July 10, 2013

W. Randy Smith  
Vice Provost  
Office of Academic Affairs  
203 Bricker Hall  
190 North Oval Mall  
Columbus, OH 43210

This letter is to acknowledge that the Office of Distance Education and eLearning and the Colleges of Nursing, Pharmacy, and Medicine have entered into an agreement. The following program has agreed to meet the standards for distance education at The Ohio State University.

<table>
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<tr>
<th>Program name:</th>
<th>Master of Applied Clinical and Preclinical Research</th>
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<tr>
<td>College:</td>
<td>Nursing, Pharmacy, and Medicine</td>
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<tr>
<td>Department:</td>
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</tr>
<tr>
<td>Primary faculty:</td>
<td>Marjorie Neidecker, PhD MEng RN</td>
</tr>
<tr>
<td>Primary contact:</td>
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</tr>
<tr>
<td>Fiscal officer:</td>
<td>Erin Delfs</td>
</tr>
<tr>
<td>Additional colleges/contacts:</td>
<td>Awais Ali, Joni Tornwall</td>
</tr>
<tr>
<td>Program produced by:</td>
<td>Colleges of Nursing, Pharmacy, and Medicine</td>
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Mike Rotherr  
Associate Vice President  
Office of Distance Education & eLearning

Bernadette M. Melnyk  
Dean  
College of Nursing

Robert Bruegger  
Dean  
College of Pharmacy

Charles Lockwood  
Dean  
College of Medicine
Addendum:
1. Master of Applied Clinical and Preclinical Research Distance Education budget model
2. ODEE checklist

ODEE Checklist

☐ ODEE and Colleges of Nursing, Pharmacy, and Medicine Memorandum of Understanding signed
  • Not yet defined for DE course support.

☐ Colleges of Nursing, Pharmacy, and Medicine agree to:
  • Meet the programs standards set forth by RACGS for alternative delivery models.
    o Pages 15-16 of RACGS Guidelines
  • Provide budget forecasting/market analysis using ODEE funding model (attached)
    o Incur the costs for Master of Applied Clinical and Preclinical Research advertising.
    o Incur additional costs associated with DE programming (e.g. student advising, discipline specific program license).
  • Communicate to prospective students their ability to seek federal financial aid.
    o Collaborate with ODEE to maintain updates on State Authorization progress
  • Communicate with ODEE regarding the plan, design, and development of courses
    o Place course activities into appropriate delivery mechanisms
      ▪ Use College of Nursing/Pharmacy/Medicine or ODEE supported tools when possible
    o Use ODEE standard syllabus language associated with DE related resources
      ▪ Not currently available, to be created
      ▪ Language may be edited to enhance the student experience as approved by the program and ODEE
    o Collaborate with ODEE on developing a course template
      ▪ Not currently available, to be created
    o Use OSU identity guidelines
    o Apply the Quality Matters course design rubric
      ▪ Each course in the program will be designed using the Quality Matters standards as a guide.
- Meet essential criteria in Standard 8 (Accessibility) on the Quality Matters rubric to address accessibility
  - Collaborate with the Web Accessibility Center (Ken Petri) as needed during course development.
- Review courses every three to five years
  - The College of Nursing/Pharmacy/Medicine will perform an internal review before course launch using the Quality Matters rubric. A similar review will occur every 3-5 years. A Quality Matters reviewer within the College of Nursing/Pharmacy/Medicine will conduct the review.
  - Substantial change in course technology and/or course objectives will result in an interim review
- Provide at least one required student participation activity each week in a course.
  - Course designers will implement activities each week of a course to verify enrollment. This is beyond a simple login to a course space, but constitutes a discussion posting, quiz attempt, artifact submission, and so on.
- Require distance education faculty/instructors/students to complete distance education training provided by either ODEE or internally by the College of Nursing/Pharmacy/Medicine.
  - College of Nursing will continue to deliver intensive workshops to program faculty who teach online. The workshops cover Carmen, CarmenConnect, and other tools for online teaching and learning as well as best practices around distance education (Quality Matters, authentic online learning, instructional design and delivery in the online environment); 1:1 consultations; tutorial videos/blog articles/technical help web documents and weekly email updates and tips.
  - College of Nursing will continue to provide an intensive student orientation (which undergoes continuous improvement each year) to the students in the program which informs them of the university and college resources necessary for distance learning. Web resources that provide technical help for students are available online and can be accessed any time.
- Collaborate with university support services such as the library, Veterans Affairs, and UCAT on an as needed basis.
- Identify student technology support for tools only used by Nursing/Pharmacy/Medicine.
- Develop the distance versions of the courses as described in the proposal.
☐ ODEE agrees to:

- Obtain state authorizations for enrolled students
  - Necessary to ensure program meets federal student financial aid guidelines
  - Communicate with the colleges the status of approved state authorizations
  - Not currently available, to be accomplished
- Provide distance education training for faculty/instructors/students
  - General Carmen support, help, workshops are currently available.
  - Additional DE-specific resources not currently available, to be created.
- Provide distance education faculty/instructors/students access to a 24/7 Tier 1 help desk for ODEE/Ocio provided tools/services.
  - Not currently available, to be accomplished
- Provide OSU Online program advertising
  - Not currently available, to be accomplished
- Collaborate with the colleges on the plan, design and development of courses
  - In progress
  - Support agreement to be defined
    - ODEE steering committee will guide resource management
Credit Hour Explanation

<table>
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<tr>
<th>Program credit hour requirements</th>
<th>A) Number of credit hours in current program (Quarter credit hours)</th>
<th>B) Calculated result for 2/3rds of current (Semester credit hours)</th>
<th>C) Number of credit hours required for proposed program (Semester credit hours)</th>
<th>D) Change in credit hours</th>
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<tr>
<td>Required credit hours offered by the unit</td>
<td>Minimum</td>
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<td>36</td>
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<tr>
<td>Maximum</td>
<td></td>
<td></td>
<td></td>
<td>41</td>
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<tr>
<td>Required credit hours offered outside of the unit</td>
<td>Minimum</td>
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<tr>
<td>Maximum</td>
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<td></td>
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<td>Required prerequisite credit hours not included above</td>
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</tr>
<tr>
<td>Maximum</td>
<td></td>
<td></td>
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</table>

Program Learning Goals

Note: these are required for all undergraduate degree programs and majors now, and will be required for all graduate and professional degree programs in 2012. Nonetheless, all programs are encouraged to complete these now.
Program Learning Goals

- Design clinical and preclinical trial protocols using sound research methodologies, the results from which will inform decision making in clinical research and practice.
- Apply statistical methods to the design of clinical and preclinical trials, evaluation of medical products, and interpret results for dissemination.
- Explain the function of drugs in managing and treating medical diseases and conditions.
- Assess the challenges and ethical considerations in conducting research with vulnerable populations and demonstrate a thorough understanding of human subject regulations from a national and international perspective.
- Formulate research plans and documentation to be consistent with responsible conduct of research practices, including Institutional Review Board (IRB) protocols, IRB submission packets, and human subject consent forms.
- Identify the US and international regulatory systems and agencies governing the commercialization of medical product development and conduct of clinical trials.
- Compare and evaluate regulatory compliance pathways and issues for various categories of medical products.
- Analyze the importance of quality systems in each stage of medical product development and production.
- Develop the key operational components required to manage and coordinate a clinical trial, including the study budget, study implementation timeline, study initiation plan, subject recruitment plan, case report forms, and study closure procedures.
- Critically evaluate potential unanticipated study problems, such as protocol deviations, adverse events, and medical product accountability discrepancies, and analyze their impact on trial results and conclusions.
- Analyze the informatics and technology requirements of a project and plan and implement information technology (IT) solutions for data collection, capture, and management.
- Analyze the complexities of ethical data management and integration from multi-site domestic and international clinical trials per global industry-wide standards.
- Formulate a data management and analysis plan applying best practices in case report and survey form design, database construction, technology assessment, data quality assurance, and data security.
- Apply scientific writing and analytical skills in the preparation and critique of content for a scientific research publication.
- Synthesize clinical trial information and data to compose a final clinical study report and to prepare regulatory applications.
- Employ professional written communication skills in the preparation of research study and regulatory documentation.
- Assume a leadership role as a clinical research or regulatory professional among an interdisciplinary team in an industry-based project.

Assessment

Assessment plan includes student learning goals, how those goals are evaluated, and how the information collected is used to improve student learning. An assessment plan is required for undergraduate majors and degrees. Graduate and professional degree programs are encouraged to complete this now, but will not be required to do so until 2012.

