

UNIVERSITY SENATE REVIEW AND CONSULTATION SUMMARY SHEET

Proposal Title: New Program Proposal – Master of Science in Clinical Research

Proposal Contact: Dr. Richard Kryscio
 121 Washington Avenue, Room 200
 257-4064 or via email at kryscio@uky.edu

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	Contact person	Consequences of Review	Date of Proposal Review	Review Summary Attached?
Council on Post-Secondary Education	James Applegate, Vice President of Academic Affairs	Approved	12-13-06	Yes
Academic Affairs Committee	Marta Mendiondo, Chair	Approved	12-7-07	Yes
Faculty Council	Glyn Caldwell, Chair	Approved	12-13-07	Yes
Office of Academic Affairs	Linda Alexander, Associate Dean	Approved	1-18-08	Yes
HCCC	Heidi Anderson	Approved	7/15/08	—

Brothers, Sheila C

From: Mendiondo, Marta
Sent: Monday, March 16, 2009 1:16 PM
To: Brothers, Sheila C
Cc: Arrington, Michael; Barnes, Thomas G; Hayes, Jane E; Schoenberg, Nancy E; Smith, Richard; Waterman, Richard; Wermeling, Daniel
Subject: SAPC

Sheila,

At the March 13th, 2009 meeting the Senate Academic Programs Subcommittee decided:

Recommend the approval of the:

- 1) New Program: MS Clinical Research** - Recommend its approval provided the name of the program is revised, due to the generality of this name and the potential confusion with the **Masters of Science in Clinical and Translational Science** already being offered (<http://ccts.uky.edu/TEAM/curriculum.aspx>).
- 2) New MS/PhD in Reproductive Sciences** – Recommend its approval provided there is no funding issues. The College of Health Sciences is offering to provide two fellowships and is asking for support for two additional ones
- 3) New University Scholars Program: BS Mining Engineering and MS Mining Engineering**
- 4) Suspend Program: Minor in Merchandising, Apparel and Textiles**

Let me know if you need any additional details.

The committee plans to discuss (and approve if there are no problems) via email the **New PhD in Epidemiology and Biostatistics** and **New MS in Epidemiology** as soon as the members have time to review them. We are trying to facilitate this year's Senate approval of these programs so they can start in August 09.

By the way, the **New MS in Epidemiology** is the full name, without **Biostatistics** for the **MS**.

Marta

*Marta S. Mendiondo, PhD
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UNIVERSITY OF KENTUCKY

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COLLEGE OF PUBLIC HEALTH

M E M O R A N D U M

TO: Health Care Colleges Council

FROM: Linda A. Alexander, EdD
Associate Dean for Academic Affairs

SUBJECT: New Program Proposal – MS in Clinical Research

DATE: January 31, 2008

It is the intention of the College of Public Health to begin offering a new degree program – a Master of Science in Clinical Research.

In November 2006, our college applied to the Kentucky Council for Post-Secondary Education for permission to develop a proposal for this new degree. The CPE posed several questions of us, which we answered, and on December 13, 2006, Provost Subbaswamy received notification that the CPE granted permission for us to develop the program.

After the full proposal was completed, it was reviewed and approved by the Academic Affairs Committee and the Faculty Council, according to our college's established bylaws.

After this initial approval, a name change was proposed and both of the reviewing bodies of the college approved it. Documentation of this approval is also attached.

Further information about this course can be obtained by contacting the program's proposed DGS, Dr. Richard Kryscio, at 257-4064 or via email at kryscio@uky.edu.

MEMORANDUM

To: Faculty Council



From: Marta S. Mendiando
Chair, Academic Affairs Committee

Date: December 7, 2007

The Academic Affairs committee at their December 6, 2007 meeting has approved the New Program Request for the MS in Clinical Research.



Received

DEC 20 2006

KENTUCKY COUNCIL ON
POSTSECONDARY EDUCATION

Office of the Provost

Ernie Fletcher
Governor

1024 Capital Center Drive, Suite 320
Frankfort, Kentucky 40601
Phone (502) 573-1555
Fax (502) 573-1535
<http://cpe.ky.gov>

Thomas D. Layzell
President

December 13, 2006

Kumble Subbaswamy
Provost
University of Kentucky
106 Gillis Building
Lexington, Kentucky 40506-0033

Dear Swamy :

The 45-day review period for the University of Kentucky's proposed Master of Science in Clinical Research has ended. You are now free to complete your internal program development and approval process. Because the program falls outside the university's program band, it is subject to full review by the Council on Postsecondary Education prior to implementation.

We look forward to receiving the full proposal once your governing board has taken action. The format for the full proposal, including the financial analysis form, can be found at the bottom of the KPPPS main menu at <http://apps.cpe.ky.gov/kppps/MainMenu.asp>.

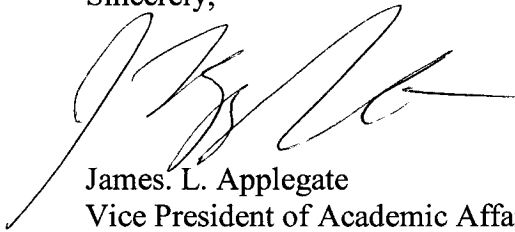
In the full proposal, please address the issues raised by CPE staff in the December 7th posting on KPPPS:

1. If the program is to start in January 2007, how will practicing physicians, dentists, nurses, pharmacist and psychologists will be recruited to participate?
2. Distance Learning is addressed as being an alternative delivery system. How many of the courses are currently offered online? How many are expected to be offered online in the next three years?
3. What is the estimated degree production in this program?
4. What is the documented demand for such a degree?
5. Is this program necessary to do population-based research and clinical trials?
6. Will the curriculum be taught by existing faculty? Will new resources be needed for this degree program?

Kumble Subbaswamy
December 13, 2006
Page Two

If you have any questions, please contact Melissa Bell at Melissa.Bell@ky.gov or 502-573-1555 ext. 357.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Applegate', written over a white background.

James. L. Applegate
Vice President of Academic Affairs

Response to Comments from CPE Master of Science in Clinical Research

1. *If the program is to start in January 2007, how will practicing physicians, dentists, nurses, pharmacist and psychologists will be recruited to participate?*

With approval of the program by CPE, we will begin to follow the University of Kentucky and CPE guidelines for the development and approval of new programs in January 2007. We anticipate recruiting students into the program no earlier than January 2008.

2. *Distance Learning is addressed as being an alternative delivery system. How many of the courses are currently offered online? How many are expected to be offered online in the next three years?*

Our response to the delivery of distance learning coursework was based on the question on the KPPPS Posting Form. We intend to accept coursework taken as a part of a distance learning program offered at other institutions as it relates to clinical research on a case-by-case basis with approval of the program director. Specifically, we are planning to accept the introductory courses in biostatistics and epidemiology offered on-line through the School of Public Health at the University of Louisville.

There are no current plans by the University of Kentucky College of Public Health to develop on-line courses for this program. As we do with all of our graduate-level programs, we will assess during the next three years whether there is a need to offer courses related to this Master's degree via a distance learning model.

3. *What is the estimated degree production in this program?*

The estimated degree production in this program is at least six per year.

4. *What is the documented demand for such a degree?*

The current K-30 Certificate program is the basis for this Master's degree program and has had 25-30 participants at any given time during the last six years.

Funding for the K-30 program is being phased out and is being replaced by the Clinical Translational Sciences Award (CTSA) Program. Medical schools across the country are applying for these awards, and a required component for CTSA is the development of a new academic discipline in clinical translational science. The proposed MS in Clinical Research is consistent with the requirements of the CTSA application.

For detailed information about the K-30 Certificate Program and the CTSA Awards, please visit:

<http://www.mc.uky.edu/medicine/research/clinical/ctsa/default.asp>

5. *Is this program necessary to do population-based research and clinical trials?*

Yes. The MS in Clinical Research provides physicians and other health care professionals with the competencies to perform population-based research and clinical trials in accordance with the concept of bench-to-bedside (translational) practice.

6. *Will the curriculum be taught by existing faculty? Will new resources be needed for this degree program?*

Yes, the curriculum will be taught by existing faculty; no additional resources are required at this time. However, as the program expands there may be a need for additional faculty.

REQUEST FOR A NEW PROGRAM

Degree title: Master of Science in Clinical Research

Major title: Option: Major code in SIS:

Primary College: College of Public Health

CIP Code: 51.1401 Medical Scientist, MS

Accrediting Agency: N/A

Contacts:

**The following two individuals have agreed to be co-Directors of Graduate Studies for this degree program: Richard J. Kryscio
kryscio@email.uky.edu 257-4064 David M. Mannino
Dmannino@uky.edu 323-6608**

I. Abstract

A. Purpose

The proposed program is designed to prepare practicing health care professionals and students pursuing a terminal degree to conduct population-based research and clinical trials.

B. Target Audience

Practicing health care professionals (MDs, DMDs, PharmDs, Clinical Psychologists, etc.) and those pursuing a terminal PhD in fields like pharmacy, nursing, and psychology, who wish to enhance their translational research skills, and knowledge of population-based health and clinical trials. Clinicians with academic appointments at the University of Kentucky (UK) and physicians off campus, including community-based physicians who wish to participate in clinical research, will be targeted for this program. Providing community-based clinicians this degree program is novel and helps UK build a community-based research infrastructure throughout the commonwealth.

C. Need

The critical need for health care professionals qualified to conduct population-based research or clinical trials is evidenced by the fact that institutional eligibility for a Clinical Translational Sciences Award (CTSA), which are currently being

granted by the National Center for Research Resources, requires the existence of a graduate school accredited to award higher degrees in clinical research. In order for UK's application for this award to be competitive, translational research must be defined as a discipline.

MDs interested in an academic appointment will find that this degree program will make them competitive for the best positions, where research skills are becoming the norm. Others, such as doctoral candidates in the basic sciences, pharmacy, dentistry, nursing, and psychology, will also find this program attractive for similar reasons. Researchers in the basic sciences and pharmaceutical sciences are under increasing pressure to conduct translational research, while researchers in dentistry, nursing and psychology are being encouraged to take an active role in community-based research.

D. Relation to Certificate in Clinical Research Skills program

The program is designed to accommodate graduates of the Certificate in Clinical Research Skills program in clinical and translational science for health-based professionals. The MS program is designed so that once a student has completed the graduate certificate he/she can seamlessly transfer into the program. This is true for students enrolled in the current graduate certificate housed within the College of Public Health, as well as students who will be enrolled in the new proposed graduate certificate program in clinical research skills housed within the College of Medicine (www.ctsc.uky.edu/team_curriculum.htm). All credits earned for the certificate count toward the proposed MS program as either a required or elective course. Hence, the certificate programs are feeder programs for the MS degree, especially for those certificate students seeking to earn a formal degree in population-based research.

The certificate programs emphasize competency training in clinical and translational research methodologies, leadership, communication, and teamwork skills. The program also requires formal training in ethical conduct of clinical research and elementary biostatistics. However, the certificate is not considered to be a strong enough credential for clinicians and doctoral students seeking to do population-based research. A degree at the master's level with didactic training in epidemiology and biostatistics provides these minimum skills. The curriculum requires creating no additional courses other than what are already offered for other degree programs.

E. Relation to current MPH Program

The current MPH program now requires 42 credit hours, which includes a three credit hour practicum course and a required capstone project. The proposed MS program will be an attractive alternative to the MPH, requiring fewer credit hours for those students looking to build their translational science research skills who

do not need the public health practitioner focus of the current MPH degree program. Faculty seeking training grants will also find this program attractive, and the program is designed to appeal to these potential students as well.

F. Mentorship

The proposed master's program requires formal mentoring and a formal graduate level thesis. To facilitate these activities, the newly formed Career Development Office will support the recruiting of graduates of the certificate programs into this MS program. If the CTSA application is successful, it plans to provide financial resources to enable students who have completed a certificate to finish this program in one year's time. Regardless of funding, it will also act as a conduit to match students with mentoring teams that will facilitate the successful completion of the mentored research experience, as well as the MS thesis.

G. Collaboration Opportunities

Currently there are no plans to collaborate with other institutions on this program. Participation in the Kentucky Virtual University will be limited to accepting, on a case by case basis, credit for courses completed on the web, provided the Director of the program approves the course for credit. There are no plans to develop or offer the curriculum over the Kentucky Virtual University as insufficient demand would make developing this curriculum over the web too costly. Since the mentoring and thesis supervision components of the degree program are where the additional effort will be needed on the part of faculty, the goal is to offer this curriculum while utilizing as few additional resources for the program as possible to cover formal classroom instruction.

H. Summary

In summary, the goal of the proposed MS program is to provide training in a new discipline: clinical translational science with an emphasis on population-based health knowledge and clinical trials. As all coursework required in the existing certificate program is directly transferrable into the MS degree program, students will experience a seamless transition from the current and revised graduate certificate program in clinical translational science. The requirement of a formal mentored thesis in the program assures that earning this degree will necessitate the development of research skills.

II. Program Description

Curriculum

Students will complete a minimum of 31 credit hours of study. The core curriculum consists of 13 hours comprising five courses, two each in epidemiology and

biostatistics, and a one-credit-hour course that will serve as a broad introduction to public health. Students will also complete a minimum of 12 credit hours of electives. In addition, a three-credit-hour practicum in mentored research and three credit hours of thesis research are required.

Core curriculum (13 hours)

- CPH 605 Introduction to Epidemiology (3) This is an initial graduate level course in the principles of epidemiology and applications in preventive medicine and environmental health. The course consists of lectures and informal discussions. Principles and methods of epidemiologic research with a focus on issues of study design and analysis will be presented.
- STA 580 Biostatistics I (3) Descriptive statistics, hypothesis testing, paired and unpaired tests, ANOVA, contingency tables, log rank test, and regression with biostatistics applications.
- CPH 712 Advanced Epidemiology (3) This course provides specialized epidemiologic content and method designed to meet the research and practice needs of health professionals. Practice-based problem sets and hands-on computer assignments will complement this seminar-oriented course, focusing on the role of epidemiology in the prevention of disease and injury.
- CPH 630 Biostatistics II (3) Students will learn statistical methods used in public health studies. This includes receiver operator curves, multiple regression logistic regression, confounding and stratification, the Mantel-Haenszel procedure, and the Cox proportional hazardous model. Lecture, two hours; laboratory, two hours per week.
- CPH 701 Current Topics in Public Health (1) A survey seminar course for students in M.S. and PhD programs in the College of Public Health. The course introduces broad concepts on the role, responsibilities, structure, funding etc of public health. While all core areas of public health will be introduced special attention will be given to health behavior/behavioral health, environmental health and health policy/management.

Electives (12 hours – selections to be approved by the DGS)

- CPH 665 Ethical Issues in Clinical Research (3) Based on NIH guidelines for Responsible Conduct of Research, this course presents ethical and regulatory guidelines for conducting clinical research.
- CPH 664 Biostatistics in Clinical Trials (3) This course will introduce the fundamental concepts used in the design of Phase IV clinical trials and statistical methodology associated with trial data analysis.

- CPH 612 Infectious Disease Epidemiology (3) The theory/concepts of infectious diseases epidemiology, such as epidemic modeling expostulated through a systematic study of the more recent emerging diseased.
- CPH 616 Cardiovascular Epidemiology (3) This course is designed to study and evaluate the broad array of epidemiologic studies on cardiovascular disease and the impact on prevention policy.
- CPH 618 Epidemiology of Aging (3) This course introduces the application of epidemiologic methods to the study of older persons.
- CPH 631 Design and Analysis of Health Surveys (3) Students will learn design and analysis issues associated with well-known national health surveys, including reliability and validity of measurements, instrument validation, sampling designs, weighing of responses, and multiple imputations. Students will learn how to use statistical software to analyze data from complex survey designs.
- CPH 632 Mixed Models in Public Health (3) Students will learn statistical techniques for analyzing those longitudinal studies in public health that involve repeated measures and random effects. This course will cover multilevel regression models, Poisson regression models, logistic Models with random effects, crossover experiments, and nonlinear pharmacokinetic models.
- CPH 636 Data Mining (3) This course concerns statistical techniques for and practical issues associated with the exploration of large public health data sets, the development of models from such data sets, and the effective communication of one's findings.
- CPH 647 Research Methods (3) This course provides the student with basic knowledge about the design and analysis of research in the field of health behavior. The theory, design, applications, and analytic strategies used for various types of research are presented in a sequential format. Goals of the course include: 1) gaining the ability to critically evaluate research in health behavior 2) achieving competence in research methodology, and 3) understanding the conceptual application of analytic techniques to data.
- CPH 711 Chronic Disease Epidemiology (3) A survey course on the leading chronic diseases in the U.S., including cardiovascular disease, cancer and diabetes with focus on surveillance and risk factors.
- CPH 718 Molecular Epidemiology (3) Principles of molecular epidemiology, cancer prevention and control. This course serves as a Special Topics Elective in the College of Public Health and is designed primarily for graduate public

health students with professional interests in molecular epidemiology as this topic relates to cancer prevention and control. This course also is appropriate for students in other related health professions (i.e., medicine, nursing, pharmacy) and the biological sciences.

CPH 669 / BSC 731 Methods and Technologies in Clinical Translational Research (3) This course is an introductory graduate level course intended for students pursuing focused research training in clinical and translational science.

CPH 670 / BSC 732 Interdisciplinary Protocol Development (2) This graduate level course is intended for students pursuing focused research training in clinical and translational science to develop an understanding of and appreciation for the elements of leadership and teamwork in clinical and translational research.

CPH 671 / BSC 733 Seminar in Clinical and Translational Science (1) This seminar course is designed to orient students to clinical and translational research community and activities at the University of Kentucky and to incorporate a multidisciplinary cooperative approach to clinical and translational research. Students are expected to apply their knowledge of effective scientific communication, responsible conduct of research, and methods and technologies of clinical & translational science to ongoing discussions.

Mentored Research and Master's Thesis (Plan A)

CPH 779 Independent Studies in Public Health: Mentored Research (3) Designed for advanced students with research or special study interests in Public Health. Students are under guidance and confer individually with faculty.

CPH 778 Special Topics in Public Health: Thesis Research (3) This course will engage in reading, projects, lectures and/or discussions to address current topics of special interest or concern in public health.

31 total credit hours

The following competencies for the MS in Clinical and Translational Research are based on the core courses for the degree:

1. Utilize the basic terminology and definitions of epidemiology and biostatistics.
2. Calculate basic epidemiology measures.
3. Evaluate the strengths and limitations of epidemiologic reports.
4. Draw appropriate inferences from epidemiologic data.
5. Communicate epidemiologic information to lay and professional audiences.

6. Calculate tests and confidence intervals commonly encountered in univariate biostatistics including those based on t-tests, chi-square tests, and one-way and two-way analysis of variance.
7. Evaluate the strengths of limitations of basic designs used in biostatistics.
8. Interpret regression models including multivariate linear models, logistic models, and proportional hazards models.
9. Communicate biostatistics results to lay and professional audiences.
10. Demonstrate a familiarity with the public health system in this country.

Representative Programs of Study

Case 1: full time student without previous graduate certificate

Fall, Year 1: CPH 605, STA 580, and Elective #1 (most likely CPH 665)
 Spring, Year 1: CPH 611, CPH 630, Elective #2
 Fall, Year 1: Elective #3, Elective # 4, CPH 778
 Spring, Year 2: CPH 779, CPH 701
 Assumption: all electives chosen are three credit hour courses

Case 2: part time student who completed Graduate Certificate in CPH

Fall, Year 1: CPH 611
 Spring, Year 2: CPH 630
 Fall, Year 2: Elective # 3
 Spring, Year 2: Elective # 4
 Fall, Year 3: CPH 778
 Spring, Year 3: CPH 779, CPH 701

Case 3: part time student who completed the Graduate Certificate in Medicine

Fall, Year 1: CPH 605
 Spring Year 1: CPH 611
 Fall, Year 2: CPH 630
 Spring, Year 2: Elective # 4
 Fall, Year 3: CPH 778
 Spring, Year 3: CPH 779, CPH 701

Evaluation of Program

Program success will be evaluated by the proportion of students attaining the following endpoints within one year of completing the MS degree: (1) acceptance of manuscript based on thesis research for publication in a refereed medical journal and (2) grant submissions. The latter includes one funded intramural grant to generate pilot data to support at least one extramural grant application. Other indicators of success will be

presentations at scientific meetings, with the goal being at least two presentations: one oral presentation at the local level and one poster presentation at the national level.

III. Resources

This proposed program will require no additional resources in terms of finance, faculty, or facilities. One additional course is being created in the College of Public Health to familiarize students with the public health system in this country. This will also be required by other proposed programs in the college that are not the MPH or DrPH degrees. Hence this new one credit hour course is not specific to this degree program request but rather responds to accreditation requirements that state that all students in the college should become familiar with public health on a broad level, even if they are not pursuing a MPH or DrPH degree. All other didactic courses are currently being taught (or, in the case of the revised Graduate Certificate Program in Translation Research, will be taught) with existing faculty. Because the anticipated enrollment in the new program is only 5-10 students per year there are enough seats in the core and elective courses within the College of Public Health to accommodate increased student enrollment due to the creation of this program. The new Center for Clinical and Translational Science will be identifying faculty to mentor independent studies and to direct the thesis research of program participants. The latter is key to the success of this MS degree program.

IV. Academic Program Approval Checklist

Note: this is a graduate program meaning most of the questions raised in this part of the application are not applicable (N/A).

01: Are more Kentuckians ready for postsecondary education?

- A. Entrance requirements: all prospective students must be either MDs or graduate students completing an advanced degree (PhD) in another discipline.
- B. Transfer requirements: N/A
- C. Recruitment Plans: all recruitment for this program will be through the Center for Clinical and Translational Research.

02: Are more students enrolling?

- A. Program demand: MDs and doctoral-level students who wish to conduct clinical translational research will need to obtain an advanced degree. Anticipated number of students is approximately seven per year.
- B. Detailed recruiting plans: see 01.C above
- C. Equity: this program will not discriminate on the grounds of race or gender.

03: Are more students advancing through the system?

- A. Time to graduation: since most students will be taking this program on a part-time basis, and since the heart of the program is the mentored research and thesis research, we anticipate that it will take 3 years for a student to complete this program. A typical student will do the Certificate Program in year 1, the MS core courses and electives in year 2, mentored research in the first half of year 3 and thesis in the last half of year 3.
- B. Practicum experience: this is the mentored research. Typically a student will work under close supervision of a faculty member on a research project that both mutually agree will lead to background and pilot data for a thesis and grant application.
- C. Reason for offering the program: see abstract
- D. Delivery. No plans are being made to offer this program over the Kentucky Virtual University. However, if a student wants to take a core course or an elective course over the Internet, then this will be allowed provided prior approval of the course is obtained from the program director.
- E. Collaborative Efforts. There are no such plans at this point in time.

04. Are we preparing Kentuckians for life and work?

- A. How does the program prepare Kentuckians for life and work? It provides the minimal credentials to assure reviewers of future research manuscripts and research proposals that a graduate of this program has had formal training in the new discipline of clinical translational research.
- B. Accreditation expectations. No formal accreditation is needed for this program. However, a major part of the criteria for being awarded a competitive Clinical Translational Science Award by the National Center for Research Resources rests on establishing this MS degree program.
- C. Are there licensure, certification, or accreditation requirements for graduates of this program? No.
- D. Expected degree productivity: at least seven per year.

05. Are Kentucky's communities and economy benefiting?

- A. External Advisory Groups: The Center for Clinical and Translational Research will have an External Advisory Committee which will review and offer advice on this degree program.
- B. Employment expectations: This degree program is supplemental to the primary academic degree (MD, DDS, PharmD, PhD); it is designed to make these graduates more competitive for conducting clinical translational research. The latter is fast becoming a discipline unto itself.
- C. Other benefits. This degree program is designed to increase the clinical research skills of our younger faculty and senior graduate students. It should be viewed as an integral part of the university's quest for top 20 status since to achieve that status the clinical research program at this university must improve.
- D. Specific benefits. See above.

University of Kentucky College of Public Health
CPH-605: Introduction to Epidemiology
Fall 2007

Course Demographics

- Meeting day/s, time and place: 12 – 2:30 p.m., Tuesday in Wethington Bldg 415

Instructor Information

Steven T. Fleming, Ph.D.

Office: SPH Building Room 213C

Telephone: (859) 257-5678 ext. 82330 (Phone Epidemiology Office)

(859) 257-5678 ext. 82229 (Phone: Work-Office)

Office Hours: Tuesday 2:30 – 4:30 PM or by appointment

Teaching Assistant: Rachel Hall rehall2@uky.edu

CPH Room 213A

257-5678 ext. 82016

Office Hours: Monday 11-3, Tuesday 12-2, and by appointment

Course Rationale

This course describes the concepts and principles of epidemiology, which is the distribution and determinants of disease in human populations. The purpose is to describe epidemiology as a set of tools for clinical or managerial decision-making. The course includes discussions of the theory and methods of epidemiology, including key concepts such as incidence, prevalence, mortality, morbidity, risk, exposure and the interaction of agent, host, environment across the constructs of time, person, and place. The course also expostulates the basic types of epidemiologic investigation (retrospective and prospective observational studies and experimental designs) and distinctive features/problems associated with these designs such as relative risk, odds ratio, sensitivity, specificity, and various types of bias.

Course Goals

After completion of this course in Introduction to Epidemiology the student will be able to:

1. Define epidemiology and differentiate between a clinical and an epidemiological approach.
2. Describe the historical evolution of epidemiology.
3. Identify the contributions of biology, statistics, demography, and sociology as they relate to the science of epidemiology.
4. Describe the concepts of agent, host, environment, risk, exposure, person, place, and time.
5. differentiate between incidence and prevalence of disease; calculate mortality and morbidity rates; describe adjustment and standardization in time, by age, sex, and other risk factors.
6. Differentiate between various kinds of study designs in terms of validity, cost, advantages and disadvantages.
7. Describe the following types of epidemiologic studies: (a) case-control; (b) cohort; (c) randomized clinical trials; (d) community trials.

8. Identify sources of bias and missclassification in epidemiological studies
9. Describe how physicians use epidemiologic methods in the practice of medicine

Relationship to Public Health Degree Program Goal(s) and Objectives

This course relates directly to the accomplishment of the educational program goals for the M.P.H. and Dr.P.H. degrees. The MPH goal and objectives are described in the Student Handbook which students received upon enrollment into the MPH degree program. Similarly, the Dr.P.H. goal and objectives are described in the Student Handbook which students receive upon enrollment into the Dr.P.H. degree program. Please reference the appropriate educational program goals throughout the semester, as they will provide a framework for this course and as such will contribute to your preparation for successfully completing other degree program requirements (e.g., capstone, practicum, and Dr.P.H. comprehensive examination).

Relationship Of This Course To Epidemiology Concentration Area Terminal Objectives

In relationship to the MPH degree, this course contributes toward fulfillment of the following terminal objectives for students concentrating in epidemiology.

1. Explain the purposes and applications of epidemiology.
2. Search and/or critically review the epidemiology literature.
3. Identify and use appropriate epidemiology study designs & principles.
4. Collect and manage data for investigating epidemiology issues
5. Analyze epidemiological data using appropriate statistical methods.
6. Interpret and clearly communicate findings.
7. Assess the ethical issues that confront epidemiology and appropriately address these issues.
8. Integrate principles of epidemiology into the practice of public health.

