

SoCRA CLINICAL SCIENCE COURSE FOR CLINICAL RESEARCH PROFESSIONALS

Selected Faculty Overview

Introduction to ICH and Human Research Protections

Steve Steinbrueck, MPH, is the President of Stonebridge GCP Consulting Inc., an international consultancy offering GCP, Bioethics and SOP training; SOP development; and clinical auditing services. He has a unique 35+ year career combining clinical research, health care, academic and international training experience. Steve holds an MPH from the University of South Carolina and currently serves as on the adjunct graduate faculties of the Drexel University College of Medicine Clinical Research Organization & Management and the Temple University School of Pharmacy Regulatory Affairs/Quality Assurance graduate programs. Immediately before founding Stonebridge, Steve was the Associate Director of Global Quality, Procedures & Training at Bristol-Myers Squibb. Previously he was the Director of Training & Development for SCIREX Corporation and led an international training group at Janssen Research Foundation. Steve has been a clinical research associate for a both a contract research organization and a small biotechnology firm. Prior to joining the industry, he served as Clinical Director of the Physician Assistant Program at the Medical College of Georgia. He began his healthcare career as an Army corpsman and later served as a physician assistant in family practice, family planning and pediatric settings.

Clinical Program Management and Budgeting

Bryan Mark Soronson, BS, MPA, is the Senior Administrator, Department of Neurology, University of Maryland Medical Center. He is responsible for financial and administrative duties of the Department. He develops, manages, and administers the Department's 14 million dollar budget which includes the school, hospital and practice research grant and contract funds; coordinates preparation and submission of grants and contracts and federal and private sources including two center grants-, coordinates administrative aspects of eleven University Multi-Center clinical trial; coordinates personnel and procurement activities; oversees departmental group practice; serves as departmental administrative compliance liaison; supervises clerical, accounting and activities; coordinates relocations and renovations of the Department; manages administrative aspects of the Ambulatory Practice; chaired the Education section of University Physicians Compliance Committee; coordinated selection of grant accounting package for most of the Departments of the Medical School, and initiated campus-wide research compliance initiative.

Clinical Pharmacology and AE Reporting

John M. Kessler, PharmD, Dr. Kessler is the Founder and Chief Clinical Officer of SecondStory Health. He has a special interest in medication safety. He has chaired and served on national and state committees to improve patient safety. His research is focused on medication safety in clinical trials. Dr. Kessler currently serves as Chairman of the Duke University Health System IRB. He has been a member of the Duke IRB since 1990. His former positions include Chairman of the North Carolina Ethical Review Board and Director of the Duke University Hospital Investigational Drug Service. Dr. Kessler completed a Fellowship in Post-marketing Surveillance at the University of Cape Town, South Africa. He received his Pharmacy degree from West Virginia University and his Doctorate degree from Duquesne University.

IRBs and Informed Consent

George H. D'Addamio, PhD is President of PharmConsult, Inc., a consulting firm in Atlanta, GA that specializes in the preparation of clinical development documents. During 8 years at SmithKline & French Laboratories (now Glaxo SmithKline), Dr. D'Addamio was responsible for preparing protocols, case report forms, integrated study reports, and regulatory submissions in Clinical R & D and Medical Affairs. As Scientific Manager, Clinical R & D, he was responsible for coordinating clinical research programs in Canada and Latin America. In Medical Affairs, he managed operational groups responsible for medical writing, clinical monitoring, and CRF safety reviews and auditing. After leaving SmithKline & French, Dr. D'Addamio worked with a CRO for 1.5 years before forming PharmConsult. His consulting experience includes project management and statistical services in addition to medical writing in various therapeutic areas for both domestic and foreign pharmaceutical companies.

Research Ethics

Victor M. Santana, MD, is the Division Director for Solid Tumors, Department of Hematology – Oncology, St. Jude Children's Hospital. Dr. Santana has received national recognition for the care he provides pediatric cancer patients at St. Jude Children's Research Hospital. Voted one of the "Best Doctors in America" two years in a row, Dr. Santana is an expert on Neuroblastoma in children. He has collaborated with other St. Jude physicians and researchers to create innovative treatment plans for cancer patients. Dr. Santana chairs the Institutional Review Board at St. Jude. He is an associate professor in the department of pediatrics at the University of Tennessee in Memphis,

Tennessee. Before joining St. Jude in 1984, Dr. Santana completed a six-year tenure at Johns Hopkins Hospital in Baltimore, Maryland.

Anatomy and Physiology, Genetics, and Cell Biology

Richard Sloane, MS, teaches Anatomy and Physiology, and Cell Biology at Durham Technical Community College. He received his MS from the University of Rochester, Rochester, NY, where he concurrently worked in their Center for Brain Research. Since then, he has had broad research experience in Inhalation/Respiratory Toxicology, Cardiovascular Toxicology, Liver Studies, and Reproductive Toxicology and Teratology at the National Institute of Environmental Health Sciences in the Research Triangle Park, NC. He was also an active member of Toastmasters International for over 13 years, achieving highest honors, and gives classes in effective speaking techniques.

Chemical Analysis of Laboratory Values

Linda L. Seefried, MA is currently a Clinical Line Manager, in Clinical Operations for PAREXEL International. Ms. Seefried has been with PAREXEL for over 9 years and is experienced in clinical trials in Phase I, II and III studies. Her bachelor's degree is in Clinical Laboratory Science from Salisbury State University and master's degree is in Counseling Psychology from Immaculata College. She possesses more than 6 years of experience in managing CRAs and clinical teams as well as over 11 years of experience in laboratory science education and 6 years in clinical laboratory management. She is certified in clinical laboratory science as both a generalist and a laboratory manager. Ms. Seefried has practiced as a clinical laboratorian in an acute care hospital, a reference laboratory, and a physician's office endocrinology practice. She has taught laboratory medicine for clinical laboratory technicians, clinical laboratory scientists, Physician Assistants, and nurse clinicians on faculty at Hahnemann University in Philadelphia, PA and later at Duke University in Durham, NC. She is past president of two state societies of the American Society for Clinical Laboratory Science in both Pennsylvania and North Carolina. For 8 years, she was on the exam council for the National Certification Agency for the Clinical Laboratory Science certification exams.

Epidemiology and Statistics

Brad Pollock, PhD, is a Professor of Pediatrics and Medicine and Director of the Center of Epidemiology and Biostatistics at the University of Texas Health Science Center at San Antonio. He also is the Associate Director of the Children's Cancer Research Institute and directs the biostatistics core for the San Antonio Cancer Institute, an NCI funded cancer center. Dr. Pollock received his M.P.H. and Ph.D. at University of California, Los Angeles. At the University of Florida, he served as a statistician for the Pediatric Oncology Group for 13 years. He has taught several courses on epidemiology and biostatistics and has been on the faculty for the SoCRA Clinical Science educational program since its inception.