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March 19, 2007

Cleophus Price
Assistant Dean, Graduate Academic Services
University of Kentucky
Gillis Building
CAMPUS 0033

Re: 6-year Review: Graduate Certificate in Clinical Research Skills

Dear Dr. Price:

Thank you for your letter of January 26, 2007, requesting information to support the 6-year review of the Graduate Certificate in Clinical Research Skills. Attached is a description of the certificate program with modifications approved as of October 17, 2005. You provided a list of graduates of the certificate program with the letter. We would like to bring to your attention the following individual who completed the program in September of 2006 but who does not appear on your list:

Cunningham, Larry; DDS, MD

You have requested information on the following issues:

1. A one-or-two sentence statement of the basic academic objective of the certificate.

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.

2. A listing of faculty affiliated with the certificate curriculum

Thomas H. Kelly, PhD (Director)
Jane S. Harrison, PhD (co-Director)
Richard J. Kryscio, PhD (Biostatistician)
C. William Balke, MD
Thomas Foster, PharmD
Jimmi Hatton, Pharm D
Carl G. Leukefeld, PhD

Ada Sue Selwitz, MA
Steve Shedlofsky, MD
Susan S. Smythe, MD
Mary E. Vore, PhD

3. Statement of current admissions requirements/procedures

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 College of Public Health Admissions Committee.

4. Current requirements for the completion of the certificate

To be awarded the Certificate, participants must complete the following course work (12 - credit hours) with an overall GPA of at least 3.0:

CPH 605	Introduction to Epidemiology (or other existing approved course in epidemiology)	3 credit hours
CPH 664	Design and Analysis of Clinical Trials	3 credit hours
CPH 665	Ethical Issues in Clinical Research	3 credit hours
Elective	(Approved by the Director)	3 credit hours
	Research Practicum	0 credit hours

The research practicum requirements involves the selection of a mentor, the submission of a proposal for a K30 seed grant of $5,000 (optional), IRB approval of the proposed research, successful completion of the project, a presentation related to their mentored clinical research experience at a local curriculum-related retreat, a presentation related to their mentored clinical research experience at a national or international meeting, and submission of a paper (journal article) or a funding proposal (K or R01 series) based on the mentored clinical research experience.

5. Rationale for continuation of the Graduate Certificate in Clinical Research Skills

The University of Kentucky is developing a Center for Clinical & Translational Science. C. William Balke, MD, is the Director of this Center. Thomas H. Kelly, PhD, will serve as director of the Training, Education and Mentoring (TEAM) functions of the CCTS. In January 2007, the University of Kentucky applied for an NIH grant to support the development of the CCTS. Graduate-level clinical and translational research education and training programs are under development, and the Graduate Certificate in Clinical Research skills will serve as the entry point for the curriculum.

6. Advertisement for the Graduate Certificate in Clinical Research Skills

Advertisement for the Graduate Certificate in Clinical Research Skills is located on the web at http://www.mc.uky.edu/k30/default.asp

7. A copy of the certificate awarded to graduates is attached.

Please let me know if I can provide any additional information or clarification, and thank you for your help in this matter.

Sincerely,

Thomas H. Kelly
Robert Straus Professor

Career Training in Therapeutics and Translational Research

In recognition of his completion of all requirements of
The University of Kentucky's K30 Curriculum,
This certificate is presented to

XXX

December 2006

Thomas H. Kelly, Ph.D., Program Director

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UNIVERSITY OF KENTUCKY
College of Medicine

GRADUATE CERTIFICATE IN CLINICAL RESEARCH SKILLS

6-Year Review

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 was "Career Training in Therapeutics and Translational Research." The goal of the K30 program was 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.

NIH Funding for the K30 Program (K30-HL004163) ended on August 31st, 2006. However, the training program will be continued with direct support from the College of Medicine Dean's Office. An NIH Roadmap Clinical and Translational Science Award application (C. William Balke, PI) has also been submitted, and the Graduate Certificate in Clinical Research Skills as an integral part of the application.

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 College 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 – now 12 - credit hours) with an overall GPA of at least 3.0:

CPH 605	Epidemiology (or other existing approved course in epidemiology)	3 credit hours
CPH 664	Design and Analysis of Clinical Trials	3 credit hours
CPH 665	Ethical Issues in Clinical Research	3 credit hours
Elective	(Approved by the Director)	3 credit hours

In a document dated June 12, 2003, from Dr. Douglass Kalika, Acting Dean of the Graduate School, to Dr. F. Douglas Scutchfield, it was agreed that 12 credit hours from the Certificate could be transferred towards a Masters in Public Health (MPH). If a student fails to obtain the Certificate, up to 9 credit hours of completed classwork could still be transferred.

CPH 605: 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.

CPH 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.

CPH 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.

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.

Practicum in Clinical Research The focus of the 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 seminar series and in two annual conferences. 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 mentored clinical research experience involves the selection of a mentor, the submission of a proposal for a seed grant of $5,000, IRB approval of the proposed research, and successful completion of the project, with a written summary of the findings. Participants will give a presentation related to their mentored clinical research experience at a local curriculum-related conference and at a national or international meeting. Participants will also prepare a paper (journal article) or a funding proposal (K or R01 series) based on the mentored clinical research experience.

Scholars will have to complete each of the required experiences and have these documented by the Director of the Program. Despite the removal of earned credit hours, trainees will still be expected to complete the work described in the original Certificate Proposal.

Certificate Director

Claire Pomeroy, MD, was appointed as the initial Certificate Director. Dr. Pomeroy left the University of Kentucky in 2003 and is now the Dean of the College of Medicine at the University of California, Davis. Steven I. Shedlofsky, MD, from the College of Medicine, served as the PI for the K30 grant and director of the Certificate Program through August, 2006. Dr. Shedlofsky accepted new administrative responsibilities with the General Clinical Research Center and Thomas H. Kelly, PhD,

became the director at that time. Dr. Kelly is the Director of Training, Education and Mentoring for the Roadmap Clinical and Translational Science Award application.

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 Steve Shedlofsky, MD, Jimmi Hatton, Pharm D, Richard J. Kryscio, PhD, Ada Sue Selwitz, MA, Thomas Foster, PharmD, C. William Balke, MD, Susan S. Smyth, MD, Carl Leukefeld PhD, and Mary Vore, PhD.

Certificate Duration

We request that the Certificate be authorized for an additional six years, with potential renewal thereafter. Funding for the program extends to August 31, 2011. We will seek to continue the curriculum with additional funding once this 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 scholars 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. The Certificate will appear on each Scholar's transcript as an official entry.