In relationship to the Dr.P.H. degree, this course contributes toward fulfillment of the following terminal objectives for students concentrating in epidemiology.

1. Explain and apply the principles and methods of epidemiology in a wide variety of clinical, community, environmental and public health situations.
2. Search, critically review, and synthesize and interpret the epidemiologic and public health literature to impact public health policy.
3. Identify and employ appropriate epidemiologic study designs to develop fundable epidemiologic and public health programs.
4. Direct the collection, compilation, and management of epidemiologic data for surveillance and investigation of epidemiologic issues.
5. Direct the analysis of epidemiologic data using advanced statistical methods.
6. Interpret and clearly communicate complicated epidemiological findings to collaborators, legislators, administrators, and the public to effect public health policy.
7. Summarize and assess ethical issues that confront epidemiology and public health and integrate appropriate strategies to resolve those issues.
8. Effectively lead, educate, and mentor students, coalitions, clinicians, legislators, administrators, public health practitioners, and other persons to utilize epidemiological data, methods and findings to impact public health and public health practice.

Course Content

Class Date	Topic	Reading Assignment (Gordis)
08/28/07	Description of the course: introduction and overview	Gordis Chapter 1 Dalton CB, C.C. A, Sobel J, et al. An outbreak of gastroenteritis and fever due to listeria monocygenes in milk. N Engl J Med 1997; 336: 100-105. Hepatitis A Outbreak Associated with Green Onions at a Restaurant --- Monaca, Pennsylvania, 2003. MMWR. November 28, 2003 / 52(47): 1155-1157. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5247a5.htm
09/04/07	History of epidemiology Epidemiologic concepts: exposure, disease transmission	Gordis Chapter 2 TI: Assessing the contributions of John Snow to epidemiology: 150 years after removal of the broad street pump handle. AU: Paneth,-N SO: Epidemiology . 2004 Sep; 15(5): 514-6. Interview. John Snow interviewed by Kenneth J. Rothman. AU: Snow,-J SO: Epidemiology . 2004 Sep; 15(5): 641-4
09/11/07	Epidemiologic concepts: agent, host, environment	Are there social determinants of health and disease? AU: Thisted,-R-A SO: Perspect-Biol-Med . 2003 Summer; 46(3 Suppl): S65-73
09/18/07	Epidemiologic concepts: incidence, prevalence	Gordis Chapter 3 Streiner DL. Let me count the ways: measuring incidence, prevalence, and impact in epidemiological studies. Canadian Journal of Psychiatry 1998 43(2): 173-179
09/25/07	Measuring mortality: direct and indirect standardization	Gordis Chapter 4 Kliewer EV, Smith KR. Breast cancer mortality among immigrants in Australia and Canada. J Nat Canc Inst 1995;87:1154-1161.
10/02/07	Measuring morbidity: sensitivity, specificity, PPV, NPV	Gordis Chapter 5 Johnson KM. 1999. The two by two diagram: a graphical truth table. J Clin Epidemiol 52(11): 1073-1082.

10/09/07	Measuring mortality: risk adjustment	Gordis Chapter 4
10/16/07	MID-TERM EXAM	
10/23/07	Infectious Disease: Influenza and Avian Flu, Dr. Glyn Caldwell	
10/30/07	Overview of study design and causal inferences	Gordis Chapter 14
11/06/07	Cohort studies	Gordis Chapters 9 and 11 Samet JM and A. Munoz. 1998. Evolution of the cohort study. <i>Epidemiologic reviews</i> 20(01): 1-14. Szklo M. 1998. Population-based cohort studies. <i>Epidemiologic Reviews</i> 20(1): 81-90. Willett WC and Colditz GA. 1998. Approaches for conducting large cohort studies. <i>Epidemiologic Reviews</i> 20(1): 91-99.
11/13/07	Randomized Controlled Trials	Gordis Chapters 7 and 8
11/20/07	Case-control	Gordis Chapters 10 and 13 Abenhaim L., Y. Moride, F. Brenot, S. Rich, J. Benichou, X. Kurz, T. Higenbottam, C. Oakley, E. Wouters, M. Aubier, G. Simonneau, B. Begaud. 1996. Appetite-suppressant Drugs and the Risk of Primary Pulmonary Hypertension. International Primary Pulmonary Hypertension Study Group. <i>N Engl J Med.</i> 335(9): 609-16. Daling, J. R., L. A. Brinton, L. F. Voigt, N. S. Weiss, R. J. Coates, K. E. Malone, J. B. Schoenberg, and M. Gammon. 1996. Risk of Breast Cancer Among White Women Following Induced Abortion. <i>Am. J. Epidemiol</i> 144(4): 373-380. Rookus, M. A. and F. E. van Leeuwen. 1996. Induced Abortion and Risk for Breast Cancer: reporting (recall bias in a Dutch base-control study. <i>J. Nat. Canc. Inst.</i> Dec. 4; 88(23): 1759-1764.
11/27/07	Causal inferences: bias, confounding, interaction	Gordis Chapters 12, 14 and 15

		Hammal DM and Bell CL. Confounding and bias in epidemiological investigations. <i>Pediatric Hematology/Oncology</i> 2002 19(6): 375-381.
12/04/07	Review	
12/13/07	Final Examination	

Instructional Strategies

The course will consist of thirteen 2 ½ hour lectures given on Tuesday 6:00 – 8:30 in Wethington Room 415.

Assessment and Evaluation

- | | |
|---------------------|-----------------|
| 1. Two examinations | 40% (each exam) |
| 2. Problem sets | 20% |

All exams will cover both lecture material and readings from the text. Any student who misses a class session is responsible for obtaining notes or other handout materials from a fellow classmate. No make-up exams will be given unless arrangements are made with the instructor in advance of the scheduled exam. Any student who fails to take a scheduled exam without making prior arrangements with the instructor in advance of the exam will receive a "0" for the scheduled test. This same policy will be applied to exercises and special projects.

Each student is expected to participate in class discussions each week by reading and discussing the reading assignments.

Instructional Resources

Required Text:

Gordis L, *Epidemiology* (3rd Edition). Philadelphia: W.B. Saunders Company, 2004.

Other Recommended (reference) epidemiology books:

- 1) Rothman, KJ. *Epidemiology: An Introduction*. New York: Oxford UP, 2002
- 2) Last, JM ed. *A Dictionary of Epidemiology* (4th Ed.). New York: Oxford UP, 2001.
- 3) Aschengrau, A. & Seage GR. *Essentials of Epidemiology in Public Health*. Sudbury: Jones and Bartlett Publishers, 2003.
- 4) Timmreck TC, *An Introduction to Epidemiology* (3rd Ed.). Boston: Jones and Bartlett, 2002.
- 5) Fleming ST, Scutchfield FD, Tucker TC. *Managerial Epidemiology*. Chicago: Health Administration Press, 2000.
- 6) Garrett, Laurie, *The Coming Plague*, New York: Penguin Books, 1995.

Additional readings: Most class sessions include additional readings. Full text versions are available on-line. Students will not be tested from the readings, except to the extent that they are covered in class lectures.

Administrative Comments/Course Policies

Expectations with regard to academic honesty:

Academic honesty is fundamental to the activities and principles of a university. All members of the academic community must be confident that each person's work has been responsibly and honorably prepared, developed, and presented. Any effort to gain an advantage not given to all students is dishonest whether or not the effort is successful. The academic community regards academic dishonesty as an extremely serious matter, with serious consequences that range from a grade of "E" to expulsion from the University. Both cheating and plagiarism are considered academic dishonesty. Cheating refers to any unauthorized assistance during examinations, such as notes or handouts. It also includes either giving or taking the answers to examination questions to/from other student(s). Plagiarism is academic "theft", and includes not properly crediting another author for his/her work or idea. Any paraphrase or direct quotation from a published or unpublished work should be properly cited with a footnote or reference. Students must be particularly careful not to engage in plagiarism, even inadvertently, since computers and internet web-browsing seem to facilitate this process.

Enabling Accommodations:

If you have a documented disability that requires academic accommodations, please see me as soon as possible during scheduled office hours. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the Disability Resource Center (www.uky.edu/TLC/grants/uk_ed/services/drc.html). If you have not already done so, please register with the Disability Resource Center (Room 2 Alumni Gym, 257-2754, jkarnes@uky.edu) for coordination of campus disability services available to students with disabilities.

STA 580-001/002: Biostatistics I
Course Information and Syllabus Document

Fall 2007
Dr. Charnigo

Contact information

Instructor: Dr. Richard Charnigo

Office: 203-B College of Public Health

Phone: 859.257.5678 x 82072

E-Mail: richc@ms.uky.edu, RJCharn2@aol.com

Home Page: www.ms.uky.edu/~richc

Office Hours: 2:00 to 3:00 p.m. on Mondays, except 03 September and 01 October

Teaching Assistant: Mr. Benjamin Hall

Office: 857 Patterson Tower

Phone: 859.257.9202

E-Mail: bhall2@ms.uky.edu

Office Hours: TBA at the first class meeting

Biostatistics Department Walk-In Help: Ms. Erin Abner

Office: TBA at the first class meeting

Office Hours: TBA at the first class meeting

About this course

Course Description: STA 580 introduces the basic principles of biostatistics used in the univariate analysis of data commonly encountered in biomedical studies.

Objectives:

1. You will learn the elements of hypothesis testing, including power, sample size, and tests of significance.
2. You will learn methods for analyzing data from one-way and two-way layouts, including multiple comparisons and contrasts.
3. You will learn the analysis of contingency tables, including related concepts of relative risks and odds ratios.
4. You will be introduced to the concepts of regression modeling and correlation.
5. You will be introduced to the analysis of time-dependent data subject to right censoring.

College of Public Health Terminal Objectives in Biostatistics: The last two pages of this document indicate the College of Public Health terminal objectives in biostatistics and their associated competencies. The entries in the third column indicate the minimal level of attainment for someone who has successfully completed STA 580: a “1” represents awareness, a “2” represents knowledgeability, and a “3” represents proficiency. Your personal level of attainment upon completion of STA 580 and upon completion of your degree program may be higher.

Relationship to Public Health Degree Program Goals: This course relates directly to the accomplishment of the educational program goals for the M.P.H. degree, which are described in the most current student handbook. Please reference the educational program goals throughout the semester, as they will provide a framework for this course and will contribute to your preparation for successfully completing other degree program requirements (e.g., capstone and practicum).

Textbook: Rosner, Bernard (2005). *Fundamentals of Biostatistics*, sixth edition. Belmont, CA: Thomson.

Prerequisite: MA 109 (or equivalent).

Course policies and logistics

Class Meetings: Lectures will take place on Thursdays from 3:30 to 5:20 p.m. in NURS 115 (except 22 November). Section 001 laboratories will take place on Thursdays from 6:00 to 7:50 p.m. in NURS 602J (except 30 August, 18 October, 22 November, 06 December) Section 002 laboratories will take place on Mondays from 3:30 to 5:20 p.m. in NURS 602J (except 03 September, 22 October, 26 November).

E-mail Memoranda and Course Materials: I will be sending e-mail memoranda regularly to distribute course materials, post grade information (for those who request it), and make announcements. Course materials will also be available from my home page, (www.ms.uky.edu/~richc). Please inform me if you are not receiving the memoranda.

Written Assignments: There will be six written assignments for you to prepare in laboratory and outside of class, tentatively due at 5:20 p.m. on the Thursdays of 13 September, 27 September, 11 October, 01 November, 15 November, and 06 December. You are encouraged to work in self-selected groups of two or three, in which case it suffices to hand in one copy of the assignment for the group; however, you may work individually if you prefer. Many items on the written assignments will require the use of statistical software. Do not worry if you have little or no prior experience with statistical software, as you will become familiar with SAS during laboratory. Written assignments are to be submitted in hard copy and to me in person, unless you have obtained permission to use an alternative mechanism for submission.

Examinations: There will be an in-class midterm examination from 3:30 p.m. to 5:20 p.m. on Thursday 18 October. There will be a final examination at the University's designated time from 3:30 to 5:20 p.m. on Thursday 13 December. The examinations are open-book in the sense that you may refer to any printed materials that you care to bring, including the textbook and your notes. However, you may not share printed materials or calculators during examinations, you may not use a computer or otherwise go "online" during examinations, and there is to be no collaboration on examinations.

Grading: Your grade for the course will be determined by the written assignments (30%), the midterm examination (35%), and the final examination (35%). There may be opportunities to earn bonus points. The cutoff for an “A” will be no higher than 90%, the cutoff for a “B” will be no higher than 75%, and the cutoff for a “C” will be no higher than 60%.

Late Policy: Cases involving any of the following will be handled individually: University-excused absences, University-prescribed academic accommodations, recommendations from an appropriate Dean or the Ombud. Otherwise, a written assignment may be submitted up to 24 hours late, subject to a 25% penalty; such a late submission should be left under my office door (CPH 203-B) and noted in an e-mail to me (richc@ms.uky.edu) that same day.

Makeup Policy: Cases involving any of the following will be handled individually: University-excused absences, University-prescribed academic accommodations, recommendations from an appropriate Dean or the Ombud, legitimate scheduling difficulties of which I am informed at least seven days in advance. Otherwise, a makeup examination for an unexcused absence will be available within 120 hours of the scheduled examination, at a mutually acceptable time and subject to a 25% penalty; a request for such a makeup examination should be noted in an e-mail to me (richc@ms.uky.edu) as soon as possible.

Accommodations: If you have a documented disability that requires academic accommodations, please see me as soon as possible during scheduled office hours. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the Disability Resource Center (www.uky.edu/TLC/grants/uk_ed/services/drc.html). If you have not already done so, please register with the Disability Resource Center (Room 2 Alumni Gym, 257-2754, jkarnes@uky.edu) for coordination of campus disability services available to students with disabilities.

Academic Honesty: The Department of Statistics, Department of Biostatistics, College of Arts and Sciences, College of Public Health, and the University of Kentucky place a premium on academic honesty. Please refer to the University of Kentucky Student Rights and Responsibilities document (www.uky.edu/StudentAffairs/Code/part2.html).

Unforeseen Contingencies: In the unlikely event that an unforeseen contingency requires additional course policies, you will be promptly notified in an e-mail memorandum.

Tentative schedule

Lecture Laboratory	Lecture topics (Relevant sections of the textbook) Laboratory agenda (Approximate time allocation)
R 08/23 R 08/23 or M 08/27	Numerical and graphical summaries of data (2.1 - 2.8) Getting started with SAS (~70%), working on Assignment 1 and asking TA questions individually (~30%)
R 08/30 NO LABORATORY	Probability; conditional probability; Bayes' theorem (3.1 - 3.7)
R 09/06 R 09/06 or M 09/10	Random variables; sums of random variables and the Central Limit Theorem; population and sample (4.1 - 4.9, 5.1 - 5.7, 6.2) Getting started with SAS (~50%), working on Assignment 1 and asking TA questions individually (~50%)
R 09/13 R 09/13 or M 09/17	Point and interval estimation for a mean, a variance, and a proportion (6.5, 6.7, 6.8) Some SAS pointers (~30%), working on Assignment 2 and asking TA questions individually (~50%), TA-led group discussion of Chapter 6 methods (~20%)
R 09/20 R 09/20 or M 09/24	Introduction to hypothesis testing; test concerning a mean; power and sample size (7.1 - 7.6) Some SAS pointers (~30%), working on Assignment 2 and asking TA questions individually (~50%), TA-led group discussion of Chapter 7 methods (~20%)
R 09/27 R 09/27 or M 10/01	Relating estimation to testing; test concerning a variance; test concerning a proportion (7.7, 7.9, 7.10) Some SAS pointers (~20%), working on Assignment 3 and asking TA questions individually (~60%), TA-led group discussion of Chapter 7 methods (~20%)
R 10/04 R 10/04 or M 10/08	Paired and unpaired tests concerning two means; test concerning two variances (8.1 - 8.7) Some SAS pointers (~20%), working on Assignment 3 and asking TA questions individually (~60%), TA-led group discussion of Chapter 8 methods (~20%)
R 10/11 R 10/11 or M 10/15	Outliers; power and sample size; test concerning two proportions; chi-square test for association (8.9 - 8.10, 10.1 - 10.2, 10.6) Working on Assignment 4 and asking TA questions individually (~80%), TA-led group discussion of Chapter 10 methods (~20%)
R 10/18 NO LABORATORY	<i>Midterm examination (covers Lectures 1 through 7)</i>

R 10/25 R 10/25 or M 10/29	Scales of measurement; sign test; signed rank test; rank sum test (9.1 – 9.4) Working on Assignment 4 and asking TA questions individually (~80%), TA-led group discussion of Chapter 9 methods (~20%)
R 11/01 R 11/01 or M 11/05	One-way layouts and the analysis of variance; multiple comparisons and linear contrasts (12.1 – 12.4) Working on Assignment 5 and asking TA questions individually (~80%), TA-led group discussion of Chapter 12 methods (~20%)
R 11/08 R 11/08 or M 11/12	Kruskal-Wallis test and Dunn procedure for one-way layouts; two-way layouts and the analysis of variance (12.7, 12.6) Working on Assignment 5 and asking TA questions individually (~80%), TA-led group discussion of Chapter 12 methods (~20%)
R 11/15 R 11/15 or M 11/19	Epidemiologic study design; relative risks and odds ratios (13.1 – 13.3) Working on Assignment 6 and asking TA questions individually (~80%), TA-led group discussion of Chapter 13 methods (~20%)
NO LECTURE NO LABORATORY	
R 11/29 R 11/29 or M 12/03	Simple linear regression; least squares principle; inferences about coefficients; estimation and prediction; correlation (11.1 - 11.8) Working on Assignment 6 and asking TA questions individually (~80%), TA-led group discussion of Chapter 11 methods (~20%)
R 12/06 NO LABORATORY	Survival function; censoring; Kaplan-Meier estimation; log-rank test (14.8 - 14.10)
R 12/13	<i>Final examination (emphasizes Lectures 8 through 14)</i>

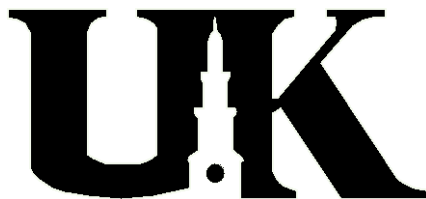
Competency attainment

Terminal Objectives in Biostatistics	Competencies	Level of Attainment
1. Explain basic principles of statistical estimation and inference.	<ul style="list-style-type: none"> a. Conceptualize sample measurements as realizations of random variables; b. Conceptualize estimates of population parameters as realizations of random variables; c. Construct confidence intervals for population parameters; d. Formulate statistical hypothesis tests concerning population parameters; e. Quantify the power of some basic hypothesis tests; f. Determine appropriate sample sizes for some basic hypothesis tests; g. Articulate the relationship between confidence intervals and hypothesis tests. 	<ul style="list-style-type: none"> 2 2 2 2 2 2 2
2. Identify and use standard experimental and sampling designs.	<p>Be conversant in the use of the following:</p> <ul style="list-style-type: none"> a. designing and analyzing a two way lay out with interaction; b. designing and analyzing experiments with repeated measures; c. designing and analyzing simple cross over experiments; d. adjusting for the effects of confounders and/or stratifying variables; e. explaining the biostatistical components of a clinical trial including large prevention trials in public health and community intervention studies; f. monitoring the progress of a disease over time using time series analysis or disease surveillance methods; g. applying spatial statistics to a problem in public health that has a geographic component. 	<ul style="list-style-type: none"> 1
3. Understand elementary probability concepts used in Public Health.	<ul style="list-style-type: none"> a. Characterize conditional probability both mathematically and intuitively; b. Express the specificity of a diagnostic test as a conditional probability; c. Express the sensitivity of a diagnostic test as a conditional probability; d. Construct and interpret the receiver operator curve of a diagnostic test; e. Apply Bayes' Theorem to calculate the predictive positive value of a diagnostic test from the specificity, sensitivity, and disease prevalence; f. Describe the binomial probability model and the contexts in which it arises; g. Describe the Poisson probability model and the contexts in which it arises; h. Employ Markov chains to describe random phenomena with a special probabilistic structure. 	<ul style="list-style-type: none"> 1 1 1
4. Apply statistical methods commonly encountered in univariate data analysis.	<ul style="list-style-type: none"> a. Use descriptive statistics effectively; b. Perform paired and independent t-tests to compare means; c. Calculate chi squared statistics to compare proportions as well as construct confidence intervals for odds ratios and relative risk; d. Analyze data obtained from one way ANOVA designs (including multiple comparisons and contrast); e. Fit a simple linear regression model; f. Construct Kaplan Meier curves for right censored observations and compute the log rank statistic to compare these curves between two groups. 	<ul style="list-style-type: none"> 2 2 2 2 2 2

5. Apply statistical methods commonly encountered in multivariate data analysis.	<ul style="list-style-type: none"> a. Identify and apply appropriate multivariate statistical models including multiple linear regression, logistic regression, Poisson regression, proportional hazards regression, and mixed models; b. Critically interpret the outcomes of the multivariate analysis; c. Conduct graphical and analytical model diagnostics, and recommend remedies based on the diagnostics; d. Integrate the outcomes of multiple studies using meta analysis. 	
6. Gather, organize, and manage health survey data.	<ul style="list-style-type: none"> a. Design a health survey instrument; b. Assess instrument/item reliability and validity; c. Draw and analyze a simple random sample of measurements; d. Implement and analyze more complex survey designs including stratified samples, clustered samples, and multistage samples; e. Process incomplete data using imputation; f. Adopt an appropriate weighting scheme for observations in a health survey. 	1
7. Effectively use statistical software to collect, manage, and analyze Public Health data.	<ul style="list-style-type: none"> a. Master the use of SAS analyst, a click and point statistical software; b. Acquire the skills necessary to write code for SAS programs; c. Understand the principles of data acquisition, verification, and validation; d. Become skilled at editing, combining, and linking data sets; e. Learn the fundamentals of data manipulation and analysis; f. Efficiently create tables, graphs, and reports; g. Learn the fundamentals of the SAS macro facility; h. Learn to use nQuery Advisor, a sample size calculation software program. 	1
8. Critically review biostatistical issues arising in Public Health literature.	<ul style="list-style-type: none"> a. Demonstrate they can select appropriate statistical methods for the problem; b. Resolve controversial issues associated with competing solutions in biostatistics for the same problem (discussing strengths and weaknesses). 	1 1
9. Interpret and clearly express findings.	<ul style="list-style-type: none"> a. Interpret univariate statistical models; b. Interpret complex multivariate statistical models; c. Express their findings clearly both verbally and in writing. 	2 1
10. Integrate principles of biostatistics in the practice of Public Health.	<ul style="list-style-type: none"> a. Use statistical methodology to analyze public health data; b. Recognize the potential for statistics to aid in the development of guidelines and policies, the implementation and management of programs, and the evaluation of programs. 	1

CPH 712
Advanced Epidemiology

Syllabus
&
Schedule



University of Kentucky
College of Public Health

University of Kentucky
College of Public Health

Course Syllabus

Title:	Advanced Epidemiology
Course Number:	CPH 712 / 910
Time:	Mondays 6:00 – 8:30 pm
Credit:	3 Semester Hours
Class Location:	CPH Room 115
Faculty:	Steven R. Browning, MSPH, Ph.D. College of Public Health / College of Medicine Phone: 859-257-5678 EXT. 82235 E-mail: srbrown@email.uky.edu Office Hours: Monday 3-4:30 PM and by appointment

Course Description:

This course provides students with the understanding of advanced issues in the design, analysis, and interpretation of epidemiologic studies. The course text and associated readings will focus on study designs and the methodologic approaches to addressing bias, confounding, and error in the design of population-based health research. The development of a systematic approach for evaluating evidence from epidemiologic studies as it relates to demonstrating causality will be emphasized. Focusing on study design, measures of associations, confounding, interaction, sources of bias and error, the student will gain an understanding of epidemiology and its role in the medical and public health sciences.

Prerequisites: Introduction to Epidemiology (CPH 605) or consent of instructor

Credit: 3 semester hours.

Course Objectives:

After completion of this course in Advanced Epidemiology the student will be able to:

1. Differentiate between epidemiologic study designs and assess their strengths relative to causal inference.
2. Understand the multiple approaches to measuring disease frequency, association, and impact and which measures are applicable to various study designs.
3. Evaluate the potential for confounding and interaction in epidemiologic data and understand several approaches for addressing these validity issues in epidemiologic research.
4. Appreciate the issues associated with sample size estimation and the precision of estimates in the design and evaluation of epidemiologic research.
5. Perform and interpret stratified analysis of epidemiologic data for point and interval estimation of measures of association for typical study designs.
6. Be familiar with the interpretation, strengths, limitations, and assumptions associated with using various statistical modeling procedures for the analysis of epidemiologic data.
7. Evaluate epidemiologic literature in a systematic and critical manner in assessing the “state-of-the-science”.

Course Structure:

The course will consist of seminar/discussion classes, lectures, and self study. The course will be enhanced by an online component in Blackboard which will provide resources for accessing class materials including assignments and readings. Students will be required to complete a series of problem sets, take a midterm and final exam, and write a brief critique of an epidemiologic study.

Relationship to Public Health Degree Program Goal(s) and Objectives:

This course relates directly to the accomplishment of the educational program goals for the M.P.H. and the Dr. P.H. degrees. The MPH goal and objectives are described in the Student Handbook which students received upon enrollment in the MPH degree program. Similarly, the Dr.P.H. goals and objectives are described in the Student Handbook which students receive upon enrollment in the Dr. P.H. degree program.

Relationship of Course to Epidemiology Concentration Area Terminal Objectives:

In relation to the MPH degree, this course contributes toward the fulfillment of the following terminal objectives for students concentrating in epidemiology:

1. Explain the purposes and applications of epidemiology.
2. Search and/or critically review the epidemiology literature.
3. Identify and use appropriate epidemiology study designs and principles.
4. Collect and manage data in the conduct of research.
5. Analyze epidemiologic data using appropriate statistical methods.
6. Interpret and clearly communicate findings and study results.
7. Assess the ethical issue that confront epidemiology and appropriately address these issues.
8. Integrate principles of epidemiology into the practice of public health.

In relationship to the Dr. P.H. degree, this course contributes toward the following terminal objectives for students concentrating in epidemiology:

1. Explain and apply the principles and methods of epidemiology in a wide variety of clinical, community, environmental, and public health situations.
2. Search, critically review, synthesize, and interpret the epidemiologic and public health literature to impact public health policy.
3. Identify and employ appropriate epidemiologic study designs to develop fundable epidemiologic and public health programs.
4. Direct the collection, compilation, and management of epidemiologic data for surveillance and investigation of epidemiologic issues.
5. Direct the analysis of epidemiologic data using advanced statistical methods.
6. Interpret and clearly communicate complex epidemiologic findings to collaborators, legislators, and administrators to effect public health policy.
7. Summarize and assess ethical issues that confront epidemiology and public health and integrate appropriate strategies to resolve these issues.
8. Effectively lead, educate, and mentor students, coalitions, clinicians, legislators, administrators, public health practitioners, and other persons to use epidemiological data, and results to impact public health and public health practice.

Course Materials:

A course packet, including the syllabus, will be distributed on the first day of class to all students who are officially enrolled in the course. The course packet will contain a topic schedule for the course and a listing of the reading assignments. Problem sets will be either handed out in class or posted on Blackboard. Additional course materials will be distributed as the class progresses.

