MEMORANDUM

DATE: October 29, 2009

TO: David Randall
    University Senate Council

FROM: Jeannine Blackwell, Dean
      The Graduate School

RE: New Ph.D. in Clinical and Translational Science

Graduate voted to approve the proposal for a new Ph.D. in Clinical and Translational Science at its meeting on October 29, 2009.

A few comments from the Graduate School:

1. The program requests that the Graduate School waive the requirement of the GRE, since all students admitted to the new program are required to have a terminal professional doctoral degree (M.D., D.M.D., D.D.S., Pharm. D., D.O., D.N.P., D. Sc., or D. P.H.). The Graduate School regularly waives the requirement for those possessing such a terminal doctoral degree. We will do so on this case as well.

2. The program requests that the Graduate School accept the prior professional degree substitute for 18 hours of the 36 credit Ph.D. minimum requirement. This is in line with our current practice of substituting an earned master’s degree for 18 credits toward the doctorate. It is also in line with the amount of shared coursework accepted for the dual degree program M.D./Ph.D., which is also one year of residence credit, or the equivalent of 18 credits. We will accept the previous professional degree in lieu of 18 credits toward the requirement.

3. The Graduate School currently has a requirement that 3 of the four members of a doctoral advisory committee be from the student’s doctoral program. However, the Graduate School waives this requirement frequently in the case of interdisciplinary degrees (such as Nutritional Sciences or the several programs in pharmacological sciences). We will waive the 3 member rule for CTS students when there is an argument to be made for an interdisciplinary committee.
**UNIVERSITY SENATE REVIEW AND CONSULTATION SUMMARY SHEET**

**Proposal Title:** PhD in Clinical and Translational Science  
Name/email/phone for proposal contact: Thomas Kelly, PhD / thkelly@uky.edu / (859) 323-5206

**Instruction:** To facilitate the processing of this proposal please identify the groups or individuals reviewing the proposal, indentify a contact person for each entry, provide the consequences of the review (specifically, approval, rejection, no decision, and vote outcome, if any) and please attach a copy of any report or memorandum developed with comments on this proposal.

<table>
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<tr>
<th>Reviewed by: (Chairs, Directors, Faculty Groups, Faculty Councils, Committees, etc.)</th>
<th>Contact person Name (phone/email)</th>
<th>Consequences of Review:</th>
<th>Date of Proposal Review</th>
<th>Review Summary Attached? (yes or no)</th>
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<tr>
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<td>Approved</td>
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REQUEST FOR A NEW PROGRAM

Degree title: PhD in Clinical & Translational Science

Major title: Option: Major code in SAP:

Primary College: Medicine

CIP Code: 51.9999 Health Professions and Related Clinical Sciences, Other
Accrediting Agency: N/A

Contacts: Thomas H. Kelly thkelly@uky.edu 323-5206

I. Abstract

The goal of the PhD in Clinical and Translational Science (CTS) program is to improve the health of the citizens of the Commonwealth of Kentucky and the nation by training professionals with terminal professional health care degrees to conduct clinical and translational science research. CTS is an academic discipline that focuses on acceleration of the translation of basic science advances to tangible improvements in public health. The primary target audience for the PhD in CTS program will be exceptional health professionals (e.g., physicians, nurses, dentists, pharmacists, public health professionals) committed to furthering their academic research careers in CTS. The program includes a curriculum providing education in the core competencies of CTS; advanced interdisciplinary education and research training tailored to the research interests and career objectives of the exceptional scholar; and mentored research training. The primary emphasis of mentored research training is to permit scholars to create well-reasoned original research contributions to the discovery of clinical health knowledge and its application. The PhD in CTS will support the development of the next generation of innovative, productive, and transformative researchers and leaders in CTS who will support the translation of discovery into improved patient care and delivery of evidence-based health care to the Commonwealth of Kentucky and to the nation.

II. Program Description

a) Background: Research developments over the past thirty years have resulted in unparalleled advances in basic science discovery within the health sciences. Over this same time frame, the pace of translation of new discoveries into innovations in health care, and the rate of diffusion of new evidence-based health care interventions into communities throughout Kentucky and the nation have remained modest and well below the remarkable rate of advancement in basic science discovery. CTS improves the effectiveness and efficiency by which basic science discovery is translated into improved health care and by which new evidence-based health care innovations are provided to the citizens of the Commonwealth of Kentucky and the nation.