Is this a degree program (undergraduate, graduate, or professional) or major proposal? Yes

Does the degree program or major have an assessment plan on file with the university Office of Academic Affairs? No

A full assessment plan has been submitting using the survey form.
# Program Specializations/Sub-Plans

If you do not specify a program specialization/sub-plan it will be assumed you are submitting this program for all program specializations/sub-plans.

<table>
<thead>
<tr>
<th>Program Specialization/Sub-Plan Name</th>
<th>Program Specialization/Sub-Plan Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Management</td>
<td>Synthesize clinical research project management principles, regulations, and best practices to generate a comprehensive clinical research operations plan.</td>
</tr>
<tr>
<td></td>
<td>Critically examine the clinical trial process to design evidence-based quality improvement initiatives.</td>
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<tr>
<td></td>
<td>Investigate quality systems and standards and summarize their impact on public safety and the protection of health care providers.</td>
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<tr>
<td></td>
<td>Apply the principles of cost-effectiveness analysis to clinical research evaluation, including the use of various strategies of evaluating costs and health effects, interpretation of results, and related forms of decision analysis.</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>Investigate quality systems and standards and summarize their impact on public safety and the protection of health care providers.</td>
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<tr>
<td></td>
<td>Organize an evidence-based scientific review team to critically analyze a product risk mitigation plan using established principles of project management.</td>
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<tr>
<td></td>
<td>Provide rationale for conclusions developed in regulatory reviews using sound oral and written communication techniques.</td>
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<tr>
<td></td>
<td>Identify and explain consumer protection laws and regulations of drugs, medical devices, and biologics by the Food and Drug Administration.</td>
</tr>
<tr>
<td>Safety Pharmacology</td>
<td>Identify, monitor, and explain potential undesirable pharmacodynamics effects in preclinical trials to improve the discovery, development, and safe use of biologically active substances.</td>
</tr>
<tr>
<td></td>
<td>Apply and interpret appropriate tests to evaluate drug effects on cardiovascular, respiratory, and central nervous systems using in vitro and animal model assays.</td>
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<tr>
<td></td>
<td>Apply pharmacokinetic principles to determine safe drug dosing of animals in preclinical trials and humans in clinical trials.</td>
</tr>
<tr>
<td></td>
<td>Conduct a structured risk-benefit assessment for a new drug entity that accurately and concisely describes the benefit and risk considerations for regulatory decision-making.</td>
</tr>
<tr>
<td>Clinical Pharmacology</td>
<td></td>
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</table>
Program Specialization/Sub-Plan Goals

• Explain the relationship between pathophysiologic processes and pharmacologic interventions for common disease states.

• Demonstrate a significant knowledgebase (indication, mechanism of action, drug-drug interactions, genetic influence, and expected adverse effects) of commonly used medications and major drug classes.

• Apply pharmacokinetic principles to the design of clinical drug trials incorporating disease- and population-specific considerations.

• Synthesize preclinical drug study outcomes and considerations for expected toxicity and intended patient populations to design the synopsis for a phase 1 (first-in-human) drug trial.

• Evaluate decisions at critical points in the clinical drug development process to ensure patient safety, regulatory compliance, and product success in the postmarketing environment.

Pre-Major

Does this Program have a Pre-Major? No

Attachments

• M Applied Clinical and Preclinical Research (approval package) 2012.11.16 Rev. 2013.03.22.pdf: PDP, Letters of Support, Course Syllabi

(Proposal Proposal. Owner: Neidecker, Marjorie Vermeulen)

Comments

• Revised proposal (approved by Graduate School) has been uploaded. Proposal that was initially submitted has been deleted. Degree title has been changed from MS to MACPR. - MN (by Neidecker, Marjorie Vermeulen on 05/02/2013 03:27 PM)

• Margie,

Returning this proposal so that you can substitute the revised version.

--SH (by Herness, M Scott on 05/02/2013 02:23 PM)
## Workflow Information

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<td>Soave, Melissa A</td>
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March 22, 2013

Dr. Marjorie Neidecker, PhD MEng RN
Clinical Assistant Professor
Colleges of Nursing and Pharmacy

Master Applied Clinical and Preclinical Research

Margie,

The Graduate School Curriculum Committee met yesterday, March 21st, and considered the re-submission of the proposal to establish an interdisciplinary master’s degree in applied clinical and preclinical research. The GSCC felt the re-submission was highly responsive to their previous comments which I had relayed to you in my letter dated February 8th. The committee has no further concerns with the proposal. As well, they again expressed their thanks for submitting such a well written and thorough proposal.

I will next present the proposal to the Graduate Council for their consideration. After the proposal is released from the Graduate School, it will be presented to the Council on Academic Affairs, to the University Senate, and finally to the Board of Trustees. After the proposal has obtained approval from the University Senate, we will begin the submission process to the Ohio Board of Regents, as we’ve previously discussed.

Please don’t hesitate to contact me with questions or clarifications.

Many thanks,

Scott Herness
Associate Dean
The Graduate School
February 8, 2013

Dr. Marjorie Neidecker, PhD MEng RN
Clinical Assistant Professor
Colleges of Nursing and Pharmacy

Master Applied Clinical and Preclinical Research

Margie,

My personal thanks to you, Dr. Karen Ahijevych and Dr. Cynthia Carnes for joining our Graduate School Curriculum Committee (GSCC) meeting on January 24th to discuss the proposal to establish an interdisciplinary master’s degree in applied clinical and preclinical research. I commend you on the well written and thorough proposal which you submitted for our review. I believe our discussion with the three of you was very productive. As you know, our goal is not only to gain Graduate School approval of this new degree but also to strengthen the proposal for the subsequent approval steps it will require as it moves towards the Board of Trustees and the Board of Regents.

The proposal deserves special comment for its well-ordered and comprehensive presentation. It is the obvious product of a large amount of planning and forethought. The committee appreciated the well-organized interdisciplinary nature of the degree, the provided letters of support and concurrence, and the projected fiscal impact statement.

Here I’d like to summarize changes and clarifications to the proposal as a result of our discussion.

- The proposal is not appropriate for a Master’s of Science degree. A non-thesis degree would be more suitable for a tagged Master’s, such as a Master in Applied Clinical and Preclinical Research. I will be happy to work with you on the name for this degree.

- Absent from the proposal were essential aspects of program administration and student advising. Among the items that should be discussed:
  - The formation/composition of the Graduate Studies Committee and its Chair.
  - The formation/composition of the Advising Committee/Candidacy Committee/Thesis Committee for the student.
  - The approval procedure for students choosing an advisor and for the topic of his/her thesis.
Discussion of how progress of student will be monitored.

- Please be mindful in the planning of participatory faculty of those who are and are not eligible for graduate faculty status. Clinical faculty cannot hold regular Graduate Faculty status (Graduate Handbook, Section XV). Clinical faculty may teach and, by petition, may serve on student committees; they may not advise students or serve on the Graduate Studies Committee.

- It may be helpful to list courses as pre-existing, new, or in development.

- As with all capstone courses, it is essential to monitor the quality of the experience students will encounter. Since this is an online program and some of these capstone experiences will occur at distant (i.e., out-of-state) sites, how the quality for these experiences will be monitored with the site-mentors should be described.

- It should be stated that Admission criteria should not only be consistent with the College standards for Nursing, Pharmacy and Medicine, but also with the criteria set by the Graduate School. Applicants who achieved less than a combined GPA of 3.0 on their undergraduate work will require approval by the Graduate School for a conditional admission.

Please resubmit the revised proposal to me at your convenience. After we receive it, I will schedule it for review an upcoming Graduate School Curriculum meeting. Subsequently, the proposal will be submitted to the Graduate Council, to the Committee on Academic Affairs, to the University Senate, and finally to the Board of Trustees. After the proposal has obtained approval from the University Senate, we will begin the submission process to the Ohio Board of Regents. Additionally, I will be in contact with Michael Hofherr, Assistant VP for Distance Education & eLearning, to ensure the proposal is consistent with the evolving new University practices. Throughout all, I will be working with you, helping to shepherd this proposal through all its path among these committees.

Please don’t hesitate to contact me with questions or clarifications.

Many thanks,

Scott Herness
Associate Dean
The Graduate School

THE OHIO STATE UNIVERSITY
GRADUATE SCHOOL
Advancing graduate education for over 100 years
November 16, 2012

Scott Herness, PhD
Associate Dean
Graduate School Administration
250D University Hall
230 N. Oval Mall
Columbus, OH 43210

W. Randy Smith, PhD
Vice Provost for Academic Affairs
Office of Academic Affairs
203 Bricker Hall
190 North Oval Mall
Columbus, OH 43210

Dear Drs. Herness and Smith,

I am delighted to forward the attached proposal for the new Master of Science in Applied Clinical and Preclinical Research program.