There is one required text for the class and several recommended texts (see below). The texts for the course may be purchased at the Kennedy Bookstore (405 S. Limestone) or purchased online from Oxford University Press. Additional reading materials will either be on reserve in the College of Public Health student lounge or available through Blackboard.

Required Textbook:

Elwood Mark. *Critical Appraisal of Epidemiological Studies & Clinical Trials. Third Edition.* Oxford University Press. 2007. (price = \$65.00 paperback) ISBN 978-0-19-852955-2

Recommended (optional) Textbooks:

Szklo, M and Nieto J. *Epidemiology: Beyond the Basics* (2003). Jones and Bartlett Publishing.

Kelsey, J.L., Thomson, W.D. and Evans, A.S. (1996). *Methods in Observational Epidemiology.* Oxford University Press, New York. [Extremely useful explanations of issues involved in case-control, retrospective, and prospective studies. A good discussion of matching, stratification, and design issues.]

Required Readings (other than text):

Required readings from journal articles, manuscripts, and other documents are listed in the daily assignments. Most of the journal articles for readings will be on reserve in the Department of Epidemiology graduate student area (room 209). Some of these are available as electronic documents in Blackboard.

In addition, we have highlighted (in the assignments) those readings for which articles are available electronically from the e-journals at the medical library (www.mc.uky.edu/medlibrary/resources/ejournals/). Students are responsible for securing their own copies of the readings and reviewing the materials prior to the class.

Evaluation:

Assignments and Tests	Points
Mid-term examination (take-home) [25%]	250
Problem Sets (4) [40%] 100 points for each.	400
#1 Measures of frequency and association	100
#2 Case control, confounding, and other biases	100
#3 Interaction assessment	100
#4 Multiple logistic regression	100
Lead class discussion [5%]	50
Brief study appraisal [10%]	100
Final Exam (in class) [20%]	200
TOTAL	1000

Letter grades for the course will be assigned on a percentage basis (as given below) for the student's total score as a percentage of the total number of points possible for the course. In accordance with the Graduate School Bulletin, grading for the course will use the grading scale of the Graduate School. D grades may not be awarded to graduate students. The incomplete grade ("I") is intended only for students who are not able to complete the assigned course work on schedule due to serious illness or other highly unusual personal circumstances.

<u>Grade</u>	<u>Definition</u>	<u>%</u>	<u>Points</u>
			<u>(3 credit)</u>
A	High Achievement	90-100	900-1,000
B	Satisfactory Achievement	80-89	800-899
C	Minimum Passing grade	70-79	700-799
E	Failure	< = 69	<=699

Midterm exam:

There will be a take-home mid-term exam due on **March 3**. The exam will emphasize material covered in the assigned readings, lectures, and assignments. The mid-term will cover material considered until **February 25**. The test will be given to the class on or before (if posted on BB) **February 25** and need to be submitted by **March 3**. The midterm exam is expected to be the student's own work.

Reading discussion and class participation.

Students enrolled in the class are required to lead a discussion of the reading materials for a given class. This requires that he/she is well prepared in having read the assigned literature and has prepared a series of questions or other activities for generating a discussion on the reading materials. A short presentation of major issues, controversies, or the "basics of the technique" may be presented to the class. It's an opportunity to be creative. A schedule will be established at the beginning of the semester for students leading the discussion.

Problem Sets:

The problem sets are due on the dates indicated below. The assignments involve applied computations relevant to epidemiologic analysis. The assignments must be completed and handed in on the due date. The assignments must be a student's own work (i.e. each student must turn in a completed assignment) but students are encouraged and allowed to work together in solving the problems and assisting each other with the exercises. **Points will be deducted for problem sets which are submitted after the due date.** Problem sets will be discussed in the class.

Number	Topic	Due Date
Set #1	Measures of frequency and association	Feb. 11
Set #2	Case control studies, confounding, and other biases	Feb. 25
Set #3	Interaction assessment	March 24
Set #4	Multiple logistic regression	April 21

Critical Appraisal of Study:

For this assignment, select a study (case control, cohort, randomized clinical trial, or community intervention) from the published literature and write a critical appraisal of the research (8-10 double spaced pages). This assignment should be guided by the format developed by Elwood in your course text on "Critical Review of Epidemiologic Studies and Clinical Trials". Chapters 10-15 of the text provide examples for the appraisal of various epidemiologic study designs and it would be wise to review the chapter that is pertinent to the study design that you have chosen for your appraisal. It is recommended that you include the following section headings in your evaluation of the study.

1. Abstract of the study (1 page). Briefly summarize the purpose, methods, results, and conclusions from the study.
2. Rationale for the study (1 page). Evaluate the literature on the topic and discuss the context on which this study was undertaken.
3. Assess the internal validity of the study with respect to confounding, bias, and error (2-3 pages).
4. Assess the implications of the study with respect to meeting the criteria for causality (time sequence, dose-response, biological plausibility, comparison with other studies, etc.) (3 pages).
5. Evaluate the external validity and generalizability of the study with respect to the source population. (1 page)
6. Final assessment. Provide your overall opinion of the study with respect to its strengths, limitations, and the next steps for research.

The critical appraisal will be due on **April 7**.

Final exam:

There will be an in-class final exam. The final exam will cover material in the assigned readings, lectures, and assignments for the entire course but emphasize the topics following the midterm exam. The test will be given to the class on **April 28** at the regular class time. In the event that you have circumstances that make it difficult to take the exam at this time, please notify the instructor of this issue at least 2 weeks prior to the exam so that other arrangements can be made.

Guidelines for the Use of Blackboard as a Supplement to the Course:

Blackboard 7 is comprehensive and flexible e-learning software platform that delivers a course management system for online learning at the University of Kentucky. The system can be accessed via the internet at the following website :

<http://www.uky.edu/Blackboard/index.php>)

Students in the class should be automatically enrolled in the course when they register. Course materials including a copy of the syllabus and schedule, assignments, examinations, electronic datasets, course readings will be available from Blackboard. In addition, Blackboard provides access to websites related to the content of the course.

Since the class only meets once per week, the Blackboard environment will permit students to discuss problems and assignments with each other and will allow the instructor to make general announcements to the class through the announcements frame or the e-mail facility. It is recommended that you check in at Blackboard at least once early in the week prior to class for any announcements relevant to the upcoming class.

This portion of the course is still under development. Your comments and insights related to the web-based adjunct to the class will be much appreciated during the semester.

Topic Outline:

Class	Month	Date	Topic	Faculty
1	January	14	Orientation / Review	Browning
	January	21	Academic Holiday / No class	-----
2	January	28	Causality and measurement of disease	Browning
3	February	4	Study design I (case control)	Browning
4	February	11	Study design II (cohort studies)	Browning
5	February	18	Analysis of trends for rates and ecologic studies	Hopenhayn
6	February	25	Analysis I (simple analysis / review and extensions)	Browning
7	March	3	Analysis II (stratified analysis and confounding)	Browning
	March	10	No Class / Spring Break	-----
8	March	17	Analysis III (interaction assessment)	Chattopadhyay
9	March	24	Bias (selection and information)	Browning
10	March	31	Sample size estimation / Study implementation	Browning
11	April	7	Multivariable analysis –Logistic Regression I	Browning
12	April	14	Logistic regression II	Browning
13	April	21	Survival analysis basics	TBA
14	April	28	Final exam (in class)	Browning

The lecture schedule is subject to change depending on the schedules of faculty. Students will be given notice in the event that a change needs to be made to the schedule.

	Topic	Reading Assignment
Class 1	Orientation / Review	<ul style="list-style-type: none"> None . Optional: Taubes, G. Epidemiology faces its limits. <i>Science</i> 1995; 269: 164-9.
	Academic Holiday / No class	<ul style="list-style-type: none"> None
Class 2	Causality and measurement of disease	<ul style="list-style-type: none"> Elwood, Chapter 1. "Importance of causal relationships..." Schoenbach, V. Measuring Disease and Exposure. Chapter 5 from "Understanding the Fundamentals of Epidemiology: An Evolving Text". (Accessible on Blackboard). Rothman, KJ. Causes. <i>American Journal of Epidemiology</i>. 1976; 104:587-592 Hofler, M. The Bradford Hill considerations on causality: a counterfactual perspective. <i>Emerging Themes in Epidemiology</i>. 2005; 2: 11
Class 3	Study design I (case control)	<ul style="list-style-type: none"> Elwood, Chapter 2. "Study designs..." Wacholder S, Silverman DT, Mclaughlin JK, Mandel JS. 1992 Selection of controls in case control studies. I. Principles. <i>Am J. Epidemiology</i>. 135 1019-1028. Saldana, T. Carbonated Beverages and Chronic Kidney Disease. <i>Epidemiology</i>. July 2007. pp. 501-506
Class 4	Study design II (cohort)	<ul style="list-style-type: none"> Elwood, Chapter 3. "Results obtained from studies..." Elwood, Chapter 4. "Selection of subjects for study..." Zhang J and Yu KF. 1998 What's the relative risk? A method for correcting the odds ratio in cohort studies for common outcomes. <i>JAMA</i> 280: 1690-1691 * Whelan, B. et al. Work Schedule During pregnancy and Spontaneous Abortion. <i>Epidemiology</i>. May 2007.
Class 5	Analysis of trends for rates; ecologic studies.	<ul style="list-style-type: none"> Radon, K. Environmental Exposure to Confined Animal Feeding Operations and respiratory health of neighboring Residents. <i>Epidemiology</i>. May 2007. Morgenstern. H . Ecologic Studies in Epidemiology: Concepts, principles, and methods. <i>Annual Review of Public Health</i>. 1995
Class 6	Analysis I: Simple analysis	<ul style="list-style-type: none"> Elwood, Chapter 7. "Chance variation....." . Part 1. pp. 225-234 Woolson, Robert F. and Joel C. Kleinman. Perspectives on statistical significance testing. <i>Annual Review of Public Health</i> 1989 (10)
Class 7	Analysis II: Stratified analysis and confounding .	<ul style="list-style-type: none"> Elwood, Chapter 6. "Confounding...." . pp. 157-205 Greenland S, Morgenstern H. Confounding in health research. <i>Annual Rev Public Health</i> 2001;22:189-212. (advanced reading) Notes on Stratified Analysis and Confounding by SR Browning.
	Spring Break/ no class	<ul style="list-style-type: none">
Class 8	Analysis III. Effect modification and interactions	<ul style="list-style-type: none"> Elwood, Chapter 7. "Chance variation". Part 2 Statistical methods in more complex situations. pp. 241-256 Tuut, M and Hense HW. "Smoking, other risk factors and fibrinogen levels: evidence of effect modification". <i>AEP</i>, Vol. 11, #4 May 2001, 232-238
Class 9	Selection and information bias	<ul style="list-style-type: none"> Elwood, Chapter 5. "Error and bias in observations..." Morabia, A. 1997 Case control studies in clinical research: mechanism and prevention of selection bias. <i>Prev. Med.</i> 26 (5 pt 1) : 674-677.

Class 10	Sample size estimation and practical aspects of study implementation.	<ul style="list-style-type: none"> • Sample size reading to be distributed. • Chapter 15. “Practical Aspects of Epidemiologic Research” by Victor Schoenbach. (www.sph.unc.edu/EPID168/) • Data management and analysis by H. Arrighi (to be posted)
Class 11	Multivariable analysis – Logistic regression I	<ul style="list-style-type: none"> • Elwood, Chapter 6. “Confounding...”. pp. 205-220 • Greenland, S. Modeling and variable selection in epidemiologic analysis. Am J Public Health. 1989 Mar;79(3):340-9. • Kleinbaum, David. Chapter 1. Introduction to Logistic Regression. In Logistic Regression: A self-Learning Text. Springer-Verlag. Statistics in the Health Sciences. (chapter to be distributed).
Class 12	Logistic regression II	<ul style="list-style-type: none"> • Kleinbaum, David. Chapter 6. Modeling Strategy Guidelines. In Logistic Regression: A self-Learning Text. Springer-Verlag. Statistics in the Health Sciences. (chapter to be distributed).
Class 13	Survival analysis basics	<ul style="list-style-type: none"> • Elwood, Chapter 7. Part 3 Lifetable methods. pp. 264-277 • Bull, Kate and D. Spiegelhalter. Tutorial in Biostatistics: Survival analysis in observational studies. Statistics in Medicine, 1997. Vol. 16, 1041-1074
Class 14	Final exam (In class)	

Summary of Important Dates:

Problem Set # 1	February 11
Midterm distributed	February 25
Problem Set # 2	February 25
Midterm exam due	March 3
Problem Set # 3	March 24
Problem Set # 4	April 21
Critical Appraisal	April 7
Final exam.	April 28

Policy on absences and late submittal of work:

Students are expected to attend all classes but are not required to do so in order to pass the class. Although attendance is not required and does not serve as a criterion for a grade in the course, examinations may include materials not covered in the texts, readings, or problem sets. Additionally, a point assignment is given for class participation.

Students are expected to take the examinations on the day scheduled in the syllabus. Students who cannot take the examination on the scheduled day must have an excused absence (illness of student or family member, death of family member, university sponsored trip, etc.) as defined in the *Student Rights and Responsibilities* handbook. Students should inform the faculty in advance of the examination if a problem exists with respect to taking the exam on the designated day. Students will be given the opportunity to make up missed work or exams in the event of excused absences. Students are entitled to excused absences for the purpose of observing their major religious holidays.

It is expected that all work submitted for a grade in the course be the work of the individual student. Students are allowed and encouraged to collaborate on assigned problems and problem sets for the course but must submit their own work. Students are encouraged to review sections 6.3.1 on plagiarism and 6.3.2 on cheating in the *Student Rights and Responsibilities* handbook.

Incomplete or “I” grades:

It is at the discretion of the faculty member to assign an 'I' grade at the students request. The student and faculty should agree on (1) what is needed to complete the course requirements to be assigned a final letter grade, and (2) faculty and student should agree on the time frame to complete this work. Please be aware that the faculty ARE NOT REQUIRED to give the student the entire 12 month period to complete the work. In fact, for this course, it is assumed that any necessary extensions needed to complete the work will be short and essentially equivalent to the amount of time that the student could not work on the assignments due to illness, family emergency, or other circumstances. The faculty member would work with the student in developing a time frame which is appropriate for the situation and manageable for both the faculty and student schedules. This will be agreed to in writing by both the student and faculty. Students are strongly encouraged to complete all assignments in the given semester as the policy to assign an “I” is at the discretion of the faculty member and will only be applied when circumstances are warranted.

Enabling Accommodations:

If you have a documented disability that requires academic accommodations, please see me during scheduled office hours. In order to receive accommodations in this course, you must provide me with a letter of accommodation from the Disability Resource Center. If you have not already done so, please register with the Disability Resource Center for the coordination of campus disability services.

Key Periodicals and Journals:

Consulting these journals will be helpful when searching for articles.

Public Health Reports
American Journal of Public Health
American Journal of Epidemiology
American Journal of Industrial Medicine
New England Journal of Medicine
Journal of the American Medical Association (JAMA)
Morbidity and Mortality Weekly Reports (MMWR)
Archives of Environmental Health
Journal of Occupational Medicine
Epidemiology

Supplemental Textbooks with a biostatistics / data analysis orientation:

Hatcher, L., & Stepanski, E.J. (1994). A step-by-step approach to using the SAS System for univariate and multivariate statistics. Cary, NC: The SAS Institute, Inc.

Munro, B.H., & Page, E.B. (1997). Statistical methods for health care research (3rd Ed.). Philadelphia: J.B. Lippincott.

Abramson, J.H. (1994). Making sense of data (2nd Ed.). New York: Oxford University Press.

Jaeger, R.M. (1990). Statistics: A spectator sport (2nd Ed). Thousand Oaks, CA: Sage.

Kanji, G. (1999). 100 statistical tests. Thousand Oaks, CA: Sage.

Krishnamwity, G., Kasovia-Schmitt, P., & Ostroff, D. (1995). Statistics: An interactive text for the health and life sciences. Boston: Jones and Bartlett.

Matthews, D.E., & Farewell, V.T. (1988). Using and understanding medical statistics (2nd Revised Ed.). New York: Karger.

Pedhazur, E.J. (1982). Multiple regression in behavioral research (2nd Ed.). Fort Worth, TX: Holt, Rinehart, and Winston, Inc.

Tabachnick, B. G., & Fidell, L.S. (1989). Using multivariate statistics (2nd Ed.). New York: Harper Collins.

Vogt, W. P. (1999). Dictionary of statistics & methodology: A nontechnical guide for the social sciences (2nd Ed.). Thousand Oaks, CA: Sage.

Wallgren, A., Wallgren, B., Person, R., Jorner, U., & Haaland, J. (1996). Graphing statistics & data. Thousand Oaks, CA: Sage.

Wassertheil-Smoller, S. (1995). Biostatistics and epidemiology: A primer for health professionals (2nd Ed.). New York: Springer-Verlag.

Wright, D. (1996). Understanding statistics: An introduction for the social sciences. Thousand Oaks, CA: Sage.

Supplemental Textbooks with an epidemiology orientation:

Principles of Epidemiology: An Introduction to Applied Epidemiology and Biostatistics. 2nd Edition (1992). US Department of Health and Human Services, Centers for Disease Control and Prevention.

Hennekens, Charles H and Buring, Julie E. (1987) *Epidemiology in Medicine*. Little Brown and Company. Boston.

Streiner, David L. & Norman, Geoffrey R. *PDQ Epidemiology* (2nd Edition). Mosby Publishers.

Rose, Geoffrey (1992). *The Strategy of Preventive Medicine*. New York. Oxford University Press.

Lilienfeld, David E. and Stolley, Paul D. (1994). *Foundations of Epidemiology*. 3rd Edition. Oxford University Press.

Last, John M. (1995). *A Dictionary of Epidemiology*. 3rd Edition. New York. Oxford University Press.

Mausner, J.K. and Kramer S. (1985). *Mausner & Bahn: Epidemiology—An Introductory Text*. 2nd Edition. WB Sanders Co., Philadelphia.

Kelsey, J.L., Thomson, W.D. and Evans, A.S. (1996). *Methods in Observational Epidemiology*. Oxford University Press, New York. [Extremely useful explanations of issues involved in case-control, retrospective, and prospective studies. A good discussion of matching, stratification, and design issues.]

Abramson, J.H. (1988). *Making Sense of Data: A Self-Instruction Manual on the Interpretation of Epidemiological Data*. Oxford University Press, New York.

Fletcher, R.H., Fletcher, S.W., Wagner, E.H. (1988). *Clinical Epidemiology: The Essentials*. 2nd Edition. Williams and Wilkins, Baltimore.

Fleiss, J.L. (1982). *Statistical Methods for Rates and Proportions*, 2nd Edition. New York: John Wiley and Sons. [An excellent second-level statistics text concerned with the analysis of categorical data.]

Rothman, K.J. (1986). *Modern Epidemiology*. Boston: Little, Brown. [An advanced text that covers both design and statistical issues. The focus is on observational epidemiologic studies and is directed more toward the researcher than the clinician.]

Kleinbaum, D.G., Kupper, L.L. and Morgenstern, H. (1982). *Epidemiologic Research: Principles and Quantitative Methods*. Belmont, CA. Wadsworth. [An advanced text primarily for those conducting observational epidemiologic research.]

Instructor: Dr. Heather Bush

Lectures: W 3:30 – 5:30 NURS511

Labs: W 6:00 – 8:00 NURS602J

Text Book: *Fundamentals of Biostatistics*, 6th Ed.
Bernard Rosner

Prerequisite: STA580 or equivalent

Contact Info:

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205C CPH Building

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Learning Objectives:

Upon successful completion of this course, a student will be able to identify appropriate statistical methods for his or her research and be prepared to critically review the statistical methods incorporated in public health literature. Specifically, the objectives of the course are as follows:

1. Learn basic principles of probability for binomial and Poisson distributions.
2. Utilize statistical methodologies such as multiple regression, logistic regression, Poisson regression, and the Cox proportional hazards model.
3. Learn basic principles for designing and analyzing epidemiologic studies, including confounding, standardization, and stratification.
4. Develop a familiarity with the design and analysis of studies routinely used in public health and medicine: crossover studies, equivalence studies, meta-analysis studies, and studies with clustered responses.

Method of Evaluation:

Biostatistics in Public Health Literature (30%):

Students will be responsible for obtaining examples of statistical methods discussed during the weekly lectures in public health literature. Students will be asked to answer a series of questions pertaining to these articles and will be prepared for a discussion of the statistical methods during lecture. (See handout for additional information).

Statistical Methods Application (60%)

Students will be expected to complete four writing assignments in biostatistics applications. For each of these assignments, students will be expected to provide written reports which may include the analysis and interpretation of data.

(See handout for additional information).

In-Class Assignments (10%)

The primary purpose of in-class assignments is to facilitate the retention of main ideas covered in lecture and group discussion. These will be completed in-class, so late assignments or make-ups for unexcused absences will not be accepted. Only students with excused absences will be permitted to make-up or submit late assignments.

Grading Scale: 100 – 90 = A
89 – 75 = B
75 – 60 = C

Unforeseen Contingencies: In the unlikely event that an unforeseen contingency requires additional course policies, you will be promptly notified in an e-mail memorandum.

Policies:

Attendance Policy: The course is designed so that students should be successful with *active participation* and regular, punctual attendance. It is understandable that students may miss class; however, it is the student's responsibility to determine what assignments were missed and what material was covered. Students missing 5 or more class periods (excused or unexcused) will receive an E for the course.

Late Work: Only students with university excused absences or circumstances which the instructor finds a reasonable cause for non-attendance will be allowed to submit late work without penalty. Late work is defined as any work handed in after the scheduled due date and time. It is the student's responsibility to make arrangements for determining and handing in missed work, preferably in advance, but no later than one week after the absence. In all other cases, late work will be penalized 25% for each day late, and assignments will not be accepted more than one week late.

Academic Integrity: The Department of Biostatistics, the College of Public Health, and the University of Kentucky place a premium on academic honesty. Please refer to the University of Kentucky Student Rights and Responsibilities document.

Accommodations: If you have a documented disability that requires academic accommodations, please contact me as soon as possible. In order to receive accommodations in this course, you must provide a Letter of Accommodation from the Disability Resource Center.

Course Description:

STA 681/CPH 630 covers statistical methods used in public health studies. This includes receiver operator curves, multiple regression, logistic regression, confounding and stratification, the Mantel-Haenszel procedure, and the Cox proportional hazards model.

Tentative Schedule of Topics and Assignments:

Date	Topic	Readings	Due Dates
Aug 22	A Review of Descriptive Statistics and Statistical Tests Understanding the ANOVA Table	ROSNER: 2, 8, 10, 11.1-11.6, 12.1-12.5 SASHELP: SAS Basic SASHELP: Simple Procedures 1 SASHELP: Simple Procedures 2	
Aug 29	Multiple Linear Regression: Mechanisms	ROSNER: 11.9-11.11 SASHELP: Creating Tables SASHELP: Linear Regression	
Sep 05	Multiple Regression: Confounding and Variable Selection	ROSNER: 11.9-11.1, 13.4 SASHELP: Linear Regression	Review 1
Sep 12	Multiple Linear Regression: Diagnostic Tests and Residuals	ROSNER: 11.9-11.11 SASHELP: Linear Regression	
Sep 19	Categorical Methods: Measures of Association	ROSNER: 13.1-13.6 SASHELP: Categorical Outcomes	Project 1
Sep 26	Logistic Regression: Mechanisms	ROSNER: 13.7 SASHELP: Logistic Regression	
Oct 03	Logistic Regression: Diagnostics	ROSNER: 13.7 SASHELP: Logistic Regression SASHELP: ROC Curves	Review 2
Oct 10	Logistic Regression Wrap-Up Meta-Analysis	ROSNER: 13.7-13.8 SASHELP: Logistic Regression	
Oct 17	Crossover Designs Equivalence Studies	ROSNER: 13.9-10	Project 2
Oct 24	Incidence Rates Clustered Responses	ROSNER: 14.1-14.7	Review 3
Oct 31	Survival Analysis: Introduction and Mechanisms	ROSNER: 14.8-14.9 SASHELP: Time to Event Outcomes	Review 4
Nov 07	Survival Analysis: Log-Rank Test and Cox Regression	ROSNER: 14.10-11 SASHELP: Time to Event Outcomes SASHELP: Cox Regression	
Nov 14	Cox Regression: Diagnostics and Variable Selection	ROSNER: 14.11 SASHELP: Cox Regression	Review 5
Nov 21	No Class Happy Thanksgiving!		Project 3 Due
Nov 28	Generalized Linear Models: Poisson Regression	SASHELP: Count Outcomes	
Dec 05	Sample Size and Power Calculations		Review 6
Dec 10	Exam Week		Project 4

Literature Review 1: Multiple Linear Regression; ANCOVA

Literature Review 2: Logistic Regression

Literature Review 3: Crossover Design; Equivalence Study; Meta-Analysis (Alternative Questions Provided)

Literature Review 4: Incidence Rates; Clustered Responses

Literature Review 5: Log-Rank Test; Cox Regression

Literature Review 6: Re-review Reviews 1, 2, or 5; Poisson Regression

Biostatistics in the Literature

Overview: A key component of your professional career will involve literature reviews. The purpose of these assignments is to give you the opportunity to perform literature searches on specific statistical methods in your areas of interest. Reviewing the statistical methods in your areas of interest will provide you with current examples of the uses of biostatistics in your field.

Assignment: You will be responsible for obtaining a published article that uses the statistical method highlighted in the lecture. For each article, you will be expected to address the following general questions:

1. Journal and Author information: Journal title, authors, date of publication.
2. What was the main research question? What was the primary endpoint?
3. What was the study design? The study population?
4. What statistical methods were used?
 - a. Provide a complete list of all statistical methods used including a brief statement on why these methods were appropriate or not?
 - b. What statistical test/method was used as the “final analysis”? Was it appropriate?
 - i. What null and alternative hypotheses correspond to this statistical test?
 - ii. What were the key results obtained from using this method?
 - iii. What conclusions and interpretations were drawn (How do the results provide evidence to answer the research question)? Were these conclusions appropriate?
5. Was there anything “missing” from the reporting of the results? Anything with respect to the statistical analysis or study design you would have done differently?
6. How could you use the methods presented in the article in your own area of research?

Written assignments should be **typed** and are due (in **hard-copy** unless otherwise instructed) at the **start** of each lecture. The article reviewed must accompany the written assignment. In addition to the written portion of the assignment, you should be prepared to briefly summarize the research question, design, and the statistical methods of the article in an informal oral presentation. Although, these summaries should be very brief (1-2 minutes) you should be prepared to participate in a more involved discussion of your article and/or the articles of others.

Late written presentations for unexcused absences will be penalized 25% for each day late, and assignments will not be accepted more than two days late. Oral presentations for unexcused absences may not be made-up. If you are unable to attend class for an excused absence, the written presentation will be accepted as 100% of the assignment (see syllabus for policy on attendance and late work).

