

## REQUEST FOR NEW COURSE

<b>1. General Information.</b>					
a.	Submitted by the College of: Pharmacy		Today's Date: 11/23/09		
b.	Department/Division: Pharmacy Practice & Science				
c.	Contact person name: Tamela Harper	Email: tjharp00@email.uky.edu	Phone: 257-9384		
d.	Requested Effective Date:	<input type="checkbox"/> Semester following approval	OR	<input checked="" type="checkbox"/> Specific Term/Year <sup>1</sup> :	Spring 2010
<b>2. Designation and Description of Proposed Course.</b>					
a.	Prefix and Number: PPS 701				
b.	Full Title: Pharmacoepidemiology				
c.	Transcript Title (if full title is more than 40 characters): Pharmacoepidemiology				
d.	To be Cross-Listed <sup>2</sup> with (Prefix and Number): N/A				
e.	Courses must be described by <u>at least one</u> of the meeting patterns below. Include number of actual contact hours <sup>3</sup> for each meeting pattern type.				
	3 Lecture	_____ Laboratory <sup>1</sup>	_____ Recitation	_____ Discussion	_____ Indep. Study
	_____ Clinical	_____ Colloquium	_____ Practicum	_____ Research	_____ Residency
	_____ Seminar	_____ Studio	_____ Other – Please explain: _____		
f.	Identify a grading system:	<input checked="" type="checkbox"/> Letter (A, B, C, etc.)	<input type="checkbox"/> Pass/Fail		
g.	Number of credits: 3				
h.	Is this course repeatable for additional credit?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>		
	If YES: Maximum number of credit hours: _____				
	If YES: Will this course allow multiple registrations during the same semester?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>		
i.	Course Description for Bulletin:	Study of the use of and effects of medications in large numbers of people. Combines special knowledge of clinical pharmacology and epidemiology. _____			
j.	Prerequisites, if any:	Graduate standing, one course in epidemiology and one course in statistics that covers regression methods. Concurrent courses are allowed and concurrent STA 681 is recommended.			
k.	Will this course also be offered through Distance Learning?	YES <sup>4</sup> <input type="checkbox"/>	NO <input checked="" type="checkbox"/>		
l.	Supplementary teaching component, if any:	<input type="checkbox"/> Community-Based Experience	<input type="checkbox"/> Service Learning	<input type="checkbox"/> Both	
3.	Will this course be taught off campus?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>		
<b>4. Frequency of Course Offering.</b>					

<sup>1</sup> Courses are typically made effective for the semester following approval. No course will be made effective until all approvals are received.

<sup>2</sup> The chair of the cross-listing department must sign off on the Signature Routing Log.

<sup>3</sup> 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)

<sup>4</sup> You must *also* submit the Distance Learning Form in order for the proposed course to be considered for DL delivery.

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a. Course will be offered (check all that apply):  Fall  Spring  Summer

b. Will the course be offered every year? YES  NO   
 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? 15

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 pgm? YES  NO   
 If YES, explain: It may be of interest to other students in areas of health policy or health services research or CET graduate students or Dual degree Pharm.D. students.

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   
 If YES, name the proposed new program: Ph.D. Pharmaceutical Outcomes & Policy

b. Will this course be a new requirement<sup>5</sup> for ANY program? YES  NO   
 If YES<sup>5</sup>, 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 and graduate 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.

<sup>5</sup> In order to change a program, a program change form must also be submitted.

# REQUEST FOR NEW COURSE

## Signature Routing Log

**General Information:**

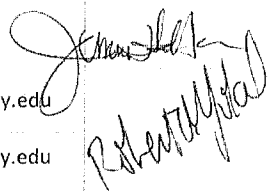
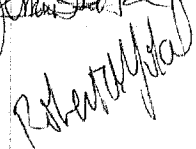
Course Prefix and Number: PPS701 Pharmacoepidemiology

Proposal Contact Person Name: Jeffery Talbert Phone: 260-1960 Email: jeff.talbert@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 Faculty	11-30-09	Jimmi Hatton / 323-0268 / jhatt1@email.uky.edu	
Graduate Program Committee	10-29-09	Robert Yokel / 257-4855 / ryokel@uky.edu	
College Graduate Faculty	11-23-09	Robert Yokel / 257-4855 / ryokel@uky.edu	
		/ /	
		/ /	

