

New Course Request

NOV 11 2008 **Indiana University** 2008

Indianapolis Campus

Check Appropriate Boxes:

Undergraduate credit

Graduate credit

Professional credit 90

1. School/Division Science, Biostatistics 2. Academic Subject Code BIOS

3. Course Number 527 (must be cleared with University Enrollment Services) 4. Instructor C. Yiannoutsos

5. Course Title Introduction to Clinical Trials

Recommended Abbreviation (Optional) _____
(Limited to 32 Characters including spaces)

6. First time this course is to be offered (Semester/Year): Fail/2008

7. Credit Hours: Fixed at 3.0 or Variable from _____ to _____

8. Is this course to be graded S-F (only)? Yes _____ No X

9. Is variable title approval being requested? Yes _____ No X

10. Course description (not to exceed 50 words) for Bulletin publication: _____

P: STAT 512, exposure to survival analysis; or consent of instructor. Prepares biostatisticians for support of clinical trial projects. Topics: fundamental aspects of the appropriate design and conduct of medical experiments involving human subjects, including ethics, design, sample size calculation, randomization, monitoring, data collection analysis and reporting of the results.

11. Lecture Contact Hours: Fixed at 3 or Variable from _____ to _____

12. Non-Lecture Contact Hours: Fixed at _____ or Variable from _____ to _____

13. Estimated enrollment: 5-10 of which 100 percent are expected to be graduate students.

14. Frequency of scheduling: fall Will this course be required for majors? yes

15. Justification for new course: Required course for new biostatistics Ph.D. program

16. Are the necessary reading materials currently available in the appropriate library? yes

17. Please append a complete outline of the proposed course, and indicate instructor (if known), textbooks, and other materials.

18. If this course overlaps with existing courses, please explain with which courses it overlaps and whether this overlap is necessary, desirable, or unimportant.

19. A copy of every new course proposal must be submitted to departments, schools, or divisions in which there may be overlap of the new course with existing courses or areas of strong concern, with instructions that they send comments directly to the originating Curriculum Committee. Please append a list of departments, schools, or divisions thus consulted.

Submitted by:

Bertin Baker Date 6/6/08
Department Chairman/Division Director

Date _____
Dean of Graduate School (when required)

Approved by:

James M. Murphy Date 6/25/2008
Dean

Marjorie L. Quence Date 11/4/08
Chancellor/Vice-President

Date _____
University Enrollment Services

Jessie O'Fallon ^{BS} APPROVED OCT 01/08
UPUI Curriculum Committee Date

After School/Division approval, forward the last copy (without attachments) to University Enrollment Services for initial processing, and the remaining four copies and attachments to the Campus Chancellor or Vice-President.

BIOS 527
Introduction to Clinical Trials

Syllabus

BIOS 527 – Introduction to Clinical Trials (3 cr.)

Instructor: Constantin T. Yiannoutsos

A. Description

This is a standard course that prepares biostatisticians for support of clinical trial projects. The course will cover fundamental aspects of the appropriate design and conduct of medical experiments involving human subjects (clinical research/trials) including ethics, design, sample size calculation, randomization, monitoring, data collection analysis and reporting of the results.

There will be three homework projects assigned with about four weeks allowed for completion, plus two examinations and a final class project. The relative importance of these in the final grade are given below.

B. Prerequisites

STAT 512 and some exposure to survival analysis (or GRAD G652), or permission of the instructor

C. Textbook

- Piantadosi, Steven. (2005). *Clinical trials: a methodologic perspective, 2nd ed.*, Hoboken, NJ : Wiley-Interscience.
- Notes and handouts provided by the instructor.

D. Description for Bulletin:

P: STAT 512, exposure to survival analysis; or consent of instructor. Prepares biostatisticians for support of clinical trial projects. Topics: fundamental aspects of the appropriate design and conduct of medical experiments involving human subjects including ethics, design, sample size calculation, randomization, monitoring, data collection analysis and reporting of the results.

E. Instructor

Constantin T. Yiannoutsos, Ph.D.