Category	Literature Review Points Awarded				
	5 - "Wow"	4 - "Solid"	3 - "Competent"	2 - "Disjointed"	1 - "Incoherent"
Journal Info and Discussion	Provide complete and readable copy of article. Provide complete title, authors, and date of publication. Able to succinctly (1-2 minutes) and correctly describe methods used . Able to provide informed answers to questions.	Provide copy of article. Provide complete title, authors, and date of publication. Able to succinctly (1-2 minutes) and correctly describe methods used. Some difficult in providing informed answers to questions.	Provide copy of article. Missing any one of the following: complete title, authors, and date of publication. Short (1-2 minutes) description but unable to correctly identify the methods. Good responses to questions.	Provide copy of article. Missing any two of the following: complete title, authors, and date of publication. Short (1-2 minutes) description but unable to correctly identify the methods. Poor responses to questions.	Do not provide a copy of the article. Rambling description of methods. Unable to provide informed answers.
Research Question	Clearly identified the main endpoint of the publication. Able to give a short summary in "own words" of the research question.	Clearly identified the main endpoint of the publication. Summary of research question "quoted".	Partial identification of the main endpoint. Able to give a short summary in "own words" of the research question.	Partial identification of the main endpoint. Summary of research question "quoted".	Unable to correctly identify and summarize main research question.
Study Design	Demonstrates clear understanding of study design. Able to succinctly summarize with correct use of terminology. Identified whether study was prospective, retrospective, etc... Correctly describes study population	Demonstrates clear understanding of study design. Incomplete description of whether study was prospective, retrospective, etc... Correctly describes study population	Partial description of study design or Incorrectly describes study population.	Partial description of study design. Incorrectly describes study population.	Poor description of study design. Incorrectly described study population.
Statistical Methods	Provides a complete list of all statistical methods used.	Partial list of "initial" statistical methods. Main statistical methods provided.	Incomplete list of "initial" statistical methods. Main statistical methods provided.	Omits all "initial" statistical methods. Main statistical methods provided.	Omits main statistical methods for paper.
Rationale for Methods	Provides a complete and correct explanation/rationale for all statistical methods presented. Methods outside the scope of class may be omitted.	Provides a complete and correct explanation/rationale for most of the statistical methods presented. Methods outside the scope of class may be omitted.	Provides a complete and correct explanation/rationale for some of the statistical methods presented. Methods outside the scope of class may be omitted.	Provides a complete and correct explanation/rationale for a few of the statistical methods presented. Methods outside the scope of class may be omitted.	Explanations are predominately incomplete, incoherent, or incorrect.

Category	Literature Review Points Awarded				
	5 - "Wow"	4 - "Solid"	3 - "Competent"	2 - "Disjointed"	1 - "Incoherent"
Results	Pinpoints the main result of interest. Provides the final result (estimate, model, etc...) correctly and completely.	Pinpoints the main result of interest. Provides the final result (estimate, model, etc...) with only minor errors.	Pinpoints the main result of interest. Provides the final result (estimate, model, etc...) with some errors.	Provides a laundry list of results with no apparent idea of what the "point" of the study was.	Does not provide the correct final result.
Hypotheses	Able to create appropriate null and alternative hypotheses that correspond to research question. Correct use of parameters, all parameters identified, correct use of symbols.	Able to create appropriate null and alternative hypotheses that correspond to research question. Null and alternative hypotheses are correctly stated with appropriate parameters. Minor mistakes in the use of symbols/parameters.	Research question does not correspond to hypotheses. Null and alternative hypotheses are correctly stated with appropriate parameters. Correct use of parameters, all parameters identified, correct use of symbols.	Able to create appropriate null and alternative hypotheses that correspond to research question. Major mistakes in the use of symbols/parameters or in statement of hypotheses.	Research question does not correspond to hypotheses. Null and alternative hypotheses are incorrectly stated. Major mistakes in the use of symbols/parameters.
Conclusions (What do the results mean?)	Provides an accurate interpretation of the main result. Demonstrates a clear understanding of the result and the interpretation.	Provides an accurate interpretation of the main result. Interpretation has minor errors. Demonstrates an understanding of the result and the interpretation.	Provides an accurate interpretation of the main result. Interpretation has some errors. Demonstrates an understanding of the basic concepts behind the results.	Interpretation of result is incorrect. Work reflects little to no understanding of concepts.	No interpretation is provided or conclusions are incoherent.
Suggested Changes	Demonstrates knowledge/insights in the field of study. Applies principles discussed in class to improving the design, use of data, analysis, or data handling. Arguments are justified and well-posed.	Demonstrates knowledge/insights in the field of study. Applies principles discussed in class to improving the design, use of data, analysis, or data handling. Arguments are not completely justified or thought-out.	Applies principles discussed in class to improving the design, use of data, analysis, or data handling. No justification to arguments.	Incorrect application of principles discussed in class to modify design, use of data, analysis, or data handling.	"Everything in this study was fine"
Using These Methods	Clear and concise description of how to apply the methods. Demonstrates an obvious understanding for the type of problems that are appropriate for these methods.	Clear and concise description of how to apply the methods. Demonstrates a good understanding for the type of problems that are appropriate for these methods.	Description of how to apply the methods with few errors. Demonstrates a basic understanding for the type of problems that are appropriate for these methods.	Description of how to apply the methods is confusing or has errors. Questionable whether there is a basic understanding for the type of problems that are appropriate for these methods.	Inappropriate application of methods.
TOTALS	50	40	30	20	10

Statistical Methods Application

Overview: At some point in your profession, you will want to explore your own research questions. Many times you will be able to do this using data that has already been collected. You will need experience obtaining the data, putting it into an analysis dataset, and performing statistical analysis (descriptive measures and hypothesis testing). The goal of these assignments is to provide you with experience in handling data, performing statistical analyses, and providing a written presentation of the results and conclusions.

Assignment: The main topics discussed in this course are as follows: receiver operator curves, multiple regression/ANOVA, logistic regression, confounding and stratification, the Mantel-Haenszel procedure, and the Cox proportional hazards model. You will be expected to employ these methods as you develop and answer research questions that stem from datasets provided to you. Please note that these assignments will require the use of statistical software. You will become familiar with SAS in the lab sessions, but you may use any software that can perform the required computations. Written assignments are to be submitted in **hard copy**, unless you have obtained permission to use an alternative mechanism for submission.

Assignments may include a data analysis report. The typed report must be submitted with background, methods, statistical analysis, results, and discussion sections on or before the due date/time. **Reports are not to exceed 5 pages.**

Background Section: After reviewing the dataset and any codebooks that are supplied, you should formulate an appropriate research question. It may be necessary for you to consult other published works/references in order to determine an appropriate research question. The background section should provide the reader with a brief overview of the data, purpose of the study, and the main research question to be answered.

Methods Section: The method of data collection, the study design, and the study population can be described here. Additionally, the rationale for choosing confounding variables and any manipulations to the data are typically provided in this section.

Statistical Analysis Section: All of the statistical methods that were used to achieve the results and a brief statement explaining why these techniques were chosen should be given here.

Results Section: Include tables and figures in this section. In general, it is a good idea to have a table which provides simple statistics and at least one other table that provides the results of your final analysis. In addition to the tables and figures, you should discuss the descriptive statistics, estimates obtained, and results of statistical tests. Note: This does not suggest a listing of means and percentages in the text. This is where you should highlight results and describe what the results mean.

The results of your main ("final") analysis are provided here. These are typically provided in a table or figures. Results that answer/support your research question should be correctly interpreted and discussed thoroughly. Appropriate null and alternative hypotheses and model statements corresponding to the main ("final") analysis should also be provided. Be sure to include statements that discuss and correctly interpret the results of the "final analysis".

Discussion Section: In this section you should briefly remind the reader of your original research question and how the results provided go about answering this question. This section also provides you the opportunity to draw conclusions and give informed guesses as to why certain trends and results appeared. Feel free to add any study limitations in this section.

In addition to the data analysis report, you might also be asked to provide short answers to questions that may or may not require data analysis. The above requirements do not apply to these short answer questions. The answers to these questions must be typed and handed in with the data analysis report but should not be incorporated into the data analysis report.

The project must be **submitted by** the due date/time. Late reports for unexcused absences will be penalized 25% for each day late, and assignments will not be accepted more than two days late (see syllabus for policy on attendance and late work).

Category	Data Analysis Points Awarded				
	5 - "Wow"	4 - "Solid"	3 - "Competent"	2 - "Disjointed"	1 - "Incoherent"
Grammar	College reading level, no noticeable spelling mistakes or typos, appropriate sentence structure, elegant flow of ideas	College reading level, limited spelling mistakes or typos, appropriate sentence structure, clear flow of ideas	Complete sentences, limited spelling mistakes or typos, appropriate sentence structure, coherent flow of thought	Limited sentence fragments, multiple spelling mistakes or typos, confusing flow of thought	Multiple sentence fragments, multiple spelling mistakes or typos, poor sentence structure, incoherent flow of thought
Background	Consulted outside sources to support research question. Research question is clearly and correctly stated. Background sufficiently backs up research question.	Research question is clearly and correctly stated. Background sufficiently backs up research question.	Research question is correct but not clearly stated. Background sufficiently backs up research question.	Research question is not clearly or correctly stated. Some background provided.	Research question is not clearly or correctly stated. Little to no background/introduction given.
Methods	Complete and correct statement of data collection, study design, and study population. Discussion of any data handling or selection of variables.	Complete and correct statement of study population. Discussion of any data handling or selection of variables.	Complete and correct statement of study population. Incomplete discussion of any data handling or selection of variables.	Little to no or partially incorrect discussion of data collection, study design, or study population. Incomplete discussion of any data handling or selection of variables.	No or incorrect discussion of data collection, study design, or study population. Little to no or incorrect discussion of data handling or selection of variables.
Statistical Analysis	Complete description of statistical methods used in analysis. Correct choice of statistical methods.	Incomplete description of statistical methods used in analysis. Correct choice of statistical methods.	Complete description of statistical methods used in analysis. Partially correct choice of statistical methods.	Incomplete description of statistical methods used in analysis. Partially correct choice of statistical methods.	Incomplete description of statistical methods used in analysis. Incorrect choice of statistical methods.
Tables/Figures	Tables/Figures provided for initial and final analyses. Tables/Figures are clear and easy to read. Information provided in tables/figures are correct.	Tables/Figures provided for initial and final analyses. Display of information in table not clear. Information provided in tables/figures are correct.	Tables/Figures provided for initial and final analyses. Display of information in table not clear. Problem with information provided in tables/figures.	Missing tables/figures provided for initial or final analyses. Display of information in table not clear. Problem with information provided in tables/figures.	Missing tables/figures provided for initial or final analyses. Display of information in table not clear. Information in table/figure is irrelevant or nonexistent.
Results	Discussion of results provided in tables/figures. Clear and correct explanation of the statistical concepts/interpretations involved in the results.	Incomplete discussion of results provided in tables/figures. Clear and correct explanation of the statistical concepts/interpretations involved in the results.	Incomplete discussion of results provided in tables/figures. Partial or incorrect explanation of the statistical concepts/interpretations involved in the results.	Incomplete or partially incorrect discussion of results provided in tables/figures. Incomplete or incorrect explanation of the statistical concepts/interpretations involved in the results.	No discussion of the results from the preliminary/supplementary analysis.

Category	Data Analysis Points Awarded				
	5 - "Wow"	4 - "Solid"	3 - "Competent"	2 - "Disjointed"	1 - "Incoherent"
Hypotheses	Correct use of parameters, all parameters identified, correct use of symbols. Research questions correspond to hypotheses	Null and alternative hypotheses are correctly stated with appropriate parameters. Research questions correspond to hypotheses. Moderate mistakes in the use of symbols.	Null and alternative hypotheses are correctly stated with appropriate parameters. Research questions correspond to hypotheses. Glaring mistakes in the use of symbols.	Null and alternative hypotheses are correctly stated or stated only in words. Research questions correspond to hypotheses. Inappropriate use of parameters and incorrect use of symbols	Null and alternative hypotheses incorrectly stated.
Statement of Model	Correct use of parameters in model equation, all parameters and variables identified, correct use of symbols, assumptions stated.	Correct use of parameters in model equation, all parameters and variables identified, moderate mistakes in the use of symbols, assumptions stated.	Correct use of parameters in model equation, all parameters and variables, correct use of symbols, assumptions NOT stated.	Mistakes in the use of parameters in model equation, all parameters and variables NOT identified, assumptions NOT stated.	Incorrect model statement, all parameters NOT identified, assumptions NOT stated.
Final Analysis and Results	Correct identification of final analysis method. Correct and complete description of model choice. Correct and complete interpretation of results.	Correct identification of final analysis method. Correct but incomplete description of model choice. Correct and complete statement of interpretation of results.	Correct identification of final analysis method. Correct but incomplete description of model choice or Partial interpretation of results.	Correct identification of final analysis method. Incorrect or incomplete description of model choice or Little interpretation of results.	Incorrect identification of final analysis method or no interpretation of results.
Discussion	Demonstrate insights in trends and results. Provide discussion of how the results relate to research question. Able to make reasonable conclusions based on analysis. Provide accurate comments on limitations of the study	Provide discussion of how the results relate to research question. Able to make reasonable conclusions based on analysis. Provide accurate comments on limitations of the study	Able to draw appropriate conclusions based on analysis. Provide comments on limitations	Provides a summary of analysis. Some demonstration of how the results relate to research question. Provide comments on limitations of the study	Little to no evidence of how results tie to research question. No discussion of limitations.
TOTALS	50	40	30	20	10

CPH701
Current Issues in Public Health:
Public Health's Role and Responsibilities in Maintaining and Improving Health

Date of the Week
Time of Class
Location of Class

Course Instructor: Stephen W. Wyatt, DMD, MPH
College of Public Health
121 Washington Avenue
Suite 112
Lexington, KY 40506
(859) 257-5678 ext 82014 (changing)
Office hours: By appointment only

Course Requirements

Research Paper	400 points
Class Attendance/Participation	100 points

A schedule for the weekly seminars will be provided at the beginning of the semesters. Papers not completed according to class schedule will be subject to point reductions for each day they are late. To encourage class attendance/participation a subjective class participation grade will be assigned.

Course Text

Essentials of Public Health
Bernard Turnock, MD
Jones and Bartlett Publishers
ISBN: 978-0-7637-4525-7
Text Location: UK Medical Bookstore

Course Description

A survey seminar course for students in M.S. and PhD programs in the College of Public Health. The course introduces broad concepts on the role, responsibilities, structure, funding etc of public health. While all core areas of public health will be introduced special attention will be given to health behavior/behavioral health, environmental health and health policy/management.

Course Objectives

To provide a broad introduction to public health to non-MPH or DrPH students enrolled in graduate academic programs.

Specific Competencies

This course addresses the following competencies (Knowledgeable):

1. Identify the main component and issues of the organization, financing and delivery of health services and public health systems in the U.S. (K)
2. Describe the legal and ethical bases for public health. (K)
3. Identify the cases of social and behavioral factors that affect the health of individuals and populations. (K)
4. Describe the merits of social and behavioral science interventions and policies. (K)
5. Develop public health programs and strategies responsive to the diverse cultural values and traditions of the communities being served. (K)
6. Describe the direct and indirect human, ecological and safety effects of major environmental and occupational agents. (K)

Academic Dishonesty

Academic honesty is fundamental to the activities and principles of a university. All members of the academic community must be confident that each person's work has been responsibly and honorably prepared, developed, and presented. Any effort to gain an advantage not given to all students is dishonest whether or not the effort is successful. The academic community regards academic dishonesty as an extremely serious matter, with serious consequences that range from a grade "E" to expulsion from the University. Both **cheating** and **plagiarism** are considered academic dishonesty. Cheating refers to any unauthorized assistance during examination questions to/from other student(s). Plagiarism is academic "theft", and includes not properly crediting another author for his/her work or idea. Any paraphrase or direct quotation from a published or unpublished work should be properly cited with a footnote or reference. Students must be particularly careful not to engage in plagiarism, even inadvertently, since computers and Internet we-browsing seem to facilitate this process.

Week 1	Course Overview History of Public Health Introduction to Roles and Responsibilities
Week 2	International, National, State and Local Public Health Systems What are they, how do they function and how are they funded? Guest Speaker: F. Douglas Scutchfield, MD
Week 3	The Centers for Disease Control and Prevention; America's Public Health Agency. How is it organized what are the responsibilities, how does it function? Guest Speaker: CDC Staff
Week 4	State Public Health Systems; different models and how do they function
Week 5	Kentucky's Public Health System Guest Speaker: State Health Officer
Week 6	Local Public Health Systems; how are they different, how are they organized and what do they do? Guest Speaker: Melinda Rowe, MD, MPH, MBA
Week 7	Disease Surveillance in Kentucky Guest Speaker: State Epidemiologist
Week 8	Behavioral Surveillance in Kentucky Guest Speaker: Robin Vanderpool, DrPH
Week 9	Public Health's role in protecting the environment
Week 10	Public Health Law Guest Speaker: Julia Costich, JD, PhD
Week 11	Theoretical Constructs of Human Behavior Change Guest Speaker: Linda Alexander, EdD
Week 12	Disease Prevention/Intervention Programs Guided by Public Health Practice in Kentucky Guest Speaker:
Week 13	Continuation of Week 12
Week 14	Politics and Public Health
Week 15	Integrative Paper Due and Reports

PHR665/CPH 665
Ethical Issues in Clinical Research
Spring 2007
Location: CON 213
Time: 4-5:50pm - Tuesdays

Faculty*

Jimmi Hatton, Pharm.D.	323-5161	jhatt1@uky.edu	Course Director
Ada Sue Selwitz, MA			Course Coordinator
Tom Foster, Pharm.D.			Course Coordinator

***Additional faculty will be presenting materials in their individual areas of expertise.**

Course Description

The scientist of the future must be equipped in fundamental ethical principles guiding the conduct of translational research projects that integrate clinical and basic investigational activities. This course will address issues relevant to ethically sound study design, responsible conduct of research, regulatory and fiscal compliance, and scientific misconduct, among others. Through participation in this course students will undergo research integrity education and mentoring as individual investigators or interdisciplinary project team members and become better prepared for future outreach to community research partners.

This course is designed to engage students in the practical application of ethical principles in the conduct of translational research projects. The faculty will utilize cases and current literature to guide classroom discussions during the two hour weekly meeting. Assignments for reading and/or follow-up will be posted onto the Blackboard course site. The goal of this course is to alert individual investigators to ethical and regulatory considerations to be applied in the design, conduct and publication of animal and human research.

Course Objectives

- 1) Discuss national policies outlining investigator obligations and incidents influencing their development.**
- 2) Communicate rationale for investigator actions in specific case-based scenarios, supporting individual positions using established ethical and regulatory principles.**
- 3) Describe protection methods for animals and humans participating in research protocols.**

- 4) **Discuss informed consent and ethical considerations for scientists conducting human subject research.**
- 5) **Explain the ethical and regulatory implications of study designs including:**
 - a. **Vulnerable populations**
 - b. **Tissue banking**
 - c. **Genetics/Genomics**
 - d. **Placebo Study Design**
- 6) **Describe investigator ethical and regulatory obligations for conflict of interest, publication, data sharing and collaboration.**
- 7) **Evaluate current, relevant national issues of interest in clinical research.**
- 8) **Describe the ethical conduct and responsibilities of mentors in developing future translational research scientists.**
- 9) **Assist investigators in application of ethical principles through peer review of research projects.**
- 10) **Describe the ethical and regulatory considerations when conducting research with community based partners.**

Course Requirements/Grading

Class Attendance: 50%

Students are expected to attend scheduled classes and actively participate. Students are expected to be prepared BEFORE each lecture by reading assigned material and answering questions or cases as assigned. The majority of class meetings will be interactive and require student commentary to facilitate the class discussion.

Discussion Boards/Blackboard Assignments: 20%

Blackboard will be employed to generate additional discussions between students and faculty. Each student will receive a grade for participation in the on-line format.

Case Discussions: 10%

During the class, some topics will be presented as cases for input by groups that will be assigned at the start of the semester. The individuals in each group will be assigned the same score, based on attendance and participation along with classroom assessment.

Student Projects: 20%

This will involve an actual research project presentation and investigator assessment of ethical issues relevant to the design and conduct of the trial.

Final Course Grade will be assigned as:

A = 90% - 100%

B = 80% - 89%

C = 75%- 79%

D = 65% - 74%

E = < 65%

Disability/Accommodation Reporting Procedure

Students requesting an accommodation because of a disability should notify Dr. Hatton and the Student Affairs Office no later than the first week of classes. The Student Affairs Office will 1) work with the student and the University Disability Resource Center to document/verify the disability, 2) obtain guidelines for appropriate accommodation and 3) notify the faculty member of the appropriate accommodation.

General Policy:

Students who have requested and obtained accommodations in the previous semester need only notify Dr. Hatton. The Student Affairs Office will forward the guidelines from the University Disability Resource Center to the faculty member in charge of the course at the beginning of the semester.”

Student Responsibility:

- 1. Report disability need to each course director and to the Student Affairs office no later than third day of class.**
- 2. Provide appropriate documentation to the Disability Resource Center.**
- 3. Thorough verification of the disability will not be available until after Disability Resource Center gathers information (and/or performs testing), the student should notify faculty members that such information may be coming.**
- 4. Work with faculty member to arrange appropriate accommodations.**

CPH 664: Design and Analysis of Clinical Trials
Fall term: 2007

Instructors: Richard Kryscio (kryscio@email.uky.edu, 257-4064, 230 Center on Aging)

Meeting times: Tues 3:30-5:50 p.m., NURS 214

Course Text: None. See reading list at bottom of course syllabus. Reading material from the texts denoted (P) and (FFD) are mandatory.

Prerequisite: STA 580 or STA 570 (Biostatistics sections) or consent of instructor

Course objectives:

1. Introduce the fundamental concepts used in the design of Phase I-III clinical trials including endpoint determination, randomization, masking, power, and interim stopping rules.
2. Present key statistical issues that need to be considered when interpreting clinical trial results especially as they pertain to public health.
3. Introduce statistical methodology associated with the analysis of data from clinical trials including factorial designs, crossover designs, prevention trials, and group randomized trials. Meta analysis will also be discussed.

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

Course requirements: final grades will be determined by the following activities

1. Homework assignments worth 35 %
2. Mid-term examination worth 25 % (Given out October 23; return by Nov 2)
3. Debate a controversial topic in clinical trial design or analysis worth 15 % (Debates begin September 25)
4. Final examination worth 25 % : a class presentation and accompanying written document on a proposed multi-center trial

Course grades: letter grades A, B, and C for course grade of 90 % or better, 80 % or better, and less than 80 %, respectively.

Classroom etiquette: please turnoff all portable electronic devices during class time

CPH 612
INFECTIOUS AND EMERGING DISEASES EPIDEMIOLOGY
Spring 2007

Time: Monday 3:00 pm 5:30 pm
Place: School of Nursing 214
Course Instructor: Glyn G. Caldwell, MD
502-695-1149
glyncaldwell@dcr.net
Office Hours Monday 1:00 pm to 2:45 pm in CPH 213 or by appointment

COURSE DESCRIPTION

This course will focus on the epidemiology, history, methods, and ancillary laboratory tools used in the study and control of infectious diseases, including discussions of key concepts and theory, basic types of epidemiological investigations and study designs, distinctive problems associated with each class of infectious agents. The course will discuss how epidemiological methods can be applied to the study, investigation, prevention, and control of infectious diseases and emerging infectious diseases.

COURSE GOAL

The course goal is to produce a public health practitioner with the knowledge and skills to investigate, study, prevent, and control infectious and emerging diseases in the public health setting.

COURSE OBJECTIVES

This course will outline the history, epidemiological concepts, microbiological methods, and ancillary laboratory tools used in the study and control of infectious diseases in human populations. The course includes discussions of theory and methods, including key concepts of incidence, prevalence, mortality, transmission, reservoir, life cycle, prevention and control of infectious diseases. The course will define and outline the basic types of epidemiological investigations and distinctive features/problems associated with each.

Students will, upon examination, be able to describe and discuss the following:

- I. Principles of Infectious Disease Epidemiology
 1. Differentiate between a clinical and an epidemiological approach to the study and control of infectious diseases.
 2. Describe the historical evolution of infectious diseases epidemiology.
 3. Identify the contributions of microbiology and epidemiology as they relate to the prevention and control of infectious diseases.
 4. Understand and be able to apply the correct methods to investigate a suspected infectious disease outbreak/epidemic.
 5. Describe the concepts and interactions of agent, host, environment, vector,

- incubation time, transmission, life cycle (where appropriate) and reservoir.
6. Understand and be able to apply the concepts, methods, and appropriate study designs to the study of emerging infectious diseases and their potential etiologic agent(s).
 7. Describe and understand the evolution and epidemiology of emerging and re-emerging infectious diseases.

II. Principles of Infectious Disease Control and Prevention

1. Describe history of infectious diseases prevention and control.
2. Describe the diagnostic methods appropriate to infectious and emerging diseases.
3. Describe the various methods of prevention and control of communicable and emerging diseases.
4. Describe how physicians use epidemiological methods in their practice.

RELATIONSHIP TO COLLEGE OF PUBLIC HEALTH TERMINAL OBJECTIVES

This course relates directly to the accomplishment of the educational program goals for both the MPH and DrPH degrees. The MPH and DrPH goals and objectives are described in the Student Handbook which students received upon enrollment into either the MPH or DrPH degree program. Please reference the appropriate educational program goals throughout the semester, as they will provide a framework for this course and as such will contribute to your preparation for successfully completing other degree program requirements (e.g. capstone, practicum, and DrPH comprehensive examination).

Relationship of This Course To the Epidemiology Concentration Area Terminal Objectives

In relationship to the MPH degree, this course contributes toward fulfillment of the following terminal objectives for students concentrating in epidemiology.

1. Explain the purposes and applications of epidemiology as they apply to infectious and emerging infectious diseases.
2. Search and/or critically review the epidemiological and infectious disease literature.
3. Identify and use appropriate study designs for study of infectious and emerging diseases.
4. Collect and manage data for the investigation of infectious and emerging disease outbreaks.
6. Interpret and clearly communicate epidemiological and infectious disease data and findings.
8. Integrate the principles of epidemiology of infectious and emerging diseases into public health practice.

In relationship to the DrPH degree, this course contributes toward fulfillment of the

following terminal objectives for students concentrating in epidemiology.

1. Explain and apply the principles and methods of epidemiology as they apply to infectious and emerging diseases in a wide variety of clinical, community, environmental and public health situations.
2. Search, critically review, and synthesize and interpret the infectious and emerging diseases epidemiologic and public health and infectious disease literature to impact public health policy.
3. Identify and use appropriate epidemiologic and microbiological study designs for study of infectious and emerging diseases.
4. Collect and manage data for the investigation of infectious and emerging disease outbreaks.
6. Interpret and clearly communicate complicated epidemiological and infectious disease data and findings to collaborators, legislators, administrators, and the public to effect modification of public health policy.
8. Effectively lead, educate, and mentor students, coalitions, clinicians, legislators, administrators, public health practitioners, and other persons to utilize infectious and emerging disease data, methods, and findings to impact public health and public health practice.

COURSE REQUIREMENTS

1. Two examinations 30 percent (each examination)
2. Four brief papers and a presentation 40 percent (8 percent each paper and presentation)
3. Each student is expected to prepare and present a bibliography and an outline of an assigned infectious disease epidemiology topic (8 percent of grade for each). Topics will be assigned individually depending on class size to review the literature, prepare an outline and a bibliography about the assigned topic. In the presentation and outline, the student should look specifically for disease or microorganism's characteristics, epidemiological concepts, methods, issues, and problems that remain unresolved and in need of further research. The bibliography and outline should comply with the format provided and should cover at least: 1) history of discovery, 2) incidence, prevalence, and mortality rates, demographics and distribution, 3) transmission, reservoir, incubation and communicable periods, and 4) preventive and control methods. Each student should be prepared to briefly present (~10 minutes) a summary of the assigned topic. For each discussion please e-mail a copy of the bibliography, outline, any table or charts used in the presentation to the instructor.
4. Examinations will cover both the lecture material, readings from the texts, and student presentations. Any student who misses a class session is responsible for obtaining notes or other handout materials from a fellow classmate. No make-up examinations will be given unless arrangements are made with the instructor in advance of the scheduled examination. Any student who fails to take a scheduled examination will receive a zero ("0") for that examination. This same policy

will be applied to exercises and special projects.

