conducted at or sponsored by our institution complies with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

All clinical studies that include gene therapy and/or recombinant organism uses in human subjects must receive approval from the IBC in addition to IRB approval prior to study initiation. The submission of the Biohazardous Use Authorization form (BUA) is required, along with applicable documents, including the NIH Recombinant DNA Advisory Committee (RAC) Review letter, the clinical protocol, Responses to Appendix M of the NIH Guidelines, the informed Consent Form, the Investigator’s Brochure, and any or all correspondence (e.g. RAC recommendations and response letters, approval letters, FDA correspondence, sponsor information or delegation, etc.). The IBC meets monthly.

To understand the scope of NIH requirements and the review process for human gene transfer trials, please see this link: [http://oba.od.nih.gov/rdna/rdna_faq.html](http://oba.od.nih.gov/rdna/rdna_faq.html).

All studies that involve biohazardous materials require Institutional Biosafety Committee (IBC). Biohazardous materials include: recombinant DNA (e.g., plasmids or viral vectors); potentially infectious microorganisms (e.g., viruses, bacteria, fungi, prions, etc.); biologically derived toxins, such as those classified as Select Agents and human cell lines, tissue, blood, or other human/nonhuman primate materials. Approval, in addition to IRB approval prior to initiating the study, and must be registered with the IBC. Biohazardous materials include recombinant DNA, potentially infectious microorganisms, bacteria-derived toxins, human cell lines, tissue, blood or other human/nonhuman primate material. The IBC meets once a month.

**RADIATION SAFETY COMMITTEE (RSC)**

The Radiation Safety Committee evaluates all proposals involving use of radioactive materials and radiation-producing equipment within the University. All studies that use radiation exposure for investigational purposes that is not clinically indicated and/or that differs from standard clinical practice, requires Radiation Safety Committee (RSC) approval. This includes CT scan/PET scans, etc. that are being done for research purposes and that are not considered standard of care for the study.

All new studies that use radiation in an investigational manner must receive approval by the RSC in addition to IRB approval prior to initiating the study. An RSC “Application for Use of Radiation Producing Devices in Clinical Research” is submitted to the RSC with a copy of the IRB application, the Informed Consent Form(s), and sponsor’s protocol (if applicable). The Radiation Safety Committee meets at least quarterly. RSC review produces an approval letter that must be uploaded onto iStar.

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The **Radioactive Drug Research Committee (RDRC)** functions as a subcommittee of the USC Radiation Safety Committee, although it is sanctioned as an independent entity reporting to the FDA under the provisions of 12 CFR 36.1. It provides a vehicle to use radioactively labeled agents or drugs to be used in human imaging research for purpose of obtaining information about their basic pharmacology, biodistribution, and dosimetry (usually 30 or fewer patients per trial). These agents, or their parent molecules, are required to have already been used in human subjects, where toxicology is known, or they are a naturally found agent within the body such as an amino acid. The process allows this type of research without the need for an IND; an IND would be required to research larger patient populations, where there is no prior human use, or where the purpose is to study efficacy, as examples. All RDRC protocols must also be approved by the USC IRB and by the USC Radiation Safety Committee. The RDRC membership includes physicians, physicists, radiochemists, radiation safety and administrative staff, and any other ad hoc specialists that might be needed for the particular type of studies to be performed.

### STEM CELL RESEARCH OVERSIGHT (SCRO) COMMITTEE

The **Stem Cell Research Oversight Committee** reviews, approves, and provides oversight over all issues related to the derivation and use of human pluripotent stem cells. Research under SCRO jurisdiction may not begin until approved by the SCRO.

### CLINICAL INVESTIGATIONS COMMITTEE (CIC) — USC NORRIS COMPREHENSIVE CANCER CENTER

The Clinical Investigations Committee (CIC) is a multidisciplinary scientific peer review committee that is established to fulfill the National Cancer Institute requirement for a Protocol Review and Monitoring System at NCI designated comprehensive cancer centers. The CIC review is designed to ensure that clinical research trials at the USC Norris Comprehensive Cancer Center are of the highest scientific quality and integrity by review of the scientific merit, feasibility, priorities and progress. The committee is composed of 26 faculty members with representation from medical oncology, hematology, radiation oncology, radiology, surgery, neurologic oncology, gynecologic oncology, and preventive medicine. Furthermore, the committee has three senior statisticians and several managers from CISO who focus on operational aspects of clinical trials.

All clinical and translational protocols at USC that involve human subjects and are designed to address a cancer focused scientific question must be reviewed and approved by CIC prior to IRB review and approval. The cancer focused scientific question may be related to cancer diagnosis, screening, prevention, or treatment. It is relevant to note that CIC is not only an oversight committee, but also a critically important resource; the CIC members and reviewers are experienced trialists and scientists who can provide very important and constructive feedback that improves the study design and conduct, and therefore benefit the investigator’s research. More information about the CIC can be found in the USC Norris Cancer Center **Clinical Investigator’s Manual**, developed by CISO.

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QUALITY ASSURANCE MONITORING COMMITTEE (QAMC) — NORRIS COMPREHENSIVE CANCER CENTER

The QAMC has two main functions: 1) to monitor study accrual and progress at regular intervals; 2) to ensure quality in study conduct through the performance of audits on investigator initiated/institutional trials as well as NCI supported trials, the review of all protocol violations, and the review of protocol amendments. It is not infrequent for the QAMC to proposed amendments to the investigator in order to ensure that the study is performed with the highest degree of compliance as well as optimize the chances of being able to address the endpoint of the trial. The QAMC meets on a monthly basis. All clinical trials that have been approved by the CIC are subject to QAMC oversight.

