UNIVERSITY
OF KENTUCKY

College of Public Health

Office of Academic Affairs
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M E M O R A N D U M

TO: **Health Care Colleges Council**

FROM: **William Pfeifle, MBA, EdD**
Associate Dean for Academic Affairs

SUBJECT: **New Course Proposal – CPH 713 Pharmacoepidemiology**

DATE: **May 12, 2011**

The Department of Epidemiology has proposed a new course to complement their concentration electives/selectives.

This course provides an overview of the field of pharmacoepidemiology and its relationship to health care research. Pharmacoepidemiology is the study of the use and effects of medications in large numbers of people. This specialty combines information from Clinical Pharmacology and Epidemiology to form a unique area of study. Various topics including methodology and analytical issues relevant to the conduct of pharmacoepidemiologic research will be covered. Time will also be spent critically evaluating pertinent papers in the field of pharmacoepidemiology.

This proposal has been reviewed and approved by the Academic Affairs Committee and the Faculty Council, according to the College of Public Health established bylaws.

Please contact the course director, Dr. Douglas Steinke, if you require additional information.

MEMO

DATE: **March 1, 2011**

TO: Associate Dean for Academic Affairs

FROM: Chair, Faculty Council

SUBJECT: New Course Approval

New Course Proposal CPH 713 Pharmacoepidemiology was approved.

MEMO

DATE: May 12, 2011

TO: Associate Dean for Academic Affairs

FROM: Chair, Faculty Council

SUBJECT: New Course Approval

CPH 713 – Pharmacoepidemiology – new course proposal
New course proposal for CPH713 was approved with the revised syllabus.

NEW COURSE FORM

1.	**General Information**				
a.	Submitted by the College of:	College of Public Health		Today's Date:	20 Dec, 2010
b.	Department/Division:	Department of Epidemiology			
c.	Contact person name:	Douglas Steinke	Email: Dtsei2@email.uky.edu	Phone:	323-3843
d.	Requested Effective Date:	☒ Semester following approval	OR ☐ Specific Term/Year[1]	_____	
2.	**Designation and Description of Proposed Course**				
a.	Prefix and Number:	CPH 713			
b.	Full Title:	Pharmacoepidemiology			
c.	Transcript Title (if full title is more than 40 characters):	PharmacoEpi			
d.	To be Cross-Listed[2] with (Prefix and Number):	PPS701 (or this could be PPS760-1)			
e.	Courses must be described by at least one of the meeting patterns below. Include number of actual contract hours[3] for each meeting pattern type.				
	45 Lecture	_____ Laboratory[1]	_____ Recitation	_____ Discussion	_____ Indep. Study
	_____ Clinical	_____ Colloquium	_____ Practicum	_____Research	_____Residency
	_____ Seminar	_____ Studio	_____Other – Please explain:		
f.	Identify a grading System:	☒ Letter (A, B, C, etc.)	☐ Pass/Fail		
g.	Number of credits:	3.0			
h.	Is this course repeatable for additional credit?			YES ☐	NO ☒
	If YES: Maximum number of credit hours:	_____			
	If YES: Will this course allow multiple registrations during the same semester?			YES ☐	NO ☒
i.	Course Description for Bulletin:	This course will provide an overview of the field of pharmacoepidemiology and its relationship to health care research. Various topics including methodology and analytical issues relevant to the conduct of pharmacoepidemiologic research will be covered. Time will also be spent reviewing existing papers in the field of pharmacoepidemiology.			
j.	Prerequisites, if any:	CPH 605 and STA 580 or equivalent; may be concurrent.			
k.	Will this course be offered through Distance Learning?			YES[4] ☐	NO ☒
l.	Supplementary teaching component, if any:	☐ Community-Based Experience	☐ Service Learning	☐ Both	
3.	**Will this course be taught off campus?**			YES ☐	NO ☒
4.	**Frequency of Course Offering**				
a.	Course will be offered (check all that apply):	☐ Fall	☒ Spring	☐ Summer	
b.	Will the course be offered every year?			YES ☒	NO ☐

[1]Courses are typically made effective for the semester following approval. No course will be made effective until all approvals are received

[2]The chair of the cross-listing department must sign off on the Signature Routing Log.

NEW COURSE FORM

[3]In general, undergraduate courses are developed on the principle that one semester hour of credit represents one hour of classroom meeting per week for a semester, exclusive of any laboratory meeting. Laboratory meeting, generally, represents at least two hours per week for a semester for one credit hour. (from *SR 5.2.1*)

[4]You must *also* submit the Distance Learning Form in order for the proposed course to be considered DL delivery.

