REQUEST FOR NEW COURSE

1. General Information.
   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
   d. Requested Effective Date: ☐ Semester following approval OR ☑ Specific Term/Year²: Spring 2010

2. Designation and Description of Proposed Course.
   a. Prefix and Number: PPS 700
   b. Full Title: Introduction to Pharmaceutical Outcomes & Policy
   c. Transcript Title (if full title is more than 40 characters): Intro Pharm Outcomes & Pol
   d. To be Cross-Listed³ with (Prefix and Number): N/A
   e. Courses must be described by at least one of the meeting patterns below. Include number of actual contact hours³ for each meeting pattern type.
      2-3 Lecture _______ Laboratory¹ _______ 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: 2-3
   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 provides an overview of approaches to the study of pharmaceutical outcomes and public policy. The course is designed to give students an introduction to the field, provide an opportunity to conduct introductory research in one of the various approaches, and experience the research environment through 3 half day research rotations in selected areas. ______
   j. Prerequisites, if any: Graduate standing and permission of instructor.
   k. Will this course also be offered through Distance Learning? YES ☐ NO ☑
   l. Supplementary teaching component, if any: ☐ Community-Based Experience ☐ Service Learning ☐ Both

3. Will this course be taught off campus? 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.
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 5.2.2)
⁴ You must also submit the Distance Learning Form in order for the proposed course to be considered for DL delivery.

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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 ☐
      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 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; Pharm.D. Gateway certificate
   b. Will this course be a new requirement* for ANY program? YES ☐ NO ☒
      If YES*, 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.

* In order to change a program, a program change form must also be submitted.

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Signature Routing Log

General Information:

Course Prefix and Number: PPS 700 Introduction to Pharmaceutical Outcomes & Policy
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:

<table>
<thead>
<tr>
<th>Reviewing Group</th>
<th>Date Approved</th>
<th>Contact Person (name/phone/email)</th>
<th>Signature</th>
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</thead>
<tbody>
<tr>
<td>Department Faculty</td>
<td>11-30-09</td>
<td>Jimmi Hatton / 323-0268 / <a href="mailto:jhatt1@email.uky.edu">jhatt1@email.uky.edu</a></td>
<td></td>
</tr>
<tr>
<td>Graduate Program Committee</td>
<td>10-29-09</td>
<td>Robert Yokel / 257-4855 / <a href="mailto:ryokel@uky.edu">ryokel@uky.edu</a></td>
<td></td>
</tr>
<tr>
<td>College Graduate Faculty</td>
<td>11-23-09</td>
<td>Robert Yokel / 257-4855 / <a href="mailto:ryokel@uky.edu">ryokel@uky.edu</a></td>
<td></td>
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</tbody>
</table>

External-to-College Approvals:

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<thead>
<tr>
<th>Council</th>
<th>Date Approved</th>
<th>Signature</th>
<th>Approval of Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undergraduate Council</td>
<td>3/16/10</td>
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<td>Graduate Council</td>
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<td>Health Care Colleges Council</td>
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<td>Senate Council Approval</td>
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Comments:

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* Councils use this space to indicate approval of revisions made subsequent to that council's approval, if deemed necessary by the revising council.
PPS 700: Introduction to Pharmaceutical Outcomes and Policy

Graduate Course [Section 001] Tuesday 3:00-5:50 p.m.
3 credit hours; includes 2 exams, literature review, and paper)
and
Gateway Program [Section 002] Tuesday 3:00-5:00 p.m.
(2 credit hours; includes 2 exams, literature review)

Instructors:
Jeffery Talbert (260-1960)
JTALB1@email.uky.edu
Karen Blumenschein (257-5778)
KBLUM1@email.uky.edu

Office: Talbert
UK Credit Union Building, Suite 280
1080 Export Street (just off Virginia Ave)

Blumenschein: Bradley Hall

Department: Pharmacy Practice and Science

Office Hours: Talbert
Tuesday 1:00-3:00, and by appointment
Blumenschein: by appointment

Location: 145 BioPharm (College of Pharmacy)

Required Assigned Readings

The course materials include books, chapters, and articles from the literature.


