

UNIVERSITY SENATE REVIEW AND CONSULTATION SUMMARY SHEET

REVISION of

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 35206 | <i>[Signature]</i> | <i>[Signature]</i> | NO |
| College of Medicine Curriculum Committee | C DARRYL JENNINGS cdjenn@uky.edu 7-5286 | APPROVED <i>[Signature]</i> | 2-6-09 | NO |
| College of Medicine Faculty Council | JENNIFER BRUECKNER jennifer.brueckner@uky.edu 3-5261 | <i>[Signature]</i> | 2-18-09 | NO |
| College of Medicine Dean | Jay Parman 3-6582 | <i>[Signature]</i> | 2-19-09 | NO |

Subject: Graduate Certificate issue

Date: Friday, December 19, 2008 12:07 PM

From: Randall, David C <randall@email.uky.edu>

To: "Thomas H. Kelly" <thkelly@uky.edu>

Cc: "Brothers, Sheila C" <sbrothers@uky.edu>

Tom,

Sheila Brothers, whom you will come to know well, has helped me on the certificate issue for CTS. Her minutes have not been approved yet, but that's not a problem. The text of the relevant portion reads:

"There were a variety of issues raised by SC members; one of the thorniest involved a proposed requirement of a six-month research practicum. SC members were concerned that there was no mention of a specific course, no mention of whether or not the six-month's research was at full-time or part-time student status, and no mention of the number of associated credit hours.

The SC determined that the proposal for a new Graduate Certificate in Clinical and Translational Sciences should be returned to the department for revision. It was thought that a revised proposal might not need additional formal review by all the relevant councils – review by a council chair could be sufficient."

My reading and recollection is that the SC thought the proposal would not need to jump through all the customary hoops – perhaps Heidi and Jeannine (HCCC and GC chairs, respectively) can review it and sign off on the changes. Since the Senate's Academic Programs Committee did not identify any problems with the proposal, it doesn't seem like a good use of their time to re-review something they didn't object to in the first place. Therefore, if Heidi/Jeannine have no objections, I believe that the SC can review this again in January. I am not sure about what other committees you have to run this by within the MC, but that had probably better be done prior to sending it to the two council chairs.

Once this is ready for council chair/SC approval, please forward the proposal to Sheila, and she will take care of sending it to Jeannine and Heidi and putting it on an SC agenda.

Hope this helps!!

Dave



UNIVERSITY OF KENTUCKY

Memorandum

To: Carl Leukefeld, PhD

From: Thomas H. Kelly, PhD
Director, Certificate in Clinical and Translational Science

Date: December 22, 2008

Re: Modification of Proposed Certificate in Clinical and Translational Science

College of Medicine
Department of Behavioral Science
College of Medicine Office Bldg.
Lexington, KY 40536-0086
(859) 323-5771
Fax: (859) 323-5350
www.uky.edu

The Senate Council has requested modifications of the proposed Certificate in Clinical and Translational Science to address two concerns.

First, students should be given information on the time requirements and expectations for the research practicum, along with a means of determining whether they have successfully completed the requirement.

To address this concern, we propose adding a 1-credit independent research course requirement to the Certificate curriculum. Students can take BSC 790 to meet this requirement, although any equivalent course is available, as well. This requirement will serve as a minimum standard for completing the research practicum requirement and should provide guidelines and feedback for students as requested by the Senate Council. This change will increase the Certificate curriculum from 12 credit hours to 13 credit hours.

Second, only faculty having graduate faculty status should be included as program faculty.

We have removed the two individuals who do not currently have graduate faculty status from the Curriculum faculty.

These changes are identified in track-change mode on the attached file.

Since the Certificate in Clinical and Translational Science had been approved by all committees prior to Senate Council review, the Senate Council suggested that the proposal modification would not need to jump through all the customary hoops – and that Drs. Anderson and Blackwell (HCCC and GC chairs, respectively) could review it and sign off on the changes.

This memorandum is to request your approval of these changes prior to sending them to Drs. Anderson and Blackwell for consideration.

