

PROPOSAL FOR A GRADUATE CERTIFICATE IN CLINICAL RESEARCH SKILLS

Background

In September 2000, the University of Kentucky received \$1 million in funding from the National Institutes of Health through the K30 institutional training grant program. The title of the UK program funded by this award is “Career Training in Therapeutics and Translational Research.” The goal of the K30 program is to provide trainees with the skills necessary to successfully pursue careers in clinical research. The program offers an intensive two-year curriculum that combines didactic course work, mentored clinical research experiences, and innovative special program initiatives such as workshops and various lecture series. An important component of the overall K30 program is the creation of a Graduate Certificate in Clinical Research Skills, which will be awarded to participants who complete core didactic courses and a mentored clinical research experience.

Target Audience and Admission Requirements

The Certificate in Clinical Research Skills will be available to (a) physicians in postgraduate training at the College of Medicine, including residents and fellows; (b) pharmacists in postgraduate training at the College of Pharmacy, including residents and fellows; (c) PhD candidates in Clinical Pharmaceutical Sciences; and (d) faculty members from the Colleges of Medicine, Pharmacy, Dentistry, Nursing, Public Health, and Allied Health who are planning to participate in clinical research but lack previous training and the skills necessary for clinical research. Curriculum trainees will make a substantial time commitment (80%) to their clinical research and career development.

Students admitted to the Certificate curriculum must meet the minimum Graduate School requirements for admission either for postbaccalaureate status or as degree-seeking students, if applicable, and must be approved for admission by the Director of the Certificate and the School of Public Health Admissions Committee.

Goals of the Certificate Curriculum

The Certificate curriculum is intended to offer participants the necessary coursework, informational sessions, and mentored clinical research opportunities necessary to provide them with a strong background in the knowledge and skills necessary to succeed in clinical research. The knowledge and skills obtained should improve participants’ ability to attract research funding and to publish the results of that work in appropriate peer-reviewed journals. The Kentucky School of Public Health will be the organizational unit responsible for the Certificate. The hours earned by students toward the Certificate may be used by students who wish to continue their study and earn an additional degree, such as the Master’s degree in Public Health (MPH).

Certificate Requirements

To be awarded the Certificate, participants must complete the following course work (a total of 15 credit hours) with an overall GPA of at least 3.0:

PM 620	Introduction to Epidemiology (or other existing approved course in epidemiology)	3 credit hours
SPH 664	Design and Analysis of Clinical Trials	3 credit hours
SPH 665	Ethical Issues in Clinical Research	3 credit hours
SPH 666	Practicum in Clinical Research I	1 credit hour
SPH 667	Practicum in Clinical Research II	1 credit hour
SPH 668	Practicum in Clinical Research III	1 credit hour
Elective	(Approved by the Director)	3 credit hours

PM 620: Introduction to Epidemiology. This required course for the Master's degree in Public Health (MPH) covers the principles and methods of epidemiologic investigations, research methodology, and statistical integration. Primary topics include etiologic factors of disease and injury, the distribution of health problems within populations, levels of prevention, and the concept of risk. The design of retrospective, cross-sectional, and prospective studies is examined to illustrate odds ratio, relative risk, life tables, and person-years. Students are required to complete and submit a research proposal, present a topic paper, and serve as a co-facilitator for an article discussion. Students may fulfill this requirement by substituting a different epidemiology course with permission of the curriculum director.

SPH 664: Design and Analysis of Clinical Trials. This is a new biostatistics course developed by Dr. Richard Kryscio, a faculty member in the K30 program. Taught for the first time in the Fall semester of 2001 as PM 780-002: Special Problems in Preventive Medicine and Public Health: Biostatistics for Clinical Trials, this course addresses the statistical knowledge necessary to successfully design, carry out, and analyze clinical research studies. To be eligible for this course, participants must have taken STA 570, 671, 672, or an equivalent, or must demonstrate to Dr. Kryscio in advance a knowledge of basic statistics sufficient for enrollment in the course.

SPH 665: Ethical Issues in Clinical Research. This course was offered during the Spring 2001 semester as a tele-education course in partnership with the University of Louisville. The instructor was Dr. Osborne P. Wiggins, Department of Philosophy, University of Louisville. Dr. Wiggins came to Lexington for two of the class meetings; the rest were offered by live, interactive television. All courses were videotaped for those who were unable to attend a particular session. The course required a mid-term examination and a final examination, and final course grades were based on an average of the grades from the two examinations. The course facilitator at UK was Dr. Rose Booze.

During the Spring semester of 2002, a newly developed UK-based ethics course was offered as HSM 775-004: Special Topics in Health Administration: Ethical Issues in Clinical Research. This course focused on the nine factors defined by the NIH as necessary for the Responsible Conduct of Research. The instructor of record was Jimmi Hatton-Kolpek, PharmD, and the other course directors were Thomas S. Foster, PhD; Edward Kasarskis, MD; and Ada Sue Selwitz, MA. This course was well-received and will form the basis of SPH 665.