Course Overview

This course provides an overview of approaches to the study of pharmaceutical outcomes and public policy. The course is designed to give students an introduction to the field, provide an opportunity to conduct introductory research in one of the various approaches, and experience the research environment through 3 half day research rotations in selected areas.

Our goal is to develop a solid understanding of theory and research bearing on important dimensions of pharmaceutical outcomes and policy formulation. What sorts of theories and models are available to describe and explain those processes? What evidence supports the
theories and models? What theories of health outcomes or public policy might we be able to generate and how might we go about testing those theories? During our consideration of assigned readings, we want to maintain a critical attitude. That involves looking for shortcomings in theory, logic, and evidence in the materials, but it also involves asking how the materials can be extended in new directions to further enhance our knowledge of pharmaceutical outcomes and the policy-making process.

A central objective of the course is to introduce students to major research dealing with pharmaceutical outcomes and public policy formulation so that you will know and understand some of the most important work in the field. A second objective is to encourage you to develop your own research interests and skills. In other words, we want to promote scholarship, which is concerned with the development, testing, and application of theory.

In the small group of a seminar, everyone has an important role. All members of the seminar will be expected to contribute to our joint education. You can do this through presentations, leadership of discussions, and active involvement in discussions. The seminar will work to the extent that everyone plays her or his role.

Course Objectives

1. Describe the field of Pharmaceutical Outcomes and Policy.
2. Identify and describe the research areas within Pharmaceutical Outcomes and Policy.
3. Discuss the role and relevance of Pharmaceutical Outcomes and Policy within health care delivery.
4. Identify policies that affect pharmacy practice.
5. Describe the relationship between pharmaceutical policy and health outcomes.
6. Identify different types of non-randomized studies and recognize their role in assessing clinical care outcomes.
7. Identify different types of databases used in policy and outcomes assessment
8. Compare and contrast various databases used in pharmaceutical policy and outcomes assessment.
9. Given a scenario, defend the use of a specific pharmaceutical policy and outcomes database.
10. Identify the methods of analysis used in outcomes assessment.
11. Compare and contrast the various components encapsulated within the umbrella term “Patient Reported Outcome” and provide an example for each component.
12. Given a scenario, select and defend appropriate patient reported outcome measures that could be utilized to inform clinical care or clinical research.

Course Assignments

1. Presentations/weekly reading summaries and leadership of class discussion of assigned material. Each participant will be assigned a reading approximately every other week for which that individual will lead the class discussions. Weekly summaries are 1-2 page written critical assessments of the literature.
Leading the discussion involves explaining critical questions regarding the readings.

1. What are we trying to explain?
2. How are we trying to explain it?
3. What are the key concepts and theoretical propositions?
4. Do the measures fit the concepts?
5. Is the research design sufficient?
6. So what? Why would anyone be interested in this? What is the policy implication/outcome?

Although individuals will be assigned to lead the discussion of particular readings, I expect everyone to be prepared for each class period, including having read all readings assigned for that session.

Presentations: For your presentation, you should be prepared to

1. quickly summarize the reading,
2. identify the critical issues of theory and research that it addresses,
3. critique it by discussing strengths and weaknesses of the analysis,
4. indicate possible extensions of the analysis,
5. lead your classmates in a discussion related to the article.

All summaries should be emailed to me by Monday evening and I will prepare copies for everyone before the start of class on Tuesday.

2. Preparation of a literature review assessing the literature dealing with some aspect of pharmaceutical outcomes. The literature review should trace the development of the theoretical and empirical literature. It should identify the major contributions in that area, discuss ambiguities in theories and concepts, identify strengths and weaknesses in the literature, and suggest directions for further theoretical or empirical development. The literature review is due October 27. (For students in the gateway portion of the class, the literature review becomes the course research paper).