COURSE TEXTS

Required:

Nelson, KE, CM Masters, and NMH Graham. Infectious Disease Epidemiology Theory and Practice. Aspen Publishers Incorporated, Gaithersburg, Maryland, 2007.

Alternate: Nelson, KE, CM Masters, and NMH Graham. Infectious Disease Epidemiology Theory and Practice. Aspen Publishers Incorporated, Gaithersburg, Maryland, 2000.

Useful, but not mandatory:

Chin, James, Editor. Control of Communicable Diseases Manual, 18th Edition. American Public Health Association, Washington, D. C. 2000.

ACADEMIC DISHONESTY

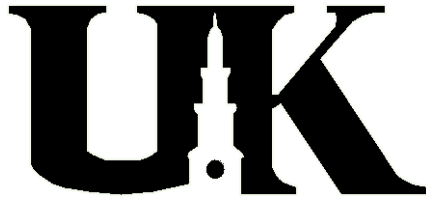
Academic honesty is fundamental to the activities and principles of a university. All members of the academic community must be confident that each person's work has been responsibly and honorably prepared, developed, and presented. Any effort to gain an advantage not given to all students is dishonest whether or not the effort is successful. The academic community regards academic dishonesty as an extremely serious matter, with serious consequences that range from a grade of "F" to expulsion from the University. Both cheating and plagiarism are considered academic dishonesty. Cheating refers to any unauthorized assistance during examinations, such as notes or handouts. It also includes either giving or taking the answers to examination questions to/from other student(s). Consequently, the use of cell phones (with or without an internal camera) during examinations, without explicit permission will result in a charge of cheating. Plagiarism is academic "theft", and includes not properly crediting another author for his/her work or idea. Any paraphrase or direct quotation from a published or unpublished work should be properly cited with a footnote or reference. Students must be particularly careful not to engage in plagiarism, even inadvertently, since computers and Internet web browsing seem to facilitate this process.

ENABLING ACCOMODATIONS

If you have a documented disability that requires academic accommodations, please see me as soon as possible during scheduled office hours. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the disability Resource Center (www.uky.edu/TLC/grants/uk_ed/services.drc.html). If you have not already done so, please register with the Disability Resource Center (Room 2 Alumni Gym 859-257-2754, jkarnes@uky.edu) for coordination of campus disability services available to students with disabilities.

CPH 616
Cardiovascular Epidemiology

Syllabus
&
Schedule



University of Kentucky
College of Public Health

University of Kentucky
College of Public Health

Course Syllabus

Title:	Cardiovascular Epidemiology
Course Number:	CPH 616
Time:	Wednesdays 3:00 – 5:30 pm
Credit:	3 Semester Hours
Class Location:	CPH Room 202
Faculty:	Steven R. Browning, MSPH, Ph.D. College of Public Health / College of Medicine Phone: 859-257-5678 EXT. 82235 E-mail: srbrown@email.uky.edu Office Hours: Monday 3-4:30 PM and by appointment

Course Description:

This course provides students with an introduction to major topics in the substantive area of cardiovascular epidemiology. Cardiovascular disease is the leading cause of death in the United States and other countries and the burden is increasing among developing countries. While some CVD risk factors have been declining, other risk factors such as obesity and diabetes have been rapidly increasing. With respect to total CVD death rates, Kentucky has typically ranked among the five worst states in the nation and usually is in the top three with respect to the prevalence of smoking. The course will review the epidemiology of cardiovascular disease with respect to local, national, and international trends, will examine current issues related to screening for cardiovascular disease, and evaluate the scientific evidence for our understanding of both established and novel risk factors for cardiovascular disease. Further, discussion of the issues about strategies for primary prevention using population-based versus high-risk individual approaches will be emphasized.

The course will involve lectures from established researchers in cardiovascular disease, focused independent readings, evidence-based debates, and the development of projects addressing current issues in the epidemiology of cardiovascular disease. This is the first offering of this course in the College of Public Health. Student input and suggestions are encouraged in the development of the structure and the materials for this class.

Prerequisites: Introduction to Epidemiology (CPH 605) or consent of instructor.

Credit: 3 semester hours.

Course Objectives:

After completion of this course in Cardiovascular Epidemiology the student will have:

1. Developed an understanding of the etiology and trends of atherosclerotic cardiovascular disease.
2. Reviewed the risk factors and associated interventions and strategies related to prevention of cardiovascular diseases.
3. Developed an appreciation for the diverse issues associated with cardiovascular disease in special populations (children, seniors, diverse ethnic groups).
4. Gained further skills in the development of a research proposal, white paper, or applied data analysis project in the field of cardiovascular epidemiology.
5. Considered some of the current challenges for the prevention of cardiovascular disease in communities and populations.

Course Structure:

The course will consist of lectures and presentations from the course instructor as well as several guest faculty members who are researchers in the area of cardiovascular disease. Independent study of the course text as well as classroom discussions and debates will be important learning components in the course. The students will have the option of selecting and completing a class project relevant to cardiovascular disease epidemiology. This project may include the preparation of an abbreviated grant proposal, the development of a white paper/policy analysis, or an original data analysis project using relevant primary or secondary data. The assignment of the class project is to develop a project of “worth” which may be compatible with student thesis or capstone requirements or the development of an independent research project. A midterm exam, presentation of the class project, and class participation will be considered in the evaluation of the course grade.

Relationship to Public Health Degree Program Goal(s) and Objectives:

This course relates directly to the accomplishment of the educational program goals for the M.P.H. and the Dr. P.H. degrees. The MPH goal and objectives are described in the Student Handbook which students received upon enrollment in the MPH degree program. Similarly, the Dr.P.H. goals and objectives are described in the Student Handbook, which students receive upon enrollment in the Dr. P.H. degree program.

This course addresses the following MPH competencies (**K**nowledgeable, **P**roficient):

1. Explain the importance of epidemiology for informing scientific, ethical, economic and political discussion of health issues. **(K)**
2. Describe a public health problem in terms of magnitude, person, time and place. **(P)**
3. Apply the basic terminology and definitions of epidemiology. **(P)**
4. Identify key sources of data for epidemiologic purposes. **(K)**
5. Calculate basic epidemiology measures. **(K)**
6. Evaluate the strengths and limitations of epidemiologic reports. **(K)**
7. Draw appropriate inferences from epidemiologic data. **(P)**
8. Communicate epidemiologic information to lay and professional audiences. **(P)**
9. Comprehend basic ethical and legal principles pertaining to the collection, maintenance, use and dissemination of epidemiologic data. **(P)**
10. Identify the principles and limitations of public health screening programs. **(K)**

Course Materials:

A syllabus will be distributed on the first day of class to all students who are officially enrolled in the course. The syllabus will contain a topic schedule for the course and a listing of the reading assignments. Additional course materials will be distributed as the class progresses.

There is one required text for the class. The text for the course may be purchased at the Kennedy Bookstore (405 S. Limestone) or online. Additional reading materials will either be on reserve in the Department of Epidemiology or available online in Blackboard.

Required Textbook:

The required textbook for the course is Preventive Cardiology: A Practical Approach (Second Edition) by Nathan D. Wong, Henry R. Black, and Julius M. Gardin. *Masters in Cardiology*. (ISBN 0-07-140996-3). Price is approximately \$90.00 at the bookstore.

As quoted from the back cover of the text: "This practical reference blends a readable summary of the vast literature on cardiovascular disease epidemiology with clear, evidence-based, patient-oriented strategies for screening, identifying, and controlling cardiovascular risks".

Recommended (optional) Textbooks:

- Epidemiology and Prevention of Cardiovascular Diseases: A Global Challenge by Darwin R. Labarthe. Aspen Publishers; 1st edition (January 15, 1998) ISBN-10: 0834206595 ISBN-13: 978-0834206595.
- Coronary Heart Disease Epidemiology: From aetiology to public health. Second Edition Edited by Michael Marmot and Paul Elliott ISBN13: 9780198525738 ISBN10: 019852573. Oxford University Press.
- The Strategy of Preventive Medicine by Geoffrey Rose. ISBN13: 9780192624864. ISBN10: 0192624865. Oxford University Press.

Required Readings (other than text):

Required readings from journal articles, manuscripts, and other documents are listed in the daily assignments. Most of the journal articles for readings will be on reserve in the Department of Epidemiology graduate student area (room 209). Some of these are available as electronic documents in Blackboard. Students are responsible for securing their own copies of the readings and reviewing the materials prior to the class.

Evaluation:

Assignments	Points
Class Project (grant, evidence-based manuscript, or data analysis project)	400
<ul style="list-style-type: none"> • Presentation and student evaluation (averaged ranking by class) 	100
<ul style="list-style-type: none"> • Instructor evaluation of written document (see criteria: 200 pts) and presentation (100 pts). 	300
Midterm exam	200
Classroom debate preparation and participation	100
Class participation and attendance	100
Total points	800

Letter grades for the course will be assigned on a percentage basis (as given below) for the student's total score as a percentage of the total number of points possible for the course. The instructor reserves the right to "curve" class grades and round grades as appropriate to student performance in the class. The class project comprises 50% of the grade for the course. Class members will be involved in the final evaluation of the class project and will anonymously assign an evaluative score (based on 100 points) to class projects. Scores from all class members will be averaged and will comprise 25% of the score of the final class project.

Grade	%	Points (3 credit)
A	90-100	720-800
B	80-89	640-719
C	70-79	560-639
E	<=69	<559

Reading discussion and class participation.

Students enrolled in the class are required to participate in the “class debates” and in the discussion of course readings. This requires that he/she is well prepared in having read the assigned literature and in preparing notes for the assigned class debate. It’s an opportunity to be creative. A schedule will be established at the beginning of the semester for student for the debate assignment.

Class Project:

The class project for the course comprises 50% of the grade (400 points) for this course. Consequently, this is the assignment where a substantial portion of student effort should be directed. The project is intended to be a practical assignment of “worth” that may further the development of student capstones, theses, or dissertation research. Students will present their projects during the final two classes. They may use a Powerpoint format or any other audiovisual or presentation mode (e.g. poster, handouts, etc.) they wish.

Students are encouraged to select topics which are of interest to them. Emphasis is further placed on projects which may have relevance and application to the cardiovascular health issues in our region and state. The instructor encourages projects which generally fit one of the following three classifications: 1) development of an abbreviated research grant proposal, 2) development of a white paper / policy analysis that uses epidemiologic data and other evidence-based research, and 3) development of an original data analysis / research project using either primary or secondary data. The instructor recognizes that there are a range of interests, abilities, experiences, and aptitudes in the class and encourages original and creative efforts in undertaking this project.

1. **Abbreviated grant proposal.** This project should generally follow and use the format of the PHS 398 forms and include (at minimum) the following sections: Introduction, Specific Aims, Brief Literature Review, Study Design, Measures Used, Data Analysis, Strengths and Limitations, and References. The length of the final document should be 20-25 pages and should include at least 15 references. Students are encouraged to research current funding opportunities for ideas on topics.
2. **White paper / policy analysis, meta-analysis.** The intent of this paper is to develop evidence-based policy recommendations that incorporate current epidemiologic and medical research data on cardiovascular outcomes. These outcomes could broadly include diabetes, obesity, nutrition recommendations, physical activity, workplace health interventions, etc. For example, there is currently a national debate over whether we should more aggressively screen for early cardiovascular disease using non-invasive techniques. Is the evidence sufficient to recommend such a policy? Would it be cost-effective? How would we pay for it? The length of the final document should be 20-25 pages and should include at least 15 references. This project cannot be a simple review of the literature; a meta-analysis should include some quantitative assessment of the reviewed studies.

- 3. Data Analysis Project.** Students who have the requisite prior experience in using SAS, SPSS or other data analysis software and have had previous coursework in biostatistics or epidemiology may choose to undertake an original data analysis project using either primary or secondary data. Data may be obtained from online sources or a faculty member. Secondary analysis of public domain data sources may not necessarily require IRB approval, although other projects may necessitate expedited IRB approval or be covered under an investigator's current grant funding. Given the time constraints of the semester, students choosing this option may also choose to investigate sources of cardiovascular data from grant-funded investigations and develop a detailed manuscript proposal/data analysis plan for use of the data source. Such an approach would be appropriate for data sources such as the Framingham data, Atherosclerosis Risk in Communities Study (ARIC), or other sources.

Students will present projects during the last two class sessions and submit their final project papers on April 25. They will also participate in the evaluation of student project presentations.

Class Debates.

There will be three class "debates" on current topical issues in the field of cardiovascular epidemiology / preventive cardiology. The schedule for the debates is given in the topic outline below. Each member of the class will be assigned to a "team" of two-three persons (depending on class size) at the beginning of the semester. In general, there will be two members of the affirmative team and two members of the negative team. The format will generally follow the Oxford style of debate, familiar to members of high school debate teams. Each member will have about 10 minutes to either present their case or be involved in the rebuttal arguments. Students must generally use evidence-based methods and data in their presentations. The debates will last for roughly 1 hour of the scheduled time in the class session. Additional information will be provided to the class.

Debate	Month	Date	Topic	Teams
1	Feb.	7	Population screening for cardiovascular diseases using currently available noninvasive techniques such as carotid IMT or coronary calcium are needed to prevent heart attacks and other cardiovascular outcomes.	TBA
2	March	7	Kentucky needs to invest in population-based primary prevention efforts to decrease the burden of cardiovascular disease in the state since there is sufficient evidence for the effectiveness of such programs.	TBA
3	March	28	Community based smoking bans should be more widely adopted across the state as the evidence suggests that there is a marked reduction in cardiovascular outcomes following their implementation.	TBA

Midterm exam:

There will be a take-home midterm exam. The midterm will cover material in the assigned readings, lectures, and guest presentations. Students may use their course notes, the text, and other materials but may not consult with others. The test needs to be his/her own work. The midterm will be worth 200 points and cover course material through February 28th. The test will consist of multiple choice, short answer, essay, and study critique questions. The test will be given to the class on February 28th and need to be submitted to the instructor at the beginning of the class on March 7.

Websites:

Here is a partial listing of some web sites that would be relevant to the course:

American Heart Association: <http://www.americanheart.org/>.

American College of Cardiology: <http://www.acc.org/>.

Association for the Eradication of Heart Attack : <http://www.aeha.org/>.

Atherosclerosis Risk in Communities Study: <http://www.escc.unc.edu/aric/index.htm>.

CDC Cardiovascular Health Program: <http://www.cdc.gov/dhdsp/redirect.htm>.

Framingham Heart Study: <http://www.nhlbi.nih.gov/about/framingham/index.html>.

The Heart.Org : <http://www.theheart.org/>.

University of Kentucky Cardiovascular Research Center:
<http://www.mc.uky.edu/cvrc/index.html>.

Topic Outline:

Class	Month	Date	Topic	Faculty
1	January	10	Orientation / Epidemiologic Contributions to CVD	Browning
2	January	17	Epidemiology II. Trends and Risk Factors	Browning
3	January	24	Screening for Cardiovascular Disease	Bailey / Browning
4	January	31	Framingham, ARIC and cardiovascular data sources.	Browning
5	February	7	The strategy of preventive medicine and Geoffrey Rose / Debate Topic 1	Browning
6	February	14	The Epidemiology of Hypertension and CKD	Johann Herberth
7	February	21	Obesity, Physical Activity, and Diabetes: Focus on Children	L. Scott
8	February	28	Heart Failure Research / Midterm distributed.	D. Moser
9	March	7	Nutrition and Cardiovascular Diseases / Debate Topic 2 / Midterm due.	T. Lennie
	March	14	Spring Break ---- No class	
10	March	21	Clinical decision-making in cardiovascular epidemiology	S. Fleming
11	March	28	Tobacco Use, Passive Smoking, and Public Health / Debate Topic 3.	E. Hahn
12	April	4	Primary prevention in cardiovascular diseases.	Browning / Boisseau
13	April	11	Psychosocial and behavioral factors and CVD	N. Schoenberg
14	April	18	Student presentations	Browning
15	April	25	Student presentations	Browning

The lecture schedule is subject to change depending on the schedules of faculty. Students will be given notice in the event that a change needs to be made to the schedule.

Readings:

	Topic	Reading Assignment
Class 1	Orientation	<ul style="list-style-type: none"> Wong. Chapter 1. Global Cardiovascular Risk Evaluation.
Class 2	Epidemiology II. Trends and Risk Factors	<ul style="list-style-type: none"> Wong. Chapter 2. Global trends in cardiovascular disease. American Heart Association. Heart Disease and Stroke Statistics—2006 Update. Dallas, Texas. American Heart Association. Heart Disease and Stroke Statistics---2006 Update. Thom, T; Haase N et al. Circulation 2006; 113;85-151. http://circ.ahajournals.org/cgi/content/full/113/6/e85
Class 3	Screening for Cardiovascular Disease	<ul style="list-style-type: none"> Wong. Chapter 3. Noninvasive ultrasonographic assessment of cardiovascular disease. Wong Chapter 4. Surrogate Measures of Atherosclerosis.
Class 4	Framingham, ARIC, and CVD data sources.	<ul style="list-style-type: none"> Wong Chapter 8. Dyslipidemia. Framingham Review articles TBA. Kannel W. Lessons from curbing the coronary artery disease epidemic for confronting the impending epidemic of heart failure. Medical Clinics of North America. 88 (2004). 1129-1133.
Class 5	The strategy of preventive medicine and Geoffrey Rose	<ul style="list-style-type: none"> Rose, G. Sick Individuals and sick populations. International Journal of Epidemiology. 2001 30: 427-432 Rose, G. Ancel Keys lecture. Circulation 1991; 84; 1405-1409
Class 6	The Epidemiology of Hypertension and CKD	<ul style="list-style-type: none"> Wong. Chapter 7. Hypertension. CKD article (TBA)
Class 7	Diabetes, Obesity and Physical Activity: Focus on Children	<ul style="list-style-type: none"> Wong. Chapter 9. Diabetes and the Metabolic Syndrome. Wong. Chapter 10. Obesity and Weight Control. Schulze M. Primary Prevention of Diabetes: What can be done and how much can be prevented? Annual Review of Public Health. 2005. 26: 445-67
Class 8	Failures of the Heart	<ul style="list-style-type: none"> Wong. Chapter 17. Seniors. Moser articles (TBA) Kannel, W. Incidence and Epidemiology of Heart Failure. Heart Failure Reviews, 5, 167-173, 2000.

Class 9	Nutrition and Cardiovascular Diseases: Reverse epidemiology in heart failure related to body mass index and hypercholesterolemia.	<ul style="list-style-type: none"> • Wong. Chapter 11. Nutrition. • Kalantar-Zadeh, K. Reverse Epidemiology of Conventional Cardiovascular Risk Factors in Patients with Chronic Heart Failure. Journal of the American College of Cardiology. Vol. 43, No. 8, 2004.
Class 10	Clinical decisionmaking in cardiovascular epidemiology	<ul style="list-style-type: none"> • Hunink MGM. 2001. In search of tools to aid logical thinking and communicating about medical decision making. Medical Decision making 21: 267-277. • Bogardus ST, Homboe E, Jekel JF. 1999. Perils, pitfalls, and possibilities in talking about medical risk. JAMA 281: 1037-1041.
Class 11	Tobacco Use, Passive Smoking, and Public Health	<ul style="list-style-type: none"> • Wong. Chapter 5. Tobacco Use, Passive Smoking, and Smoking Cessation. • Bartecchi, C et al. Reduction in the Incidence of Acute Myocardial Infarction Associated with a Citywide Smoking Ordinance. Circulation. 2006. 114; 1490-1496.
Class 12	Primary prevention in cardiovascular diseases.	<ul style="list-style-type: none"> • Wald. NJ and M R Law. A strategy to reduce cardiovascular disease by more than 80%. BMJ 2003; 326. • Grundy S. et al. Primary prevention of coronary heart disease: guidance from Framingham. Circulation 1998; 97: 1876-1887.
Class 13	Psychosocial and behavioral factors and CVD	<ul style="list-style-type: none"> • Wong. Chapter 14. Psychosocial Factors. • Everson-Rose, S. et al. Psychosocial Factors and Cardiovascular Diseases. Annual Review of Public Health, 2005. 26:469-500. • Schoenberg papers (TBA)
Class 14	Student presentations	
Class 15	Student presentations	

Summary of Important Dates:

Debate Topic 1	February 7
Class project selection date	February 14
Midterm distributed	February 28
Midterm exam due	March 7
Debate Topic 2	March 7
Debate Topic 3	March 28
Student Presentations	April 18 and 25
Class Project (written) due	April 25

Policy on absences and late submittal of work:

Students are expected to attend all classes but are not required to do so in order to pass the class. Although attendance is not required and does not serve as a criterion for a grade in the course, examinations may include materials not covered in the texts, readings, or problem sets. Additionally, a point assignment is given for class participation.

Students are expected to take the examinations on the day scheduled in the syllabus. Students who cannot take the examination on the scheduled day must have an excused absence (illness of student or family member, death of family member, university sponsored trip, etc.) as defined in the *Student Rights and Responsibilities* handbook. Students should inform the faculty in advance of the examination if a problem exists with respect to taking the exam on the designated day. Students will be given the opportunity to make up missed work or exams in the event of excused absences. Students are entitled to excused absences for the purpose of observing their major religious holidays.

It is expected that all work submitted for a grade in the course be the work of the individual student. Students are encouraged to review sections 6.3.1 on plagiarism and 6.3.2 on cheating in the *Student Rights and Responsibilities* handbook.

Incomplete or “I” grades:

It is at the discretion of the faculty member to assign an 'I' grade at the students request. The student and faculty should agree on (1) what is needed to complete the course requirements to be assigned a final letter grade, and (2) faculty and student should agree on the time frame to complete this work. Please be aware that the faculty ARE NOT REQUIRED to give the student the entire 12 month period to complete the work. In fact, for this course, it is assumed that any necessary extensions needed to complete the work will be short and essentially equivalent to the amount of time that the student could not work on the assignments due to illness, family emergency, or other circumstances. The faculty member would work with the student in developing a time frame which is appropriate for the situation and manageable for both the faculty and student schedules. This will be agreed to in writing by both the student and faculty. Students are strongly encouraged to complete all assignments in the given semester as the policy to assign an “I” is at the discretion of the faculty member and will only be applied when circumstances are warranted.

Enabling Accommodations:

If you have a documented disability that requires academic accommodations, please see me during scheduled office hours. In order to receive accommodations in this course, you must provide me with a letter of accommodation from the Disability Resource Center. If you have not already done so, please register with the Disability Resource Center for the coordination of campus disability services.

CPH 618/GRN 618: EPIDEMIOLOGY OF AGING SPRING 2005

Class Meetings: Thursdays 3 to 5:45 p.m., 304E Health Sciences Building

Credit Hours: 3

Instructor: Suzanne L. Tyas, PhD
Graduate Center for Gerontology
306B Health Sciences Building, 900 South Limestone Street
University of Kentucky, Lexington, KY 40536-0200
tel: (859) 257-1450 x80195
fax: (859) 323-5747
e-mail: styas@uky.edu

Office Hours: Thursdays 2 to 3 p.m. or by appointment

A. COURSE RATIONALE

The aging of the world's population reflects the achievements of social development and public health in combating death and disease. This demographic transition, however, intensifies the need to understand the challenges raised by an aging population. Epidemiology has an established role in promoting the health of an aging population by providing information on health status, risk factors, and current and future needs for prevention and care.

This course introduces the application of epidemiologic methods to the study of older persons. This lecture/discussion course will begin with a brief overview of core epidemiologic concepts and methodologic issues in epidemiologic studies of older persons. We will then study predictors of health and three major health outcomes: longevity/mortality, functional status/disability, and disease. Students will critically evaluate research in gerontological epidemiology and will investigate a specific topic in this field in depth.

Relationship to Public Health Degree Program Goals and Objectives

This course relates directly to the accomplishment of the educational program goals for the MPH degree, which are described in the Student Handbook that students receive upon enrollment into the MPH degree program. Please reference the educational program goals throughout the semester as they will provide a framework for this course and will contribute to your preparation for successfully completing other degree program requirements (e.g., capstone, practicum, Dr.P.H. comprehensive examination).

Relationship to the College of Public Health Terminal Objectives

The last page of this document describes the College of Public Health terminal objectives for MPH students concentrating in epidemiology and their relationship to this course.

Prerequisites

Prerequisites for this course are an introductory epidemiology course, GRN 650 or permission of the instructor. A brief review of basic epidemiologic principles will be provided at the beginning of the course. However, this review will be fairly rapid; students without a foundation in epidemiology should be prepared to allocate additional time to gain competence in this area (see recommendations under Instructional Resources). Highly motivated students without any background in epidemiology are welcome but are encouraged to meet with the Instructor before the course begins.

B. COURSE EXPECTATIONS**Course Goals**

The aims of this course are for students to develop proficiency in conducting literature searches, critically appraising epidemiologic studies and writing critical literature reviews, and to become familiar with major risk factors, conditions and diseases related to aging.

Course Objectives

Following successful completion of the course, students should be able to:

1. describe key methodologic and ethical issues in conducting epidemiologic studies of older persons;
2. apply the principles and methods of epidemiology to critically evaluate research in gerontological epidemiology;
3. discuss the epidemiology of selected conditions and diseases common to old age; and
4. analyze in depth a topic in gerontological epidemiology.

Course Requirements

To attain the course goals and learning outcomes, students will have to access books and journal articles through the Internet and the University of Kentucky libraries. Students will need to use skills in literature searches, word processing, and written and oral communication.

Instructional Resources

Course readings are organized by weekly session. Completion of readings before each session is necessary so that students can participate fully in discussions. The required text is available for purchase through the Kennedy and University Book Stores and is also on reserve at the UK Medical Center library. Journal articles and book chapters will supplement the text readings and will be available from the instructor or the University of Kentucky libraries.

Required Text

Ebrahim S, Kalache A. Epidemiology in old age. London: BMJ Publishing Group, 1996.

This comprehensive text is the primary source for background readings on the epidemiology of aging.

Instructional Resources (cont.)

Recommended Resources

These and other epidemiologic resources are available for reference in the Instructor's office. Resources indicated with an asterisk are also available through the University of Kentucky libraries.

*Gordis L. *Epidemiology*. 2nd edition. Philadelphia: Saunders, 2000.
WA 105 G661e 2000 Medical Center Library
A good introductory epidemiology text.

*Wallace RB, Woolson RF. *The epidemiologic study of the elderly*. New York: Oxford University Press, 1992. WT 30 E635 1992 Medical Center Library
On reserve; good discussion of methodologic issues in epidemiologic studies of older persons.

Intermediate Epidemiology

Buck C et al. (eds). *The challenge of epidemiology: issues and selected readings*. Washington, DC: Pan American Health Organization (PAHO) Scientific Publication #505, 1988.
A collection of classic epidemiologic articles.

