

April 14, 2008

TO: Kaveh Tagavi  
Senate Council  
201 Main Bldg.  
CAMPUS 0032

Dear Dr. Tagavi,

I am transmitting to you the Proposal for the Graduate Certificate in Clinical and Translational Science. The Graduate Council approved this Certificate on April 10, 2008.

Sincerely Yours,

Jeannine Blackwell, Dean  
The Graduate School

Cc: Sheila Brothers

## Brothers, Sheila C

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**From:** Mendiondo, Marta  
**Sent:** Monday, November 17, 2008 12:22 PM  
**To:** Brothers, Sheila C  
**Cc:** Mendiondo, Marta  
**Subject:** Senate Academic Programs Committee Meeting Nov 14th

Sheila,

The Senate Academic Programs Committee approved the following programs, assuming all necessary routing sheets are available:

Graduate certificate in Clinical and Translational Science

Tx,  
Marta

*Marta S. Mendiondo, PhD*  
*University of Kentucky College of Public Health - Biostatistics Department*  
*121 Washington Avenue - Suite 201 - Lexington, Kentucky 40536-0003*  
*Sanders Brown Center on Aging*  
*Rm 309B Sanders-Brown Bldg. - 800 S. Limestone St. - Lexington, KY 40536 - 0230*  
*(859) 257-1412 ext 274 - FAX (859) 323-2866*  
[marta@email.uky.edu](mailto:marta@email.uky.edu)

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**UNIVERSITY SENATE REVIEW AND CONSULTATION SUMMARY SHEET**

**Proposal Title:** *Insert name here* GRADUATE Certificate in Clinical and Translational Science  
**Name/email/phone for proposal contact:** *Insert information here* Thomas H. Kelly / thkelly@uky.edu / 3-5206

**Instruction:** To facilitate the processing of this proposal please identify the groups or individuals reviewing the proposal, identify 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.

Reviewed by: (Chairs, Directors, Faculty Groups, Faculty Councils, Committees, etc)	Contact person Name (phone/email)	Consequences of Review:	Date of Proposal Review	Review Summary Attached? (yes or no)
Dept. of Behavioral Science	Tom Kelly thkelly@uky.edu 3-5206	APPROVED <i>[Signature]</i>	10-4-07	no
Co Medicine Curriculum Committee	Ed DARRILL Jennings edjenn@uky.edu 7-5286	APPROVED <i>[Signature]</i>	11-19-07	no
Co Medicine Faculty Council	Jennifer BRUECKNER jenn.f.brueckner@uky.edu 3-3780	Jennifer Brueckner APPROVED	1-31-08	no
Co Medicine Dean	Jay PERMAN 3-6582	<i>[Signature]</i>	2-1-08	no
HCCC	3-6589	<i>[Signature]</i>	3/18/08	No

## REQUEST FOR A NEW PROGRAM

Please Circle One				
Associate	Bachelor	Masters	Doctoral	Professional

Degree Title: Graduate Certificate in Clinical and Translational Science

Major Title:                      Option:                      Major code in SIS:

Primary College: Medicine

CIP Code (contact Registrar's Office if unknown): 51.1099 Clinical/Medical Laboratory Science and Allied Professions, Other

Accrediting Agency (if applicable)

Within the Department, who should be contacted for further information about the proposed program?

Name: Thomas H. Kelly Email: thkelly@uky.edu Phone 3-5206

I. Submit a 1-2 page abstract narrative of the program proposal summarizing how this program will prepare Kentuckians for life and work, plans for collaboration with other institutions, and participation in the Kentucky Virtual University.

II. Provide a comprehensive program description [complete curriculum, (Note: for Undergraduate program they would include this: by course/hours; i.e., College required courses, University Studies, Premajor courses, major courses, option courses, electives;)] Include how program will be evaluated and how student success will be measured (evaluative items may include retention in the major from fall to fall, success rate of completion for core courses, academic performance in suggested program electives. . . .)

III. Explain resources (finances, facilities, faculty, etc.) needed and available for program implementation and support.

