

University Graduate School 2007–2008 Academic Bulletin

# **Clinical Research**

School of Medicine Indianapolis

**Program Director** 

Professor Kurt Kroenke\*

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## **Graduate Faculty**

(An asterisk [\*] denotes membership in the University Graduate School faculty with the endorsement to direct doctoral dissertations.)

## **Distinguished Professor**

Clement J. McDonald\* (Emeritus, Medical Informatics)

### **Professors**

Christopher Callahan\* (Geriatrics), David Crabb\* (Gastroenterology), James Croop (Pediatrics), Kimberly Quaid De Cordon\* (Medical and Molecular Genetics), Scott Denne\* (Pediatrics), Bradley N. Doebbeling\* (Medicine), Michael J. Econs\* (Endocrinology), Martin Farlow (Neurology), Rose Fife\* (Rheumatology), David Flockhart\* (Clinical Pharmacology), Dennis J. Fortenberry\* (Adolescent Medicine), Stephen D. Hall\* (Pharmacology/Toxicology), Hugh Hendrie\* (Psychiatry), Siu Hui\* (Biostatistics), Thomas Imperiale (Medicine), Thomas S. Inui\* (Medicine), Barry Katz\* (Biostatistics), James A. Lemons (Neonatal-Perinatal), Patrick J. Loehrer Sr. (Hematology/Oncology), Lawrence Lumeng\* (Gastroenterology/ Hepatology), Christopher McDougle\* (Child Psychiatry), Eric Meslin\* (Bioethics), Sharon Moe (Nephrology), Donald Orr\* (Adolescent Medicine), Marc Overhage (Infectious Diseases), Munro Peacock\* (Endocrinology), Ora Hirsch Pescovitz\* (Pediatrics), Stanley Spinola\* (Infectious Diseases), William Tierney (Medical Informatics), David Wilkes\* (Medicine), Domenick Zero\* (Dentistry)

## **Associate Professors**

Naga Chalasani (Gastroenterology), Stephen Downs\* (Pediatrics and Health Services Research), Michael Dube (Infectious Diseases), Kathleen Hall (Psychiatry), Aimee Mayeda\* (Psychiatry), Homer Twigg\* (Pulmonary), Frederick Unverzagt (Neuropsychology), Michael Weiner (Geriatrics), Linda Williams (Neurology)

### **Assistant Professor**

Gwendolyn Morrison (Health Economics)

# **Degree Offered**

Master of Science

## **Special Departmental Requirements**

See also general University Graduate School requirements.

## **Master of Science in Clinical Research**

Indiana University's Master of Science in Clinical Research degree program prepares health care professionals for a career in clinical research. This program offers a combination of course work and practical research experience and is a core component of Indiana University's Clinical Investigator Training Enhancement (CITE) program. The program also constitutes the formal didactic requirements for certain types of federal training grants (such as K-23s) and other career awards. Following completion of the program, graduates can embark on a career in clinical research with the skills necessary to successfully compete for grant funding, conduct and analyze research findings, and publish work in scientific journals.

## **Course Requirements**

The Master of Science program is divided equally between two main components: (1) completion of the formal curriculum and (2) active involvement in clinical research under the mentorship of a faculty scientist. Both elements are critical in preparation of the candidate for successful research following graduation.

Besides didactic classes, there is substantial research training in scientific writing and grant preparation. The curriculum is designed to cover core competency areas through a combination of course work and mentored research. The two-year M.S. program consists of a 30 credit hour curriculum, which includes the following core courses—G504, G651, G655, G660, G661, G664, N802—and two approved electives.

#### **Grades**

An overall average of at least a B (3.0) is required.

#### Thesis

Research project (see GRAD G664 Mentored Clinical Research) is completed in lieu of thesis.

## Courses

**G504 Research Ethics (2-3 cr.)** An introduction to both the theory and practice of research ethics. The course also covers key ethical principles and concepts.

**G651 Biostatistics I (3 cr.)** The use of computers and statistical software for data analyses, fundamental statistical concepts including probability and distributions, and application of parametric and nonparametric statistics on continuous and categorical data.

**G655 Research Communication (2 cr.)** A core didactic set of classes that includes the key elements of scientific writing.

**G660 Clinical Research Methods (3 cr.)** This course provides instruction in the major types of study design (other than clinical trials) used in clinical research, including cohort, case-control, cross-sectional, survey, and secondary database studies. Also, fundamental themes and special topics in clinical research are covered.

**G661 Clinical Trials (3 cr.)** This course includes topics in conducting clinical trials, including design, recruitment, informed consent, randomization, blinding, data collection and analysis, safety monitoring, study closeout, and alternative designs such as crossover and nonrandomized trials. Some important research areas besides clinical trials are also covered.

**G664 Mentored Clinical Research (7-9 cr.)** This is an organized research project in the form of an organized scientific contribution or comprehensive analysis conducted under the mentorship of a faculty scientist from the individual CITE enrollee's core discipline. The capstone experience is submission of an abstract to a scientific meeting, defense of one's research before an advisory committee, and completion of a first-authored paper deemed suitable for publication in a scientific journal.

**N802 Techniques in Effective Grant Writing (3 cr.)** A core didactic set of classes along with the requirement for completion of a grant to be submitted for intramural or external funding.

**Electives (4-6 cr.)** Electives (approved by program director) include graduate-level courses in more advanced biostatistics, epidemiology, clinical pharmacology, genetics, molecular biology, computer sciences, or other courses relevant to the individual student's field of clinical research.