Elwood JM. *Critical appraisal of epidemiologic studies and clinical trials*. 2nd ed. New York: Oxford University Press, 1998.
A discussion, with examples, of issues to consider when reviewing epidemiologic research.

Reference

*Last JM (ed). *A dictionary of epidemiology*. 3rd ed. New York: Oxford University Press, 1998.
WA 13 D553 1998 Medical Center Library Reference

*Michael M III, Boyce WT, Wilcox AJ. *Biomedical bestiary: an epidemiologic guide to flaws and fallacies in the medical literature*. Boston: Little, Brown and Company, 1984.
WA950 M621b 1984 Young Library

General Interest

Roueché B. *The medical detectives*. New York: Truman Talley Books/Plume, 1991.

Stolley PD, Lasky T. *Investigating disease patterns: the science of epidemiology*. New York: Scientific American Library, 1998.

C. COURSE CONTENT

Week	Date	Topic	Text Chapters*	Assignments
1	Jan. 13	Introduction to the epidemiology of aging	1,3,4,6	
2	Jan. 20	Ethical and methodologic issues in the study of older persons	2	
3	Jan. 27	Review of epidemiologic concepts	7,8	
4	Feb. 3	Critical appraisal of epidemiologic literature		
5	Feb. 10	Predictors of health outcomes	18–22, 25	Practice Critique
6	Feb. 17	Health outcomes: Longevity/mortality	44	Critique
7	Feb. 24	Health outcomes: Functional status/disability I <i>Frailty and healthy aging</i>	5, 17, 23, 24	Critique
8	March 3	Health outcomes: Functional status/disability II <i>Elder abuse</i>		Critique
9	March 10	Health outcomes: Functional status/disability III <i>Injuries</i>	36, 37, 39–41	Term paper outline, Critique
10	March 17	NO CLASS (Spring break)		
11	March 24	Health outcomes: Diseases of older persons I <i>Alzheimer's disease and vascular disease</i>	26–30, 42	Critique
12	March 31	Health outcomes: Diseases of older persons II <i>Arthritis</i>	31–33	Critique
13	April 7	Health outcomes: Diseases of older persons III <i>Infectious diseases</i>		Critique
14	April 14	Health outcomes: Diseases of older persons IV <i>Cancer</i>	34, 35, 38	Critique
15	April 21	Student presentations I		Presentations
16	April 28	Student presentations II		Presentations, term paper

*Journal articles and additional background readings will also be assigned.

Note: This outline is subject to adjustment as the course proceeds.

D. INSTRUCTIONAL STRATEGIES

The course will consist of 15 sessions of approximately 2 hours and 45 minutes each, given on Thursdays at 3 p.m. in Room 304E of the Health Sciences Building. In most sessions, the first half of the class will be a lecture and the second half will be a class discussion of two assigned journal articles. The course will include lectures, class discussions, class critiques of research literature, student presentations, and an independent term paper.

E. ASSESSMENT AND EVALUATION

Critical Appraisal of Readings (16 critiques @ 2.5% each) 40%

A 3-page (double-spaced) typewritten critique on each assigned article is due at the beginning of each class in Weeks 6 to 9 and 11 to 14. Two readings to critique are assigned for each of these eight classes (2 articles x 2.5% x 8 weeks = 40%). The readings will be journal articles of epidemiologic research in older adults. The written critiques are intended to provide practice in the critical appraisal of epidemiologic literature and to stimulate class discussions on major topics in the epidemiology of aging. Please note that these commentaries are not intended to be simply summaries, as in an abstract for an article, but instead should be critical evaluations of the research.

Commentaries must be organized under the following headings:

- Purpose and Major Findings
- Methodologic Strengths and Weaknesses
- Study Significance
- Personal Reaction

Commentaries will be marked out of 5 and evaluated on the basis of the following criteria.

1. Purpose and Major Findings (1 point)
 - Have you identified the purpose of the study and summarized the major findings?
2. Methodologic Strengths and Weaknesses (2 points)
 - Have you critically appraised the methodologic strengths as well as the weaknesses (e.g., study design, sample, measurement, analysis, interpretation)?
3. Study Significance (1 point)
 - Have you discussed the importance of the research question?
 - Have you discussed the particular study's contribution to knowledge in this area?
4. Personal Reaction (1 point)
 - Have you discussed your own reactions (e.g., your overall opinion, what you liked and disliked about the study, how you might improve it)?
 - Have you incorporated background material from the text readings and lectures, as appropriate?

In addition, correct grammar and an effective writing style are expected and will be considered in evaluating the critiques.

Note: Bring two copies of your commentaries to each class: one to hand in and one to refer to during the class discussion.

ASSESSMENT AND EVALUATION (cont.)**Discussion Leader 5%**

Each student will lead one discussion of the weekly readings. The discussion leader's notes (e.g., introductory summary, discussion questions) should be submitted with his/her critique. In addition to the weekly critiques that everyone will hand in, the discussion leader is responsible for, and will be evaluated on, the following tasks.

1. Provide a brief summary of the topic at the beginning of the discussion. (Incorporate information from the textbook; you may want to do some extra background reading.)
2. Generate discussion of the topic (e.g., by preparing questions to generate discussion). A good discussion question should stimulate critical thinking rather than simply recall of information.
3. Manage the discussion (e.g., keep the discussion on topic, ensure everyone has the opportunity to contribute, keep within the time limit).
4. At the end of the discussion, summarize verbally the most important points raised.

Term Paper 55% (Outline 5%, Class Presentation 15%; Written paper 35%)

Students may select a topic of their choice for their critical review of epidemiologic research but should confirm this choice with the instructor to ensure appropriateness and feasibility. An outline is required to encourage you to start working on your paper early and to provide an opportunity for the instructor to give you feedback. Topics should not change after submission of the outline unless discussed with the instructor. To share what you have learned during preparation of your term paper, each student will present his/her findings to the class. A separate information sheet on guidelines for the term paper will be handed out in class.

Date Due: The outline is due on **March 10**. Presentations are scheduled for **April 21 and 28**. The paper is due at the beginning of the last class (**April 28**).

There is no final test/examination in this course.

Grading

Only full letter grades will be given for the final grade.

A: 90-100%

B: 80-89%

C: 70-79%

E: Failure (<70%)

Any revisions to this grading scale will be to the benefit of the student.

F. ADMINISTRATIVE COMMENTS/COURSE POLICIES

Please feel free to talk with the instructor about any ideas, questions, or concerns you may have regarding this course.

Attendance

Class discussions are an integral part of this course and thus attendance and active participation are expected. If for any reason you cannot attend a class meeting, please contact the instructor as far in advance of the anticipated absence as possible. Unexcused absences (see S.R. 5.2.4.2 in www.uky.edu/StudentAffairs/Code/part2.html for definitions of excused absences) may result in a reduction of the final course grade. The instructor shall give the student an opportunity to make up the work missed during an excused absence.

Submission of Assignments

All written assignments must be typed and paper copies submitted at the beginning of the class session. Because the critiques will be discussed in the class in which they are due, late critiques cannot be accepted and will result in a mark of 0. Presentations (leading discussions and term paper presentations) that are not completed when scheduled will receive a 0. In fairness to those students who submit their work on time, late term paper outlines and final papers will be penalized by 10% for each day overdue, including weekends and holidays.

Accommodations

If you have a documented disability that requires academic accommodations, please see me as soon as possible during scheduled office hours. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the Disability Resource Center (www.uky.edu/TLC/grants/uk_ed/services/drc.html). If you have not already done so, please register with the Disability Resource Center (Room 2, Alumni Gym, 257-2754; jkarnes@uky.edu) for coordination of campus disability services to students with disabilities.

Academic Offenses and Procedures

The College of Public Health and the University of Kentucky place a premium on academic honesty. Please refer to the University of Kentucky Student Rights and Responsibilities document (www.uky.edu/StudentAffairs/Code). The information below is provided as a convenience to students and is not a substitute for review of the original publication. Please note that the minimum penalty for plagiarism or other forms of cheating is an E (failure) in the course, with suspension and dismissal also possible.

Excerpted from the University of Kentucky publication "Student Rights and Responsibilities" (revised June 6, 2000).

6.3.0 ACADEMIC OFFENSES AND PROCEDURES Students shall not plagiarize, cheat, or falsify or misuse academic records. (US: 3/7/88; 3/20/89)

Academic Offenses and Procedures (cont.)

6.3.1 PLAGIARISM All academic work, written or otherwise, submitted by students to their instructors or other academic supervisors, is expected to be the result of their own thought, research, or self-expression. In cases where students feel unsure about a question of plagiarism involving their work, they are obliged to consult their instructors on the matter before submission.

When students submit work purporting to be their own, but which in any way borrows ideas, organization, wording or anything else from another source without appropriate acknowledgment of the fact, the students are guilty of plagiarism.

Plagiarism includes reproducing someone else's work, whether it be published article, chapter of a book, a paper from a friend or some file, or whatever. Plagiarism also includes the practice of employing or allowing another person to alter or revise the work which a student submits as his/her own, whoever that other person may be. Students may discuss assignments among themselves or with an instructor or tutor, but when the actual work is done, it must be done by the student, and the student alone.

When a student's assignment involves research in outside sources or information, the student must carefully acknowledge exactly what, where and how he/she has employed them. If the words of someone else are used, the student must put quotation marks around the passage in question and add an appropriate indication of its origin. Making simple changes while leaving the organization, content and phraseology intact is plagiaristic. However, nothing in these Rules shall apply to those ideas which are so generally and freely circulated as to be a part of the public domain.

6.3.2 CHEATING Cheating is defined by its general usage. It includes, but is not limited to, the wrongfully giving, taking, or presenting any information or material by a student with the intent of aiding himself/herself or another on any academic work which is considered in any way in the determination of the final grade. Any question of definition shall be referred to the University Appeals Board.

6.3.3 FALSIFICATION OR MISUSE OF ACADEMIC RECORDS (US: 3/20/89; US 4/10/00) Maintaining the integrity, accuracy, and appropriate privacy of student academic records is an essential administrative function of the University and a basic protection of all students. Accordingly, the actual or attempted falsification, theft, misrepresentation or other alteration or misuse of any official academic record of the University, specifically including knowingly having unauthorized access to such records or the unauthorized disclosure of information contained in such records, is a serious academic offense. As used in this context, "academic record" includes all paper and electronic versions of the partial or complete permanent academic record, all official and unofficial academic transcripts, application documents and admission credentials, and all academic record transaction documents. The minimum sanction for falsification, including the omission of information, or attempted falsification or other misuse of academic records as described in this section is suspension for one semester.

Relationship of this course to the College of Public Health terminal objectives

This course meets the following College of Public Health terminal objectives for MPH students concentrating in epidemiology.

Objectives	Met by CPH/GRN 618?	How objective is met
Explain the purposes and applications of epidemiology	Yes	Content (lectures, readings)
Search and/or critically review the epidemiologic literature	Yes	Content (lectures, readings) Products (critiques, term paper)
Identify and use appropriate epidemiologic study designs and principles	Yes	Content (lectures, readings) Products (critiques, term paper)
Collect and manage data for investigating epidemiologic issues		
Analyze epidemiologic data using appropriate statistical methods		
Interpret and clearly communicate findings	Yes	Content (lectures, readings) Products (critiques, term paper, oral presentation)
Assess the ethical issues that confront epidemiology and appropriately address these issues	Yes	Content (lectures, readings)
Integrate principles of epidemiology into the practice of public health		

CPH 631 - Design and Analysis of Health Surveys

Instructor: Dr. Marta S. Mendiondo (marta@email.uky.edu)

207A Sanders-Brown Center on Aging 257-1412 x274

Office hrs: Thursdays 2 – 3:00 CPH room #201B or by appointment.

Lab Assistant: Margaret Sundquist (msslucc2@email.uky.edu)

Course meeting times: CPH 207 Thursdays Lecture 3:00 – 4:50 PM

Lab 4:50 – 6:30 PM

Course Prerequisite: STA580 or equivalent

Course Description:

Students will learn design and analysis issues associated with well known national health surveys, including reliability and validity of measurements, instrument validation, sampling designs, weighting of responses, and multiple imputations. Students will learn how to use statistical software to analyze data from complex survey designs.

Major Teaching Objectives:

1. Students will learn elementary sampling designs including simple random sampling, stratified random sampling, and cluster sampling.
2. Students will become familiar with more advanced sampling designs including multistage sampling, sampling proportional to size, and random digit dialing.
3. Students will become familiar with quantitative issues involved in evaluating survey data, including nonresponse, imputation, poststratification, weighting of responses.
4. Students will learn statistical software used in survey data analysis, including survey procedures in SAS.
5. Students will become familiar with at least one national health survey such as: National Health and Nutrition Examination Survey (NHANES), National Hospital Discharge Survey (NHDS), National Maternal and Infant Health Survey (NMIHS), and National Mortality Followback Survey (NMFS).

Course Grading Policy:

Course grades will be based on four equally weighted components: two midterm in class examinations, a final take home project, and graded homework (lab) exercises. The midterms are tentatively scheduled for February 23 and March 30, 2006. Final projects will be presented on Thursday, May 4, 2006 (3:00 PM – 5:30 PM).

Letter Grades:

A, B, and C grades correspond to a minimum average performance of 90, 80, and 70, respectively.

Homework:

It will be assigned every class and will be due on Monday, 10 days later.

Spring '06 Course Syllabus: CPH 631**Design and Analysis of Health Surveys**

Date	Topic	Text reference
January 12	Principles of Survey design	Ch. 1-4, AJ ; Ch. 1 GR
January 19	Principles of Survey design / Basic concepts	Ch. 2, LL
January 26	Simple random sampling	Ch. 3, LL
February 2	Systematic sampling	Ch. 4, LL
February 9	Stratified sampling / Ratio Estimation	Ch. 5 & 6, LL
February 16	Ratio estimation / Review for Midterm 1	Ch. 7, LL
February 23	MIDTERM 1	
March 2	Cluster sampling (one stage)	Ch. 8 & 9, LL
March 9	Two stage (and multi stage) cluster sampling	Ch. 10, LL
March 16	Spring Break	
March 23	PPS Cluster sampling / Review for Midterm 2	Ch. 11, LL
March 30	MIDTERM 2	
April 6	Variance estimation- complex survey designs Non-Response /Missing Data / Cross Cultural Surveys	Ch. 12, LL Ch. 13, LL – GR - JH
April 13	Use of sample weights	Ch. 4 & 5, KG - GR
April 20	TBA	
April 27	Final Exam - Presentation of Course Projects	

Possible Alternate Topics for April 13 – April 27

Analysis of cross sectional surveys
 Analysis of longitudinal surveys
 Telephone surveys
 Testing and Evaluating Survey Questionnaires

References:

- LL *Sampling of populations*, by P.S.Levy and S. Lemeshow, 3rd. ed., Wiley, N.Y., 1999
- KG *Analysis of health surveys*, by E.L. Korn and B.I. Graubard, Wiley, N.Y., 1999
- AJ *Designing and conducting health surveys*, by L.A. Aday, 2nd. Ed., Jossey-Bass, S.F., 1996
- GR *Survey Methodology*, by R. M. Groves et al, Wiley, N.Y., 2004
- JH *Cross Cultural Survey Methods*, by J. A. Harkness, Wiley, N. Y., 2003
- SP *Testing and Evaluating Survey Questionnaires*, by S. Presser et al, Wiley, N. Y., 2004

Instructor: Dr. Heather Bush

Lectures: R 12:00 – 2:30 CPH207

Text Book: *Applied Mixed Models in Medicine*,
2nd Ed. by Brown and Prescott

Prerequisite: STA580 or equivalent

Contact Info:

Office: 121 Washington Avenue
205C CPH Building

Office Hours: By Appointment

Phone: 859.257.5678 Ext. 82080

E-mail: Heather.Bush@uky.edu

Website: www.ms.uky.edu/~hbush

Learning Objectives:

Upon successful completion of this course, a student will be able to identify appropriate statistical methods for analyzing longitudinal data in his or her research and in current public health and medical literature. Specifically, the objectives of the course are as follows:

Presents statistical techniques for analyzing those longitudinal studies in public health that involve repeated measures and random effects. This course will cover multilevel regression models, Poisson regression models, logistic models with random effects, crossover experiments, and nonlinear pharmacokinetic models.

1. Learn the fundamental principles of linear mixed model mechanisms;
2. Utilize statistical methodologies such as multilevel regression models, Poisson regression models, logistic models with random effects;
3. Develop a familiarity with the design and analysis of longitudinal studies routinely used in public health and medicine: crossover studies, multi-center trials, and studies with clustered responses.

Method of Evaluation:

Homework and Case Studies (30%):

Weekly homework and/or case study assignments will be given to allow students to practice methods discussed during lecture. Case studies may require statistical software (SAS) and literature reviews. Students should be prepared for class discussions of homework and case studies.

Mixed Models Application Projects (60%)

Students will be expected to complete four projects in mixed modeling applications. These assignments may require the use of statistical software (SAS) and include written reports describing analysis and interpretation.

In-Class Assignments (10%)

The primary purpose of in-class assignments is to facilitate the retention of main ideas covered in lecture and group discussion. These will be completed in-class, so late assignments or make-ups for unexcused absences will not be accepted. Only students with excused absences will be permitted to make-up or submit late assignments.

Grading Scale: 100 – 90 = A
89 – 75 = B
75 – 60 = C

Unforeseen Contingencies: In the unlikely event that an unforeseen contingency requires additional course policies, you will be promptly notified in an e-mail memorandum.

Policies:

Attendance Policy: The course is designed so that students should be successful with *active participation* and regular, punctual attendance. It is understandable that students may miss class; however, it is the student's responsibility to determine what assignments were missed and what material was covered. Students missing 5 or more class periods (excused or unexcused) will receive an E for the course.

Late Work: Only students with university excused absences or circumstances which the instructor finds a reasonable cause for non-attendance will be allowed to submit late work without penalty. Late work is defined as any work handed in after the scheduled due date and time. It is the student's responsibility to make arrangements for determining and handing in missed work, preferably in advance, but no later than one week after the absence. In all other cases, late work will be penalized 25% for each day late, and assignments will not be accepted more than one week late.

Academic Integrity: The Department of Biostatistics, the College of Public Health, and the University of Kentucky place a premium on academic honesty. Please refer to the University of Kentucky Student Rights and Responsibilities document.

Accommodations: If you have a documented disability that requires academic accommodations, please contact me as soon as possible. In order to receive accommodations in this course, you must provide a Letter of Accommodation from the Disability Resource Center.

Course Description:

CPH632 presents statistical techniques for analyzing those longitudinal studies in public health that involve repeated measures and random effects. This course will cover multilevel regression models, Poisson regression models, logistic models with random effects, crossover experiments, and nonlinear models.

Tentative Schedule of Topics and Assignments:

Date	Topic	Readings
Aug 23	Review of Linear Models Introduction to Linear Mixed Models	Rosner 11.1-11.11; 12.1-12.6 BP Chapter 1
Aug 30	Introduction and Definition of LMM Common Mixed Models: Split-Plot Designs	BP 2.1 Handout
Sep 06	Linear Mixed Models Repeated Measures (Part 1)	BP 6.1-6.3, 6.5-6.71 Handout
Sep 13	Linear Mixed Models Repeated Measures (Part 2)	BP 6.1-6.3, 6.5-6.71 Handout
Sep 20	Linear Mixed Models Missing Data	Handout
Sep 27	Linear Mixed Models Common Mixed Models: Multicenter Trials	BP 5.1-5.5 Handout
Oct 04	Linear Mixed Models Random Effects Models	Handout
Oct 11	Linear Mixed Models ANCOVA	Handout
Oct 18	Generalized Linear Mixed Models Introduction	BP Chapter 3 Handout
Oct 25	Generalized Linear Mixed Models Binomial and Poisson	BP Chapter 3 Handout
Nov 01	Nonlinear Mixed Models Introduction Growth Curves, ZIP	Handout
Nov 08	Mixed Models Applications Wild Card	
Nov 15	Mixed Models Applications Crossover Trials	BP Chapter 7
Nov 22	No Class Happy Thanksgiving!	
Nov 29	Mixed Models Applications Cluster Randomized Trials	BP 8.10, 8.16 Handout
Dec 06	Mixed Models Applications Spatial Variability	Handout
Dec 11	Final Exam Week	

BP: Brown and Prescott, Mixed Models in Medicine 2nd Edition.

Tentative Due Dates for Mixed Model Application Projects:

Project 1: September 27, 2007

Project 2: October 25, 2007

Project 3: November 15, 2007

Project 4: December 11, 2007, 5:00pm

CPH 636: Data Mining in Public Health

Course Information and Syllabus Document

Spring 2008
Dr. Charnigo

Contact information

Instructor: Dr. Richard Charnigo

Office: 851 Patterson Office Tower and 203-B College of Public Health

Phone: 859.257.2550 and 859.257.5678 x 82072

E-Mail: richc@ms.uky.edu

The MS network is known to have problems from time to time, so if your e-mail to me is bounced or if you are expecting a reply from me and do not get it within 48 hours, try my backup e-mail address: RJCharn2@aol.com .

Home Page: www.ms.uky.edu/~richc

Office Hours: 2:15 to 3:30 p.m. on Wednesdays in 203-B College of Public Health, beginning on Wednesday 16 January (no office hours on Wednesday 12 March)

About this course

Course Description: This course familiarizes students with statistical techniques for and practical issues associated with the exploration of large public health data sets. Emphases are placed on the development of models from such data sets and on the effective communication of one's findings.

Course-Specific Objectives: Students who complete CPH 636 will be able to do the following:

1. Articulate the challenges associated with the acquisition and analysis of large public health data sets;
2. Judiciously apply linear regression methodology to problems in public health;
3. Judiciously apply linear classification methodology, including logistic regression, to problems in public health;
4. Employ classification and regression trees to analyze large public health data sets;
5. Employ neural networks and nearest neighbor methods to analyze large public health data sets;
6. Articulate the strengths and weaknesses of various supervised learning techniques; and,
7. Apply unsupervised learning techniques to problems in public health.

College of Public Health Terminal Objectives in Biostatistics: The last two pages of this document indicate the College of Public Health terminal objectives in biostatistics and their associated competencies. The entries in the third column indicate the minimal level of attainment for someone who has successfully completed CPH 636 and its prerequisites in the College of Public Health: a "1" represents awareness, a "2" represents knowledgeability, and a "3" represents proficiency. Your personal level of attainment upon completion of CPH 636 and upon completion of your degree program may be higher, depending on your degree program, your area of concentration, and your choices of selectives.

Relationship to Public Health Degree Program Goals: This course relates directly to the accomplishment of the educational program goals for the M.P.H. and Dr.P.H. degrees, which are described in the most current student handbooks. Please reference the educational program goals throughout the semester, as they will provide a framework for this course and will contribute to your preparation for successfully completing other degree program requirements (e.g., capstone, practicum, and Dr.P.H. comprehensive examination).

Textbook: Fernandez, George (2003). *Data Mining Using SAS Applications*. Boca Raton, FL: Chapman & Hall/CRC.

Prerequisites: STA 570/STA 580 and CPH 535, or consent of instructor. Regarding non-completion of STA 570/STA 580, you have the instructor's consent if you have completed a comparable graduate course in statistical methods at another university or if you have completed any of the following at UK: STA 503, STA 671, CPH 630, CPH 930. Regarding non-completion of CPH 535, you have the instructor's consent if you have some familiarity with SAS (not merely the SAS Analyst point-and-click interface) from STA 503, STA 580, STA 671, CPH 630, CPH 930, another course, or a job.

Instructional Strategies: Learning will take place in three different settings: in lecture, in laboratory, and at home. Lectures will motivate and describe data mining techniques. Laboratory sessions will provide opportunities to practice data mining techniques. Home study, including the completion of substantive written assignments and a project, will strengthen your understanding of concepts, your data mining skills, and your ability to effectively communicate what you discover when data mining.

Course policies and logistics

Class Meetings and Computers: We will meet on Mondays from 3:30 to 5:30 p.m. (lecture) and from 6:00 to 8:00 p.m. (laboratory) in 207 College of Public Health, except for Monday 21 January and Monday 10 March (academic holidays).

We have computers available for students to use while in 207 College of Public Health. You are advised to save your work on memory sticks since you may not have access to the same computer each week. The computers are equipped with SAS software and the Enterprise Miner add-on, which is rather expensive and does not routinely accompany SAS software. The author of your textbook has provided several SAS macros that allow a number of data mining techniques to be implemented without Enterprise Miner. We will make good use of these macros. However, there are a few techniques for which the author does not provide SAS macros. For these we will use Enterprise Miner or write our own code.

If you prefer to use your own laptop computer, you will need to have a recent version of SAS software installed. Inquiries about acquiring a personal SAS license may be directed to Aric Schadler of the SSTARS Center at schadler@ms.uky.edu. Since I anticipate that we will need Enterprise Miner on only three occasions, I cannot reasonably suggest that you purchase Enterprise Miner for the sake of this course; on those occasions, you can use the computers in 207 College of Public Health.

E-mail Memoranda and Course Materials: I will be sending e-mail memoranda regularly to distribute course materials, post grade information for those who request it, and make announcements. Course materials will also be available from my home page, www.ms.uky.edu/~richc. Please inform me if you are not receiving the memoranda.

Written Assignments: There will be five written assignments for you to work on during laboratory and outside of class. Tentatively, the assignments will be due at the end of lecture on 04 February, 18 February, 03 March, 24 March, and 07 April. Each assignment will cover the two lectures preceding its due date.

You are encouraged to work in self-selected groups of two or three, handing in one copy of the assignment for the group; however, you may work individually if you wish. Written assignments are to be submitted in hard copy and to me in person unless you have approval to do otherwise.

Final Project: There will be a non-collaborative final project entailing both an oral presentation and a written report. You will choose a moderate to large public health or medical data set that has not been considered in any of the lecture or laboratory sessions prior to Spring Break. The sample size must be at least 200, there must be at least 5 distinct variables, and at least 2 of the variables must be continuous. You are welcome to use the data set that you are analyzing for your capstone or thesis if it meets the above requirements; otherwise you can obtain a suitable data set from an Internet

repository. *To ensure that you have sufficient time to comfortably complete the final project, I strongly suggest that you choose your data set by Monday 24 March.*

During or shortly after Spring Break, I will furnish guidelines on what I expect for the oral presentation and written report. Oral presentations will be given on **Monday 14 April**. We will use both the lecture time and the laboratory time for this purpose. Each oral presentation will last approximately 15 minutes, unless we need to cut the time due to larger-than-expected enrollment. Written reports will be due on **Monday 28 April** at 4 p.m. and are to be submitted to me in person or left under my office door (203-B College of Public Health). You are welcome to submit your written report on Monday 21 April, but I cannot require this because of University regulations on dead week.

Grading: Your grade for the course will be determined by the written assignments (60%) and the final project (15% for oral presentation and 25% for written report). There may be opportunities to earn bonus points (e.g., for finding mistakes in course materials or for outstanding participation). The cutoff for an “A” will be no higher than 90%, the cutoff for a “B” will be no higher than 75%, and the cutoff for a “C” will be no higher than 60%. Anyone with the prerequisites who takes the course seriously should get no lower than a “B”.

Attendance Policy: I do not have an attendance policy *per se*, although for your own sake you are advised to attend consistently.

