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
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attachments

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

JUL 15 2002

ORIGINAL
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 Application(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

014 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.
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.
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. Prefix and Number SPH 664
   b. Title* Design and Analysis of Clinical Trials
      *NOTE: If the title is longer than 24 characters (including spaces), write
      A sensible title (not exceeding 24 characters) for use on transcripts Clinical Trials Analysis
   c. Lecture/Discussion hours per week 3
   d. Laboratory hours per week
   e. Studio hours per week
   f. Credits 3
   g. Course description
      This course will introduce the fundamental concepts used in the design of Phase I-IV clinical trials and statistical methodology associated with trial data analysis.
   h. Prerequisites (if any)
      STA 570 or permission of instructor
   i. May be repeated to a maximum of ___________________________ (if applicable)

4. To be cross-listed as
   Prefix and Number __________________________________________
   Signature, Chairman, cross-listing department ___________________________

5. Effective Date Spring 2003 (semester and year)

6. Course to be offered
   □ Fall  ✔ Spring  □ Summer

7. Will the course be offered each year? ✔ Yes  □ No
   (Explain if not annually) ___________________________________________

8. Why is this course needed?
   No other course presenting advanced biostatistics associated with clinical trials exists. Course required for proposed Graduate Certificate in Clinical Research Skills.

9. a. By whom will the course be taught? Richard Kryscio, PhD
   b. Are facilities for teaching the course now available?
   ✔ Yes  □ No
      If not, what plans have been made for providing them? ___________________________________________
10. What enrollment may be reasonably anticipated?  **15 to 25 students per semester**

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

12. 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

13. Is this course part of a proposed new program?  
   If yes, which?  
   ☐ Yes  ☑ No

14. Will adding this course change the degree requirements in one or more programs?*  
   If yes, explain the change(s) below  
   ☑ Yes  ☐ No

15. Attach a list of the major teaching objectives of the proposed course and outline and/or reference list to be used.

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

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

*NOTE: Approval of this course will constitute approval of the program change unless other program modifications are proposed.
APPLICATION FOR NEW COURSE

Signatures of Approval:

Department Chair: [Signature]
Date: 1/14/01

Dean of the College: [Signature]
Date: 11/20/01

*Academic Council for the Medical Center: [Signature]
Date of Notice to the Faculty: 1/7/02

Curriculum Committee: [Signature]
Date: 1/15/02

Undergraduate Council: [Signature]
Date: 7/11/02

Faculty Council: [Signature]
Date of Notice to University Senate: [Signature]

*University Studies: [Signature]

*Graduate Council: [Signature]

*Senate Council (Chair): [Signature]

*If applicable, as provided by the Rules of the University Senate

ACTION OTHER THAN APPROVAL

Rev 11/98
**SPH 664: Design and Analysis of Clinical Trials**

**Course Director: Richard Kryscio, PhD**

Biostatistics Consulting Unit, 323 Sanders-Brown Center 0298
Telephone: 257-5904; kryscio@uky.edu

**Course Credit: Three (3) semester hours.**

**Course Materials:** None required. The following books will be on reserve in the Medical Center Library for reading assignments:


**Course Prerequisites:** STA 570 (Biostatistics section) or permission of instructor. Students should be familiar with reading SAS output.

**Course Objectives:**

1. Introduce the fundamental concepts used in the design of Phase I-IV clinical trials, including sample size issues, power, and use of interim stopping rules.

2. Introduce statistical methodology associated with the analysis of data from clinical trials, including factorial designs, crossover designs, bioequivalence trials, and meta-analysis.

At the end of this course, students should know how to draft selected sections of a protocol that involve biostatistical issues and should know how to read critically the results of a clinical trial as published in the literature.

**Course Requirements:**

1. Two examinations: one at mid-term, emphasizing Objective 1; and one at the time of semester finals, emphasizing Objective 2. Both examinations will be take-home. Each examination is worth 33 points.

2. Homework assignments, at least one of which will be a group project requiring a presentation. Worth 34 points.

**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.
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<th>Date</th>
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<td>28 Aug</td>
<td>Phase I trials</td>
<td>Dose escalation studies, Bayesian probability</td>
<td>4, 20(S), 4(P), 3 (GBC)</td>
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<tr>
<td>4 Sep</td>
<td>Phase II trials</td>
<td>Emphasizes oncology trials</td>
<td>4(P), 3, 4(GBC)</td>
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<td>11 Sep</td>
<td>Endpoints</td>
<td>Primary, secondary, surrogate</td>
<td>6(P), 2(FD)</td>
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<td>18 Sep</td>
<td>Randomization</td>
<td>Blocking, stratification, unequal allocation, masking</td>
<td>5, 6(FFD), 9(P), 4(E), 6(S)</td>
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<td>25 Sep</td>
<td>Sample size</td>
<td>Compare means, proportions, and waiting time to events</td>
<td>7(FFD), 7(P), 13(S)</td>
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<td>2 Oct</td>
<td>Interim stopping</td>
<td>DSM committees, repeated significance testing</td>
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<tr>
<td>9 Oct</td>
<td>Interim stopping</td>
<td>Group sequential designs, O'Brien-Fleming and Pocock</td>
<td>15(FFD), 10(P), 5(GBC), 19(S)</td>
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<td><strong>MIDTERM: Take-Home Exam</strong></td>
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<td>16 Oct</td>
<td>Parallel designs</td>
<td>Factorial designs, interaction effects</td>
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<td>23 Oct</td>
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<td>30 Oct</td>
<td>Analysis issues I</td>
<td>Intent to treat, noncompliance, regression to the mean, subgroup analyses, baseline measurements</td>
<td>16(FFD), 7, 8(GBC), 10, 11(S)</td>
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<td>Analysis issues II</td>
<td>Covariate adjustment (prognostic factor analysis), misuse of cutpoints, confounding, Center effects (multicenter studies)</td>
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<td>20 Nov</td>
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<td>4 Dec</td>
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