The online program will educate graduates to be successful administrators, regulators, and research team members involved in both clinical and preclinical research. Each of the specialization areas, clinical research management, regulatory affairs, safety pharmacology, and clinical pharmacology, will prepare highly qualified research professionals for numerous research careers in healthcare, the pharmaceutical industry, and government regulatory agencies. MS graduates with this education are needed for the complexity of research protocols and the growing demand for health practitioners to actualize their innovative ideas for products and processes to improve health.

This new interdisciplinary program is the result of collaboration between the Colleges of Nursing, Pharmacy, Medicine, and Veterinary Medicine. The program will be co-administered by the Colleges of Nursing, Pharmacy, and Medicine, and the College of Veterinary Medicine will contribute additional elective courses.

The MS in Applied Clinical and Preclinical Research program has been reviewed and endorsed by the following committees and individuals: the College of Nursing Graduates Studies Committee; the College of Pharmacy Graduate and Research Committee; the College of Medicine Department of Pharmacology Education Committee; and Dan Clinchot, MD, vice dean for education in the College of Medicine. The program has been approved by the faculty in the College of Nursing, the graduate faculty in the College of Pharmacy, and the faculty in the College of Medicine Department of Pharmacology. Attached to the proposal are letters of support from the deans of the Colleges of Nursing, Pharmacy, and Medicine, as well as letters of concurrence from the Colleges of Veterinary Medicine and Public Health.
We are submitting this program proposal to you for approval at the Graduate School and university level. Thank you in advance for your consideration.

Warm regards,

Bernadette Mazurek Melnyk, PhD, RN, CPNP/PMHNP, FNAP, FAAN
Associate Vice President for Health Promotion
University Chief Wellness Officer
Dean and Professor, College of Nursing
Professor of Pediatrics & Psychiatry, College of Medicine

Attachment
The Ohio State University
Colleges of Nursing, Pharmacy, Medicine, and Veterinary Medicine

Master of Applied Clinical and Preclinical Research

Program Development Plan

November 16, 2012
Revised March 22, 2013

Prepared by:
Marjorie Neidecker, PhD, MEng, RN
Clinical Assistant Professor,
Colleges of Nursing and Pharmacy
Adjunct Assistant Professor,
Dept. of Pharmacology, College of Medicine
The Ohio State University
neidecker.1@osu.edu
# Master of Applied Clinical and Preclinical Research

## Program Development Plan

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1. Program Designation, Focus, and Purpose

The proposed Master of Applied Clinical and Preclinical Research (MACPR) program will train graduates to be effective administrators, regulators, and research professionals supporting the principal investigator in clinical and preclinical research. The program will provide students with an in-depth knowledge and understanding of federal and international regulations guiding clinical and preclinical research; the phased procedures involved in the development of new drugs, medical devices, biologics, vaccines, and other medical-related consumer products; research protocol development; institutional review board requirements; and business aspects of the clinical research trials industry. The MACPR major takes a multidisciplinary approach in providing an education which balances the theory and practice of research methods and statistics, the ethics of human subject research, the science of pharmacology and medical product regulation, and the professional operations and management skills required to regulate, manage, and conduct clinical and preclinical trials. The curriculum covers research performed at both the preclinical stage (i.e., safety testing of drugs conducted in the laboratory and in animals, which must occur before testing on humans) and in clinical trials (i.e., all phases of medical product testing in human subjects).

Four interdisciplinary specializations will be offered:
1. **Clinical Research Management** – focuses on the management of systems and processes in the conduct of clinical trials to prepare graduates to lead complex national and international clinical research operations.
2. **Regulatory Affairs** – assures the safe and effective development and use of medical products throughout the product life cycle through regulatory oversight and strategy.
3. **Safety Pharmacology** – seeks to improve the discovery, development, and safe use of biologically active substances by identifying, monitoring, and characterizing potential undesirable effects in preclinical studies.
4. **Clinical Pharmacology** – focuses on the application of pharmacological principles in clinical research, connecting the gap between laboratory science and clinical practice.

The program is designed to be flexible and conducive to the adult learner at either the mid-career or career-entry level. All ACPR courses are offered online. The program will accept applicants with any undergraduate degree and is particularly well suited for graduates with a degree in the biological/life sciences or pharmaceutical sciences and health care professionals. The program includes a cumulative capstone project or internship with contracted clinical research sponsors that synthesize and apply clinical research project management principles, regulations, and best practices in solving common operational and implementation issues.

The new degree program is offered through a collaboration of the College of Nursing, the College of Pharmacy, the Department of Pharmacology in the College of Medicine, and the College of Veterinary Medicine.

2. Curriculum

2.1 Coursework and Competencies

The MACPR is a 39-credit-hour professionally oriented master’s degree program designed to be completed as either a full- or part-time program of study in 16-32 months. The program is designed with a set of core courses covering the application of clinical and preclinical research principles and a set of
specialization courses providing in depth learning in an area of focus chosen by the student. The core of the program requires 21 credit hours of coursework plus a 6-credit-hour capstone. A minimum of 12 credit hours in the specialization coursework is required. A listing of the coursework requirements is provided in Appendix A; sample plans of study are shown in Appendix B. The MACPR curriculum has been developed in accordance with the program competencies shown in Appendix C, which will also serve as the basis for future accreditation and evaluation of the program.

The cumulative capstone project or internship will be contracted with clinical/preclinical research or regulatory industry sponsors. Potential industry sponsors include pharmaceutical, medical device, and biotechnology companies; contract research organizations; and academic researchers and medical centers. The capstone experience will synthesize and apply clinical research management principles, regulations, and best practices in solving common operational and implementation issues. A capstone committee will be comprised of two faculty of appropriate status according to OSU Graduate School policy, of which one member will be the student’s capstone advisor. Capstone projects will be designed jointly by the student and the advisor, pre-approved by the capstone committee, and monitored jointly by the advisor and the site mentor. The quality of the capstone experience and the progress of the student will be monitored through several mechanisms: via teleconferences with the student, mentor, and faculty advisor; mid-semester and end-of-semester evaluations by the mentor; and an end-of-the semester evaluation by the student. Student competencies will be assessed by the capstone committee through the progress reports, a written research paper, and a final project presentation to be given either on campus or via web conferencing.

Development and demonstration of professional writing skills will be an important part of the curriculum. Each student will compile an ePortfolio of written work produced in the coursework and during the capstone experience. Some examples of potential ePortfolio documents include:

- research protocol,
- informed consent form,
- research operational plan, including budget, timeline, quality assurance plan, and study closure procedures,
- data management and analysis plan,
- submission strategy for a new medical product,
- research journal abstract, and
- final capstone report.

The ePortfolio will illustrate knowledge, activities, and achievement in the areas of clinical/preclinical research and regulation.
2.2 Program Accreditation

The Consortium of Academic Programs in Clinical Research (CoAPCR, coapcr.org) has developed competencies for the accreditation of academic programs in clinical research. CoAPCR is a coalition of educational institutions, clinical institutions, professional associations, and industry formed to facilitate the development of high-quality educational programs encompassing all areas of clinical research that are based in academic credit-granting institutions. The Colleges of Nursing, Pharmacy, Medicine, and Veterinary Medicine will collectively seek accreditation of the MACPR program from CoAPCR when it officially obtains the status as the accreditation body for such programs, anticipated in mid-2013. The program will be among the first accredited programs in the country provided the program fulfills the requirements for accreditation.

The eight core courses in the MACPR program will provide outcomes-based learning according to the competencies defined by CoAPCR. These competencies fall into eight learning domains:

1. Scientific Concepts and Principles of Research Design,
2. Ethical Considerations and the Responsible Conduct of Clinical Research,
3. Medical Product Development and Regulatory Compliance,
4. Clinical Study Operation,
5. Study and Site Management,
6. Data Management and Informatics,
7. Communication of Scientific Data,

Each specialization in the program has an additional set of competencies developed by the supporting college(s) to provide students with the knowledge, attitude, and skills to achieve successful professional outcomes in their chosen field of study.

2.3 Certification

Upon completion of the MACPR degree, graduates with one year of qualifying work experience performing clinical research functions will be eligible to sit for certification from either of two professional associations: the Association of Clinical Research Professionals (ACRP, www.acrpnet.org) and the Society of Clinical Research Associates (SoCRA, www.socra.org). ACRP offers either a Clinical Research Coordinator (CRC) or a Clinical Research Associate (CRA) certification while SoCRA offers a Certified Clinical Research Professional” (CCRP) certification. These certifications are widely acknowledged among industry professionals. The certifications demonstrate achievement in the clinical research industry and validate clinical research knowledge, skills, and application.