	If NO, explain: _____		
5.	**Are facilities and personnel necessary for the proposed new course available?**	YES ☒	NO ☐
	If NO, explain: _____		
6.	**What enrollment (per section per semester) may reasonably be expected?**	20	
7.	**Anticipated Student Demand**		
a.	Will this course serve students primarily within the degree program?	YES ☒	NO ☐
b.	Will it be of interest to a significant number of students outside the degree program?	YES ☒	NO ☐
	If YES, explain:	Pharmacy PhD, Nursing PhD, Dentistry, Medicine	
8.	**Check the category most applicable to this course:**		
	☐ Traditional – Offered in Corresponding Departments at Universities Elsewhere		
	☐ Relatively New – Now Being Widely Established		
	☒ Not Yet Found in Many (or Any) Other Universities		
9.	**Course Relationship to Program(s)**		
a.	Is this course part of a proposed new program?	YES ☐	NO X ☒
	If YES, name the proposed new program: _____		
b.	Will this course be a new requirement[5] for ANY program?	YES ☐	NO ☒
	If YES[5], list affected programs: _____		
10.	**Information to be Placed on Syllabus**		
a.	Is the course 400G or 500?	*YES* ☐	*NO* ☒
	If YES, the *differentiation for undergraduate students must be included* in the information required in ***10.b.*** You must include: (i) identification of additional assignments by the graduate students; and /or (ii) Establishment of different grading criteria in the course for graduate students. (See *SR 3.1.4.*)		
b.	☐ The syllabus, including course description, student learning outcomes, and grading policies (and 400G-/500 level grading differentiation if applicable, from ***10.a*** above) are attached.		*NO* ☐

[5]In order to change a program, a program change form must also be submitted.

NEW COURSE FORM

Signature Routing Log

General Information:

Course Prefix and Number: CPH 713 Pharmacoepidemiology

Proposal Contact Person Name: Douglas Steinke Phone: 323-3843 Email: Dtsei2@email.uky.edu

Becki Flanagan Phone: 218-2092 Email: becki@uky.edu

INSTRUCTIONS:
Identify the groups or individuals reviewing the proposal; note the date of approval; offer a contact person for each entry; and obtain signature of person authorized to report approval.

Internal College Approvals and Course Cross-listing Approvals:

Reviewing Group	Date Approved	Contact Person (name/phone/email)	Signature
Department of Epidemiology	12/20/2010	Wayne Sanderson/218-2330/wsa223@uky.edu	
Academic Affairs Committee	3/1/2011	Jim Holsinger/323-6314/jwh@email.uky.edu	
Faculty Council	5/11/2011	Graham Rowles/218-0145/growl2@email.uky.edu	
Academic Dean	5/12/2011	William Pfeifle/218-2054/pfeifle@uky.edu	

External-to-College Approvals:

Council	Date Approved	Signature	Approval of Revision[6]
Undergraduate Council			
Graduate Council		Dr. Brian A. Jackson Digitally signed by Dr. Brian A. Jackson DN: cn=Dr. Brian A. Jackson, o=University of Kentucky, ou=Graduate School, email, c=US Date: 2011.10.07 16:09:06 -04'00'	
Health Care Colleges Council	6/21/11		
Senate Council Approval		University Senate Approval	

Comments:

[6] Councils use this space to indicate approval of revisions made subsequent to that council's approval, if deemed necessary by the revising council.

UNIVERSITY OF KENTUCKY
COLLEGE OF PUBLIC HEALTH

Draft, Subject to change

Course Syllabus
CPH 713-001 Pharmacoepidemiology
Spring semester, 2012

BPC 236 (College of Pharmacy), Thursdays; 3:00-5:30 pm

Contact information

Instructor: Douglas Steinke, BSc(Pharm), MSc, PhD
Rm 247 BPC College of Pharmacy

Telephone: Tel (859) 323-3843

E-mail: dtstei2@email.uky.edu

Office Hours: Mondays 3-5 pm in BPC Rm 247

Course description

University Bulletin description.
This course will provide an overview of the field of pharmacoepidemiology and its relationship to health care research. Various topics including methodology and analytical issues relevant to the conduct of pharmacoepidemiologic research will be covered. Time will also be spent critically evaluating pertinent papers in the field of pharmacoepidemiology.