DATA AND SAFETY MONITORING COMMITTEE (DSMC) — NORRIS COMPREHENSIVE CANCER CENTER

The Data and Safety Monitoring Committee (DSMC) is an independent body responsible for the safety of study subjects through the review of new protocols to ensure an adequate adverse event assessment/reporting plan, study stopping rules and through the real-time and periodic monitoring of severe adverse events (SAEs) or those AEs that require expedited reporting. The DSMC performs quarterly and annual safety reviews as well as interim efficacy/futility analyses on institutional trials.

PHASE I COMMITTEE — Norris Comprehensive Cancer Center

All Phase I trials are reviewed by the Phase I Committee that meets twice a month. It is responsible for reviewing and adjudicating all dose-limiting toxicities (DLT), dose escalations and appropriateness of the escalation, cohort expansion, subject replacements and confirmation of attainment of maximal tolerated dose. Each patient is reviewed individually after the end of their DLT/assessment period and evaluability/replacement and DLT are determined, as specified in the protocol. All findings are documented in CAFÉ (see below). Special toxicities are queried as needed and a summary is prepared and made available to the CIC, QAMC and DSMC. The Phase I committee also maintains a waiting list of all patients waiting for slots and assigns slots to patients as they become available.

OTHER RESOURCES & ENTITIES

CANCER CENTER DATABASE (CAFÉ)

Cancer Center Database (CAFÉ): CAFÉ provides platform for creation of Research Database Applications. CAFÉ is an object-oriented development environment which empowers developers to create applications quickly and inexpensively. CAFÉ was initially developed for protocol management,
patient enrollment and electronic data capture to manage clinical and translational research studies at the USC Norris Cancer Center. It has now been generalized and has been used for tissue microarray data capture, epidemiologic studies, prevention trials, laboratory management, tissue repositories and administrative systems at USC. For investigator initiated studies at the Norris Comprehensive Cancer Center, electronic case report forms (eCRFs) must be developed prior to opening a trial to enrollment. CAFÉ Tracker provides step-by-step protocol status information in real time from time of receipt of protocol by CISO until the study is open to accrual. The Regulatory Manager assigned to the study is responsible for updating the CAFÉ Tracker. At the beginning of each month, the investigators receive an automated email from the Regulatory Manager generated by CAFÉ providing the status of their studies. Investigators also receive email reminders with deadlines for CIC protocol submission forms and CIC stipulation submission. These email reminders help investigators to track the progress of their studies. The reminder and status emails stop once the study is open to accrual.

RESEARCH FACILITIES & CORE LABORATORIES AT USC

USC’s research facilities and core laboratories support the conduct of research and clinical trials through services in critical areas such as high performance computing, genomics, cellular and molecular analysis, biomedical imaging, nanoscience, and data analysis and management. Core laboratories offer shared-use research facilities and provide technological support for research projects carried out by faculty across academic disciplines and clinical specialties. Contact information for USC research facilities and core laboratories is provided in Appendix 4.

OFFICE OF RESEARCH ADMINISTRATION (KSOM)

The Office of Research Administration at the KSOM oversees grant and contract administration and research compliance to support and facilitate funding and adherence to university and federal, state and local regulations and sponsor policies and procedures. It serves as the point of contact for KSOM research faculty to obtain Dean’s approval of grant or contract submissions, exceptions to F&A rates, advance funding, pre-award costs, cost sharing and transfer of unexpended fixed price contract balances. The office provides support to investigators in the following areas: (1) Grant submission and post-award; (2) Training (seminars & on-line, as needed) and (3) Compliance (in conjunction with the USC Office of Compliance).

USC OFFICE OF RESEARCH

The Office of Research supports individual and interdisciplinary research that addresses societal needs. The office invests in research initiatives, promotes USC research among sponsors, and provides services that ensure USC achieves the highest ethical standards in its research. Offices/units that fall under the Office of Research include: the Research Advancement Office (Washington, DC), the Department of Contracts & Grants, Institutional Review
Boards (Office for the Protection of Research Subjects), the Department of Animal Resources and the Institute for Creative Technologies. The office is the university point of contact for issues such as:

- Complaints pertaining to research misconduct.
- Financial disclosures or conflict of interest statements
- Identifying sources of research funding, both inside and outside the university.
- Support for submission of research proposals.
- Participation in, and initiation of, major inter-disciplinary university research programs and formation of research units.
- Education to prepare investigators for funding strategies and proposal preparation.
- Clearance for research competitions that limit the number of proposals submitted by the University.

**DEPARTMENT OF CONTRACTS AND GRANTS (DCG)**

The [Department of Contracts and Grants](#) supports USC's investigators through proposal submission, award negotiation, sub-awards, account set-up and account close-out, ensuring that grants and contracts are consistent with university standards for academic freedom, research ethics and fiscal responsibility. While the DCG does not prepare proposals or budgets for basic research proposals, its clinical trials office provides this service for industry-sponsored trials.

**USC STEVENS CENTER**

The [USC Stevens Center for Innovation](#) is a university-wide resource for USC innovators. The Center manages the intellectual property portfolio and technology transfer process for the university, as well as provides ongoing review and updating of relevant university policies. It collaborates with all 17 schools and the College at USC to promote existing programs and develop new ones by providing USC investigators with greater access to technology translation professionals, expanded startup support services and a streamlined industry interface. Support services also include identification of translational funding and mentoring opportunities.

**Stevens Center Contact Information:**

Phone: (213) 821-5000