



SCHOOL OF MEDICINE

DATE: March 2, 2011

TO: Sherry Queener, Ph.D.
Associate Dean of Graduate School

FROM: Simon Rhodes, Ph.D.
Associate Dean of Graduate Studies

SUBJ: MS in Clinical Degree Program

A handwritten signature in blue ink, reading "S. J. Rhodes".

I approve of the revised curriculum proposal for the Master of Science in Clinical Research degree program. Attached are the details and justifications for the request to modify the current curriculum. Please submit to the GAC for approval.

Thank you.

OFFICE OF THE DEAN

GRADUATE DIVISION

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INDIANA UNIVERSITY
SCHOOL OF MEDICINE

February 23, 2011

Simon J. Rhodes, Ph.D.
Associate Dean for Research and Graduate Studies
Indiana University School of Medicine
Medical Science Building, Room 207
635 N. Barnhill Drive
Indianapolis, IN 46202

Dear Dr. Rhodes,

Attached please find a revised curriculum proposal for the Master of Science in Clinical Research degree program. The proposal outlines the details and justification for the request to modify the current curriculum. The revised program still requires a total of 30 credit hours including 7-9 credits for the mentored clinical research project which is required in lieu of a thesis. I believe that the proposed course requirements will better serve the postdoctoral health care professionals, who participate in this program.

If you have questions or concerns, please contact me.

Sincerely,

Kurt Kroenke, MD
Professor of Medicine, Indiana University School of Medicine
Senior Scientist, Regenstrief Institute for Health Care
Director, CITE Program and Master of Science in Clinical Research Degree

Master of Science in Clinical Research

Proposal for Revised Curriculum – February 2011

Rationale for Revised Curriculum Requirements

The MS in Clinical Research degree focuses on formal training in clinical research for health care professionals, who desire to make clinical research either a predominate focus, or a substantive part of their long-term career goals. Potential applicants must have a doctoral degree (e.g., MD, PhD, DNS, DDS), or be in training for a doctoral degree, and are health care professionals committed to a career in clinical research.

This program has helped prepare a cadre of trained clinical investigators successfully compete for federal, foundation, and industry funding, and to conduct clinical research and publish their findings, thereby further enhancing the stature of Indiana University as a leader in biomedical research: and to conduct research that will enhance the health of residents of the state of Indiana.

The past 8 years have seen a change in the population of potential applicants to this program, as well as, a change in relevant coursework available on the IUPUI campus. In addition, we have found that the audience for this degree program is so varied among departments on campus, a program tailored to each individual's needs is essential to meet the needs of each student.

In order to take advantage of these changes, we propose to incorporate the following curriculum changes:

- To complete the research ethics requirement, students will be required to complete either, Research Ethics (G504), or Ethical and Policy Issues in International Research (P555). Many applicants to this program are international students, who plan to complete the degree and return to their home countries, or students who plan to work and conduct research in a foreign country. In these cases, we believe that a course in international ethics (P555) is more relevant for these students' research and career goals.
- In the past, the MS in Clinical Research requirements have included the course, Techniques of Effective Grant Writing. We propose that this course be included as a potential elective for a select number of students, but eliminated as a required course due to the following issues:
 1. Small class size – maximum of 10 students. Many of the MS in Clinical Research students have not been allowed to register due to the class size restrictions.
 2. Instructor changes – in the past 4 years, this class has had three different instructors, and student evaluations are missed regarding knowledge of course content, etc.
 3. Our student population consists of post-doctoral trainees, who have experience in writing grants, and many are funded by NIH, foundations, etc.

We would propose that students be given the opportunity to take an approved course that would be more relevant to a trainee, or an alternate course approved by the Program Director (see list of approved courses below).

- Students may elect to complete an elective relevant to their research, or career goals in place of the course, Seminars in Research Communications (G504). Again, due to the advanced nature of our degree clientele, we propose that students, who have advanced communication skills (writing articles, abstracts, etc.), have the option to take a course (from the approved course list or a course that is more relevant to their individual research, and career goals. We would propose that students be given the opportunity to take an approved course that would be more relevant to a trainee, or an alternate course approved by the Program Director (see list of approved courses below).

M.S. in Clinical Research

Most or all of the courses necessary to deliver the curriculum will be offered on an annual basis. Generally, students will average 6 credit hours in each of the fall and spring semesters and 3-5 credits in the summer. Most students will complete their independent research (G664) during the two years of the program. Students will still complete a total of 30 credit hours with an overall grade point average of 3.0.

Required Courses

Clinical Research Methods (G660, 3 credits)

Clinical Trials (G661, 3 credits)

Biostatistics I (G651, 3 credits)

Mentored Clinical Research (G664, 7-9 credits)

Research Ethics (G504, 2-3 credits) or Ethical & Policy Issues in International Research (P555, 3 credits)

Approved Electives

Selections may include, but are not limited to the following offerings:

G652 Biostatistics II

G668 Tools & Techniques in Translational Research

W540 Patient Reported Outcomes & Economic Evaluation

G655 Seminars in Research Communications

N802 Effective Techniques of Grant Writing

In addition to the list above, other graduate courses consistent with each student's research and career goals may be approved by the Program Director and/or each student's advisory committee.

The proposed changes do not decrease the total number of didactic courses required for this degree, but will enable each student to complete coursework, that we believe will enhance and prepare each student for his/her career in clinical research.

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