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 Comm. ttee | E DARRILL JENNINGS edjenn@uky.edu 7-5286 | APPROVED C. Arnold Goyens | 11-19-07 | NO |
| CO MEDICINE Faculty Council | Jennifer Beckner jennifer.beckner@uky.edu 3-3780 | Jennifer Beckner APPROVED | 1-31-08 | NO |
| CO MEDICINE Dean | Jay Racman 3-6582 | <i>[Signature]</i> | 2-1-08 | NO |
| HCCC | 3-6589 | <i>[Signature]</i> | 3/18/08 | NO |

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.

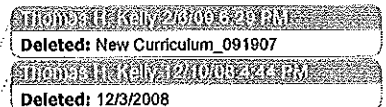
Target Audience and Admission Requirements

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 13 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 |
| BSC 790 | Research Practicum (or equivalent) | 1 credit hour |

~~11/01/08 11:46:17 AM 2/20/08 3:30 PM~~
Deleted: 12

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

~~11/01/08 11:46:17 AM 2/20/08 3:30 PM~~
Deleted:

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

~~11/01/08 11:46:17 AM 2/20/08 3:30 PM~~
Deleted: New Curriculum_091907

~~11/01/08 11:46:17 AM 2/20/08 3:30 PM~~
Deleted: 12/3/2008

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 (1 credit)

A 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. 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, and a detailed plan for measuring objectives and monitoring progress. The practicum must meet the minimum requirements of 1 graduate credit in a supervised individually directed research course, such as BSC 790, Research in Medical Behavioral Science. The research practicum must contribute to original research and peer-reviewed publications. This plan will be submitted to the Certificate Curriculum Faculty for review and approval.

- ~~Thomas H. Kelly 12/30/07 10:46 PM~~
- Deleted: Practicum**
- ~~Thomas H. Kelly 12/30/07 3:21 PM~~
- Deleted: In addition to formal coursework, a six-month**
- ~~Thomas H. Kelly 12/30/07 12:42 PM~~
- Deleted: Prior to entering the research practicum, t**
- ~~Thomas H. Kelly 12/30/07 12:42 PM~~
- Deleted:**
- ~~Thomas H. Kelly 12/30/07 3:31 PM~~
- Deleted: , a proposed timeline of scholar activities, and description of the mentoring plan**
- ~~Thomas H. Kelly 12/30/07 2:16 PM~~
- Deleted: This plan will constitute a 'contract' signed by scholar and mentor.**
- ~~Thomas H. Kelly 12/30/07 5:46 PM~~
- Deleted: .**
- ~~Thomas H. Kelly 12/30/07 2:03 PM~~
- Deleted: and research funding consideration**
- ~~Thomas H. Kelly 12/30/07 2:01 PM~~
- Deleted: New Curriculum_091907**
- ~~Thomas H. Kelly 12/30/07 4:33 PM~~
- Deleted: 12/3/2008**

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 | Full |
| Mary E. Vore PhD | Toxicology | Full |
| Mitzi Schumacher PhD | Behavioral Science | Full |
| Brian Stevenson PhD | Microbiology, Immunology & Molecular Genetics | Full |

~~Thomas H. Kelly 12/10/08 4:40 PM~~
Formatted: Strikethrough

~~Thomas H. Kelly 12/10/08 4:40 PM~~
Formatted: Strikethrough

~~Thomas H. Kelly 12/10/08 4:40 PM~~
Deleted: pending

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, Thomas Foster, PharmD, C. William Balke, MD, Susan S. Smyth, MD, Carl Leukefeld, PhD, Mary Vore, PhD, Mitzi Schumacher, PhD, and Brian Stevenson, PhD.

~~Thomas H. Kelly 2/5/09 8:42 AM~~
Deleted: , Ada Sue Selwitz, MA

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.