The essential criteria of an academic discipline include (1) a unique field of action; (2) a
defining body of knowledge; (3) active areas of research; (4) intellectually rigorous training and education; and (5) the cultivation of a discipline-specific attitude or ethos. The unique field of action for CTS is the mindset and activities that expand existing and generate new interfaces between basic, clinical, community, and population investigations. It is only at these interfaces where translation is achieved as evidenced by the launching of new collaborations and scientific directions. While derived from the basic and clinical sciences, the defining body of knowledge that emerges for the discipline of clinical and translational science centers on the skills required to engage and promote its particular field of action, namely interface generation and exploitation. This unique skill set includes boundary-spanning strategies in communication, team building, and community engagement. In this regard, the discipline of clinical and translational science can be thought of as a “horizontal” discipline that cuts across the territorial boundaries of its traditional parent disciplines with the broader goal to coordinate and synthesize in contrast to “vertical” specialties with a focus narrowed to specific anatomical areas, techniques, or methodologies. The discipline of clinical and translational science abounds with active areas of research opportunities and programs which often originate at the interface between the traditional disciplines of the basic and clinical sciences. The intellectually rigorous training and education in CTS seeks to establish a multidisciplinary and transdisciplinary mind set which will enable problems to be solved, even if they have never been encountered before. The mental discipline of CTS is promoted and perpetuated by (1) a defined curriculum with didactic and experiential components; (2) clear and accessible career development pathways, and (3) the emergence of an academic home. Members of a discipline commonly have an ethos and set of attitudes which set them apart from those of other disciplines. The ethos or “guiding beliefs” of a discipline become apparent through activities that exemplify the discipline’s unique field of action and defining body of knowledge. The ethos that defines the discipline of clinical and translational science is evident in activities that emphasize the intersections and interfaces between its parent disciplines, namely basic and clinical science, and its overlay of multidisciplinary and transdisciplinary perspectives as evidenced by the emphasis on communication, team building, and community engagement. The Department of Behavioral Science has accepted the opportunity and responsibility to provide training in this new discipline.

The Department of Behavioral Science was formally established in the College of Medicine in 1959. Since 1960, the department has provided basic, clinical and behavioral science instruction for students in the College of Medicine, as well as interdisciplinary health-related clinical research training to students enrolled in many graduate programs on campus (e.g., Anthropology, Communication, Education, Psychology, Martin School, Nursing, Nutritional Sciences, Rehabilitation Science, Sociology, and Social Work). Since its inception, the Department of Behavioral Science has provided intellectually rigorous training and education and has the requisite experience and necessary faculty resources to establish a new PhD program focused on the academic discipline of CTS.

In 2008, an administrative Center for Clinical and Translational Science (CCTS) was established at the University of Kentucky and charged with creating an integrated academic discipline of clinical and translational science at the University of Kentucky. Partial financial support for the Center came through the Office of the Provost. Additional resources for program expansion and enhancement are being pursued through a grant application to the
National Institutes of Health in response to a request for applications to establish academic units to support clinical and translational science (PI: C. William Balke, MD, Associate Provost for Clinical and Translational Science). The aims of the UK CCTS are to 1) promote the circularity of translation – from bench to bedside to community and back again; 2) nurture ongoing research and incubate new research ideas; 3) facilitate the conduct of and training in all aspects of CTS; 4) build public trust that lays the foundation for durable community partnerships, and 5) identify and disseminate nationally-relevant paradigms in interdisciplinary outreach engagement. The Department of Behavioral Science, in collaboration with the CCTS, will serve an active role in the research training of CTS scholars.

UK has significant strength in its existing health-related graduate programs and associated curricula addressing key academic content areas of relevance to clinical and translational science (e.g., Nursing, Pharmacy Practice & Science, Health Sciences, Rehabilitation Sciences, Epidemiology & Biostatistics, Psychology, Communication). In recognition of these existing strengths and resources, the academic discipline of clinical and translational science at the University of Kentucky will be established both through creating a new interdisciplinary graduate program (e.g., the PhD in CTS) and by integrating CCTS training resources and opportunities with existing health-related graduate programs.