F. Grading requirements

Three homework projects, 10% each (total 30%)

Midterm examination 20%

Final examination 30%

Class project 20%

The following grading scale will be used:

90 – 100 A's

80 – 89 B's

| | |
|---------|-----|
| 70 – 79 | C's |
| 60 – 69 | D's |
| 0 – 59 | F |

G. Schedule of lectures

1. Introduction

Description of the concept of clinical research; Review of history evolution of the concept of the clinical trials. Read chapters 1,2 from textbook.

2. Ethics of clinical trials

Concepts of equipoise and uncertainty, conflict between individual and communal rights, Helsinki and other international principles and declarations. The role of the statistician in clinical trials. Read chapter 3 from the textbook.

First homework assignment given.

3. Types of clinical trials and statistical perspectives.

Drug trials, device development, prevention trials, surgery and skill-dependent therapies, screening trials, diagnostic studies, radiotherapy. Read chapters 4 and 5 from the textbook.

4. Clinical trials as experimental designs

- a. Dose finding trials
- b. Phase I-IV trials
- c. Comparative versus non-comparative trials
- d. Factorial designs
- e. Cross over trials
- f. Meta-analysis

Read chapters 6, 7, 10, 19, 20 and 21 from the textbook.

First homework assignment due. Second homework assignment given.

5. Sample size and power calculations

Sample size and power calculations by clinical trial design (as described previously). Read chapter 11 from the textbook.

6. The study cohort: Inclusions/exclusions, representativeness and inclusiveness, treatment allocation and randomization.

Describe the process by which the study cohort is defined and the fundamental role this plays in the ultimate interpretability of the study results. Treatment allocation, randomization schemes and bias reduction. Read chapters 12 and 13 from the textbook.

7. Data management systems supporting clinical trials

The critical nature of data management support of clinical trials. The role of the clinical data manager.

8. Midterm examination

Second homework assignment due.

9. Study monitoring A

Administrative issues of study monitoring; ethics of study monitoring; data safety monitoring boards (DSMB). Read chapter 14 in the textbook.

Third homework assignment given.

10. Study monitoring A

Study monitoring, group-sequential designs, monitoring groups. Read chapter 14 in the textbook.

11. Analysis of data produced by a clinical trial

Context of data analysis. Intention-to-treat (ITT) principle versus other analyses (e.g., “as treated”). The idea of clinical trials as comparisons of treatment *policy*. Read chapter 15 from the textbook.

12. Statistical issues with analyses of clinical trials.

Statistical issues. Comparative studies, dose finding and PK studies, safety studies, superiority/inferiority studies versus equivalence trials. Read chapters 16 and 17 from the textbook.

13. Reporting and authorship of clinical trials

Authorship and publication requirements of the results of a clinical trial. Publication bias; fraud and misconduct. Read chapters 18 and 22 from the textbook.

14. Review for final examination.

Third homework assignment due.

15. Final examination

Academic Honesty:

If you are not already familiar with the statement on academic honesty in the IU Student Code of Conduct (Part 3, Section A: Student Misconduct), please take the time to read this statement carefully: http://www.life.iupui.edu/help/docs/Part_3all.html

Cheating on assignments and tests or other academic works is a violation of university policy. Any behavior that is construed as cheating or academic dishonesty will not be tolerated in this course. This includes, but it is not limited to, plagiarism, cheating during

exams, acquisition of tests or other academic materials, as well as aiding and abetting others in committing the violation.

Student Code of Conduct: The classroom protocol will be guided by the Student Code of Conduct which, among other things, asserts IUPUI's commitment "to maintain[ing] a spirit of civility in a community in which diversity is welcomed. Every student, staff, and faculty member plays a significant role in promoting an environment that is conducive to academic excellence by fostering a climate of civility and mutual respect." Consequently, in our meetings you are expected to treat one another with respect, to express your own ideas honestly, and to listen to others thoughtfully, attentively, and with a spirit of understanding. For the Student Code of Conduct, see: <http://life.iupui.edu/help/code.asp>

Statement for Students with Disabilities:

If you need any special accommodations due to a disability, please contact Adaptive Educational Services at (317) 274-3241. The office is located in CA 001E.