**External-to-College Approvals:**

Council	Date Approved	Signature	Approval of Revision <sup>6</sup>
Undergraduate Council			
Graduate Council			
Health Care Colleges Council	3/16/2010		
Senate Council Approval		University Senate Approval	

Comments:

\_\_\_\_\_

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

**PPS 701 Pharmacoepidemiology**  
**3 Semester Hours**  
**Spring 2010**  
**Wednesdays 3-5:30 PM**  
**CPH115 (in the College of Public Health)**

**This course cross-referenced as CPH 718-003: Special Topics – Pharmacoepidemiology**

**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.

**Course Coordinator:**

Douglas Steinke, BSc(Pharm), MSc, PhD  
Assistant Professor of Pharmacy Practice  
Tel: (859) 323-3843  
Email: [dtstei2@email.uky.edu](mailto:dtstei2@email.uky.edu)

There may be other guest lecturers invited to participate in the course.

**Office Hours:**

Appointments should be scheduled individually through phone or email contact. The office hours will be Mondays 3-5 pm in COP247. This time will be especially set aside for student questions and further discussion of topics from the lecture, **but students must email for an appointment time** to ensure personal attention.

**Course Information:**

This is a three hour elective course. The mode of instruction will vary between didactic lectures, problem based learning, literature critical analysis, self-directed homework activities and group work.

**Readings, textbooks and software:**

Students will need a computer with Internet access (or access to a computer) and a Blackboard user account. A course webpage will be used to post readings and announcements and facilitate communication between students and the instructor. If you do not already have a Blackboard user account, please let the instructor know immediately.

There is no required text for this course. Articles and handouts will be provided to students. Optional reading material and texts will be supplied to the Medical Center Library and processed through them if the student requires further reading.

Alternative textbooks include provided at the library:

- Strom BL (ed.) *Pharmacoepidemiology*, 4<sup>th</sup> ed. London: John Wiley & Sons; 2005 [\$320]
- Strom BL, Kimmel SE (eds.). *Textbook of Pharmacoepidemiology*. Chichester, England: John Wiley & Sons; 2006 [\$100]
- Rothman KJ, Greenland S, Lash TL (eds.). *Modern Epidemiology*, 3<sup>rd</sup> ed. Philadelphia: Lippincott Williams & Wilkins; 2008 [\$99]

### **Course Description/Purpose**

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.

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.

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 objectives**

Upon completion of the course, students should be able to

- Identify 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 a pharmacoepidemiology study
- Assess the utility of pharmacoepidemiologic methods as they apply to risk assessment, drug therapy, program planning, and policy formulation

## **Student activities and assignments:**

Students will have various opportunities for participation in class activities. As this is a graduate level class, students are expected to contribute regularly to in-class discussions and complete assigned readings and tasks. A list of required readings will be provided and students should be prepared for discussion in class.

*Article critique and discussion:* Each student will select a pharmacoepidemiologic study that was published within the past three (3) years and was not used as a required reading for this class or any previous class/journal club. The critique should include a brief summary of the study and an in-depth critique of the study with respect to methodology, analysis, results and conclusions. In addition, each student will lead a journal club discussion for their selected article.

*Assignments:* Throughout the semester, there will be several assignments distributed in class. These will be short assignments and designed to reinforce knowledge and skills in the practical and professional aspects of the course content. Students will be expected to provide typed submissions. These may be distributed to other students in the class providing a well rounded aspect to the assignment. The due dates of the homework assignments are listed in the schedule at the end of this document.

*Class project:* Using the information discussed in class a project designing a pharmacoepidemiologic study will be assigned. You should follow the general format of research proposals as provided in class by the instructor. Special consideration should be given to topics pertinent to conducting a pharmacoepidemiologic study, such as the selection of the data source, control of confounding and any special analytical approaches that may be required. Students may choose to work in groups or individually. Please note that groups are expected to work independently of each other.

## **Examinations:**

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.