The Department of Behavioral Science is establishing a PhD in CTS to support intellectually rigorous research education, training, and career development of CTS scholars at the University of Kentucky. The program will train exceptional professionals or professional scholars committed to leading interdisciplinary CTS research teams and/or sustaining independent research programs that promote innovation and new discovery in health care. As a clinical research department within the College of Medicine with a strong academic foundation of interdisciplinary clinical and translational research training, the Department of Behavioral Science has the expertise and resources to administer the PhD in Clinical & Translational Science. The department has not previously had a formal graduate training program. Chaired by Carl G. Leukefeld, PhD, the department consists of 30 core and 18 jointly appointed faculty members engaged in CTS research and training, with focused excellence in risk-related behaviors, cancer and aging, representing academic training from disciplines of Experimental Psychology, Social Psychology, Clinical Psychology, Clinical Ethics, Epidemiology, Anthropology, Human Development, Sociology, and Social Work. This department has consistently been the top NIH-funded behavioral science department in the nation ($13M in direct annual funding in FY08). Department faculty members collaborate with faculty from virtually every other academic department in the College of Medicine. Faculty members have joint appointments with basic and social science departments across campus. Department faculty in the last year served as chair, co-chair or dissertation committee member for 81 graduate students. Department faculty members regularly teach upper level graduate courses. Departmental funds and faculty research grants are supporting 23 graduate students in this academic year. The Department has a Director of Graduate Studies serving on committees of the Graduate School. Behavioral Science serves as a central focus of interdisciplinary clinical and translational science education and research training in the medical center and in graduate education at UK. The Department has a primary role in medical student teaching. The Department collaborates in graduate education and research with the Departments of Psychiatry, Psychology, Anatomy and Neurobiology, Anthropology,
Counseling and Educational Psychology, Kinesiology and Health Promotion, Pharmacology, Sociology, and with the Colleges of Nursing, Communication and Pharmacy, and with programs in Gerontology and the Nutritional Sciences. In effect, the Department of Behavioral Science serves an active role in the interdisciplinary clinical and translational science education and research training of professional students and advanced graduate students from Medicine, Dentistry, Nursing, Allied Health Professions, Pharmacy, Clinical Psychology, Counseling Psychology, Health, Social and Experimental Psychology, Anthropology, Sociology, Social Work, Educational Psychology, Gerontology, Communication and Public Health.

The PhD in CTS is an interdisciplinary training program. Scholars enrolled in the PhD in Clinical and Translational Science will have completed terminal professional training in interdisciplinary programs, and the curriculum reflects the rigorous training (e.g., medicine, dentistry, pharmacy, nursing, public health) that scholars will have completed prior to enrolling in the program. All entering scholars will complete a common 12-credit curriculum to establish core competencies in CTS. They will then complete a tailored curriculum of interdisciplinary courses designed to meet their research interests and career trajectories. This approach is both feasible and functional because of the rigorous training scholars will have already completed in their professional programs.

The PhD in CTS will not compete with existing graduate training programs. Health-related professionals with career interests that are aligned with the academic content of existing programs will be counseled to complete graduate training by enrolling in existing programs. The PhD in CTS will be marketed to those scholars with interdisciplinary research interests and career trajectories that expand beyond the boundaries of existing graduate programs.