SPH 666: Practicum in Clinical Research I, SPH 667: Practicum in Clinical Research II, and SPH 668: Practicum in Clinical Research III. These three one-hour courses are designed to give participants course credit for completing the other requirements for the Graduate Certificate in Clinical Research Skills. The focus of the

three practicum is a mentored clinical research experience; for the purposes of this Certificate, clinical research is defined by the requirement of IRB approval and human interaction. The requirements for the practicum courses include completion of a mentored clinical research project, participation in a monthly journal club, and two annual retreats. Participation in at least 70% of the scheduled activities (journal club, special sessions, and retreats) is required in addition to the mentored clinical research experience if the student is to earn the credit hours. The Journal Club meets monthly to discuss topics of interest to clinical researchers. The sessions are facilitated by senior students; presenters discuss a wide variety of topics of importance to clinical researchers. Retreats are held in the spring and fall and focus on a clinical research topic of current interest. The Spring 2001 retreat involved attendance at the program “Women’s Health in the New Millennium,” held at the VA Medical Center on May 15 and 16. The Fall 2001 retreat was held at Shakertown on November 2. That retreat focused on infectious diseases, particularly AIDS; the keynote speaker was Diane Lee Zablotsky, PhD, from the Department of Sociology, Anthropology, and Social Work of the University of North Carolina at Charlotte. The Spring 2002 retreat was held on April 12, 2002, at Spindletop; the focus was women’s health. Speakers included Deborah Kwolek, MD, Patrick McNamara, PhD, and Tom Curry, PhD. The mentored clinical research experience involves the selection of a mentor, the submission of a proposal for a K30 seed grant of \$5,000, IRB approval of the proposed research, and successful completion of the project, with a written summary of the findings. To earn credit for SPH 666, participants will give a presentation related to their mentored clinical research experience at a local curriculum-related retreat. To earn credit for SPH 667, participants will prepare an abstract related to their mentored clinical research experience for presentation at a national or international meeting. To earn credit for SPH 668, participants will prepare a paper (journal article) or a funding proposal (K or R01 series) based on the mentored clinical research experience.

Elective Course. This requirement can be fulfilled in one of several ways. First, some students will need to take an additional statistics course (STA 570, 671, or 672) as a prerequisite for Dr. Kryscio’s PM 780-002 course. Second, pharmacy students (and others who may be interested) can take the course entitled Topics in Pharmaceutical Science: Drug Development and Clinical Research (PHR 760-009), which was offered for the first time in Spring 2001. Third, some students may choose to take Clinical Epidemiology (PM 670), in which they will learn the fundamentals of designing clinical research studies of diagnostic tests, prognosis, and causation. Students will practice these skills through focused critiques of the medical literature and by designing clinical research studies. With approval of the Certificate Director, other courses may be used to fulfill this requirement.

Certificate Director

We recommend that Claire Pomeroy, MD, be appointed as Certificate Director. Dr. Pomeroy is Associate Dean for Research and Informatics and Associate Chief of Staff of the College of Medicine. She is also Professor of Medicine in the Division of Infectious Diseases. Dr. Pomeroy is the co-Program Director of UK’s K30 program, “Career Training in Therapeutics and Translational Research.”

Affiliated Faculty Members

Although a large number of faculty members may be involved in mentoring the clinical research projects of the Certificate participants, the group of faculty members who will be most closely affiliated with the Certificate and who will be involved in delivery of the course work include Claire Pomeroy, MD; Robert A. Blouin, PharmD, co-Director of the K30 program; Richard J. Kryscio, PhD, Biostatistician of the K30 program, Professor in the Department of Statistics, and head of the Division of Biostatistics; Judith Skelton, PhD, Educational Specialist of the K30 program and Assistant Professor, College of Dentistry; F. Douglas Scutchfield, MD, Director, Center for Health Services Management and Research, and Director, School of Public Health; Joel Lee, DRPH, Associate Director for Academic Affairs, Center for Health Services Management and Research; Rosemarie M. Booze, PhD, Associate Professor in the Department of Anatomy and Neurobiology; Ada Sue Selwitz, MA, Director of the Office of Research Integrity; and Edward Kasarskis, MD, Professor in the Department of Neurology. Of these, Drs. Pomeroy, Blouin, Scutchfield, and Kryscio have full graduate faculty status.

Certificate Duration

We request that the Certificate be authorized for six years, with potential renewal thereafter. Funding for the K30 program extends to August 31, 2005. We will seek to continue the curriculum with additional funding once this NIH funding expires.

Benefit to Trainees and the Institution

Receipt of the Graduate Certificate in Clinical Research Skills will indicate that the trainee has met the requirements listed above. The Certificate will reflect acquisition of skills that serve as a basis for performing high-quality research and for pursuing a career in academic medicine focused on clinical research. The Certificate offers our junior faculty members the opportunity to acquire the skills necessary to facilitate success in their chosen field and will strengthen the clinical research efforts at the University of Kentucky.