2.4 Distance Education

The ACPR degree is a distance learning program offered entirely online, predominantly in an asynchronous format. All course content will be delivered using a variety of multi-media formats including video lecture capture, audio slide shows, interactive slide shows, online quizzes and exams, and virtual discussion with instructors and classmates. Examples of online educational media that may be used include Adobe Connect (web conferencing software), Camtasia or Panopto (screen and audio capture software), and Articulate (interactive e-learning course software). All course materials will be accessible at the convenience of the student via Carmen, OSU’s course management system.
To ensure the use of best practices in online higher education, the MACPR courses will be developed using the Quality Matters Rubric. The Quality Matters (QM) Program is a nationally recognized process of reviewing the quality of online courses and online components. The Quality Matters Rubric is a widely used set of standards for the design of online courses at the postsecondary level (www.qmprogram.org/higher-education-program).

3. Administrative Arrangements

The MACPR program will be jointly administered by three colleges: Nursing, Pharmacy, and the Department of Pharmacology in the College of Medicine. The College of Veterinary Medicine will contribute one course. A full-time auxiliary faculty member, Marjorie Neidecker, PhD, MEng, RN, has been hired by the Colleges of Nursing and Pharmacy to coordinate the development, implementation, and ongoing oversight of the MACPR program. The Department of Pharmacology in the College of Medicine will provide part-time administrative support.

The primary administrative responsibility of each specialization will be handled by the supporting college(s):

<table>
<thead>
<tr>
<th>Specialization</th>
<th>Supporting Department/College</th>
<th>Faculty Advisor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Management</td>
<td>College of Nursing</td>
<td>Kim Arcoleo, PhD, MPH</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>Colleges of Nursing and Pharmacy</td>
<td>Kim Arcoleo, PhD, MPH and Cynthia Carnes, PhD, PharmD</td>
</tr>
<tr>
<td>Safety Pharmacology</td>
<td>College of Pharmacy</td>
<td>Cynthia Carnes, PhD, PharmD</td>
</tr>
<tr>
<td>Clinical Pharmacology</td>
<td>College of Medicine, Dept. of Pharmacology</td>
<td>Joseph Kitzmiller, MD, PhD</td>
</tr>
</tbody>
</table>

The Graduate Studies Committee for the MACPR program shall be comprised of a program director, three to five faculty representatives, and one graduate student representative. The representation of faculty may vary among the participating colleges with at least one member each from the Colleges of Nursing, Pharmacy, and Medicine. Faculty members of the Graduate Studies Committee must have appropriate graduate faculty status with the Graduate School. The Graduate Studies Committee members will organize the recruitment process and the review of applications. The committee members will review proposals related to new and revised courses and areas of specialization. The Graduate Studies Committee will assist the program director in the assignment of faculty for course instruction and the assignment of faculty as advisors for students. Additionally, the committee members will assist the program director with the assignment of faculty capstone advisors and the identification of industry sponsors for the capstone project or internship.

4. Evidence of Need

4.1 Need for the Advanced Degree in Clinical/Preclinical Research

Most job postings for clinical research professionals require a minimum of a bachelor’s degree but prefer a master’s degree, and positions in management typically require an advanced degree. The responsibilities of clinical research professionals have increased significantly in recent years due to an “increasing complexity
of clinical protocols combined with the global expansion of pharmaceutical product development.\textsuperscript{1} Additionally, clinical research professionals report that most of their training for their positions occurs “on the job” and “through the accumulation of work experiences.”\textsuperscript{1} Academic programs such as the professionally oriented Master of Applied Clinical and Preclinical Research can fill a critical need to help produce additional and better qualified research personnel who are ready to work in a variety of settings in this rapidly advancing field.

The decision to offer this new program was made in consultation with industry advisors, including the College of Pharmacy’s Corporate Advisory Council. The OSU Center for Clinical and Translational Science contributed funds to initiate development of the program.

4.2 Opportunities for Employment

The clinical research industry has a strong presence in the state of Ohio. According to the 2012 Ohio Bioscience Growth Report:

“Ohio’s robust clinical network and prominent medical reputation have created an ideal testing environment for biomedical innovations. Ohio hosts nearly 17% of all clinical trials conducted in the nation. As of July 2012, a total of 4,096 clinical trials were in progress or actively recruiting patients in Ohio, which ranks seventh among all states and first in the Midwest in this important indicator. A majority of these trials are in either phase II (36.1%) or phase III (38.3%), indicating that Ohio is a vital location for validating bioscience research as it approaches commercialization. Of the phase I-IV studies conducted in Ohio, 30.7% have been funded in whole or in part by the NIH.”\textsuperscript{2}

Center Watch, an international organization focused on providing information and market intelligence services for the clinical trials industry, reports that despite the slow economy, national and international clinical research sites showed growth in both employment and revenue in 2011 and forecasts continued growth in clinical research activity in 2012.\textsuperscript{3,4} The worldwide market for clinical trials is expected to see a 50% cumulative growth from 2010 to 2015 according to visiongain, an independent business information provider for the pharmaceutical industry. While much of the growth is expected to be in outsourcing of clinical trials overseas, substantial growth is expected in North America in specialized clinical trial services, particularly in the fields of cancer and central nervous system disorders, and in late-stage development services for products that will compete with drugs and devices near the end of their patent life.\textsuperscript{5} As growth of this important economic sector continues, availability of trained professionals in clinical and preclinical research, such as clinical research managers, auditors, inspectors, and regulatory oversight personnel, will be a critical component.

Graduates of this professionally oriented master’s degree program will be well qualified to serve as participants and leaders in clinical and preclinical research in a number of capacities in several industries. The Clinical Research Management specialization will train professionals for employment in clinical research

\textsuperscript{5} Mansell P. Over 50% growth to 2015 seen in global clinical trials market. Pharma Times Online. 2011 July 7, 2011.
coordination, operations, management, and auditing and monitoring. Graduates of the Regulatory Affairs specialization will be well qualified for positions in regulatory affairs, regulatory science, and clinical research auditing and monitoring. The Safety Pharmacology and Clinical Pharmacology graduates will develop skills to serve in positions in research and development, clinical research management and monitoring, and toxicology review and assessment. Safety Pharmacology professionals focus on preclinical drug development (laboratory and animal studies prior to initiation of human clinical trial) while Clinical Pharmacology professionals specialize in drug studies in humans. Employment opportunities will be found in a number of industries: the pharmaceutical industry; private medical device and diagnostics developers; governmental regulatory agencies (such as the Food and Drug Administration); private and academic clinical research sites; public, private, and academic medical institutions; and national and international contract research organizations.

The Department of Pharmacology in the College of Medicine has been offering a MS in Clinical Pharmacology for the past seven years. Graduates of this program have consistently found rewarding job placements in clinical research coordination and monitoring of drug trials, demonstrating a need for professionals with these skills. (Note: Future applicants to the Department of Pharmacology graduate programs who intend to pursue a career in clinical research administration will now be directed to the new MACPR program.)

4.3 Similar Programs in Ohio and the U.S.

There are more than 75 masters-level programs in clinical research at colleges and universities throughout the country, most falling into one of three categories: clinician/investigator programs, clinical research nursing programs, and clinical research administration programs. The majority of these programs are clinician/investigator programs, intended for clinicians and scientists who have previously earned a terminal degree (e.g., PhD, MD, DO, PharmD, NP, etc.) and desire to gain the skills necessary to conduct NIH-funded clinical and translational research. Here at OSU, the College of Public Health offers an MPH in Clinical Translational Sciences which is intended to develop independent investigators and requires candidates to hold a clinically-related doctorate. The proposed MACPR program targets a different audience, that of research team members to work with and support the clinician/investigator, in addition to targeting regulatory professionals and pharmacology specialists.

Approximately 17 masters-level programs nationwide focus on clinical research administration and management, of which seven are offered online. These programs are similar to the proposed Clinical Research Management specialization in that they focus on the skills required to manage and administer clinical research projects and accept applicants with any baccalaureate degree. Graduate programs in regulatory affairs number approximately 20 nationwide, of which eight are online. There are only two each of safety pharmacology and clinical pharmacology masters-level programs nationally. Appendix E provides a listing of master’s degree programs in the proposed areas of specialization: clinical research management, regulatory affairs, safety pharmacology, and clinical pharmacology. Only one identified program is located in Ohio, which is the University of Cincinnati’s MS in Molecular, Cellular, and Biochemical Pharmacology with an emphasis on Safety Pharmacology.

The MACPR program offers several advantages over many of the currently available programs:
- Offered entirely online, and therefore, accessible to students nationally and internationally,
- Open to baccalaureate-prepared students with any major, provided prerequisites are satisfied.

• Interdisciplinary set of core courses taught by faculty from four colleges, and a unique opportunity to specialize in one of four tracks,
• Affiliated with one of the largest academic medical campuses in the country, which is currently conducting nearly 1000 clinical trials,
• Strong industry relationships with biomedical research organizations and corporations,
• In-state tuition to all students regardless of state or country of residence,
• Potentially one of the first accredited programs in the country.

