July 11, 2002

Douglass S. Kalika, Ph.D., Chair
 Graduate Council
 359 Patterson Office Tower
 CAMPUS 0027

Dear Dr. Kalika:

At its meeting on February 26, 2002, the Academic Council for the Medical Center approved, and recommends approval by the Graduate Council, for the proposal from the College of Medicine to add SPH 664, Design and Analysis of Clinical Trials; SPH 665, Ethical Issues in Clinical Research; SPH 666, Practicum in Clinical Research I; SPH 667, Practicum in Clinical Research II; and, SPH 668, Practicum in Clinical Research III.

Thank you for your attention to this request.

Sincerely,

Phyllis P. Nash, Ed.D.
Associate Vice President for Academic and Student Affairs

PPN:co
i:\aadata\council\letters\grad.doc

attachments

c: Emery A. Wilson, M.D.
   Lois Nora, M.D.
   Jacque Hager
   Cindy Todd

JUL 15 2002

ORIGINAL
June 20, 2002

MEMORANDUM

TO: James W. Holsinger, Jr., MD
Chair, Academic Council for the Medical Center

FROM: Emery A. Wilson, MD
Dean and Associate Vice President for Clinical Services

RE: New Course Applications(s)

The Faculty Council of the College of Medicine has approved and submits for your consideration and approval the proposed course application(s) that were reviewed by the Medical Center Academic Council earlier this year. At the time of the review there were suggested changes to some of the submitted courses. Please see below.

Courses with no changes recommended and approved by the MCAC

012 SPH 664 - Design & Analysis of Clinical Trials
Description: This course will introduce the fundamental concepts used in the design of Phase I-IV clinical trials and will also introduce statistical methodology associated with the analysis of data from clinical trials.
Justification: This course presents advanced biostatistical concepts associated with clinical research. No such course currently exists. This course is required for participants in the Graduate Certificate in Clinical Research Skills program.

013 SPH 665 - Ethical Issues in Clinical Research
Description: This course will present ethical and regulatory guidelines for Conducting clinical research (i.e., clinical trials).
Justification: No other course is offered on this topic. The NIH requires ethics Education for participants in federally funded K30 research programs. As an Institution with a K30 award (Career Training in Therapeutics & Translational Research), we must provide such a course.

REVISION

Course SPH 666 - Practicum in Clinical Research – the MCAC asked that this course be changed to 3 separate courses for 1 credit hour each instead of the one 3 hour course. This has been done – please see below.
SPH 666 – Practicum in Clinical Research I
Description: This course is for participants in the Graduate Certificate in Clinical Research Skills program includes a mentored research experience with the goal of a presentation at a local program-specific retreat; attendance at monthly journal club meetings, 2 annual retreats, and special seminars; and completion of research reports.
Justification: This course will be the first of three one-credit courses that will complete the requirements of the curriculum for the Graduate Certificate in Clinical Research.

SPH 667 – Practicum for Clinical Research II
Description: This course is for participants in the Graduate Certificate in Clinical Research Skills program includes a mentored research experience with the final goal of preparing an abstract for submission for presentation at a national or international meeting; attendance at monthly journal club meetings, 2 annual retreats, and special seminars; and completion of research reports.
Justification: This course will be the second of three one-credit courses that will complete the requirements of the curriculum for the Graduate Certificate in Clinical Research.

SPH 668 – Practicum for Clinical Research III
Description: This course is for participants in the Graduate Certificate in Clinical Research Skills program includes a mentored research experience with the final goal of preparing a paper for publication or a funding proposal for submission; attendance at monthly journal club meetings, 2 annual retreats, and special seminars; and completion of research reports.
Justification: This course will be the third of three one-credit courses that will complete the requirements of the curriculum for the Graduate Certificate in Clinical Research.
June 20, 2002

MEMORANDUM

TO: Deans, Department Chairs and Members of the University Senate

FROM: Emery A. Wilson, MD
       Dean and Associate Vice President for Clinical Services

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Justification: This course will be the third of three one-credit courses that will complete the requirements of the curriculum for the Graduate Certificate in Clinical Research.
APPLICATION FOR NEW COURSE

1. Submitted by College of Medicine _________________ Date 11-9-01 _________________

Department/Division offering course School of Public Health _________________

2. Proposed designation and Bulletin description of this course:

(a) SPH 666
Prefix and Number

(b) Practicum in Clinical Research I
Title* (Clinical Research I)

(c) Lecture/Discussion hours per week ____________

(d) Laboratory hours per week ____________

(e) Studio hours per week ____________

(f) Credits 1

(g) Course description:
This course for participants in the curriculum leading to the Graduate Certificate in Clinical Research Skills includes participation in a mentored research experience with the final goal of a presentation at a local program-specific retreat; attendance at monthly journal club meetings, two annual retreats, and special seminars; and completion of research reports.

