USC University of Southern California

OFFICE OF RESEARCH
*Randolph W. Hall, Ph.D.*
*Vice President of Research*
*rwhall@usc.edu*

# MEMORANDUM

**TO:** Principal Investigators (PIs) and Staff Conducting Clinical Research

**FROM:** Randolph W. Hall, PhD

**DATE:** January 9, 2015

**SUBJECT:** Expansion of Mandatory Good Clinical Practice (GCP) Education

Excellence in clinical research depends on a well trained professional workforce. Toward this end, USC has expanded educational offerings in recent years, as well as mandated courses that are essential to quality assurance and human subject protection for our research studies.

Good Clinical Practice training has been required since 2009 for study PIs and staff conducting full board clinical trials. It is now important to extend this requirement to all clinical trials, not just full board. Effective January 26, 2015, PIs and staff on new studies and any new staff on ongoing studies meeting the NIH definition of clinical trials are required to satisfy the GCP requirement.

> A clinical trial is "*A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on* ***health-related biomedical or behavioral outcomes***"[1]

GCP training is primarily intended for study staff who have interaction, conduct interventions or have access to subject identifiable information. GCP training is offered on-line through CITI (Collaborative Institutional Training Initiative: https://www.citiprogram.org/). For a nominal fee, participants are eligible for CME (Continuing Medical Education) credits upon course completion.

As a reminder, all staff working on clinical trials are strongly encouraged to complete the USC Orientation to Clinical Research at USC, available at: http://research.usc.edu/for-investigators/training/. SOCRA certification is also encouraged for all other Research Coordinators but is required for Research Coordinator IIs and Supervisors.

A summary of education resources offered at USC is included below.

[1] Please note the expansion of the NIH definition to include "behavioral outcomes" research.

# Education Resources for Research Staff

- CITI Human Subjects Protection (HSP) Course: This course pertains to human subjects regulations, rules and ethics. HSP training must be completed by all research study staff who conduct Human Subjects Research at USC. http://oprs.usc.edu/education/citi/
- CITI Good Clinical Practices (GCP) Course: This course addresses the international, ethical and, scientific standards expected in the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. GCP training is required for key personnel on Expedited and Full Board clinical trials. http://oprs.usc.edu/education/citi/
- Responsible Conduct of Research (RCR) Course: This course addresses RCR topics including ethics, data integrity and collaborative research. RCR training is required for all students and postdoctoral scholars serving on studies funded by the National Science Foundation and may be required for some NIH programs. http://oprs.usc.edu/education/citi/
- Orientation to Clinical Research at USC: 7-hour online course provides faculty, staff and students with an overview of the processes, committees and departments necessary for submission, review, approval and conduct of human subject research at USC. https://research.usc.edu/for-investigators/training/
- Guide to Clinical Research at USC: companion manual to the Orientation to Clinical Research at USC course. https://research.usc.edu/files/2014/07/Guide-to-Clinical-Research-at-USC-Update-101314.pdf
- SOCRA Prep and GCP Review Course: one-day course that prepares coordinators for the Certified Research Professional exam. Certification formally recognizes coordinators who are knowledgeable about competencies and processes necessary to conduct clinical trials (required for RCII and RC supervisor positions and encouraged for others). http://research.usc.edu/2014/08/08/socra-research-coordinator-prep-course-certification/
- In-person education: sessions for research study staff conducted by OPRS to address Human Research Protection concerns expressed by the IRB or the research team as well as ad hoc per investigators' request. http://oprs.usc.edu/education/
- HIPAA /"Privacy Rule" Course: covers all aspects of the Health Insurance Portability and Accountability Act (HIPAA) and the protection of the privacy of individually identifiable health information. HIPAA training is required for all research study staff who have access to Protected Health Information such as patient health records. http://ooc.usc.edu/hipaa-privacy-education-program
- Grants Management Education Program: helps researchers navigate complexities of sponsored research. Grants management training is required for principal investigators, co-investigators and research administrators listed on the Proposal Approval Record (PAR) or requesting expenditure authority on a sponsored project account. http://ooc.usc.edu/grants-management-education-program
- Human Subjects Protection Booklets Created by OPRS: topics include Investigational Drug/Device exemptions, Good Clinical Practice (GCP), Informed Consent, and more. Available for research study staff and students who conduct human subject research. http://oprs.usc.edu/education/booklets/
- Responsible Conduct of Research (RCR) Booklets Created by OPRS: topics include Animal Subjects, Collaborative Research, Conflicts of Interest and Commitment, Data Management and Acquisition, Human Subjects Research, Mentoring, Peer Review, and Research/Scientific

# Education Resources for Research Staff

Misconduct. Available for research study staff and students who conduct human subject research. http://oprs.usc.edu/education/rcr/

## Medical Student Researchers

- Guide to Human Subjects Research For USC Medical Students: provides guidance for medical students who conduct biomedical, social and behavioral research or otherwise participate in research activities at the Keck School of Medicine (KSOM). The Guide is a reference tool to support completion of the medical student research project requirement. https://oprs.usc.edu/files/2013/04/Med_Student_Booklet_4.3.13.pdf

## Outreach Activities:

- Human Subjects Research Newsletter: provides online updates about federal, state and university policies as well as relevant news to the USC research community. http://oprs.usc.edu/about/listserv-2/
- Research Coordinator Bulletin: provides information, resources and updates specific to clinical research coordinators. http://oprs.usc.edu/initiatives/research-coordinators/

## Additional Resources:

- Guide to Research at USC: reference tool highlighting important USC policies related to sponsored projects. Guide meant for use in proposal preparation stages and throughout the course of research. https://research.usc.edu/files/2013/07/Guide-to-Research-8.18.14.pdf
- Research Training Finder: search tool for required and suggested research compliance training courses. Searches can be performed based on role or study responsibilities. http://researchtrainingfinder.usc.edu/
- USC Regulatory Science Program: Certificate, Master's, and Doctoral programs provide education and degree opportunities related to clinical research, regulatory affairs, and quality systems. https://regulatory.usc.edu/