5. Prospective Enrollment

Recruitment and admissions to the MACPR program will be handled by the graduate admissions offices in the supporting college for each specialization. The director of the program will coordinate these activities. The admissions criteria will be consistent with standards for other graduate programs in the College of Nursing, College of Pharmacy, and Department of Pharmacology in the College of Medicine. The full list of criteria is provided in Appendix D. Evaluation of applicants will adhere to the principles of individualized and holistic review. As such, each item will be considered as but one metric in the admissions process, with no single item considered a sole criterion for admission into the program.

Assuming approval by the Ohio Board of Regents by July, 2013, the anticipated entering class size by year and specialization is:

<table>
<thead>
<tr>
<th>Specialization</th>
<th>Initial Year (Autumn 2013)</th>
<th>Second year (Autumn 2014)</th>
<th>Subsequent years (Autumn 2015 and beyond)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Management</td>
<td>10</td>
<td>25</td>
<td>35</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>5</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>Safety Pharmacology</td>
<td>5</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Clinical Pharmacology</td>
<td>5</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Total: 25</td>
<td>Total: 60</td>
<td>Total: 85</td>
<td></td>
</tr>
</tbody>
</table>

As this online program is designed to serve both working professionals and new graduates, we anticipate 80% of the newly admitted students each year will enroll part time and 20% full time. Under this assumption, we expect the total yearly enrollment to be as follows:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Management</td>
<td>10</td>
<td>35</td>
<td>68</td>
<td>90</td>
<td>98</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>5</td>
<td>20</td>
<td>39</td>
<td>52</td>
<td>56</td>
</tr>
<tr>
<td>Safety Pharmacology</td>
<td>5</td>
<td>15</td>
<td>29</td>
<td>38</td>
<td>42</td>
</tr>
<tr>
<td>Clinical Pharmacology</td>
<td>5</td>
<td>15</td>
<td>29</td>
<td>38</td>
<td>42</td>
</tr>
<tr>
<td>Total: 25</td>
<td>Total: 85</td>
<td>Total: 165</td>
<td>Total: 218</td>
<td>Total: 238</td>
<td></td>
</tr>
</tbody>
</table>
Courses will also be open to graduate students in on-campus graduate programs. Based on demand, the creation of graduate interdisciplinary specializations will be considered utilizing these courses.

### 6. Special Efforts to Enroll and Retain Underrepresented Groups

The Colleges of Nursing, Pharmacy, and Medicine are committed to the recruitment and retention of underrepresented minority students. The MACPR program will utilize the College of Nursing’s full-time Coordinator for Diversity Recruitment and Retention who creates programs and opportunities that aim to increase and retain the number of underrepresented students for all of the college’s undergraduate and graduate programs. As an example, one new diversity recruitment initiative for the graduate programs in the College of Nursing is identifying all OSU diversity-related student groups, sororities, and fraternities and inviting their members to a College of Nursing event. In targeting OSU students, the goal of this action is to yield a competitive group whose first choice for graduate school is OSU. Similarly, in the College of Pharmacy, the Office of Student Affairs actively recruits at minority institutions for the college’s graduate programs. The College of Nursing also has a well established Diversity Committee comprised of faculty, staff, and students that meet monthly to develop opportunities to enrich cultural experiences and to create an environment that values and supports diversity. The Dean’s Advisory Committee on Diversity in Pharmacy serves a similar function in the College of Pharmacy.

### 7. Available Faculty and Facilities

The institution has an excellent infrastructure to support the development of the MACPR program. Instructors for the program will be drawn from faculty in the collaborating colleges, and faculty have already been identified to cover most of the courses. Each of the supporting colleges has several faculty members with extensive experience in clinical and preclinical research:

- **Kimberly Arcoleo, PhD, MPH** (College of Nursing) has over 25 years of experience in clinical and social/behavioral research in industry and academic institutions. She co-developed and served as the director for the Arizona State University’s MS in Clinical Research Management program for 4 years. Dr. Arcoleo also co-developed the MS in Regulatory Science and Health Safety program for Arizona State University, a collaborative program with the FDA.

- **Cynthia Carnes, PhD, PharmD** (College of Pharmacy) has active ongoing research in cardiac drug safety and has participated in pre- and post-marketing drug safety evaluations.

- **Joseph P. Kitzmiller, MD, PhD, FCP** (College of Medicine) is a board-certified clinical pharmacologist and physician with several years of experience implementing early-phase drug trials. He is also the principal investigator of an NIH-sponsored 10-year clinical trial investigating statin pharmacogenomics at the OSU Wexner Medical Center.

- **Marjorie Neidecker, PhD, MEng, RN** (Colleges of Nursing and Pharmacy) has overseen staff safety and training for phase 1 drug trials in the Department of Pharmacology in the College of Medicine.

- **Todd Guttman, MD, JD** is an adjunct professor in the Moritz College of Law and serves as the Associate Vice President for Research at Ohio State where his primary area of responsibility includes the coordination of OSU’s compliance programs related to research.

- **Mitch A. Phelps, PhD** (College of Pharmacy) has directed the design and conduct of pharmacokinetic and pharmacodynamic (PK/PD) studies in preclinical disease models and in early phase clinical trials for more than seven years. He co-directs the Pharmacological Shared Resource within OSU’s Comprehensive Cancer Center and Center for Clinical and Translational Science, which develops bioanalytical assays and supports PK/PD data analysis and modeling for development of novel drug therapies.
• Brad Bolon, DVM, MS, PhD (College of Veterinary Medicine) has participated in hundreds of preclinical efficacy, safety pharmacology, and toxicity studies during a nearly two-decade industrial career in drug development, during which time he worked for Amgen (a biopharmaceutical company), Pathology Associates International (a contract research organization), Wyeth-Ayerst Research (a pharmaceutical firm), and GEMpath (a private consulting practice).

A complete listing of faculty members who have expressed interest in participating in the program is provided in Appendix F.

Because the proposed program will be offered entirely online (other than the capstone internship experience), no physical facilities will be required for the students at OSU. However, state-of-the-art delivery of the course materials will be crucial. The Colleges of Nursing, Pharmacy, and Medicine all have highly experienced information technology specialists who will assist with the technical aspects of the online course delivery format. The College of Nursing in particular has accumulated many years of experience delivering online programs and courses to graduates students. The MACPR program director will work closely with the college’s instructional development specialist to assure smooth technical presentation and delivery of the course material.

8. Need for Additional Faculty and Facilities

In addition to existing OSU faculty teaching in the program, it is anticipated that three or four instructors with professional experience in clinical research will be hired to teach specific classes as auxiliary faculty. Several have already been contacted and have made tentative commitments to teach. These potential instructors are included in Appendix F.

Additional facilities will not be required for the proposed program.

9. Projected Additional Costs

Erin Delffs, Director of Finance and Business Administration in the College of Pharmacy, has developed a nine-year budget projection for the MACPR program (Appendix G) based on the enrollment projections given in section five. The budget includes costs associated with the program administration and hiring part time adjunct lecturers. Because the program is offered entirely online, all students, regardless of residence, will be charged the tuition cost for residents of the State of Ohio. The program becomes self-sufficient in the third year. Until then, the costs of the program will continue to be subsidized by the Colleges of Nursing and Pharmacy.
Appendix A: Coursework Requirements

The MACPR is a 39-credit-hour professional master’s degree program designed to be completed as either a full- or part-time program of study in 16-32 months. The core of the program requires 21 credit hours of course work and a 6-credit-hours capstone:

<table>
<thead>
<tr>
<th>CORE COURSEWORK</th>
<th>Course Number</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Responsible Conduct of Research</td>
<td>Nursing 7781**</td>
<td>3</td>
</tr>
<tr>
<td>(2) Introduction to General Pharmacology</td>
<td>Pharmacology 5600*</td>
<td>3</td>
</tr>
<tr>
<td>(3) Research Design and Methods for Clinical and Preclinical Research</td>
<td>Nursing/Pharmacy 7782</td>
<td>3</td>
</tr>
<tr>
<td>(4) Fundamentals of Medical Product Regulatory Affairs</td>
<td>Nursing 7770</td>
<td>3</td>
</tr>
<tr>
<td>(5) Data Analysis and Interpretation in Clinical and Preclinical Research</td>
<td>Pharmacy 7784</td>
<td>3</td>
</tr>
<tr>
<td>(6) Data Management and Informatics in Clinical Trials</td>
<td>Nursing 7481</td>
<td>3</td>
</tr>
<tr>
<td>(7) Clinical Research Operations</td>
<td>Nursing 7405</td>
<td>3</td>
</tr>
</tbody>
</table>