(h) Prerequisites (if any): Participation in curriculum leading to the Graduate Certificate in Clinical Research Skills

(i) May be repeated to a maximum of ____________ (if applicable)

3. To be cross-listed as:
Prefix and Number _________________ Signature, Chair, cross-listing department

4. Effective Date: Spring 2003 _________________ (semester and year)

5. Course to be offered (a) ______ (b) ______ (c) ______
Fall Spring Summer

6. Will the course be offered each year? Yes ______, less frequently ______
(Explain if not annually):

7. Why is this course needed:
This course will be the first of three one-credit courses that will complete the requirements of the curriculum for the Graduate Certificate in Clinical Research.

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* Note: If the title is longer than 24 characters (including spaces), write a sensible title (not exceeding 24 characters) for use on transcripts:
8. (a) By whom will the course be taught? Claire Pomeroy, MD
(b) Are facilities for teaching the course now available? No X Yes
If not, what plans have been made for providing them?

9. What enrollment may be reasonably anticipated? 5 to 10 students per semester

10. Will this course serve students in the Department primarily? No X Yes
Will it be of service to a significant number of students outside the Department? X No Yes If so, explain

Will the course serve as a University Studies Program course? X No Yes
If yes, under what Area?

11. Check the category most applicable to this course:
   traditional; offered in corresponding departments elsewhere;
   relatively new, now being widely established
   not yet to be found in many (or any) other universities

12. Is this course part of a proposed new program? X No Yes If yes, which?

13. Will adding this course change the degree requirements in one or more programs? X No Yes If yes, explain the change(s)

14. Attach a list of the major teaching objectives of the proposed course and outline and/or reference list to be used. (Attached)

15. If the course is a 100-200 level course, please submit evidence (e.g., correspondence) that the Community College System has been consulted.

16. Within the Department, who should be contacted for further information about the proposed course?
   Name Joel Lee, DRPH Phone Extension: 323-1100 X276

Note: Approval of this course will constitute approval of the program change unless other program modifications are proposed.
### Signatures of Approval:

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Department Chair</td>
<td>11/14/01</td>
</tr>
<tr>
<td>Dean of the College</td>
<td>11/20/01</td>
</tr>
<tr>
<td>Senate Council (Chair)</td>
<td>12/10/02</td>
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<tr>
<td>Undergraduate Council</td>
<td>11/15/02</td>
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<tr>
<td>Faculty Council</td>
<td>7/11/02</td>
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<td>University Studies</td>
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<td>Graduate Council</td>
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<td>Academic Council for the Medical Center</td>
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</tbody>
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*If applicable, as provided by the Rules of the University Senate

### ACTION OTHER THAN APPROVAL

Rev 11/98
Course Director: Claire Pomeroy, MD
Associate Dean for Research and Informatics; Chief of Division of Infectious Diseases
MN 672 Chandler Medical Center 0298
Telephone 323-6326; cpomer0@email.uky.edu

Course Credit: One semester hour.

Course Materials: None required.

Course Prerequisites: Participation in curriculum leading to the Graduate Certificate in Clinical Research Skills, or permission of the instructor.

Course Objectives:

Course participants will

1. Gain clinical research skills through completion of requirements for the Graduate Certificate in Clinical Research Skills, including a monthly journal club, two annual retreats, seminars, and workshops.

2. Engage in a structured mentored clinical research experience with the goal of giving a presentation at a local curriculum-related retreat.

This practicum will be the first of three one-credit courses that will ensure satisfactory completion of all nondidactic requirements of the Graduate Certificate in Clinical Research Skills.

Course Requirements:

1. The first component of the course counts for 30% of the final grade. Required activities are attendance at monthly journal clubs, a curriculum-related retreat, and seminars as announced. The minimum expectation for passing this component of the course is attendance at 70% of activities.

2. The second component of the course counts for 20% of the final grade. The required activity is timely completion of all documentation necessary for the Graduate Certificate in Clinical Research Skills (e.g., quarterly progress reports, mentor and trainee self-evaluations, program evaluations).

3. The third component of the course counts for 50% of the final grade. The required activity is a presentation at a local curriculum-related retreat.

Course Grades: A for 90% or better; B for 80% to 89%; C for 70% to 79%; E for less than 70%. The instructor may use a curve if desired.

Course Syllabus:

There is no standard course syllabus. Each student’s experience will be different because of the mentored research experience.