~~Thomas H. Kelly 2/6/09 3:41 PM~~
Deleted: New Curriculum_091907

~~Thomas H. Kelly 12/10/08 4:42 PM~~
Deleted: 12/3/2008

Brothers, Sheila C

From: Lindsay, Jim D.
Sent: Thursday, March 05, 2009 2:18 PM
To: Brothers, Sheila C
Subject: RE: Revised Proposal for Grad Cert In Clinical and Translational Science

March 5th, 2009

T R A N S M I T T A L

TO: David Randall, Chair and Sheila Brothers, Coordinator
Senate Council

FROM: Heidi Anderson, Chair and Jim Lindsay, Coordinator
Health Care Colleges Council

Dr. Heidi Anderson has reviewed and approved the revised proposal: Graduate Certificate in Clinical and Translational Science.

Jim Lindsay
Health Care Colleges Council Coordinator
Associate Provost for Faculty Affairs Office
University of Kentucky, 205 Frazee Hall
Lexington, KY 40506-0031 Ph. (859) 323.6638
www.uky.edu/Provost/AcademicCouncil/council.php

From: Brothers, Sheila C
Sent: Wednesday, March 04, 2009 11:06 AM
To: Lindsay, Jim D.; Nikou, Roshan
Cc: Kelly, Thomas; Anderson, Heidi Milia; Blackwell, Jeannine
Subject: Revised Proposal for Grad Cert In Clinical and Translational Science

Hello, Jim & Roshan! When the SC reviewed the attached document, there were a few concerns. Tom graciously took the proposal back and reworked it a tad. (The initial pages of the attached proposal outline the concerns and solution.)

At the time when this was discussed, the SC opined that full council review by both the HCCC and GC was unnecessary – review by the council chairs would be sufficient.

Could both of you ask that your respective council chair look over this proposal to ensure that the changes do not have unintended consequences, etc.? When that review is finished, please let me know and I'll again place this on a SC agenda.

Thank you,
Sheila

Sheila Brothers
Office of the Senate Council
203E Main Building, -0032
Phone: (859) 257-5872
scinn1@uky.edu
<http://www.uky.edu/usc2/>

Brothers, Sheila C

From: Jackson, Brian A
Sent: Friday, March 13, 2009 1:29 PM
To: Brothers, Sheila C
Cc: Blackwell, Jeannine; Lindsay, Jim D.; Kelly, Thomas; Nikou, Roshan
Subject: FW: Revised Proposal for Grad Cert In Clinical and Translational Science
Attachments: Grad Cert Clinical & Translational Sci - New Grad Cert_Complete1.pdf

Hi Sheila:

We are perfectly content with the modifications, but recommend one very minor wording change. In the narrative for the Research Practicum I recommended to Dr. Kelly that we delete the word "detailed" on line 6 (. . . must submit a detailed . . .). The intent is to try to reduce concerns that there appears to be a lot of work required for a one credit-hour course. Dr. Kelly is in complete agreement with this change.

Best wishes,

Brian

From: Blackwell, Jeannine
Sent: Sunday, March 08, 2009 4:18 PM
To: Jackson, Brian A
Subject: FW: Revised Proposal for Grad Cert In Clinical and Translational Science

Brian,

Did Roshan pass this on to you for review? Would you do so?

Dr. Jeannine Blackwell
Dean of the Graduate School
Interim Associate Provost for Undergraduate Education
University of Kentucky, Lexington, KY 40506-0033
859-257-1759
email: blackwell@uky.edu
website: www.gradschool.uky.edu

From: Brothers, Sheila C
Sent: Wednesday, March 04, 2009 11:06 AM
To: Lindsay, Jim D.; Nikou, Roshan
Cc: Kelly, Thomas; Anderson, Heidi Milia; Blackwell, Jeannine
Subject: Revised Proposal for Grad Cert In Clinical and Translational Science

Hello, Jim & Roshan! When the SC reviewed the attached document, there were a few concerns. Tom graciously took the proposal back and reworked it a tad. (The initial pages of the attached proposal outline the concerns and solution.)

At the time when this was discussed, the SC opined that full council review by both the HCCC and GC was unnecessary – review by the council chairs would be sufficient.

Could both of you ask that your respective council chair look over this proposal to ensure that the changes do not have unintended consequences, etc.? When that review is finished, please let me know and I'll again place this on a SC agenda.

Thank you,
Sheila