Detailed description.
Pharmacoepidemiology is the study of the use of and the effects of medications in large numbers of people. This specialty combines information from Clinical Pharmacology (the study of effects of drugs in humans) and Epidemiology (the use and effects of exposure in large populations) to form a unique area of study. Scientists that are interested in the patterns medications are used and their effects, whether beneficial or harmful, incorporate Pharmacoepidemiology theory and applications into their studies. This specialty is useful in understanding published literature that involves medication use or can be used when working within the pharmaceutical industry and government affairs.

The course content will focus on two major areas: research methods relevant to pharmacoepidemiology and application of that knowledge to design and/or evaluate pharmacoepidemiology studies. This class will not be a 'statistics' class. Although there will be some discussion of certain analytical methods as they relate to the design and conduct of Pharmacoepidemiology research projects, we will not be devoting significant time to the mechanics of those procedures. As a graduate level course the greatest benefit will come from

active participation, therefore student will be expected to come to class prepared to participate in and contribute to class discussion.

Course rationale

Health care reform and the increasing costs of medications require that we know how people are taking their medications and how/if a medication works in a population. This course will teach the student to investigate and evaluate medication utilization and outcomes. The course will identify unique methods, data and terminology that are used commonly in pharmacoepidemiology. Critical evaluation of the literature is an important aspect of the course.

Course prerequisites

The course has two prerequisites: one course in epidemiology and one course in statistics that covers regression methods. These courses can be taken concurrently with this course. A concurrent course in Biostatistics II would also be helpful. Waiver of these prerequisites is possible in limited circumstances with permission from the instructor.

Course objectives

Upon completion of this course, the learner will be able to:

- Describe the types of study designs used in pharmacoepidemiology and explain their advantages and disadvantages
- Describe the various factors (measurement, bias and confounding, data quality, analytical methods, etc.) that affect the quality of pharmacoepidemiology research
- Critically evaluate pharmacoepidemiology research studies
- Design and defend a pharmacoepidemiology study
- Evaluate the utility of pharmacoepidemiological methods as they apply to risk assessment, drug therapy, program planning, and policy formulation

Public Health Competencies for Pharmacoepidemiology

This course will fulfill the following competencies for pharmacoepidemiology:

- Identify key sources of data for pharmacoepidemiologic purposes
- Describe a pharmaceutical public health problem in terms of magnitude, person, time and place.
- Explain the importance of pharmacoepidemiology for informing scientific, ethical, economic and political discussion of health issues
- Apply terminology specific to pharmacoepidemiology
- Draw appropriate inferences from pharmacoepidemiologic data
- Critically evaluate the pharmacoepidemiologic literature
- Describe preferred methodological alternatives to commonly used statistical methods when assumptions are not met
- Interpret results of statistical analyses found in pharmacoepidemiologic studies

Student learning outcomes

At the end of the course, the student should be able to:

- Understand how pharmacoepidemiology (PEpi) studies are used by different governmental and industrial agencies.

- Identify the study design used in a PEpi study
- Discuss the advantages and disadvantages to using a particular study design for a PEpi study
- Evaluate the usefulness of a data source for a PEpi study
- Discuss the validity of a dataset
- Identify advantages and disadvantages to using a particular public dataset
- Discuss codification systems used in databases
- Measure outcomes
- Identify events with accurate codification
- Evaluate the differences between RCTs and observational studies
- Identify sources of bias and confounding
- Analyze data to modify the effects of confounding
- Identify and use a comorbidity scoring system
- Critically evaluate a journal article that uses Logistic regression
- Critically evaluate a journal article that uses Poisson regression
- Critically evaluate a journal article that uses Cox Proportional Hazard regression
- Critically evaluate a journal article that uses other typical analytical tools in the analysis of data
- Communicate effectively to peers specific topics on PEpi

Textbooks

No textbooks are required for this course. Materials will be given throughout the semester and review articles for class will be given as PDFs.

Course requirements and learner evaluation

Course grades will be based upon evaluation of the following activities:

100-90=A
89-80=B
79-70=C
0-69=F

Pharmacoepidemiology will have 1 examination during the semester and a final examination at the end of the course. Each exam will cover material from lectures, homework and discussions examining understanding of the material.

Assignments, activities and examinations will be weighted as follows when computing the course grade.