b) Admissions: Admission to the program is limited to applicants with terminal professional degrees (i.e., M.D., D.M.D., D.D.S., Pharm.D., D.V.M., D.O., D.N.P., D.Sc., or Ph.D.) with appropriate domestic licensure to practice professionally and to students in professional health colleges that have dual degree programs. The dual degree programs must permit the PhD in CTS to be used for the PhD training portion of the dual-degree program (e.g., MD/PhD program). All rights and regulations associated with PhD training in dual-degree programs will apply to PhD in CTS students enrolled in this program as part of an approved dual-degree program. Scholars desiring admission into the program will be required to apply to the Graduate School and to the Department of Behavioral Science. To obtain admission, applicants are required to meet the PhD admission standards of the Graduate School. Given that all applicants to this program must have a terminal professional degree (M.D., D.M.D., D.D.S., Pharm.D., D.V.M., D.O., D.N.P., D.Sc., or Ph.D.), we request that they be exempt from the GRE requirement. Applicants must be formally admitted by the Admissions Committee of the CCTS/Department of Behavioral Science.
c) Program of Study: Each scholar will have a PhD Advisory Committee that will play a prominent role in coordinating the curriculum, research training and career development of the scholar in the program. A faculty member in the Department of Behavioral Science who is a full member of the graduate faculty will serve as a primary or co-mentor on each scholar’s PhD Advisory committee. Other members of the PhD Advisory Committee will be selected based on their abilities to support elements of the interdisciplinary research interests and career trajectories of the scholar. Committee membership will be determined based on the scholar’s interdisciplinary research interests rather than on specific departmental affiliation.

The standard pre-qualifying residency requirement of the Graduate School is a minimum of 36 credit hours of coursework. We request that the prior professional degree substitute for 18 of this 36-hour requirement. All enrolled students would still be required to complete 18 credit hours of coursework, consisting of:

- 12 credit hours of core CTS competency-based coursework;
- A minimum of 6 hours of tailored coursework developed in consultation with the major professor and advisory committee.

The post-qualification curriculum consists of:
- A minimum of 4 credit hours of Dissertation Residency Credit coursework;

**Core CTS competency-based coursework (12 credit hours)**

The curriculum is designed to establish knowledge-based and skill-based competencies in communication; professionalism; critical thinking and synthesis of knowledge, planning, management and assessment; and leadership in five areas: 1) CTS methods and technologies, 2) scientific knowledge, 3) measurement and statistics, 4) research integrity (research ethics and responsible conduct of research), and 5) collaboration and team building. These competencies are required of all CTS scholars, regardless of level of training or academic concentration.

**BSC 731/CPH 669: Methods and Technologies in CTS (3 credits)**
This overview course is designed to introduce scholars to the major CTS methods and technologies; enable scholars to interpret and evaluate research findings using these methods and technologies; enhance appreciation for multidisciplinary approaches to CTS; and enhance interdisciplinary vocabulary. The course will consist of presentations followed by open discussion. Topics include experimental, survey and qualitative research methods; community engagement/participatory research; cultural sensitivity; proteomics; genomics; imaging; translation of basic research; clinical trials; epidemiology; health behavior models; extending evidence-based treatments to the community; and health services utilization. Assignments will include readings and experiential opportunities using CTS methods and technologies.

**BSC 732/CPH 670: Interdisciplinary Protocol Development (2 credits)**
This course is designed to orient scholars to leadership and teamwork processes involved in clinical and translational research and to train scholars to function effectively in team settings. Teams will be composed of scholars from different disciplines with a designated principal investigator. Each team will develop a conceptual model for an integrated multidisciplinary
research proposal, in response to an existing NIH Request For Application. Each team member will be responsible for developing one component of the protocol. The course objectives are to understand the role of leadership and teamwork in multidisciplinary clinical and translational research; contribute effectively to a multidisciplinary team engaged in clinical research protocol development; apply knowledge of the responsible conduct of research, statistics and CTS methodologies and technologies to protocol development; and model professional clinical and translational teamwork.

BSC 733/CPH 671: Seminar in Clinical & Translational Science (1 credit)
This seminar series serves as a training and career development resource for all CTS faculty and scholars. This seminar series includes cutting-edge CTS research presentations by faculty; ‘works-in-progress’ presentations by scholars designed specifically to offer constructive peer-review support and feedback from the CTS community; and professional development presentations.

CPH 665: Ethical Issues in Clinical Research (3 credits)
Based on NIH guidelines for responsible conduct of research, this course will present ethical and regulatory guidelines for conducting clinical research. Topics include institutional protection; regulation of human and animal research; subject recruitment/retention; vulnerable populations; research ethics; placebo and washout issues in clinical trials; ethics; genetic research; tissue/DNA banking; data ownership/sharing; misconduct; mentoring; and conflict of interest.

STA 580: Biostatistics (3 credits)
This course will present descriptive statistics; hypothesis testing; paired and unpaired t-tests; ANOVA; contingency tables; log rank test; and regression with biostatistics applications.
Note: STA 570 or equivalent course can be substituted.