Late Policy: Cases involving any of the following will be handled individually: University-excused absences, University-prescribed academic accommodations, recommendations for special consideration from the office of an appropriate Dean or the Ombud. Otherwise:

1. A late submission of a written assignment or the written report will be accepted at 75% credit within 24 hours and at 50% credit within 48 hours. If you are late with a written assignment or the written report, please leave it under my office door (203-B College of Public Health) and send me an e-mail so that I know to look.

2. If you fail to show up for your oral presentation on Monday 14 April, you may deliver your oral presentation to me personally at a mutually agreeable time later that week. In this case, the oral presentation will be accepted at 50% credit.

Accommodations: If you have a documented disability that requires academic accommodations, please see me as soon as possible during scheduled office hours. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the Disability Resource Center (www.uky.edu/TLC/grants/uk_ed/services/drc.html). If you have not already done so, please register with the Disability Resource Center (Room 2 Alumni Gym, 257-2754, jkarnes@uky.edu) for coordination of campus disability services available to students with disabilities.

Academic Honesty: The Department of Biostatistics, the College of Public Health, and the University of Kentucky place a premium on academic honesty. Please refer to the University of Kentucky Student Rights and Responsibilities document (www.uky.edu/StudentAffairs/Code/part2.html).

Unforeseen Contingencies: If an unforeseen contingency requires additional course policies, or if I must correct a genuine error in the statement of course policies or due dates, you will be promptly notified in an e-mail memorandum.

Guidelines for Auditors: Per University guidelines, students who have registered as auditors are expected to attend at least 80% of the lectures. Auditors are welcome to participate in laboratory activities, although I will neither collect nor criticize written assignments from auditors. In the event that there is a shortage of working computers in 207 College of Public Health, auditors are asked to yield the working computers to students who are taking the course for credit. Auditors will not do the final project.

Tentative syllabus

Below is a tentative plan; adjustments may be made as we proceed through the semester.

Lecture	Date	Topics (Relevant Sections of the Textbook)
1	14 January	Introduction to data mining; motivating examples in public health and other disciplines; sources of public health data; supervised versus unsupervised learning; organization of data; reading data into SAS (1.1 – 1.9, 2.1 – 2.3, 2.7)
2	28 January	Variable types; the curse of dimensionality and statistical modeling; bias-variance tradeoff; rationale for creating training data, validation data, and test data; creating training data, validation data, and test data in SAS (2.4 – 2.7)
3	04 February	Rationale for exploratory data analysis; numerical and graphical techniques for exploring continuous variables; numerical and graphical techniques for exploring categorical variables; exploratory data analysis in SAS (3.1 – 3.4)
4	11 February	Regression versus classification paradigm; the simple linear regression model; the multiple linear regression model; interpreting linear regression coefficients and quantifying explanatory ability; linear regression in SAS (5.1 – 5.3, 5.5)
5	18 February	Diagnostic plots in linear regression; model selection criteria based on training data; model selection and evaluation based on validation and test data; scoring new linear regression data in SAS (5.3, 5.6, 5.7)
6	25 February	The binary logistic regression model; interpreting logistic regression coefficients and quantifying predictive ability; diagnostic plots and model selection in logistic regression; logistic regression in SAS; scoring new logistic regression data in SAS (5.4, 5.8, 5.9)
7	03 March	Introduction to discriminant analysis; linear discriminant analysis; quadratic discriminant analysis; discriminant analysis in SAS (6.1 – 6.6, 6.9)
8	17 March	Regression trees; classification trees; missing data in the context of trees; comments about missing data in general; trees in SAS
9	24 March	Neural networks for regression; neural networks for classification; neural networks in SAS
10	31 March	Nearest neighbor methods for regression; nearest neighbor methods for classification; comments on strengths and weaknesses of various supervised learning techniques; nearest neighbor methods in SAS
11	07 April	Principal components; factor analysis; principal components and factor analysis in SAS (4.1 – 4.4, 4.6, 4.7)
---	14 April	ORAL PRESENTATIONS
12	21 April	K-means clustering; hierarchical clustering; K-means clustering in SAS (4.5, 4.6, 4.8)

Competency attainment

Terminal Objectives in Biostatistics	Competencies	Level of Attainment
1. Explain basic principles of statistical estimation and inference.	<ul style="list-style-type: none"> a. Conceptualize sample measurements as realizations of random variables; 2 b. Conceptualize estimates of population parameters as realizations of random variables; 2 c. Construct confidence intervals for population parameters; 2 d. Formulate statistical hypothesis tests concerning population parameters; 2 e. Quantify the power of some basic hypothesis tests; 1 f. Determine appropriate sample sizes for some basic hypothesis tests; 1 g. Articulate the relationship between confidence intervals and hypothesis tests. 2 	
2. Identify and use standard experimental and sampling designs.	<p>Be conversant in the use of the following:</p> <ul style="list-style-type: none"> a. designing and analyzing a two way lay out with interaction; 1 b. designing and analyzing experiments with repeated measures; 2 c. designing and analyzing simple cross over experiments; d. adjusting for the effects of confounders and/or stratifying variables; e. explaining the biostatistical components of a clinical trial including large prevention trials in public health and community intervention studies; f. monitoring the progress of a disease over time using time series analysis or disease surveillance methods; g. applying spatial statistics to a problem in public health that has a geographic component. 	
3. Understand elementary probability concepts used in Public Health.	<ul style="list-style-type: none"> a. Characterize conditional probability both mathematically and intuitively; 1 b. Express the specificity of a diagnostic test as a conditional probability; 1 c. Express the sensitivity of a diagnostic test as a conditional probability; 1 d. Construct and interpret the receiver operator curve of a diagnostic test; 1 e. Apply Bayes' Theorem to calculate the predictive positive value of a diagnostic test from the specificity, sensitivity, and disease prevalence; 1 f. Describe the binomial probability model and the contexts in which it arises; 1 g. Describe the Poisson probability model and the contexts in which it arises; h. Employ Markov chains to describe random phenomena with a special probabilistic structure. 	
4. Apply statistical methods commonly encountered in univariate data analysis.	<ul style="list-style-type: none"> a. Use descriptive statistics effectively; 2 b. Perform paired and independent t-tests to compare means; 2 c. Calculate chi squared statistics to compare proportions as well as construct confidence intervals for odds ratios and relative risk; 2 d. Analyze data obtained from one way ANOVA designs (including multiple comparisons and contrast); 2 e. Fit a simple linear regression model; 2 f. Construct Kaplan Meier curves for right censored observations and compute the log rank statistic to compare these curves between two groups. 2 	

5. Apply statistical methods commonly encountered in multivariate data analysis.	a. Identify and apply appropriate multivariate statistical models including multiple linear regression, logistic regression, Poisson regression, proportional hazards regression, and mixed models;	1
	b. Critically interpret the outcomes of the multivariate analysis;	2
	c. Conduct graphical and analytical model diagnostics, and recommend remedies based on the diagnostics;	2
	d. Integrate the outcomes of multiple studies using meta analysis.	
6. Gather, organize, and manage health survey data.	a. Design a health survey instrument; b. Assess instrument/item reliability and validity; c. Draw and analyze a simple random sample of measurements; d. Implement and analyze more complex survey designs including stratified samples, clustered samples, and multistage samples;	2
	e. Process incomplete data using imputation; f. Adopt an appropriate weighting scheme for observations in a health survey.	1
7. Effectively use statistical software to collect, manage, and analyze Public Health data.	a. Master the use of SAS analyst, a click and point statistical software;	2
	b. Acquire the skills necessary to write code for SAS programs;	2
	c. Understand the principles of data acquisition, verification, and validation;	2
	d. Become skilled at editing, combining, and linking data sets;	2
	e. Learn the fundamentals of data manipulation and analysis;	2
	f. Efficiently create tables, graphs, and reports;	2
	g. Learn the fundamentals of the SAS macro facility;	2
	h. Learn to use nQuery Advisor, a sample size calculation software program.	
8. Critically review biostatistical issues arising in Public Health literature.	a. Demonstrate they can select appropriate statistical methods for the problem;	2
	b. Resolve controversial issues associated with competing solutions in biostatistics for the same problem (discussing strengths and weaknesses).	2
9. Interpret and clearly express findings.	a. Interpret univariate statistical models;	2
	b. Interpret complex multivariate statistical models;	2
	c. Express their findings clearly both verbally and in writing.	2
10. Integrate principles of biostatistics in the practice of Public Health.	a. Use statistical methodology to analyze public health data;	2
	b. Recognize the potential for statistics to aid in the development of guidelines and policies, the implementation and management of programs, and the evaluation of programs.	1

CPH 647 001 Research Methods For Health Promotion Spring 2007

Syllabus and Course Policies Document

Dr. Crosby

Contact information

Instructor: Dr. Richard Crosby

Office: 113C CPH

Phone: 859.257.5678 ext, 82039

E-Mail: crosby@uky.edu

Office Hours: Mondays from 2:30 to 5:00 and by appointment

About this course

Course Description: This course provides the student with basic knowledge about the design and analysis of research in the field of health promotion. The theory, design, applications, and analytic strategies used for various types of research are presented in a sequential format. Goals of the course include: 1) gaining the ability to critically evaluate research in health promotion practice, 2) achieving competence in research methodology, and 3) understanding the conceptual application of analytic techniques to data.

Course-Specific Objectives:

- understand the role of behavioral science in health promotion
- distinguish the appropriate study designs used to assess the efficacy of health promotion programs
- collect, manage, analyze, and interpret data on health promotion programs using appropriate statistical and other analytic method
- apply ethical principles that confront health promotion interventions for various audiences
- critically evaluate the design, analysis, and interpretation of health promotion research
- be able to describe key elements, overall function, general utility, and appropriate application of research designs in the field of health promotion
- design a research study intended to address a specific issue in health promotion
- design, analyze, and interpret the results of experimental and observational research
- identify limitations of research studies

Textbook: Crosby, R. A., DiClemente, R. J., & Salazar, L. F. Research Methods for Health Promotion. Jossey Bass Wiley, 2006.

Prerequisite: none

Class Meetings: We will meet on Mondays from 12:00 - 2:30 in CPH 115. The intensity of this course necessitates that you be present for the entire class meeting and that you do not miss any of the meetings.

Assignments: Assignments comprise 40% of the final grade. Five assignments will be made during the semester.

Examinations: A midterm exam will be given. This exam will require the student to synthesize and apply information learned from class, class assignments, and assigned readings. The midterm exam will comprise 25% of the final grade. A final exam will be given. This exam will require the student to synthesize and apply information learned from class, class assignments, and assigned readings. This exam will be comprehensive and will comprise 35% of the final grade

Grading: Grades will be assigned according to the following scale (100 points total for the course):

Percent of all possible points	Letter grade
90 - 100	A
80-89	B
70 - 79	C

Late Policy: Cases involving University-excused absences, University-prescribed academic accommodations, or explicit requests from your Assistant or Associate Dean will be handled individually.

Accommodations: If you have a documented disability that requires academic accommodations, please see me as soon as possible during scheduled office hours. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the Disability Resource Center (www.uky.edu/TLC/grants/uk_ed/services/dre.html). If you have not already done so, please register with the Disability Resource Center (Room 2 Alumni Gym, 257-2754, jkarnes@ulcy.edu) for coordination of campus disability services available to students with disabilities.

Academic Honesty: The Department of Health Behavior, the College of Public Health, and the University of Kentucky place a premium on academic honesty. Please refer to the University of Kentucky Student Rights and Responsibilities document (www.ulcy.edu/StudentAffairs/Code/part2.html).

Provisionality: I reserve the right to clarify or amend these policies, in which case I will document the clarification or amendment by distributing an addendum to this document.

Tentative agenda

Reading assignments may be completed after the class period.

Week	Topic	Reading Assignment
1	Orientation to syllabus; overview of text; overview of research methods for health promotion Begin term paper (assignment #5 -- due on day of final examination)	Chapter 1
2	Philosophy of science; deductive and inductive approaches; theory construction/testing	Chapter 2
3	Research ethics and IRB approval procedures Begin assignment #1 (due in 2 weeks)	Chapter 3
4	Research design (practice for assignment #2)	Chapter 4
5	Conducting observational research Assignment #2	Chapter 5
6	Conducting experimental research	Chapter 6
7	Qualitative research and midterm exam	Chapter 7
8	Measurement	Chapters 9 and 10
9	Sampling (practice for assignment #3)	Chapter 11
10	Assignment #3 Preparation and writing of research articles	Chapter 14
11	Analyzing observational research	Chapter 12
12	Analyzing experimental research (practice for assignment #4)	Chapter 13
13	Grant writing Assignment #4	Chapter 15
14	Comprehensive in-class final exam	

Overview of Assignments

Term paper = 20%; 3 in-class exercises = 5% each; IRB exercise = 5%

Assignment #1: (IRB Certification) The task is to obtain your IRB certification. Begin form from the UK ORI (Office of Research Integrity) website. You will be taking the CITI program. An automated certificate will be made available to you -- please print this out and hand it in on the due date.

Assignment #2 (In class exercise: Design Identification) The task is to identify and defend the best choice of a research design for each of 10 research questions (these will be provided to you at the time of the exercise). Note: a practice session will occur the week before this exercise is conducted. In essence, the exercise will have 2 parts: 1) a written portion and 2) an oral portion -- this will be a class-based defense of answers to the written portion.

For Practice:

- a. To determine the efficacy of a 3-session intervention program designed to promote the consumption of a diet low in saturated fats among cardiac rehabilitation patients.
- b. To test the hypothesis that childhood activity levels predict obesity in early adulthood.
- c. To determine the relationship of sleep to depression in college students.
- d. To explore the role of self-efficacy in the decision to enroll in smoking cessation course.
- e. To test the hypothesis that fewer high school students are engaging in sex in 2004 compared to high school students in the 1980s.
- f. To assess whether a media program can promote the use of infant car seats.
- g. To identify the effectiveness of an alcohol use awareness program (note: you have a strong suspicion that the assessment instrument used for alcohol awareness is also likely to foster awareness -- you would like to test this suspicion as well).

Assignment #3 (In-class exercise: Sampling) The task is to identify the best (i.e., most defensible sampling design for each of seven research questions) As was true for assignment #2, we will have a practice session the week prior to this in-class exercise. Again, the exercise will have 2 parts: 1) a written portion and 2) an oral portion — this will be a class-based defense of answers to the written portion.

For Practice:

- a. To determine the efficacy of a 3-session intervention program designed to promote the consumption of a diet low in saturated fats among cardiac rehabilitation patients.
- b. To test the hypothesis that U.S. high school students who smoke are more likely to drink alcohol.
- c. To determine the relationship of SES to health status among military men.
- d. To explore the role of skill in the decision to eat a low fat diet among women receiving WIC benefits from 1981 through 2006.

- e. To test the hypothesis that homeless bisexuals will report more frequent risk behaviors for HIV infection than their stably-housed counterparts.
- f. To assess whether a media program can promote the acceptance of the flu vaccine among U.S. university students (you have only enough money to sample one university).
- g. To identify the effectiveness of an intervention program designed for low-income African American men and women diagnosed with diabetes and being 30 to 39 years of age.

Assignment #4 (In-class exercise: Analysis Exercise) The task is to match 7 research questions with the most appropriate form of statistical analysis. You will be engaged in a class-based oral defense of the answers. As before, we will have a practice session the week prior to this in-class exercise. Again, the exercise will have 2 parts: 1) a written portion and 2) an oral portion -- this will be a class-based defense of answers to the written portion.

For Practice:

- a. To determine the efficacy of a 2-arm intervention: arm 1 = standard of care; arm 2 = enhanced standard of care.
- b. To test the hypothesis that childhood activity levels (continuous measure) are associated with early sexual initiation (defined as before age 13).
- c. To determine the relationship of self-concept to mental health in veterans (both constructs were assessed using continuous measures).
- d. To determine differences between black men and white men relative to scores on a scale measure of depression (dichotomized as high vs. low).
- e. To test the hypothesis that people who have never smoked are more likely than those who have ever smoked to currently use marijuana. You want to control for several covariates.
- f. To assess the effects of a program designed to test a 12-hour intervention program and a 6-hour intervention program (shortened version) against a no-intervention (control) condition.
- g. To determine how three variables (age, race, and beliefs about cancer) contribute to men's intent levels to be screened for colo-rectal cancer.

#5 (Term Paper) The task is to prepare a mock research article. This is an opportunity to actually fabricate data -- so you can have the findings work out in your favor. I have intentionally left this task "open" (very little structure provided) so you can be creative and pursue a topic that might become your capstone. Nonetheless, the following requirements apply:

- a. The study must be quantitative.
- b. The research question(s) must be clearly stated (limit = 2) — Be sure the questions clearly state which variable(s) are X and which are Y.
- c. You must follow all guidelines provided in class.
- d. The Introduction must incorporate at least 6 (recent) references -- use either APA or biomedical style (your choice).

- e. The Results section must be focused on at least 1 visual (i.e., a Table or Figure).
- f. The Discussion section must include a heading labeled "Implications for Public Health Practice."
- g. The Title must not exceed 20 words; the text (Intro through Discussion) must not exceed 2000 words (this is a strict limit); the abstract must be structured and cannot exceed 250 words.
- h. Finally, you must treat your Data Analysis section and your Results section as though the findings are real! In other words, you are expected to report statistical findings using standard procedures (even though you will be fabricating these findings).

Please note: Use **only 12-point font and double-space** your manuscript throughout. The manuscript must take on the appearance of a work being submitted for publication (see Appendix A for a sample).

Please be sure you have included:

Title Page: Title followed by authors and their affiliations - name one person as the corresponding author and provide contact information for that person. Include word counts for abstract and text, separately.

Next page - Abstract

Next page - Introduction

1. Establish the public health "need"
2. Show that a gap exists in the empirical literature
3. Statement of the problem
4. May provide hypotheses at this point.

Methods

1. Study Participants (sampling)
2. Procedures (if experimental)
3. Data Collection & Measures--IV/predictors then DV/criterion variables
4. Data Analysis

Results

1. Characteristics of the Sample
2. Bivariate Findings
3. Multivariate Findings (if applicable)

Discussion

1. paragraph that summarizes the study and the main findings (subsequent paragraphs may elaborate on this first paragraph and provide implications for public health practice).
2. limitations paragraph and the need for further research
3. one paragraph conclusion that can be easily converted to a news release

Next page - References

1. use APA or biomedical style (depending)

Next page(s) Tables/Figures

1. these should be "free standing"

Note: number all pages in upper right hand corner - may provide a brief "running head".

CPH711: Chronic Disease Epidemiology
Fall 2007
Tuesday
12:00pm – 2:30pm
CPH 115

Course Instructor: Stephen W. Wyatt, DMD, MPH
College of Public Health
121 Washington Avenue
Suite 112
Lexington, KY 40506
(859) 257-5678 ext 82014 (changing)
Office hours: By appointment only

Course Requirements

Written Assignments/ Research Papers → Class Presentations ↗	1300 points
Examination (1)	150 points
Class Attendance/Participation	150 points

A schedule for all written/oral presentations and the one examination will be provided at the beginning of the semester. Papers/presentations/exams not completed according to the class schedule will be subject to point deductions, for each day they are late. To encourage class attendance/participation, a subjective class participation grade will be assigned.

Course Text

Chronic Disease Epidemiology, 2nd Edition
By Ross C. Brownson, Patrick L. Remington, James R. Davis
Text Location: UK Medical Bookstore

Course Description

A survey course on the leading chronic diseases in the U.S.; including cardiovascular disease, cancer and diabetes, with a focus upon chronic disease surveillance and risk factors.

Course Objectives

The purpose of this course is to provide an overview of chronic disease surveillance, risk factors, and disease burden in the United States for public health students. At the completion of this course, students should be able to:

1. Discuss the importance of chronic disease prevention and control in the U.S. using disease burden data.
2. Describe strengths and weaknesses of various chronic disease behavioral risk factor and disease burden surveillance systems in the U.S.
3. Discuss risk factors and disease burden associated with major chronic disease including cardiovascular disease, cancer, and diabetes. Including their impact on the U.S. and Kentucky.
4. Complete analyses of surveillance data, gaining experience in written and oral presentation of data.

Discipline-Specific Competencies – (Epidemiology)

This course addresses the following MPH competencies (**K**nowledgeable, **P**roficient):

1. Explain the importance of epidemiology for informing scientific, ethical, economic and political discussion of health issues. (**K**)
2. Describe a public health problem in terms of magnitude, person, time and place. (**P**)
3. Apply the basic terminology and definitions of epidemiology. (**P**)
4. Identify key sources of data for epidemiologic purposes. (**P**)
5. Calculate basic epidemiology measures. (**K**)
6. Evaluate the strengths and limitations of epidemiologic reports. (**K**)
7. Draw appropriate inferences from epidemiologic data. (**P**)
8. Communicate epidemiologic information to lay and professional audiences. (**P**)
9. Comprehend basic ethical and legal principles pertaining to the collection, maintenance, use and dissemination of epidemiologic data. (**P**)
10. Identify the principles and limitations of public health screening programs. (**K**)

Academic Dishonesty

Academic honesty is fundamental to the activities and principles of a university. All members of the academic community must be confident that each person's work has been responsibly and honorably prepared, developed, and presented. Any effort to gain an advantage not given to all students is dishonest whether or not the effort is successful. The academic community regards academic dishonesty as an extremely serious matter, with serious consequences that range from a grade "E" to expulsion from the University. Both **cheating** and **plagiarism** are considered academic dishonesty. Cheating refers to any unauthorized assistance during examination questions to/from other student(s). Plagiarism is academic "theft", and includes not properly crediting another author for his/her work or idea. Any paraphrase or direct quotation from a published or unpublished work should be properly cited with a footnote or reference. Students must be particularly careful not to engage in plagiarism, even inadvertently, since computers and Internet web-browsing seem to facilitate this process.

Course Director

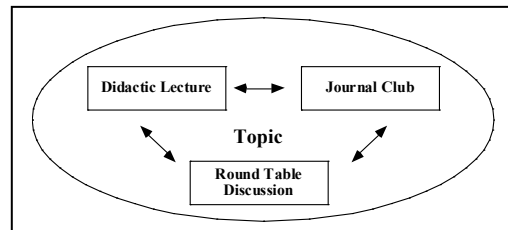
Andre Baron, M.S., Ph.D., M.P.H.
800 Rose Street
Markey Cancer Center
Ben F. Roach Building, Room 408
Lexington, KY 40536-0093
Office hours: M-F 8-12 noon by appointment

The course director and faculty will be available for consultation. Students are encouraged to consult with all participating faculty.

<u>Course Faculty</u>	<u>Phone</u>	<u>Email</u>
Andre Baron	323-1729	a.baron@uky.edu
Esther Black	323-5898	penni.black@uky.edu
Diane Davey	257-9547	ddavey2@email.uky.edu
Claudia Hopenhayn	296-6630	cmhope0@pop.uky.edu
Natasha Kyprianou	323-9812	nkypr2@uky.edu
Guo-Min Li	257-7053	gmli@uky.edu
Bert Lynn	257-2300 X287	bclynn2@uky.edu
David Mannino	323-3608	dmannino@uky.edu
Hollie Skaggs	323-1383	hsskag2@uky.edu

Course Description & Structure

Cancer Molecular Epidemiology, a 3-credit hour special topics course, will consist of lectures relating to the principles of molecular epidemiology, cancer prevention and control. This course will meet once per week (2 1/2 hr session) with an overview and/or historical review of the weekly topic presented in a didactic lecture format during the first hour by the instructor. This will be followed by an oral student presentation of a current or historically relevant research publication during the second hour using the journal club format. Finally, a round table small group discussion format will be used to focus on questions and issues relevant to the topic during the final 1/2 hour. This active teaching/learning strategy effectively involves students in the learning and discovery process, in processing new information, and in holding students accountable for learned information by asking them immediately to apply their knowledge to discuss the topic. Problem centered learning puts learning into context and facilitates learning transfer by allowing students to organize and categorize information into meaningful units, to discover relationships, and to extract and assimilate important points in an interactive and participatory venue.



Audience

This course serves as a Special Topics Elective in the College of Public Health and is designed primarily for graduate public health students with professional interests in molecular epidemiology as this topic relates to cancer prevention and control. This course also is appropriate for students in other related health professions (i.e., medicine, nursing, pharmacy) and the biological sciences.

Balance of Historic and Current Scientific Perspectives

Given the rapid pace of progress in the biological and epidemiological sciences and the exponential growth rate of relevant literature, the general philosophy that is promoted within this course is to *teach less better*. The objective here is to lay a strong foundation in cancer molecular epidemiology with the clear understanding that what is particularly relevant and important today, may not be so tomorrow. Therefore, *emphasis is placed on developing paradigms and themes in molecular epidemiology*, as well as critical review and evaluation of issues at the forefront of modern molecular epidemiology and biology as they relate to cancer prevention and control.

Commitment, Accountability, and Responsibility

Integral to this teaching philosophy is *Peer-Performance Assessment* and the *Teaching Learning Model*. These strategies create a climate in which all students are encouraged to develop their learning and teaching skills. This results in a classroom environment where students from diverse backgrounds feel welcome to fully participate in discussions and problem solving. In this way, desired student performances are tied directly to the efforts of the students themselves, to the involvement of students in the teaching-learning process, to the opportunities to make choices, and to the degree to which students interact with their peers and instructors. Emphasis is placed on organization and presentation skills, accountability tracking, peer assessment, and instructional feedback.

Course Requirements & Grading Criteria

10% class participation, quizzes, & round table discussion
30% journal club presentations
30% journal topic essays
30% term paper or student debate

1. Tests - There are no tests in this course.
2. Quizzes - Please be prepared to take a 5-minute quiz on the reading assignment at the beginning of each class.
3. Journal Club Presentations & Topic Essays - A schedule of student journal club presentations will be developed during the first class period. Journal club

presentations will only be rescheduled for legitimate reasons accompanied by verifiable documentation. In addition to the oral presentation, students will be required to provide a copy of their presentation slides (or overheads) with speaker's notes to each person in the class as a handout packet at the time of the journal club. Students will be expected to attend all class sessions and to participate in discussions and/or problem sets related to the journal club. A topic essay (single-spaced 1-2 page limit; 10-12 pt font) will be due by 12:00 midnight on Friday for grading by the instructor. The topic essay should be e-mailed to Dr. Baron at a.baron@uky.edu.

4. Term Papers or Debate – Students in the course will elect to write a term paper or have a debate on a topic relevant to cancer molecular epidemiology at the beginning of the semester. The term paper due date or debate date will be announced during the first class period and shown on the course syllabus.
5. Grading - Journal club presentation grades will be based on peer and instructor assessment. Special topic essays and term papers that are not completed in a timely manner according to the class schedule will be subject to point deductions; 5 points will be deducted for each late day past the due date. The grading standards employed will be as follows. Students who perform in these ranges will receive the indicated grades.

A:	90-100%
B:	80-89%
C:	70-79%
D:	60-69%
E:	below 60%

Special topic essays can be submitted to the course director within one week (7 days) for a re-evaluation if it is deemed that a mistake has been made in the original grading. Submissions must be accompanied by a written explanation of the perceived mistake. Upon submission, the entire problem set or topic essay may be subject to re-evaluation and all questions therein may be re-graded.

Course Text and Reference Materials

The instructors will provide all reading assignments.

