APPLICATION FOR NEW COURSE

1. Submitted by the **College of Arts and Sciences** Date: **October 25, 2001**

   Department/Division offering course: **Statistics**

2. Proposed designation and Bulletin description of this course:

   (a) Prefix and Number: **STA 653** (b) Title: **Clinical Trials** (subt. req.)

   *NOTE: If the title is longer than 24 characters (including spaces), write a sensible title (not exceeding 24 characters) for use in transcripts:

   (c) Lecture/Discussion hours per week: 3 (d) Laboratory hours per week: __________

   (e) Studio hours per week: __________ (f) Credits: 3

   (g) Course description: **Design and analysis of Phase I-III Clinical trials, interim monitoring of trials, sample size, power, crossover trials, bioequivalence, mixed models, and meta analysis.**

   (h) Prerequisites (if any): **STA 643**

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

4. To be cross-listed as: Prefix & No.

   Signature, Chairman, cross-listing department

5. Effective Date: **Fall, 2002** (semester and year)

6. Course to be offered: (a) Fall ☒ (b) Spring ☐ (c) Summer ☐

7. Will the course be offered each year? (a) Yes ☐ (b) No ☒

   (Explain if not annually): **An elective course which will be offered biannually**

8. Why is this course needed: **The majority of our graduate students seek employment in the biopharmaceutical industry where knowledge of the design and analysis of clinical trials is expected**

9. (a) By whom will the course be taught? **Richard Kryscio**

   (b) Are facilities for teaching the course now available? (a) Yes ☒ (b) No ☐

   If not, what plans have been made for providing them?
10. What enrollment may be reasonably anticipated? **Enrollment the last two times offered: 14 and 15**

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

(a) Yes ☐ (b) 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? (a) Yes ☒ (b) No ☐
If yes, which? **Elective for the Statistics/Probability and Biostatistics tracts within the Statistics Ph. D.**

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

15. Attach a list of the major teaching objectives of the proposed course, 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/e-mail: **Arnold J. Stromberg, DGS** Phone Extension: 7-6903

*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:

Constance L. Wood
Department Chair

Philip Hammond
Dean of the College

Date 03/22/02

*Undergraduate Council

Date

*University Studies

Date

*Graduate Council

Date

*Academic Council for the Medical Center

Date

*Senate Council

Date of Notice to Unv. Senate

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

ACTION OTHER THAN APPROVAL:

Rev 11/98
Course Description for STA653

Design and Analysis of Clinical Trials


Teaching Objectives:

1. Students will learn the basic statistical principles commonly encountered when designing Phase I-Phase II clinical trials.

2. Students will learn the statistical theory underlying the rules for monitoring clinical trials including the Pocock stopping boundaries, the O'Brien-Fleming stopping boundaries, and the Lan-DeMets alpha spending function.

3. Students will learn sample size and power considerations encountered when designing Phase III randomized clinical trials.

4. Students will learn some of the more common statistical principles encountered when analyzing data from a randomized clinical trial including the principles of intent to treat, covariate adjustments, interaction effects, center effects in a multicenter trial, and methods which account for patient dropouts.

5. Students learn how to design and analyze crossover studies, bioequivalence, studies, and longitudinal studies.

Outline:

Standard Phase I up-down designs
Other Phase I designs including the continual reassessment design
Phase II: Gehan's design, Simon's two-stage designs, selection designs
Phase III trials: randomization methods including stratification, blocking and adaptive randomization
Phase III trials: survival as an endpoint
Sample size and power for comparing means, proportions, and waiting times to events
Interim monitoring of trials: ARM algorithm, Pocock boundaries, O'Brien-Fleming boundaries
Interim monitoring of trials: alpha spending functions
Constructing a clinical protocol: choosing a primary endpoint, surrogate endpoints, QOL measures
Constructing case report forms; database management: the role of the statistician
Cross-over designs
Bioequivalence designs
Analysis issues: intent to treat, effect of missing responses, bias in early stopping of the trial, adjustments for covariates, adjustment for clustering of responses, center effects, interaction effects, and extending the trial
Mixed linear models in the analysis of clinical trials data: trials with repeated assessments,
Random coefficient models for longitudinal endpoints
Mixed models: meta analysis
References:


Nature of Assignments and Grading Criteria:

Periodic (at least 8) homework assignments will be given to students and then combined into one grade on a 100 point scale. Also, a midterm and final exam will be given each producing one grade on a 100 point scale. The final grade will be determined from the sum of these three scores.

Grading Scale:
90-100 – A
80-90 – B
70-80 – C
Below 70 – E
At his or her discretion, the instructor may use a curve.
INVESTIGATOR REPORT

INVESTIGATING BODY: Area A, Shelley Steiner (Area, Area Chair)

DATE FOR COUNCIL REVIEW: 4/9/02

COURSE, MAJOR OR DEGREE: STA 653

CATEGORY: NEW, CHANGE, DROP

INSTRUCTIONS: This completed form will accompany the course application to the Graduate/Undergraduate Council(s) in order to avoid needless repetition of investigation. The following questions are included as an outline only. Be as specific and as brief as possible. If the investigation was routine, please indicate this. The term "course" is used to indicate one course, a series of courses or a program, whichever is in order. Return the form to Phil Harling, Associate Dean, 231 Patterson Office Tower for forwarding to the Council(s). ATTACH SUPPLEMENT IF NEEDED.

1. List any modifications made in the course proposal as submitted originally and why.

2. If no modifications were made, review considerations that arose during the investigation and the resolutions.

3. List contacts with program units on the proposal and the considerations discussed therein.

   Dr. Wood + A committee

4. Additional information as needed.

5. A&S Area A, Natural & Mathematical Sciences Curriculum Committee Recommendation:
   - APPROVE, APPROVE WITH RESERVATION, OR DISAPPROVE

6. A&S Council Recommendation:
   - APPROVE, APPROVE WITH RESERVATION, OR DISAPPROVE

7. A&S Council Investigator, Dr. Shelley Steiner
   Date: 4-9-02

File: InvestigatorRpt