### IV. Academic Program Approval Checklist

01. Are more Kentuckians ready for postsecondary education?
  - A. Entrance requirements:
    1. Test scores (GRE, GMAT, LSAT, MCAT, ACT, SAT, etc.)
    2. High school/college GPA
    3. Other required discipline knowledge unique to the proposed program
  - B. Transfer requirements:
    1. College transfer GPA
    2. Recommended/required preparatory courses (prerequisite courses)
  - C. Recruitment plans
    1. Plans to ensure success of students coming from "feeder institutions" (either colleges or high schools)
    2. Recruitment and marketing strategies to enroll a diverse student

population

**02. Are more students enrolling?**

- A. Explain the demand for the program by providing the following information:
  - 1. Anticipated number of students from other majors (including undeclared).
  - 2. New students entering the programming (including transfers).
- B. Detail recruitment plans (include specific plans to attract non-traditional students, including minorities, and to address gender related issues).
- C. Contact the Associate Vice President for Employment Equity to obtain EEO plan and status information.

**03. Are more students advancing through the system?**

- A. What is the anticipated time-to-graduation for full-time students entering the program?
- B. Explain any cooperative or practicum experience required to complete the program.
- C. Why do you desire to offer the program? (See 2A) Why is UK the right place to offer this program?
  - 1. Include a list of other Kentucky institutions offering similar or related programs at this and other levels.
  - 2. List courses from in-state institutions that will transfer into the program
    - a. 48 Hour General Education Transfer Component
    - b. 12 Hour Transfer Articulation Agreement
  - 3. List courses offered that will transfer into similar programs at other state institutions.
  - 4. Provide information about completed, signed articulation agreements.
- D. Delivery
  - 1. What plans are in place for delivering this program through the Kentucky Virtual University or other distance learning technologies? (Council on Postsecondary Education wants special attention given to KVVU courses)
  - 2. What courses can be offered in a non-traditional mode?
- E. Collaborative Efforts
  - 1. Future proposals must provide evidence of consultation with other programs in the state and either documentation of collaborative agreements or strong arguments for why they are not feasible.
  - 2. Collaborative agreements should define shared use of resources to improve program quality, efficiency, and student placement.

- 04. Are we preparing Kentuckian's for life and work?**
- A. How does the program prepare Kentuckians for life and work?
  - B. What are the accreditation expectations for this program?
  - C. Are there licensure, certification or accreditation requirements for graduates of this program?
  - D. What are the projected degree completions? (CPE Productivity triggers are: 12 Associate and Baccalaureate, 7 Master and Specialist, 5 Doctoral per year)
- 05. Are Kentucky's communities and economy benefiting?**
- A. Describe external advisory groups involved in the development of this program (e.g., disciplinary groups, community, government, business, labor interests).
  - B. What are the employment expectations for graduates? Document the contributions of the program to current workforce needs in the state.
  - C. What other benefits to the Kentucky's community and economy will the program provide?
  - D. Explain specific benefits of the program.
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## GRADUATE CERTIFICATE IN CLINICAL AND TRANSLATIONAL SCIENCE

### Background

The University of Kentucky has established a Center for Clinical and Translational Science (CCTS). Partial financial support for this Center has been requested via 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, Senior Associate Dean for Clinical Research). Among the key elements required of the academic units of the CCTS is the development of programs to support research education, training, and career development.

The Graduate Certificate in Clinical and Translational Science will serve as the entry point for graduate-level training in clinical and translational science. 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: CTS methods and technologies, scientific knowledge, measurement and statistics, research integrity (research ethics and responsible conduct of research), and collaboration and team building. These competencies are required of all CTS scholars, regardless of level of training or academic concentration. The Certificate curriculum will integrate scholars with diverse backgrounds and training into a common training environment with group assignments and shared professional socialization experiences.

### Target Audience and Admission Requirements

The Certificate in Clinical and Translational Science will be available to (a) faculty members at the University of Kentucky who are planning to participate in clinical and translational research but lack previous training and the skills necessary for clinical and translational research, (b) professionals in postgraduate training at the University of Kentucky, including residents and fellows in the College of Medicine, College of Pharmacy, and College of Dentistry; (c) graduate students in health-related PhD and MS programs; and (d) project managers and other staff members interested in contributing to clinical and translational science; and (e) professionals practicing in the community. Trainees will make a substantial time commitment to their clinical and translational research and career development.

Students admitted to the Certificate curriculum must meet the minimum Graduate School requirements for admission either for post baccalaureate status or as degree-seeking students, if applicable, and must be approved for admission by the CCTS Training, Education, and Mentoring (TEAM) Leadership Committee.