3. Active participation in class discussions.

4. Preparation of a major research paper (PhD students only) on some aspect of the pharmacy outcomes literature. The paper may address a topic covered in the course, but it may also address other relevant topics. The paper will be a research design where you identify some aspect of policy that requires explanation, examine the relevant literature, develop a theory to explain the phenomena of interest, and prepare a research design to test the theory. For many of you, I expect that this design will be a follow-up to the literature review completed earlier in the semester. Your goal should be a research design on a significant topic that would allow you to carry out a project that would lead to
a publishable paper. Depending on data availability and research projects, you may also execute a component of a larger empirical research project. Whatever form it takes, your goal should be a publishable piece of research or a research proposal adequate for submission to a funding agency or a dissertation committee. The topic for your paper should be cleared with your major professor or the course director no later than October 7. You should prepare a draft problem statement, literature review, and theoretical exposition by November 11. The final paper is due December 2.

5. A midterm and final examination. The format will be short and long essay questions covering material from course readings.

6. Research Rotation Experiences. These experiences are a minimum of 4 hour experiences working with one of the POP faculty on an applied research project. After completing the rotation, the student will write up a one page summary and present to the class at the next class meeting.

**Grading**

Grades will be assigned as follows:

**Section 001:**

- Midterm exam --------25%
- Final exam --------25%
- Participation --------10%
- Literature review -------- 10%
- Research Paper-------- 30%

**Section 002:**

- Midterm exam --------35%
- Final exam --------25%
- Participation --------10%
- Literature review-------- 30%

**Final scores**  above 90% = A
                  above 80% = B
                  below 80% = C

**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) 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. 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. One calendar week after returned, all grades become final and no corrections will be made.

**COURSE OUTLINE**

1. Sept 1: Introduction to course and Pharmaceutical Policy (JT/KB)
   - Schweitzer: Pharmaceutical Economics and Policy
     - Chapter 1: The Pharmaceutical Industry
   - IOM Report Crossing the Quality Chasm:
     - Chapter 1: The Quality Gap
     - Chapter 6: Applying Evidence to Health Care Delivery
     - Chapter 8 Aligning Policies with Quality Improvement

2. Sept 8: Why Study Pharmaceutical Policy: benefits, risks, and costs. (JT)
   - Avorn: Powerful Medicine
     - Part One: Benefits
Part Two: Risks
Part Three Costs

   Avorn: Powerful Medicine
   Part Four: Information
   Part Five: Policy

4. Sept 17: (222 COP) How to Read and evaluate a scientific paper by Dr. Penni Black

5. Sept 22: Where Do We Start? Research Design and Data (JT)
   Evaluating the Health Care System
   Chapter 1. Introduction to Health Services Research and Policy Analysis.
   Chapter 1. The Nature of Applied Research
   Chapter 2. Defining the Focus of the Research
   Chapter 3. Selecting a Research Design
   Chapter 4. Selecting Data Collection Approaches

   Schweitzer: Pharmaceutical Economics and Policy
   Chapter 10. Public Sector Cost Containment
   Chapter 11. Private Sector Cost Containment
   Chapter 12. Pharmaceutical Regulation in Europe
   Chapter 13. Patent Protection


8. Oct 6: (222 COP) Scientific Writing and Avoiding Plagiarism by Dr. Jim Pauly


10. Oct 15: (222 COP) Guidelines for Scientific Presentations: Posters and Slides by Dr. Todd Porter
    ********************* Mid-term Exam OCT20****************************


14. Oct 12: (222 COP) How to Choose a Mentor and be a Successful Graduate Student by student panel.


16. Nov 19: (222 COP) Preparing for your Qual Exam: Writing a Grant Proposal by Drs. Todd Porter and Doug Steinke


18. Dec 1: Examples of Policies Affecting Pharmacy Practice (JF)

19. Dec 8: Examples of Pharmaceutical Policies and Outcomes: Immunizations (TRF)

20. Dec 15: Final Exam