<b>Assessment</b>	<b>Weight</b>
Article critique and discussion	15
Class project	25
Assignments	20
Mid-term examination	15
Final examination	15
Class participation	10
Total	100

Course grades will be assigned on the following basis:

> 90% = A  
80-89.9% = B  
70-79.9% = C  
< 70% = E

## **Course Policies**

### ***Academic integrity, cheating, and plagiarism***

Ethical behavior is expected of all students in the course. Each student in the class is expected to adhere to the highest standards of academic honesty. Cheating, plagiarism, and destruction of course materials violate the rules of the University and the ethical standards of professional behavior. Violations of the university's rules regarding academic honesty can lead to a failing grade in the course and expulsion from the University. Instances of academic dishonesty will be reported to appropriate University officials as required by University rules and procedures. University of Kentucky Code of Student Rights and Responsibilities defines academic offenses and details procedures for dealing with them. The Code can be viewed electronically on the University's web site: <http://www.uky.edu/StudentAffairs/Code/part1.html> All students are expected to be familiar with the content of the Code of Student Rights and Responsibilities. 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 (Room 2, Alumni Gym, 257-2754, email address [jkarnes@email.uky.edu](mailto:jkarnes@email.uky.edu)) for coordination of campus disability services available to students with disabilities.

***Classroom Behavior*** should be in compliance with the student code of conduct. Full details can be viewed at: <http://www.uky.edu/StudentAffairs/Code/part1.html>. Consistent with this policy, student behavior that detracts from the educational environment will not be tolerated. Examples of inappropriate behaviors include engaging in disrespectful debate, holding disruptive discussions with fellow classmates, reading newspapers or playing electronic games during class, receiving phone calls in the classroom, or sleeping. Students identified by the instructor will be asked to refrain from disrupting the class once (a warning) and a written warning letter will be submitted to the student and the College Academic Affairs Office. At each subsequent disruption the student(s) will be asked to leave the classroom and attend a meeting with the Dean of Academic Affairs to discuss the behavioral issue. No arguing will be allowed and professional conduct will be expected from the student. Disruptive students will be asked to leave the classroom and will receive a zero for participation points that day.

### ***Cell Phone Policy***

Generally cell phone use is not permitted in class for any reason. All cell phones must be placed in the "off" position during class. If there is a situation where a student might need to be notified

during a class period, please alert the instructor to this potential and carefully monitor your phone.

### ***Student preparedness, group work and collaboration***

Except in those instances where students are explicitly instructed to submit work done as a group, students are expected to work and submit material individually. Cheating and plagiarism will not be tolerated in this course. It is the expectation of the instructor of this course that students will not cheat, plagiarize, or attempt to gain unfair advantage, and will report any incident(s) to appropriate faculty if they become aware of such activity. When working with a group or collaborative effort, equal participation is expected of each member. Each group assignment will require an attestation of each group member's contributions to the group work attached to the returned document.

### ***Attendance***

Regular and timely class attendance is critical to success in this course. The course coordinator without prior notice of any kind will monitor attendance. Students with excused absences defined by the University Senate section 5.2.4.2

<http://www.uky.edu/StudentAffairs/Code/part2.html> will not be penalized for the missed coursework but may be required to complete missed activities. All absences must be **directly** reported to and approved by the course coordinator. The right to request appropriate verification is reserved. Unexcused absences will directly affect the final grade for this course. In the event of an unanticipated University closing all classes will be cancelled and the coursework made up during the remaining time in the semester.

Missed assessments or laboratory exercise of any kind without notification or in the light of an unexcused absence will be graded as zero. In all cases, it is the responsibility of the student to procure any missed work including handouts. Students should not expect to be provided a handout if they are not in class.

All decisions regarding excused and unexcused attendance of any kind shall be at the final discretion of the course coordinator.

### ***Verification of Absence***

Students missing work due to an excused absence bear the responsibility of informing the instructor about their excused absence within one week following the period of the excused absence (except where prior notification is required), and of making up the missed work. The instructor shall give the student an opportunity to make up the work and/or the exams missed due to an excused absence, and shall do so, if feasible, during the semester in which the absence occurred. (US: 11/10/85 and RC: 11/20/87)



### ***Make-up Work Policy***

Make-up work will be allowed only in the event of death in the immediate family or student illness accompanied by proof of physician visitation. All work must be made-up within one class period after returning to school. A grade of zero will be placed on all work missed or not completed within the specified time frame.

### ***Assignments Graded Incorrectly***

All assignments will be evaluated and returned. Any assignment graded incorrectly must be brought to the attention of the course director within one calendar week of the assignment being returned. **A written explanation of the found error and the students proposed answer of solution have to be submitted before they will be considered by the instructor.** One calendar week after returned, all grades become final and no corrections will be made.