Either:
(8a) Clinical Research Management Capstone
(8b) Regulatory Affairs Capstone
(8c) Safety Pharmacology Capstone
(8d) Clinical Pharmacology Capstone

<table>
<thead>
<tr>
<th>Course Number</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing 7597</td>
<td>6</td>
</tr>
<tr>
<td>Nursing/Pharmacy 7598</td>
<td></td>
</tr>
<tr>
<td>Pharmacy 7599</td>
<td></td>
</tr>
<tr>
<td>Pharmacology 7599</td>
<td></td>
</tr>
</tbody>
</table>

Total Credit Hours – Core   27

Each specialization will require a minimum of 12 credit hours of additional coursework:

<table>
<thead>
<tr>
<th>SPECIALIZATION COURSEWORK</th>
<th>Course Number</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(9) Healthcare Project Management</td>
<td>Nursing 7404</td>
<td>3</td>
</tr>
<tr>
<td>(10) Applied Cost-Effectiveness Analysis in Intervention Research</td>
<td>Nursing 7402</td>
<td>3</td>
</tr>
<tr>
<td>(11) Quality Systems and Standards for Medical Products</td>
<td>Nursing 7482</td>
<td>3</td>
</tr>
</tbody>
</table>

Select one:
(12) Pharmaceutical Safety & Risk Management
(19a) Pathophysiology of Altered Health States
(19b) Introduction to Pathophysiology

<table>
<thead>
<tr>
<th>Course Number</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy 7570</td>
<td>3</td>
</tr>
<tr>
<td>Nursing 7450*</td>
<td>5</td>
</tr>
<tr>
<td>Health &amp; Rehab. Sc. 5500*</td>
<td>4</td>
</tr>
</tbody>
</table>

Regulatory Affairs

<table>
<thead>
<tr>
<th>Course Number</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing 7482</td>
<td>3</td>
</tr>
<tr>
<td>Nursing 7460</td>
<td>3</td>
</tr>
<tr>
<td>Pharmacy 7572</td>
<td>3</td>
</tr>
</tbody>
</table>

Select one:
(12) Pharmaceutical Safety & Risk Management
(15) Principles of Safety Pharmacology

<table>
<thead>
<tr>
<th>Course Number</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy 7570</td>
<td>3</td>
</tr>
<tr>
<td>Pharmacy 7580</td>
<td>3</td>
</tr>
</tbody>
</table>

Safety Pharmacology

<table>
<thead>
<tr>
<th>Course Number</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy 7580</td>
<td>3</td>
</tr>
<tr>
<td>Pharmacy 7582</td>
<td>3</td>
</tr>
<tr>
<td>Pharmacy 7584</td>
<td>3</td>
</tr>
</tbody>
</table>

Select one:
(17) Animal Models in Safety Pharmacology
(21) Clinical Pharmacogenomics

<table>
<thead>
<tr>
<th>Course Number</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vet. Biosciences 7610</td>
<td>3</td>
</tr>
<tr>
<td>Pharmacy 7240**</td>
<td>2</td>
</tr>
<tr>
<td>Pharmacology 7255</td>
<td>1</td>
</tr>
</tbody>
</table>

AND (22) Special Topics in Pharmacogenomics
<table>
<thead>
<tr>
<th>Course Description</th>
<th>Course Code</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>(18) Applied Pharmacokinetics and Pharmacodynamics</td>
<td>Pharmacy 7584</td>
<td>3</td>
</tr>
<tr>
<td>Either: (19a) Pathophysiology of Altered Health States</td>
<td>Nursing 7450*</td>
<td>5</td>
</tr>
<tr>
<td>(19b) Introduction to Pathophysiology</td>
<td>Health &amp; Rehab. Sc. 5500*</td>
<td>4</td>
</tr>
<tr>
<td>(20) Principles of Clinical Pharmacology</td>
<td>Pharmacology 7600</td>
<td>3</td>
</tr>
<tr>
<td>Select one: (16) Organ System Toxicology</td>
<td>Pharmacy 7582</td>
<td>3</td>
</tr>
<tr>
<td>(21) Clinical Pharmacogenomics</td>
<td>Pharmacy 7240**</td>
<td>2</td>
</tr>
<tr>
<td>AND (22) Special Topics in Pharmacogenomics</td>
<td>Pharmacology 7255</td>
<td>1</td>
</tr>
</tbody>
</table>

**Total Credit Hours – Specialization** 12-14

Note:  
* = Current OSU online course  
** = Current OSU on-site course which will also be offered online after program approval  
All other courses are new to OSU.
Appendix B: Sample Plans of Study

The MACPR program is designed to be completed as either a full- or part-time program of study in 16 to 32 months. The summer term will include the May session, and thus will be 12 weeks in length. Core courses are listed in bold font in the table below.

### Clinical Research Management Specialization: Full-time Plan of Study (16 months)

<table>
<thead>
<tr>
<th>Year 1 – Autumn</th>
<th>Year 1 – Spring</th>
<th>Year 1 – Summer (12-week term)</th>
<th>Year 2 - Autumn</th>
</tr>
</thead>
<tbody>
<tr>
<td>Course</td>
<td>cr</td>
<td>Course</td>
<td>cr</td>
</tr>
<tr>
<td>Responsible Conduct of Research</td>
<td>3</td>
<td>Data Analysis and Interpretation in Clinical and Preclinical Research</td>
<td>3</td>
</tr>
<tr>
<td>Introduction to General Pharmacology</td>
<td>3</td>
<td>Data Management and Informatics in Clinical Trials</td>
<td>3</td>
</tr>
<tr>
<td>Research Design and Methods for Clinical and Preclinical Research</td>
<td>3</td>
<td>Quality Systems and Standards for Medical Products</td>
<td>3</td>
</tr>
<tr>
<td>Fundamentals of Medical Product Regulatory Affairs</td>
<td>3</td>
<td>Healthcare Project Management</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>12</td>
<td>6</td>
<td>9</td>
</tr>
</tbody>
</table>

### Clinical Research Management Specialization: Part-time Plan of Study (32 months)

<table>
<thead>
<tr>
<th>Year 1 – Autumn</th>
<th>Year 1 – Spring</th>
<th>Year 1 – Summer</th>
<th>Year 2 - Autumn</th>
<th>Year 2 – Summer</th>
<th>Year 3 - Autumn</th>
<th>Year 3 – Spring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Course</td>
<td>cr</td>
<td>Course</td>
<td>cr</td>
<td>Course</td>
<td>cr</td>
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### Regulatory Affairs Specialization: Part-time Plan of Study (32 months)

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Appendix C: Program Competencies

A set of core courses in the MACPR program will provide outcomes-based learning according to the competencies defined by the Consortium of Academic Programs in Clinical Research (CoAPCR, coapcr.org). The Colleges of Nursing, Pharmacy, and Medicine will collectively seek accreditation of the MACPR degree program as an academic program in clinical research when CoAPCR officially obtains its status as the accreditation body for such programs, anticipated in early 2013.

Each specialization in the MACPR program has an additional set of competencies developed by the sponsoring college(s) to provide students with the knowledge, attitude, and skills to achieve successful professional outcomes in their chosen field of study.

Core Competencies

Scientific Concepts and Principles of Research Design

1. Design clinical and preclinical trial protocols using sound research methodologies, the results from which will inform decision making in clinical research and practice. (Course: Research Design and Methods for Clinical and Preclinical Research)
2. Apply statistical methods to the design of clinical and preclinical trials, evaluation of medical products, and interpret results for dissemination. (Course: Data Analysis and Interpretation in Clinical and Preclinical Research)
3. Explain the function of drugs in managing and treating medical diseases and conditions. (Course: Introduction to General Pharmacology)

Ethical Considerations and the Responsible Conduct of Clinical Research

4. Assess the challenges and ethical considerations in conducting research with vulnerable populations and demonstrate a thorough understanding of human subject regulations from a national and international perspective. (Course: Responsible Conduct of Research)
5. Formulate research plans and documentation to be consistent with responsible conduct of research practices, including Institutional Review Board (IRB) protocols, IRB submission packets, and human subject consent forms. (Course: Responsible Conduct of Research)

Medical Product Development and Regulatory Compliance

6. Identify the US and international regulatory systems and agencies governing the commercialization of medical product development and conduct of clinical trials. (Course: Fundamentals of Medical Product Regulatory Affairs)
7. Compare and evaluate regulatory compliance pathways and issues for various categories of medical products. (Course: Fundamentals of Medical Product Regulatory Affairs)
8. Analyze the importance of quality systems in each stage of medical product development and production. (Course: Fundamentals of Medical Product Regulatory Affairs)