Assessment	Weight
Article critique and discussion	10
Assignments	20
Mid-term examination	20
Final examination	30
Class participation	20
Total	100

Instructor expectations

1. I expect you to attend every class session. The components are highly interrelated; missing a class will detract from the learning potential of subsequent sessions.
2. I expect you to be in the classroom and prepared to begin work at the scheduled starting time for each session.
3. I expect you to actively participate in the discussions. This is not the type of class where you can "sit back and listen."
4. I expect you to submit papers using proper English grammar, syntax, and spelling. You are encouraged to use spell check and grammar check prior to submitting your written work. The Writing Laboratory is available to anyone who may need assistance. Grammar, syntax, and spelling will account for 10% of the grade for written work.
5. I expect (and encourage) you to provide honest and timely feedback regarding the content and process of this course throughout the semester.
6. I expect you during the semester to interactively engage via Blackboard with the other students and the instructor.
7. I expect you to share in the responsibility for making this course an enjoyable and beneficial learning experience.
8. Wikipedia *cannot* be used as a cited reference as noted by a co-founder of Wikipedia! You may use Wikipedia to identify appropriate source material. Remember Wikipedia is *not* peer reviewed!
9. I require that each leaner will utilize the *APA Publication Manual* as a guide for writing papers for this course and the grading rubric will be based on its precepts.

Academic honesty

Academic honesty is highly valued at the University. You must always submit work that represents your original words or ideas. If any words or ideas used in a class assignment submission do not represent your original words or ideas, you must cite all relevant sources and make clear the extent to which such sources were used. Words or ideas that require citation include, but are not limited to, all hard copy or electronic publications, whether copyrighted or not, and all verbal or visual communication when the content of such communication clearly originates from an identifiable sources. Please see the University's policies concerning the consequences for plagiarism. Source: www.uky.edu/ombud/plagerism.pdf Policy: www.uky.edu/usc/new/rulesandregulationsmark.htm

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, submit to me 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 for coordination of campus disability services available to students with disabilities.

Inclement weather

The University of Kentucky has a detailed policy for decisions to close in inclement weather. The snow policy is described in detail at http://www.uky.edu/MicroLabs/documents/p-weather.pdf or you can call (859) 257-5684.

Late work policy

Written assignments may be handed in late with permission of the instructor.

Excused absences policy

Attendance, excused absences and make-up opportunities for this course will conform to the course policies established by the Office of Academic Ombud Services as found at www.uky.edu/Ombud/policies.php

OR provide specifics about your excused absence policies

Course schedule and topics

Tentative schedule of classes

Date	Content area	Topics
1/13/11	Overview of PEpi	1. Historical perspective of pharmacoepidemiology 2. Perspective of pharmacoepidemiology (academic, regulatory agencies, pharmaceutical industry, etc.)
1/20/11	Study design consideration	1. Purpose of research 2. Review of epidemiologic study methods 3. General design issues in PEpi 4. Study deigns available for PEpi studies
1/27/11	Data considerations	1. Data selection and consequences 2. Primary data versus secondary data sources 3. Public versus private data sources 4. Validity of data 5. Obtaining data
2/4/11	Data sources	1. Data sources with student presentations
2/10/11	Measurement and identification issues: Outcomes and exposures	1. Measuring exposure and outcomes 2. Measuring “exposure” 3. Identifying “events”
2/17/11	Data coding systems	2. Codification schemes with student presentations
2/24/11	Measurement and identification issues: Drug Utilization and Adherence Assignment #1 given	1. Measuring drug utilization 2. Measuring compliance, adherence and persistence
3/3/11	Methodology issues: Lack of control	1. RCTs versus PEpi studies 2. Bias and confounding 3. Overcoming lack of randomization
3/10/11	Methodology issues: comorbid disease	1. Measuring comorbidities with student presentations
3/17/11	Spring Break no classes	
3/24/11	Analytical issues Midterm exam take home	Personalized Medicine (genetic issues)
3/31/11	Analytical issues	1.Industries use of PEpi techniques and results 2.Hospital professionals using PEpi data and results
4/7/11	Analytical issues Assignment #2 given	Journal discussion with emphasis in: 1. Conditional logistic regression 2. Poisson regression
4/14/11	Analytical issues	Journal discussion with emphasis in: 1. Survival analysis

		2. Longitudinal data analysis
4/21/11	Analytical issues	Journal discussion with emphasis in: 1. Longitudinal and repeated measures overview (e.g. mixed effects, GEEs, propensity scores, etc)
4/28/11	Last class before finals	Discussion of final exam

The final exam will be a take-home written assignment. A final date will be assigned.