### ***Submission of assignments***

When written assignments are to be submitted for grading, a specific time and date will be given in the syllabus timetable. The location of assignment drop off will be explained in the class where further instruction on the paper will be given.

### ***Examinations***

Examinations that are missed without prior permission or notification to the course coordinator will be graded as a zero. If illness or other extreme circumstances force a student to be absent from an examination, the course coordinator must be contacted via phone or email prior to the scheduled exam time. Extreme circumstances (i.e. car crash on the way to the exam) will be handled on a case-by-case basis; significant documentation will be required in such circumstances in order to obtain the opportunity to take a make-up exam. Oral examinations or written papers may be required in the case of excused absences. **No additional time will be granted to the student arriving late for an examination.**

### Tentative schedule of classes

Depending on the dates of classes to be assigned in the future

Date	Content area	Topics
	Overview of PEpi	<ol style="list-style-type: none"> <li>1. Historical perspective of pharmacoepidemiology</li> <li>2. Perspective of pharmacoepidemiology (academic, regulatory agencies, pharmaceutical industry, etc.)</li> </ol>
	Study design consideration	<ol style="list-style-type: none"> <li>1. Purpose of research</li> <li>2. Review of epidemiologic study methods</li> <li>3. General design issues in PEpi</li> <li>4. Study designs available for PEpi studies</li> </ol>
	Data considerations	<ol style="list-style-type: none"> <li>1. Data selection and consequences</li> <li>2. Primary data versus secondary data sources</li> <li>3. Public versus private data sources</li> <li>4. Validity of data</li> <li>5. Obtaining data</li> </ol>
	Data considerations and Measurement issues (student presentations)	<ol style="list-style-type: none"> <li>1. Data sources</li> <li>2. Codification schemes</li> <li>3. Measuring exposure and outcomes</li> </ol>
	Measurement and identification issues: Outcomes and exposures	<ol style="list-style-type: none"> <li>1. Measuring "exposure"</li> <li>2. Identifying "events"</li> </ol>
	Measurement and identification issues: Drug Utilization and Adherence	<ol style="list-style-type: none"> <li>1. Measuring drug utilization</li> <li>2. Measuring compliance, adherence and persistence</li> </ol>
	Methodology issues: Lack of control	<ol style="list-style-type: none"> <li>1. RCTs versus PEpi studies</li> <li>2. Bias and confounding</li> <li>3. Overcoming lack of randomization</li> <li>4. Measuring comorbidities</li> </ol>
	Analytical issues	<ol style="list-style-type: none"> <li>1. Sample size</li> <li>2. 'Data fishing' versus 'data mining'</li> <li>3. Computational issues</li> </ol>
	Analytical issues	<ol style="list-style-type: none"> <li>1. Conditional logistic regression</li> <li>2. Poisson regression</li> </ol>
	Analytical issues	<ol style="list-style-type: none"> <li>1. Survival analysis</li> <li>2. Longitudinal data analysis</li> </ol>
	Analytical issues	<ol style="list-style-type: none"> <li>1. Examples (conditional logistic, Poisson, survival) and discussion/clarification</li> <li>2. Longitudinal and repeated measures overview (e.g. mixed effects, GEEs, propensity scores, etc)</li> </ol>
	Student and Project presentations	

## Student presentations as part of the syllabus schedule

Data sources to be presented by students in class

Data source	Students presenting
MEPS	
NAMCS	
UKGPRD	
Medicaid/Medicare	
NHANES	
SEER database	
FDA AERS or USP/NCC-MERP	

Codification schemes

Scheme	Students presenting
ICD-9 including CM and ICD-10	
HCPCS/CPT	
DDDs and ATC codes (drugs)	
NDC codes (drugs)	

Comorbidity and risk adjustment measurements

Measure	Students presenting
Charlson comorbidity score (including adaptations by Deyo, Manitoba and others)	
Chronic disease score (CDS)	
Index of Coexistent Disease (ICED)	
Acute Physiology and Chronic Health Evaluation (APACHE II)	
Elixhauser method (Medical Care 1998;36:8-27)	
Propensity scores	

### List of articles for reference:

These will be provided at a later date