Clinical Study Operation; Study and Site Management

9. Develop the key operational components required to manage and coordinate a clinical trial (single-site, multi-site, and international trials), including the study budget, study implementation
timeline, study initiation plan, subject recruitment plan, case report forms, and study closure procedures. (Course: Clinical Research Operations)

10. Critically evaluate potential unanticipated study problems, such as protocol deviations, adverse events, and medical product accountability discrepancies, and analyze their impact on trial results and conclusions. (Course: Clinical Research Operations)

**Data Management and Informatics**

11. Analyze the informatics and technology requirements of a project and plan and implement information technology (IT) solutions for data collection, capture, and management. (Course: Data Management and Informatics in Clinical Trials)

12. Analyze the complexities of ethical data management and integration from multi-site domestic and international clinical trials per global industry-wide standards. (Course: Data Management and Informatics in Clinical Trials)

13. Formulate a data management and analysis plan applying best practices in case report and survey form design, database construction, technology assessment, data quality assurance, and data security. (Course: Data Management and Informatics in Clinical Trials)

**Communication of Scientific Data**

14. Apply scientific writing and analytical skills in the preparation and critique of content for a scientific research publication. (Course: Research Design and Methods for Clinical and Preclinical Research, Data Analysis and Interpretation in Clinical and Preclinical Research)

15. Synthesize clinical trial information and data to compose a final clinical study report and to prepare regulatory applications. (Course: Fundamentals of Medical Product Regulatory Affairs)

**Professionalism, Teamwork, and Leadership**

16. Employ professional written communication skills in the preparation of research study and regulatory documentation. (Course: Responsible Conduct of Research, Research Design and Methods for Clinical and Preclinical Research, Fundamentals of Medical Product Regulatory Affairs, Data Analysis and Interpretation in Clinical and Preclinical Research, Clinical Research Operations, Capstone)

17. Assume a leadership role as a clinical research or regulatory professional among an interdisciplinary team in an industry-based project. (Course: Capstone)

**Additional Competencies for the Clinical Research Management Specialization**

1. Synthesize clinical research project management principles, regulations, and best practices to generate a clinical research operations plan that includes scope of work, enrollment projections, timelines for project milestone activities, staffing plan, outsourcing requirements, contract negotiations, project budgets, risk analysis, and contingency plans. (Course: Healthcare Project Management, Clinical Research Operations)

2. Critically examine the clinical trial process to design evidence-based quality improvement initiatives. (Course: Quality Systems and Standards for Medical Products)

3. Investigate quality systems and standards and summarize their impact on public safety and the protection of health care providers. (Course: Quality Systems and Standards for Medical Products)
4. Apply the principles of cost-effectiveness analysis (CEA) to clinical research evaluation, including the use of various strategies of evaluating costs and health effects, interpretation of results, and related forms of decision analysis in the health care sector.  (Course: Applied Cost-Effectiveness Analysis in Intervention Research)

**Additional Competencies for the Regulatory Affairs Specialization**

1. Investigate quality systems and standards and summarize their impact on public safety and the protection of health care providers.  (Course: Quality Systems and Standards for Medical Products)
2. Organize an evidence-based scientific review team to critically analyze a product risk mitigation plan using established principles of project management.  (Course: Pharmaceutical Safety and Risk Management)
3. Provide rationale for conclusions developed in regulatory reviews using sound oral and written communication techniques.  (Course: Writing for the Regulatory Professional)
4. Identify and explain consumer protection laws and regulations of drugs, medical devices, and biologics by the Food and Drug Administration.  (Course: Federal Regulation of Medical Products)

**Additional Competencies for the Safety Pharmacology Specialization**

1. Identify, monitor, and explain potential undesirable pharmacodynamics effects in preclinical trials to improve the discovery, development, and safe use of biologically active substances.  (Course: Principles of Safety Pharmacology, Organ System Toxicology)
2. Apply and interpret appropriate tests to evaluate drug effects on cardiovascular, respiratory, and central nervous systems using in vitro and animal model assays.  (Course: Organ System Toxicology)
3. Apply pharmacokinetic principles to determine safe drug dosing of animals in preclinical trials and humans in clinical trials.  (Course: Applied Pharmacokinetics and Pharmacodynamics)
4. Conduct a structured risk-benefit assessment for a new drug entity that accurately and concisely describes the benefit and risk considerations for regulatory decision-making.  (Course: Principles of Safety Pharmacology)

**Additional Competencies for the Clinical Pharmacology Specialization**

1. Explain the relationship between pathophysiologic processes and pharmacologic interventions for common disease states.  (Course: Introduction to General Pharmacology, Pathophysiology of Altered Health States, Principles of Clinical Pharmacology)
2. Demonstrate a significant knowledgebase (indication, mechanism of action, drug-drug interactions, genetic influence, and expected adverse effects) of commonly used medications and major drug classes.  (Course: Introduction to General Pharmacology, Principles of Clinical Pharmacology)
3. Apply pharmacokinetic principles to the design of clinical drug trials incorporating disease- and population-specific considerations.  (Course: Applied Pharmacokinetics and Pharmacodynamics, Principles of Clinical Pharmacology)
4. Synthesize preclinical drug study outcomes and considerations for expected toxicity and intended patient populations to design the synopsis for a phase 1 (first-in-human) drug trial. (Course: Applied Pharmacokinetics and Pharmacodynamics, Principles of Clinical Pharmacology)

5. Evaluate decisions at critical points in the clinical drug development process to ensure patient safety, regulatory compliance, and product success in the postmarketing environment. (Course: Fundamentals of Medical Product Regulatory Affairs, Principles of Clinical Pharmacology)
Appendix D: Admissions Criteria

The admissions criteria for the MACPR program will be consistent with standards for other graduate programs in the College of Nursing, College of Pharmacy, and Department of Pharmacology in the College of Medicine. Admission requirements will also be consistent with the criteria set by the Graduate School.

Undergraduate or Graduate Degree:

- Healthcare clinicians with a bachelor’s degree or higher (BSN or higher, PharmD, MD, etc.), or
- A bachelor’s or higher degree in any field and completion of the following prerequisites (to be completed before entry into the program; background or work experience may be substituted for prerequisite courses with permission of the program director):
  - Medical Terminology
    - OSU: HTHRHS 2500 Medical Terminology for the Health Professions (3 credit hours; online option)
    - Columbus State Community College (CSCC): MULT 1010 Medical Terminology (2 credits; online option)
    - Or an equivalent course, minimum 1 semester credit hour
  - Physiology
    - OSU: EEOB 2520 Human Physiology (3 credit hours), PHYSIO 3101 & 3102 Human Physiology I & II (3 credits each)
    - CSCC: BIO 1121 & 1122 Anatomy & Physiology I & II (4 credits each; option to complete in one semester online), BIO 2232 Human Physiology (4 credits; hybrid option)
    - Or an equivalent course, minimum 3 semester credit hours
  - Healthcare System Overview or Health Policy (required for applicants without healthcare-related experience only)
    - OSU: PUBHHMP 4650 United States & International Health Care (3 credits), PUBHHMP 6610 Introduction to Health Care Organization (3 credits), HTHRHS 5370 U.S. Healthcare Policy and Delivery System (3 credits; online option)
    - CSCC: MLT 1100 Introduction to Health Care (2 credits; online option)
    - Or an equivalent course, minimum 2 semester credit hours

The Graduate School requires a minimum 3.0 grade point average (GPA) on a 4.0 scale in all prior undergraduate and graduate level coursework. Applicants with a GPA below 3.0 may apply but are required to take the Graduate Record Exam (GRE).

Graduate Record Exam:

- Competitive scores on the Graduate Record Exam (GRE) from within the last five years are requested of all graduate applicants who do not already hold a Master’s degree (or higher). As a substitute to the GRE and with the permission of the program director, applicants may submit a two to three page topic analysis related to the field of clinical or preclinical research.
- However, consistent with OSU Graduate School admissions requirements, GRE scores will still be required for ALL applicants who meet any of the following criteria:
1) Applicant has a total combined undergraduate GPA of less than 3.0 on a 4.0 scale.
2) Applicant has a total combined graduate GPA of less than 3.0 on a 4.0 scale.
3) Applicant holds a degree from an unaccredited college or which includes transfer credit from an unaccredited college.

**Purpose and Goals Statement:**

Purpose and goals statement, including a narrative discussion of professional experience and career trajectory.

**Letters of Recommendation:**

Three letters of recommendation from individuals who are familiar with the applicant’s academic ability, work experience, contributions to clinical and preclinical research, and potential to succeed in the program.