### Goals and Objectives 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 competencies necessary to participate in clinical and translational research. The knowledge and skills obtained will support participants' ability to attract research funding and publish the results of that work in appropriate peer-reviewed journals. The Department of Behavioral Science in the College of Medicine is the organizational unit responsible for the Certificate. The hours earned 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 Medical Sciences.

After completing coursework and the research practicum, certificate scholars will be prepared to step into ongoing clinical and translational protocols with minimal training, and serve valuable roles in supporting these protocols.

### Certificate Requirements

To be awarded the Certificate, participants must complete the following coursework (currently a total of 12 credit hours) with an overall GPA of at least 3.0:

BSC 731	Methods & Technologies in CTS	3 credit hours
BSC 732	Interdisciplinary Protocol Development	2 credit hours
BSC 733	Seminar in CTS	1 credit hour
CPH 665	Ethical Issues in Clinical Research	3 credit hours
STA 580	Biostatistics I (or equivalent)	3 credit hours
	Research Practicum	

Graduate School policies regarding transfer of credit for Certificate requirements will apply.

#### **BSC 731/CPH 669: Methods and Technologies in CTS (3 credits)**

(Currently offered in the spring semester and during the summer)

This overview course is designed to introduce students to the major CTS methods and technologies, enable students 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. Homework assignments will include readings and experiential opportunities to work with these CTS methods and technologies.

#### **BSC 732/CPH 670: Interdisciplinary Protocol Development (2 credits)**

(Offered in fall 2007 as BSC 772-003; currently offered in the fall semester)

This course is designed to orient students to leadership and teamwork processes involved in clinical and translational research and to train students to function effectively in team settings. Teams will be composed of students 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 through effective interaction and communication with leadership and team members.

#### **BSC 733/CPH 671: Seminar in Clinical & Translational Science (1 credits)**

(Offered in fall 2007 as BSC 772-002; currently offered during the fall and spring semesters)

TEAM sponsors a continuously running bi-monthly seminar series that 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, 'work-in-progress' presentations by scholars designed specifically to offer constructive peer-review support and feedback from the CTS community, and professional development presentations. Depending on a scholar's stage of development, presentations may consist of project updates, reviews of papers or grants, or practice sessions for podium talks at national meetings. Discussion/critiques will be lead by a review panel consisting of the scholar's mentors and additional reviewers with relevant research experience and other program scholars. Relevant papers and grants in-preparation will be distributed several weeks in advance to provide sufficient time to prepare critiques. This series will also provide career enhancement seminars led by faculty from across the university on such topics as "Getting the Most from your Mentored Training Experience," "Grantsmanship 101: Selecting the Right Funding Mechanism," "Facilitating Neutrality in Studying Special Populations Diverse from the Backgrounds of the Research Team," and "Effective Time Management Strategies". This seminar course is designed to engage certificate scholars in critical review of clinical and translational research at University of Kentucky and to train students to incorporate a multidisciplinary cooperative approach to clinical and translational research. The course objectives are to understand and contribute to the development of clinical and translational research; develop effective interdisciplinary scientific communication skills; apply knowledge of and responsible conduct of research and CTS methodologies and technologies in oral, written communication; model professional clinical and translational demeanor through effective interaction and communication; and demonstrate respect for diverse CTS methodologies and technologies.

#### **CPH 665: Ethical Issues in Clinical Research (3 credits)**

(Next offering tentatively scheduled for fall 2008)

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 and genetic research, tissue/DNA banking, data ownership/sharing, misconduct, mentoring, and conflict of interest.

#### **STA 580: Biostatistics (3 credits)**

(Currently offered during the fall and spring semesters)

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.

#### **Research Practicum**

In addition to formal coursework, a six-month clinical and translational research practicum is required for certificate completion. Completion of Graduate Certificate coursework will include certification of the competencies needed to participate effectively in clinical and translational research. As such, Certificate scholars will be prepared to step into ongoing clinical and translational protocols with minimal training, and serve valuable roles in supporting these protocols. Prior to entering the research practicum, the certificate scholar, in collaboration with his/her mentor, must submit a detailed research training plan that includes a description of the research project, a list of objectives and expected outcomes for the scholar in relation to the project, a detailed plan for measuring objectives and monitoring progress, a proposed timeline of scholar activities, and description of the mentoring plan. The research practicum must contribute to original research and peer-reviewed publications. This plan will constitute a 'contract' signed by scholar and mentor. This plan will be submitted to the Certificate Curriculum Faculty for review, approval and research funding consideration.