Tailored Coursework (minimum of 6 credits)
The tailored curriculum will be designed to provide training needed for the scholar to lead interdisciplinary CTS research teams and/or sustain independent research programs that promote innovation and new discovery. The curriculum will also provide advanced interdisciplinary training to support the development of research skills and expertise tailored to the interests and career trajectory of the individual scholar.

Since all scholars will have completed rigorous basic science training within their professional programs, they will already have acquired a solid academic foundation. Career development for these scholars will be optimized by taking graduate-level courses selected to expand and support their research interests and career trajectories. By nature, interdisciplinary research involves the application of academic knowledge and research methodologies from two or more disciplines. It is expected that the scholar’s major professor and PhD Advisory Committee will work with the scholar to identify appropriately tailored courses and other experiences needed for the scholar to acquire the breadth and depth of knowledge and expertise needed to produce well-reasoned original interdisciplinary research contributions to the discovery of clinical health knowledge and its application. Examples of tailored curricula are provided in an
appendix. The tailored portion of the curriculum must be pre-approved by the Department of Behavioral Science Director of Graduate Studies.

**Mentored Research Training**

Mentored research training is the primary emphasis of the interdisciplinary PhD in CTS program. A major professor (i.e., primary mentor), with the support of a PhD Advisory Committee, will oversee research training and career development. Members of the PhD Advisory Committee will be selected based on their abilities to support elements of the interdisciplinary research interests and career trajectories of the scholar. The membership of the PhD advisory committee must meet established graduate school requirements. The advisory committee will oversee and evaluate the scholar’s progress in the PhD program. The committee will complete annual evaluations of the scholar’s progress towards the degree that will include considerations of coursework, research, and career development. The primary mentor, with input from other members of the advisory committee, will submit annual evaluations to the DGS in May of each year. The DGS will incorporate feedback from other members of the department (e.g., course coordinators) and provide candidates with annual written evaluations.

**Qualifying/Final Examination**

The advisory committee will also conduct qualifying and final examinations. The qualifying examination will consist of both written and oral components. The content of the examination will be tailored to match the scholar’s coursework and research interests and will be designed to evaluate the scholar’s level of interdisciplinary scholarship and competence in CTS. The written components of the qualifying exam will typically consist of a prepared document (e.g., the intellectual elements of a grant application, such as a K-type career development award or an R-type grant application, or a review paper formatted as a peer-reviewed manuscript) along with written responses to content-based questions prepared by members of the advisory committee. The oral component will typically consist of the presentation and defense of the prepared document and responses to oral content-based questions posed by the advisory committee. Successful completion of the CTS PhD final examination will be contingent upon the scholar’s completion and presentation (written and oral) of well-reasoned research that contributes clinically significant publishable CTS knowledge.
III. Resources needed and available for the program

This proposed program will require no additional resources in terms of finances, faculty, or facilities. All didactic courses are currently being taught by existing faculty. There are enough seats in the core and elective courses to accommodate increased scholar enrollment due to creation of this program. The CCTS career development office will have a primary role in identifying and recruiting faculty with requisite expertise to serve on PhD Advisory committees and mentor the research training and career development of scholars. A faculty member in the Department of Behavioral Science who is a full member of the graduate faculty will serve as a primary or co-mentor on the PhD Advisory committee and will coordinate interdisciplinary collaboration and training expectation among the Advisory committee.

IV: Academic Program Approval Checklist

01: Are more Kentuckians ready for postsecondary education?

A. Entrance requirements: all prospective scholars must either have professional degrees (MD, DMD, DDS, PharmD, DNP, DrPh) or be participating in dual-degree programs within an existing professional training program.
B. Transfer requirements: N/A
C. Recruitment Plans: This is an additional degree program for scholars possessing terminal professional degrees, and recruitment for this program will target professionals and professional scholars on campus through the Center for Clinical and Translational Science.

02: Are more students enrolling?