Reference books (Placed on reserve in the Course Director's Office):

- Molecular Epidemiology: Principles and Practices, 1993, edited by Paul A. Schulte and Frederica P. Perera, Academic Press, San Diego
- Molecular Biology of the Cell, 4th Edition, 2002, edited by Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, and Peter Walter, Garland Science, New York

- The Biological Basis of Cancer, 2000, edited by Robert G. McKinnell, Ralph E. Parchment, Alan O. Perantoni, and G. Barry Pierce, Cambridge University Press, Cambridge
- The Biology of Cancer, 2007, edited by Robert A. Weinberg, Garland Science, Taylor & Francis Group, LLC

College of Public Health Terminal Objectives in Epidemiology

Please refer to the College of Public Health student handbooks for information about general education program objectives (<http://www.ukcph.org/>). Students who take this course will be able to:

1. Assess the purpose and application of molecular epidemiology as it relates to cancer prevention and control.
2. Search and critically read and interpret publications in molecular epidemiology.
3. Identify and use appropriate epidemiological study designs and principles to address research questions in molecular epidemiology.
4. Assess how to collect and manage data for investigational molecular epidemiology studies.
5. Assess the statistical methods used to analyze molecular epidemiological data.
6. Interpret and clearly communicate molecular epidemiological research findings.
7. Assess any ethical issues that may confront molecular epidemiological studies.
8. Assess how the principles of molecular epidemiology are integrated into the practice of public health and medicine.

Academic Integrity & Honesty

Academic honesty is fundamental to the activities and principles of a university. All members of the academic community must be confident that each person's work has been responsibly and honorably prepared, developed, and presented. Any effort to gain an advantage not given to all students is dishonest whether or not the effort is successful. The academic community regards academic dishonesty as an extremely serious matter, with serious consequences that range from a grade "E" to expulsion from the University. Both **cheating** and **plagiarism** are considered academic dishonesty. Cheating refers to any unauthorized assistance during examination questions to/from other student(s). Plagiarism is academic "theft", and includes not properly crediting another author for his/her work or idea. Any paraphrase or direct quotation from a published or unpublished work should be properly cited with a footnote or reference. Students must be particularly careful not to engage in plagiarism, even inadvertently, since computers and Internet web-browsing seem to facilitate this process.

The Department of Health Services Management, the College of Public Health, and the University of Kentucky place a premium on academic honesty. Please refer to the

University of Kentucky Student Rights and Responsibilities document
(www.uky.edu/StudentAffairs/Code/part2.html).

Student's with Disabilities

If you have a documented disability that requires academic accommodations, please see me as soon as possible during scheduled office hours. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the Disability Resource Center (www.uky.edu/TLC/grants/uk_ed/services/drc.html). If you have not already done so, please register with the Disability Resource Center (Room 2 Alumni Gym, 257-2754, jkarnes@uky.edu) for coordination of campus disability services available to students with disabilities.

Provisionality

As Course Director, I reserve the right to clarify or amend these policies, in which case I will document the clarification or amendment in an email memorandum.

Week/Date	Weekly Topic, Readings, & Journal Club Paper	Instructor & Assigned Student
1/August 22nd	Introductions, Course Overview, Molecular Biology Primer, Genomics, Transcriptomics, Metabolomics, and Proteomics <u>Readings</u> <ul style="list-style-type: none"> A Conceptual and Historical Framework for Molecular Epidemiology (Schulte 1993) Molecular Biology in Epidemiology (Hurst and Rao 1993) Critical Review of Epidemiologic Studies (Aschengrau and Seage III 2003) Epidemiology informing clinical practice: from bills of mortality to population laboratories (Potter 2005) <u>Molecular Epidemiology Journal Club</u> <ul style="list-style-type: none"> Serum protein fingerprinting coupled with a pattern-matching algorithm distinguishes prostate cancer from benign prostate hyperplasia and healthy men (Adam, Qu et al. 2002) 	Baron Baron
2/August 29nd	Biomarker Discovery Using Proteomic Techniques <u>Readings</u> <ul style="list-style-type: none"> A biological atlas of functional maps (Vidal 2001) Proteomics for cancer biomarker discovery (Srinivas, Verma et al. 2002) <u>Molecular Epidemiology Journal Club</u> <ul style="list-style-type: none"> Proteomic profiling identifies cyclooxygenase-2-independent global proteomic changes by celecoxib in colorectal cancer cells (Lou, Fatima et al. 2006) 	Lynn Clayborn
3/September 5th	Cancer Screening: HPV DNA Testing, Cytology, and Cervical Cancer <u>Readings</u> <ul style="list-style-type: none"> Overview of the European and North American studies on HPV testing in primary cervical cancer screening (Cuzick, Clavel et al. 2006) Effect of prophylactic human papillomavirus L1 virus-like-particle vaccine on risk of cervical intraepithelial neoplasia grade 2, grade 3, and adenocarcinoma in situ: a combined analysis of four randomised clinical trials (Ault 2007) <u>Molecular Epidemiology Journal Club</u> <ul style="list-style-type: none"> Human papillomavirus prevalence and type distribution in male anogenital sites and semen (Nielson, Flores et al. 2007) 	Davey Cosentino-Boehm
4/September 12th	Genomics and Pharmacogenomics <u>Readings</u> <ul style="list-style-type: none"> Pharmacogenomics in cancer treatment defining genetic bases for inter-individual differences in responses to chemotherapy (Ansari and Krajinovic 2007) Current trends and strategic directions in the use of pharmacogenomics to identify translational biomarkers (Mendrick 2007) <u>Molecular Epidemiology Journal Club</u> <ul style="list-style-type: none"> A pharmacogenomics study of the human estrogen glucuronosyltransferase UGT1A3 (Caillier, Lepine et al. 2007) 	Black Dickens
5/September 19th	Cancer Susceptibility: Single Nucleotide Polymorphisms <u>Readings</u> <ul style="list-style-type: none"> SNPs in cancer research and treatment (Erichsen and Chanock 2004) <u>Molecular Epidemiology Journal Club</u> <ul style="list-style-type: none"> Prostate cancer risk and IRS1, IRS2, IGF1, and INS polymorphisms: strong association of IRS1 G972R variant and cancer risk (Neuhausen, Slattery et al. 2005) 	Baron Huang

	<ul style="list-style-type: none"> No association between genetic polymorphisms in insulin and insulin receptor substrate-1 and prostate cancer (Li, Cicek et al. 2005) 	
6/September 26th	<p>Cancer Susceptibility: DNA Damage and DNA Mismatch Repair Genes</p> <p><u>Readings</u></p> <ul style="list-style-type: none"> Genetic alterations and DNA repair in human carcinogenesis (Dixon and Kopras 2004) Interrogating DNA repair in cancer risk assessment (Paz-Elizur, Brenner et al. 2005) <p><u>Molecular Epidemiology Journal Club</u></p> <ul style="list-style-type: none"> Polymorphisms in estrogen bioactivation, detoxification and oxidative DNA base excision repair genes and prostate cancer risk (Nock, Cicek et al. 2006) DNA repair by ERCC1 in non-small-cell lung cancer and cisplatin-based adjuvant chemotherapy (Olaussen, Dunant et al. 2006) 	<p>Li</p> <p>Lasley-Bibbs</p> <p>Saman</p>
7/October 3rd	<p>Cancer Risk Assessment, Screening & Diagnosis with Serum Biomarkers</p> <p><u>Readings</u></p> <ul style="list-style-type: none"> Principles of bladder cancer screening in an intervention trial (Hulka 1990) Statistical considerations in cancer screening programs (Prorok, Connor et al. 1990) Phases of Biomarker Development for Early Detection of Cancer (Pepe, Etzioni et al. 2001) <p><u>Molecular Epidemiology Journal Club</u></p> <ul style="list-style-type: none"> Alteration of the serum levels of the epidermal growth factor receptor and its ligands in patients with non-small cell lung cancer and head and neck carcinoma (Lemos-Gonzalez, Rodriguez-Berrocal et al. 2007) Shared immunoproteome for ovarian cancer diagnostics and immunotherapy: potential theranostic approach to cancer (Philip, Murthy et al. 2007) 	<p>Baron</p> <p>Saman</p> <p>Smith</p>
8/October 10th	<p>Risk Assessment: Biomarkers of Exposure – Arsenic and Bladder Cancer</p> <p><u>Readings</u></p> <ul style="list-style-type: none"> Micronuclei in exfoliated bladder cells among individuals chronically exposed to arsenic in drinking water (Moore, Smith et al. 1997) Arsenic methylation and bladder cancer risk in case-control studies in Argentina and the United States (Steinmaus, Bates et al. 2006) <p><u>Molecular Epidemiology Journal Club</u></p> <ul style="list-style-type: none"> Interaction between environmental tobacco smoke and arsenic methylation ability on the risk of bladder cancer (Chen, Su et al. 2005) 	<p>Hopenhayn</p> <p>Smith</p>
9/October 17th	<p>Risk Assessment: Carcinogens, Inflammation, Cytokines & Growth Factors</p> <p><u>Readings</u></p> <ul style="list-style-type: none"> Mechanism-based cancer prevention approaches: targets, examples, and the use of transgenic mice (Hursting, Slaga et al. 1999) Role of the insulin-like growth factor family in cancer development and progression (Yu and Rohan 2000) <p><u>Molecular Epidemiology Journal Club</u></p> <ul style="list-style-type: none"> Systematic evaluation of genetic variants in the inflammation pathway and risk of lung cancer (Engels, Wu et al. 2007) 	<p>Baron</p> <p>Sudathip</p>

10/October 24th	<p>Risk Assessment: Biomarkers of Chronic Obstructive Pulmonary Disease and Lung Cancer</p> <p><u>Readings</u></p> <ul style="list-style-type: none"> • Carcinogenicity of metal compounds: possible role of DNA repair inhibition (Hartwig 1998) • Urinary cadmium levels predict lower lung function in current and former smokers: data from the Third National Health and Nutrition Examination Survey (Mannino, Holguin et al. 2004) <p><u>Molecular Epidemiology Journal Club</u></p> <ul style="list-style-type: none"> • Profiling serum biomarkers in patients with COPD: associations with clinical parameters (Pinto-Plata, Toso et al. 2007) 	Mannino Temprano
11/October 31st	<p>Cancer Diagnosis & Prognosis: Tumor Suppressors, Oncogenes, and Cell Cycle Regulatory Proteins</p> <p><u>Readings</u></p> <ul style="list-style-type: none"> • Tumor Suppressor Genes (Ruddon 1995) • Oncogenes (Ruddon 1995) • The cell cycle: accelerators, brakes, and checkpoints (Ivanchuk and Rutka 2004) • Regulation of telomerase by telomeric proteins (Smogorzewska and de Lange 2004) <p><u>Molecular Epidemiology Journal Club</u></p> <ul style="list-style-type: none"> • Younger age of cancer initiation is associated with shorter telomere length in Li-Fraumeni syndrome (Tabori, Nanda et al. 2007) • Analysis of p53 protein expression levels on ovarian cancer tissue microarray using automated quantitative analysis elucidates prognostic patient subsets (Psyrris, Kountourakis et al. 2007) 	Baron Clayborn Sudathip
12/November 7th	<p>Cancer Diagnosis & Prognosis: Apoptotic Regulatory Proteins</p> <p><u>Readings</u></p> <ul style="list-style-type: none"> • Mitochondria: releasing power for life and unleashing the machineries of death (Newmeyer and Ferguson-Miller 2003) • Medicine. Targeting apoptotic pathways in cancer cells (Denicourt and Dowdy 2004) • Apoptosis as a novel target for cancer chemoprevention (Sun, Hail et al. 2004) <p><u>Molecular Epidemiology Journal Club</u></p> <ul style="list-style-type: none"> • Influence of survivin and caspase-3 on cell apoptosis and prognosis in gastric carcinoma. (Li, Wang et al. 2004) 	Kyprianou Cosentino-Boehm
13/November 14th	<p>Cancer Diagnosis & Prognosis: MicroRNAs, DNA Methylation & Epigenetic Therapy</p> <p><u>Readings</u></p> <ul style="list-style-type: none"> • The power and the promise of DNA methylation markers (Laird 2003) • Epigenetics and human disease: translating basic biology into clinical applications (Rodenhiser and Mann 2006) • DNA methylation as a therapeutic target in cancer (Issa 2007) • miRNA profiling for diagnosis and prognosis of human cancer (Jay, Nemunaitis et al. 2007) <p><u>Molecular Epidemiology Journal Club</u></p> <ul style="list-style-type: none"> • Association of genetic variants of O6-methylguanine-DNA methyltransferase with risk of lung cancer in non-Hispanic Whites. (Wang, Liu et al. 2006) • Epigenetic inactivation of BRCA1 is associated with aberrant expression of CTCF and DNA methyltransferase (DNMT3B) in some sporadic breast tumours (Butcher and Rodenhiser 2007) 	Skaggs Dickens Temprano
14/November 28th	<p>Cancer Theragnosis: Tumor & Serum Biomarkers</p> <p><u>Readings</u></p>	Baron

	<ul style="list-style-type: none">• Metabolomics-based systems biology and personalized medicine: moving towards n = 1 clinical trials? (van der Greef, Hankemeier et al. 2006)• Mapping translational research in personalized therapeutics: from molecular markers to health policy (Ozdemir, Williams-Jones et al. 2007) <u>Molecular Epidemiology Journal Club</u> <ul style="list-style-type: none">• Mass spectrometry to classify non-small-cell lung cancer patients for clinical outcome after treatment with epidermal growth factor receptor tyrosine kinase inhibitors: a multicohort cross-institutional study. (Taguchi, Solomon et al. 2007)• Serum proteomic classifier for predicting response to epidermal growth factor receptor inhibitor therapy: have we built a better mousetrap? (Tsao, Liu et al. 2007)• A 25-signal proteomic signature and outcome for patients with resected non-small-cell lung cancer. (Yanagisawa, Tomida et al. 2007)	Huang
15/December 5th	<p>Transitional Studies: Biospecimens & Bioinformatics</p> <u>Readings</u> <ul style="list-style-type: none">• Biorepository and biospecimen science: a new focus for CEBP (Vaught 2006)• Sample collection, processing, and storage for large-scale studies: biorepositories to support cancer research (Ambrosone 2006) <u>Molecular Epidemiology Journal Club</u> <ul style="list-style-type: none">• Serum levels of insulin-like growth factor-I and insulin-like growth factor-I binding protein-3: quality control for studies of stored serum. (Berrigan, Potischman et al. 2007) <u>Molecular Epidemiology Debate</u>	Baron Lasley-Bibbs Student Teams
16/December 12th	Term Paper Deadline	12:00 Midnight

Complete Course Bibliography

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UNIVERSITY OF KENTUCKY COLLEGE OF MEDICINE
Departments of Behavioral Science
Methods and Technologies in Clinical & Translational Science
BSC 731/CPH 669
Spring Semester, 2008

Syllabus

Class meetings

Tuesdays from 1:30 to 4:00 P.M.
Room 104, College of Medicine Office Building (COMOB)

<u>Coordinators</u>	<u>Office</u>	<u>Telephone</u>	<u>e-mail</u>
Mitzi M. Schumacher, PhD	129 COMOB	323-6075	Mitzi.Schumacher@uky.edu
Brian Stevenson, PhD	MS 421 Wm R. Willard Med Ed Bldg	257-9358	bstev0@uky.edu

Instructors

To Be Announced

Objectives

1. Introduce students to major methods and technologies of clinical & translational science.
2. Enable students to interpret and evaluate research findings using different methods & technologies
3. Enhance appreciation for multidisciplinary approaches to clinical & translational science.
4. Enhance interdisciplinary communication skills.

Course Description

This overview course is designed to introduce student to the major methods and technologies of clinical & translational science. The course will consist of 14 presentations followed by open discussion of the presentation and assigned readings by class members. The location of classes may change based on the content of the lecture. Homework assignments will provide experiential opportunities to work with the various

methods and technologies. Active participation by all members is expected. Each weekly presentation is designed to provide a general overview of the a method or technology commonly used in clinical and translational science. Discussions are intended to integrate the information across traditional disciplinary boundaries. Homework assignments are designed to provide practical experience with the discussion topic.

Prerequisites

This course is an introductory graduate level course intended for students pursuing focused research training in clinical and translational science. No special prerequisites, other than graduate standing, are necessary.

Readings

There is no textbook for this course. Copies of assigned readings will be available in the Behavioral Science Reading Room (Room 135, College of Medicine Office Building).

Course Expectations

1. Attendance and participation in class discussions. Due to the nature of this course, there is no substitute for attendance at each session and participation in class discussions. Unexcused absences will result in a decrease of one full letter grade (i.e., 1 unexcused absence, maximum grade: 'B;' 2 unexcused absences, maximum grade 'C;' etc.). Students will be expected to compensate for excused and unexcused absences in consultation with instructors.
2. Command of assigned readings. Because the course is designed to promote discussion of interdisciplinary implications of research, students have a responsibility to the class as a whole to be prepared for discussion of assigned readings during class sessions.
3. Leadership of assigned discussions. Students will coordinate group discussions on one or more weeks of the semester. As discussion leaders, it will be the student's responsibility to coordinate topics and stimulate productive discussion related to the evening's topic. Discussion topics can be selected in consultation with the instructor for the scheduled session, but it is the responsibility of the student to contact the instructor well in advance of the scheduled class to schedule the consultation. It is expected that the discussion topics will be chosen in order to integrate the information across disciplines. A list of potential discussion topics and a brief description of the intended objectives of each topic should be turned in after the class.

Grades

Grades will be determined by a combination of class participation and leadership of assigned discussions in the following manner:

	<u>%</u>
Class Participation	50
Discussion Leadership	30
Homework Assignments	20

Progress reports will be provided to students with grades for class participation and discussion leadership every week. Student evaluations of the course are welcome at any time and will be specifically solicited at the end of the course.

University Policy on Plagiarism and Cheating

PLAGIARISM and CHEATING are serious academic offenses. The minimum penalty for those academic offenses is final grade E in the course.

The University regulations pertaining to this matter can be found at <http://www.uky.edu/StudentAffairs/Code/> Of particular relevance is Part II, SELECTED RULES OF THE UNIVERSITY SENATE GOVERNING ACADEMIC RELATIONSHIPS, Section 6.3 that can be found at <http://www.uky.edu/StudentAffairs/Code/part2.html>

These rules in particular say: PLAGIARISM All academic work, written or otherwise, submitted by students to their instructors or other academic supervisors, is expected to be the result of their own thought, research, or self-expression. In cases where students feel unsure about a question of plagiarism involving their work, they are obliged to consult their instructors on the matter before submission.

When students submit work purporting to be their own, but which in any way borrows ideas, organization, wording or anything else from another source without appropriate acknowledgment of the fact, the students are guilty of plagiarism.

Plagiarism includes reproducing someone else's work, whether it be published article, chapter of a book, a paper from a friend or some file, or whatever. Plagiarism also includes the practice of employing or allowing another person to alter or revise the work which a student submits as his/her own, whoever that other person may be. Students may discuss assignments among themselves or with an instructor or tutor, but when the actual work is done, it must be done by the student, and the student alone. When a student's assignment involves research in outside sources or information, the student must carefully acknowledge exactly what, where and how he/she has employed them. If the words of someone else are used, the student must put quotation marks around the

passage in question and add an appropriate indication of its origin. Making simple changes while leaving the organization, content and phraseology intact is plagiaristic. However, nothing in these Rules shall apply to those ideas which are so generally and freely circulated as to be a part of the public domain.

6.3.2 CHEATING Cheating is defined by its general usage. It includes, but is not limited to, the wrongfully giving, taking, or presenting any information or material by a student with the intent of aiding himself/herself or another on any academic work which is considered in any way in the determination of the final grade. Any question of definition shall be referred to the University Appeals Board.

Schedule

January 15	Course Orientation – Introduction to Clinical & Translational Science
January 22	Research Methods – Experimental Design
January 29	Research Methods – Survey Research
February 5	Research Methods – Qualitative Methods
February 12	Research Methods – Community Engagement/Participatory Research, Cultural Sensitivity, Subject Recruitment & Retention
February 19	CTS Technology – Genomics
February 26	CTS Technology – Proteomics
March 4	CTS Technology – Animal Models
March 11	Spring Break
March 18	CTS Technology – Imaging
March 25	CTS Technology – Bench ⇔ Bedside ⇔ Community Translation
April 1	CTS Technology – Clinical Laboratory Studies/Clinical Trials
April 8	CTS Technology – Epidemiology
April 15	CTS Technology – Health Behavior Models
April 22	CTS Technology – Health Services Utilization

UNIVERSITY OF KENTUCKY COLLEGE OF MEDICINE
Department of Behavioral Science
BSC 732/CPH 670: Interdisciplinary Protocol Development (2 Cr)
Fall Semester, 2007

Syllabus

Class meetings

First Monday of every month from 6:00 to 8:30 P.M.
Room 104, College of Medicine Office Building (COMOB)

<u>Coordinator:</u>	<u>Office</u>	<u>Telephone</u>	<u>e-mail</u>
Thomas H. Kelly	134 COMOB	323-5206	thkelly@uky.edu

Objectives

1. Understand the role of leadership and teamwork in multidisciplinary clinical and translational research.
2. Contribute effectively to a multidisciplinary team of investigators engaged in clinical research protocol development.
2. Apply knowledge of the responsible conduct of research, statistics, and CTS methodologies and technologies to protocol development.
4. Model professional clinical and translational teamwork through effective interaction and communication with leadership and team members.

Course Description

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. Students will be assigned to multidisciplinary teams with a designated principal investigator. Each team will be assigned to develop an integrated multidisciplinary grant application to address an assigned clinical research topic. Students are expected to apply their knowledge of effective scientific communication, responsible conduct of research, and methods and technologies of clinical & translational science to the grant application. The course will consist of 4 class periods. The first three classes will consist of an orientation to communication and the role of leadership and teamwork in multidisciplinary clinical and translational research. The final class period will be reserved for a teams organizational meeting. Supplemental team meetings are optional. Each team member will be required to complete a an individual 5-page research methods

report that is integrated into a multidisciplinary research application addressing a clinical research topic assigned to the team under the direction of an assigned principal investigator.

Prerequisites

This graduate level course is intended for students pursuing focused research training in clinical and translational science to develop an understanding of and appreciation for the elements of leadership and teamwork in clinical and translational research. Students will be expected to acquire the knowledge and skills required to be an effective member of a team. It is expected that students will have completed the Seminar in Clinical & Translational Science, Methods and Technologies in Clinical & Translational Science and Ethics in Clinical Research courses in the graduate certificate program prior to taking this course.

Readings

There is no textbook for this course. Copies of any assigned readings will be provided to students during the first three class periods.

Course Expectations

1. Attendance and participation in class and outside team activities. Due to the nature of this course, there is no substitute for attendance at each session and participation in team activities. Unexcused absences will result in a decrease of one full letter grade (i.e., 1 unexcused absence, maximum grade: 'B;' 2 unexcused absences, maximum grade 'C;' etc.). Students will be expected to compensate for excused and unexcused absences in consultation with the instructor.
2. Professional application of communication skills and knowledge of the responsible conduct of research and of clinical and translational science methodologies & technologies to team activities.
3. Completion of the multidisciplinary research application.

Grades

Grades will be determined in the following manner:

	<u>%</u>
Research Application	
Overall Grade	50
Individual Component	25
PI Evaluation	25

Student evaluations of the course are welcome at any time and will be specifically solicited at the end of the course.

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When students submit work purporting to be their own, but which in any way borrows ideas, organization, wording or anything else from another source without appropriate acknowledgment of the fact, the students are guilty of plagiarism.

Plagiarism includes reproducing someone else's work, whether it be published article, chapter of a book, a paper from a friend or some file, or whatever. Plagiarism also includes the practice of employing or allowing another person to alter or revise the work which a student submits as his/her own, whoever that other person may be. Students may discuss assignments among themselves or with an instructor or tutor, but when the actual work is done, it must be done by the student, and the student alone. When a student's assignment involves research in outside sources or information, the student must carefully acknowledge exactly what, where and how he/she has employed them. If the words of someone else are used, the student must put quotation marks around the passage in question and add an appropriate indication of its origin. Making simple changes while leaving the organization, content and phraseology intact is plagiaristic. However, nothing in these Rules shall apply to those ideas which are so generally and freely circulated as to be a part of the public domain.

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Schedule

September 13

September 27

October 11

October 25

UNIVERSITY OF KENTUCKY COLLEGE OF MEDICINE
Department of Behavioral Science
BSC 733/CPH 671: Seminar in Clinical & Translational Science (1 Cr)
Fall Semester, 2007

Syllabus

Class meetings

Second and Fourth Tuesday of every month from 5:00 to 6:30 P.M.
Room 104, College of Medicine Office Building (COMOB)

<u>Coordinator:</u>	<u>Office</u>	<u>Telephone</u>	<u>e-mail</u>
Thomas H. Kelly	134 COMOB	323-5206	thkelly@uky.edu

Academic Credit

This seminar is open to all CTS researchers and interested parties. This syllabus describes requirements for those graduate students who are formally enrolled in the course for academic credit. The course can be taken a total of 3 times for a maximum of 3 credits.

Objectives

1. Understand and contribute to the development of clinical & translational research at the University of Kentucky.
2. Utilize effective scientific communication skills in describing research interests and plans.
3. Apply knowledge of the responsible conduct of research and CTS methodologies and technologies to effectively participate in oral and written communication.
4. Develop effective communication and interaction with researchers across the entire clinical and translational science continuum that demonstrates respect for diverse methodologies and technologies, and thereby model professional clinical and translational science demeanor.

Course Description

This seminar course is designed to orient students to clinical and translational research community and activities at the University of Kentucky and to incorporate a

multidisciplinary cooperative approach to clinical and translational research. Students are expected to apply their knowledge of effective scientific communication, responsible conduct of research, and methods and technologies of clinical & translational science to ongoing discussions. The course will consist of 7 evening seminars focusing on different topics of clinical and translational research. Students will be required to present a description of their research interests and activities during one seminar. Homework assignments will require students to summarize the key elements of each seminar as related to clinical and translational research and the relevance of these issues to their own research interests and career plans. Active participation by all members is expected.

Prerequisites

This graduate level course is intended for students pursuing focused research training in clinical and translational science to integrate and apply knowledge obtained in previous coursework in the graduate certificate program. It is expected that students will have completed the scientific communication workshop offered by the Career Development Office (insert web site), as well as the Methods and Technologies in Clinical & Translational Science and Ethics in Clinical Research courses in the graduate certificate program prior to taking this seminar.

Readings

There is no textbook for this course. Copies of any assigned readings will be provided to students electronically prior to seminars.

Course Expectations

1. Attendance and participation in seminar discussions. Due to the nature of this course, there is no substitute for attendance at each session and participation in class discussions. Unexcused absences will result in a decrease of one full letter grade (i.e., 1 unexcused absence, maximum grade: 'B; 2 unexcused absences, maximum grade 'C;' etc.). Students will be expected to compensate for excused and unexcused absences in consultation with instructors.
2. Professional application of communication skills and knowledge of the responsible conduct of research and of clinical and translational science methodologies & technologies.
3. Completion of homework assignments consisting of summaries of the key elements of each seminar as related to clinical and translational research and the relevance of these issues to their own research interests and career plans.

Grades

Grades will be determined in the following manner:

	<u>%</u>
Seminar Participation	50
Research Presentation	20
Homework Assignments	30

Progress reports will be provided to students with grades for class participation and discussion leadership every four weeks. Student evaluations of the course are welcome at any time and will be specifically solicited at the end of the course.

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Schedule

September 13

September 27

October 11

October 25

November 8

November 22

December 6