

Methods in Clinical Investigation

Course Overview

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What is Clinical Research?

Research, conducted in living human beings, that is designed to further knowledge of normal human function and/or the causes and treatment of human diseases.

Examples of Clinical Research

- ✦ Human physiology and pathophysiology
- ✦ Epidemiology, including genetic epid.
- ✦ Clinical trials (drug development & testing)
- ✦ Health outcomes research
- ✦ Behavioral research
- ✦ Genetic Medicine

“Basic Skills” of Clinical Research

- ✦ Expertise in disease or discipline
- ✦ Ethics of human research
- ✦ Rules and regulations
- ✦ Biostatistics and study design
- ✦ Conduct of a clinical protocol
- ✦ Laboratory analysis
- ✦ Molecular/genetic medicine
- ✦ Computer skills and data management
- ✦ Grant writing
- ✦ Presentation and publication

Know Your Local Resources

Methods in Clinical Investigation

Introductory Course

- ✦ Gain overview of the skills required for successful clinical research
- ✦ Learn about resources at USC for training in and conduct of clinical research

Other USC Training Opportunities in Clinical Research

- Graduate Level Biostatistics Courses (via GCRC)
 - ✦ Principles of Biostatistics
 - ✦ Principles of Epidemiology
 - ✦ Design of Clinical Studies
 - ✦ Structure and Management of Clinical Trials
- ✦ Contact: GCRC Office (226-4632)
- Masters in Clinical and Biomedical Investigation
 - ✦ Director: Stan Azen (sazen@usc.edu)

NIH Career Development in Clinical Research

Mentored Career Development Award (K-23)

- Eligibility
 - ✦ Clinical Degree (MD, DDS, DO, Clinical PhD)
 - ✦ ≥1 year of specialty training
 - ✦ U.S. citizen or permanent resident
- Required Aspects of Program
 - ✦ Patient-oriented research project
 - ✦ Research training from qualified mentor
- Annual Support (3-5 years)
 - ✦ At least 75% effort (\$\$ limits) + \$20-50K M+S
- Other Aspects
 - ✦ Can apply for and hold other grants (last 2 years)
 - ✦ Not renewable

<http://grants1.nih.gov/training/careerdevelopmentawards.htm>

NIH Career Development in Clinical Research

Mid-career Investigator Award (K-24)

- Eligibility
 - ✦ Clinical Degree (MD, DDS, DO, Clinical PhD)
 - ✦ <15 years after speciality training
 - ✦ U.S. citizen or permanent resident
- Required Aspects of Program
 - ✦ Patient-oriented research project
 - ✦ Mentoring of clinical research trainees
- Annual Support (3-5 years)
 - ✦ 25-50% effort + \$50K M+S/personnel/travel/equip
- Other Aspects
 - ✦ Must hold current peer-reviewed grants
 - ✦ Renewable once

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