A. Program demand: Professionals who wish to conduct clinical and translational research will benefit from advanced research training. Anticipated number of scholars is approximately eight per year.
B. Detailed recruiting plans: see 01.C above
C. Equity: This program will not discriminate on the grounds of race, color, ethnic origin, national origin, creed, religion, political belief, sex, sexual orientation, marital status, age, veteran status, or physical disability

03: Are more students advancing through the system?

A. Time to graduation: It is anticipated that most scholars will complete training on a full-time basis with career development support. Research career development support is available intramurally (e.g., College of Medicine Physician Scientist and Clinician Scholar Programs) or extramurally (e.g., institutional or individual career-development fellowships). It is anticipated that full-time scholars will complete the PhD portion of the program in 3 to 4 years. Scholars completing the program on a part-time basis will do so in 4 to 6 years. Scholars participating in a dual-degree program typically complete both professional and PhD training in a 7-year period.
B. Practicum experience: All scholars will work under close supervision of a primary mentor and a PhD advisory committee on research projects that all agree will lead to a dissertation and to further career development opportunities.

C. Reason for offering the program: Education, training and career development are the cornerstones of the emerging academic discipline of clinical and translational science (CTS). A principal objective of the interdisciplinary PhD program is to provide education, training and career development support for professional scholars and faculty at UK. The program will train the next generation of clinical and translational scholars who will provide academic innovation, productivity, and transformations in research and leadership in all areas of academic health, as well as bring competencies in clinical and translational research to their professional practices in their community practices, thereby enhancing the infrastructure for conducting responsible research in our Kentucky communities and translating evidence-based interventions to the citizens of the Commonwealth in a more efficient manner. This education program will be a key element of the education, training and career development functions of the newly established CCTS and further the University’s efforts to integrate with the national consortium of clinical and translational science centers sponsored by the NIH.

D. Delivery. Plans are being made to offer all of the core CTS Competency courses using a distance-based platform. Courses and training opportunities focused on core competencies required of all CTS scholars, regardless of academic focus, will be available through distance-learning platforms recognizing the needs of the adult learner. However, the primary focus of this program is mentored research training that, by necessity, must be tailored to the needs of the individual scholar.

E. Collaborative Efforts. There are no such plans at this point in time.

04. Are we preparing Kentuckians for life and work?

A. How does the program prepare Kentuckians for life and work? This program is designed to provide individuals committed to leading interdisciplinary CTS research teams and/or sustaining independent research programs that promote innovation and new discovery.

B. Accreditation expectations. No formal accreditation is needed for this program. However, there are ongoing efforts at the national level to standardize the competencies needed for clinical and translational research, and this program will incorporate national standards as they become available.

C. Are their licensure, certification, or accreditation requirements for graduates of this program? No

D. Expected degree productivity: five per year

05. Are Kentucky’s communities and economy benefiting?

A. External Advisory Groups: The CCTS has an External Advisory Committee which will review and offer advice on this degree program.

B. Employment expectations: This degree program will provide expanded research training for scholars with terminal professional degrees (MD, DDS, PharmD); it is designed to establish the next generation of innovative, productive, and transformative researchers
and leaders in CTS. The interdisciplinary training program is designed to enhance opportunities for professionals to engage in and lead programs of clinical and translational research. Program graduates will have the opportunity to find employment in academic, clinical, and industrial settings requiring both professional and research opportunities and expectations.

C. Other benefits. This degree program is designed to increase the clinical research skills of our junior faculty and professional scholars. It should be viewed as an integral part of the university’s quest for top 20 research status.

D. Specific benefits. See above.
Appendix
Representative Tailored Curricula

1. For a professional scholar interested in examining genetic markers among a selected group of cancer patients, the committee might develop a curriculum that includes:

   * **BCH 608 Biomolecules and Molecular Biology**
   * **IBS 603 Cell Biology**
   * **MI 604 Experimental Genetics**
   * **CPH 664 Design and Analysis of Clinical Trials.**

2. For a scholar interested in health-services utilization among Alzheimer’s patients, the curriculum might include basic and/or applied biostatistics and/or epidemiology courses, such as:

   * **CPH 632 Mixed Models in Public Health**
   * **CPH 711 Chronic Disease Epidemiology**
   * **ANA 780 Mechanisms of Neurologic Disease**
   * **NUR 914 Population-Based Health Care Delivery.**