### Certificate Curriculum Faculty and Graduate Faculty Status

Name	Department(s)	Graduate Faculty Status
Thomas H. Kelly PhD (Director)	Behavioral Science, Psychiatry, Psychology, Nutritional Science	Full
Jane S. Harrison PhD (Co-Director)	College of Medicine Dean's Office	N/A
Richard J. Kryscio PhD (Biostatistician)	Statistics, Public Health	Full
C. William Balke MD	Physiology	Full
Thomas Foster PharmD	Pharmacy	Full
Jimmi Hatton Pharm D	Pharmacy	Full
Carl G. Leukefeld PhD	Behavioral Science, Communications, Sociology	Full
Ada Sue Selwitz MA	Behavioral Science	N/A
Steve Shedlofsky MD	Toxicology	Full
Susan S. Smyth MD	N/A	pending
Mary E. Vore PhD	Toxicology	Full
Mitzi Schumacher PhD	Behavioral Science	Full
Brian Stevenson PhD	Microbiology, Immunology & Molecular Genetics	Full

### Certificate Director

Thomas H. Kelly, PhD, Robert Straus Professor of Behavioral Science and Director of TEAM for the CCTS will serve as director.

### 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 Steven Shedlofsky, MD, Jimmi Hatton, PharmD, Richard J. Kryscio, PhD, Ada Sue Selwitz, MA, Thomas Foster, PharmD, C. William Balke, MD, Susan S. Smyth, MD, Carl Leukefeld, PhD, Mary Vore, PhD, Mitzi Schumacher, PhD, and Brian Stevenson, PhD.

### Certificate Proposal

We request that the Certificate be authorized as a new certificate, with potential renewal thereafter. Funding for the program has been provided by the Jay Perman, Dean of the College of Medicine, and 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 and Translational Science 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 clinical and translational research. The Certificate offers our scholars the opportunity to acquire the competencies necessary to facilitate research in clinical and translational science and will strengthen the clinical research efforts at the University of Kentucky and the Commonwealth of Kentucky. The Certificate will appear on each Scholar's transcript as an official entry.



UNIVERSITY OF KENTUCKY

*D r e a m • C h a l l e n g e • S u c c e e d*

COLLEGE OF PUBLIC HEALTH

September 28, 2007

Dr. Thomas Kelly  
University of Kentucky  
Behavioral Science  
134 College of Medicine Office Building  
Lexington, KY 40536-0086

Dear Dr. Kelly:

Thank you for sharing the proposal for creation of the Graduate Certificate in Clinical and Translational Science which is designed to serve as the entry point for graduate-level research training in clinical and translational science.

While the possibility of modifying the Graduate Certificate in Clinical Research Skills for this purpose was considered, the faculty of the College of Public Health requested that the curriculum for this certificate remain unchanged because it served as a recruiting platform and was effectively integrated with graduate programs in the College of Public Health. Since the Graduate Certificate in Clinical and Translational Science and the Graduate Certificate for Clinical Research Skills have distinct goals and objectives, different target populations, and modest overlap in curriculum requirements (one course: CPH 665, Ethical Issues in Clinical Research), they are distinct curricula and provide different training opportunities for scholars. Since you are serving as the director of both Certificates, you can advise scholars as to which curriculum is most suitable to their career development. I do not foresee any adverse consequences to the Graduate Certificate for Clinical Research Skills associated with the establishment of the Graduate Certificate in Clinical and Translational Science and support your efforts in this matter.

Sincerely,

*Stephen W. Wyatt*  
Stephen W. Wyatt, DMD, MPH  
Dean

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Office of the Dean

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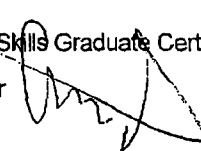
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DEPARTMENT OF STATISTICS

# Memo

**To:** Thomas H. Kelly, PhD, Clinical Research Skills Graduate Certificate Director  
**From:** Arnold Stromberg, PhD, Department Chair  
**Date:** 10/10/2007  
**Re:** Curriculum Revision: Clinical and Translational Science



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I understand that you are proposing to modify the curriculum requirements to create a new Certificate in Clinical and Translational Science. One proposed course requirement for the new certificate is for scholars to complete STA 580, Biostatistics I (or STA 570 as an equivalent course). The Department of Statistics agrees to allow STA 580 to be listed as part of the curriculum requirements for the Certificate Program and to permit scholars enrolled into the Certificate Program to take the course.