**International Students:**

Test of English as a Foreign Language (TOEFL) or International English Language Testing System (IELTS) requirements for international applicants from a non-English speaking country is:

- TOEFL paper test 600, TOEFL computer-based test 250, TOEFL internet-based test 100
- IELTS 8.0
## Appendix E: Similar Programs

<table>
<thead>
<tr>
<th>Institution</th>
<th>State</th>
<th>Program</th>
<th>Online Program?</th>
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<td>Arizona State University</td>
<td>AZ</td>
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<td>Boston University</td>
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<tr>
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<td>MS in Clinical and Transitional Rehabilitation Science</td>
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<tr>
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<td>MS in Regulatory and Clinical Research Management, specialization track Clinical Research Management</td>
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<tr>
<td>Rochester Institute of Technology</td>
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<td>Master in Applied Clinical Research</td>
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<td>Trident University</td>
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<td>MS in Health Sciences With Clinical Research Administration</td>
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<tr>
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<td>FL</td>
<td>MS in Pharmacy – Pharmaceutical Outcomes &amp; Policy, specialization track: Clinical Regulation and Ethics</td>
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<tr>
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<tr>
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<td>NC</td>
<td>MS in Clinical Research and Product Development, Clinical Research Management concentration</td>
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<tr>
<td>University of North Texas</td>
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<tr>
<td>Walden University</td>
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<tr>
<td>Washington University in St. Louis</td>
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<td>Institution</td>
<td>State</td>
<td>Program</td>
<td>Online Program?</td>
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<tr>
<td>Arizona State University, College of Nursing and Health Innovation</td>
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<td>MS in Regulatory Science &amp; Health Safety</td>
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<tr>
<td>Drexel University</td>
<td>PA</td>
<td>MS Clinical Research Organization and Management, spec. track: Regulatory Compliance and Law</td>
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<tr>
<td>George Washington University</td>
<td>DC</td>
<td>MSHS in Regulatory Affairs</td>
<td>✓</td>
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<tr>
<td>John Hopkins University, Center for Biotechnology Education</td>
<td>MD</td>
<td>MS in Bioscience Regulatory Affairs</td>
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<tr>
<td>Keck Graduate Institute</td>
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<td>MBS (Master of Bioscience), specialization track: Clinical and Regulatory Affairs</td>
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<tr>
<td>Long Island University</td>
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<td>MS in Drug Regulatory Affairs</td>
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<tr>
<td>Massachusetts College of Pharmacy and Health Sciences</td>
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<td>MS In Regulatory Affairs and Health Policy</td>
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<tr>
<td>National University</td>
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<td>MS in Clinical Regulatory Affairs</td>
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<tr>
<td>Northeastern University</td>
<td>MA</td>
<td>MS in Regulatory Affairs for Drugs, Biologics and Medical Devices</td>
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<td>MS in Quality Assurance and Regulatory Science</td>
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<td>Purdue University</td>
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<td>Regis College</td>
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<td>MS in Regulatory and Clinical Research Management, specialization track: Product Regulation</td>
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<tr>
<td>San Diego State University</td>
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<td>MS in Regulatory Affairs</td>
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<tr>
<td>St. Cloud State University</td>
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<td>MS in Regulatory Affairs and Services</td>
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<tr>
<td>St. John's University</td>
<td>NY</td>
<td>MS in Pharmacy Administration, specialization: Regulatory Affairs/Quality Assurance</td>
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</tr>
<tr>
<td>Temple University</td>
<td>PA</td>
<td>MS in Regulatory Affairs/Quality Assurance</td>
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<tr>
<td>University of Florida</td>
<td>FL</td>
<td>MS in Pharmacy -- Pharmaceutical Outcomes and Policy, specialty track: Drug Regulatory Affairs</td>
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<tr>
<td>University of Georgia, Gwinnett Campus, The</td>
<td>GE</td>
<td>MS for Regulatory Affairs</td>
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<tr>
<td>Institution</td>
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<td>Program</td>
<td>Online Program?</td>
</tr>
<tr>
<td>-------------------------------------------</td>
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<td>-------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>University of North Carolina Wilmington</td>
<td>NC</td>
<td>MS in Clinical Research and Product Development, Regulatory Affairs conc.</td>
<td>✅</td>
</tr>
<tr>
<td>University of Southern California</td>
<td>CA</td>
<td>MS in Regulatory Science</td>
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</table>

**Safety Pharmacology**

<table>
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<tr>
<th>Institution</th>
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<th>Program</th>
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<tbody>
<tr>
<td>Michigan State University</td>
<td>MI</td>
<td>Professional Science Masters in Integrative Pharmacology</td>
<td></td>
</tr>
<tr>
<td>University of Cincinnati</td>
<td>OH</td>
<td>MS in Molecular, Cellular, and Biochemical Pharmacology: Emphasis on Safety Pharmacology</td>
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</table>

**Clinical Pharmacology**

<table>
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<tbody>
<tr>
<td>Thomas Jefferson University</td>
<td>PA</td>
<td>MS Pharmacology, specialty track: Clinical Pharmacology</td>
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<tr>
<td>Keck Graduate Institute</td>
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<td>MBS (Master of Bioscience), specialization: Pharmaceuticals</td>
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</table>
## Appendix F: Faculty Available

The following faculty members are potential instructors and have expressed interest in participating in the program:

<table>
<thead>
<tr>
<th>College, Faculty</th>
<th>Area of Instruction</th>
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<tbody>
<tr>
<td><strong>College of Medicine:</strong></td>
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<tr>
<td>Joseph P. Kitzmiller, MD, PhD, FCP</td>
<td>Clinical Pharmacology</td>
</tr>
<tr>
<td>Research Assistant Professor, Department of Pharmacology</td>
<td></td>
</tr>
<tr>
<td>Stephen G. Moon, MS, FAMI, CMI</td>
<td>Pathophysiology</td>
</tr>
<tr>
<td>Instructor, School of Health and Rehabilitative Sciences</td>
<td></td>
</tr>
<tr>
<td>Kirk Mykytyn, PhD</td>
<td>General Pharmacology</td>
</tr>
<tr>
<td>Professor, Department of Pharmacology</td>
<td></td>
</tr>
<tr>
<td>Wolfgang Sadee, Dr.rer.nat.</td>
<td>Pharmacogenomics</td>
</tr>
<tr>
<td>Professor and Chair, Department of Pharmacology</td>
<td></td>
</tr>
<tr>
<td><strong>College of Nursing:</strong></td>
<td></td>
</tr>
<tr>
<td>Kimberly Arcoleo PhD, MPH</td>
<td>Ethics in Human Subjects Research</td>
</tr>
<tr>
<td>Associate Professor</td>
<td></td>
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<tr>
<td>Esther Chipps, PhD, RN</td>
<td>Research Design and Methods</td>
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<tr>
<td>Clinical Assistant Professor</td>
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<tr>
<td>Jodi McDaniel, PhD, RN</td>
<td>Pathophysiology</td>
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<tr>
<td>Assistant Professor</td>
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<tr>
<td>Marjorie Neidecker, PhD, MEng, RN</td>
<td>Cost-Effective Analysis, Data Analysis</td>
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<tr>
<td>Clinical Assistant Professor</td>
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<tr>
<td><strong>College of Pharmacy:</strong></td>
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<tr>
<td>Cynthia Carnes, PharmD, PhD</td>
<td>Safety Pharmacology</td>
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<tr>
<td>Professor and Associate Dean, Graduate Studies and Research</td>
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<tr>
<td>Jeffrey S. Johnston, PhD</td>
<td>Pharmacogenomics</td>
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<tr>
<td>Senior Lecturer, Pharmaceutics and Pharmaceutical Chemistry</td>
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<tr>
<td>Mitch A. Phelps, Ph.D.</td>
<td>Pharmacokinetics and Pharmacodynamics</td>
</tr>
<tr>
<td>Assistant Professor, Pharmaceutics and Pharmaceutical Chemistry</td>
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</table>
College, Faculty

Lane J. Wallace, PhD
Professor and Chair, Pharmacology

College of Veterinary Medicine:

Brad Bolon, DVM, MS, PhD
Associate Professor-Clinical, Dept. of Veterinary Biosciences

Moritz College of Law:

Todd G. Guttman, MD, JD
Adjunct Professor

Potential Lecturers (new positions):

Vanessa Hill, MSHS, CCRC
Assistant Director of Research
Ohio State University College of Medicine Office of Research

Sandra Shire, DMD MPA
Former Director, MS Regulatory Science and Health Safety
Arizona State University

Area of Instruction

Organ System Toxicology
Safety Pharmacology
FDA Regulation
Clinical Research Operations
Regulatory Affairs
## Appendix G: Marginal Gain of Master of Applied Clinical and Preclinical Research

<table>
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<tr>
<th></th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
<th>FY17</th>
<th>FY18</th>
<th>FY19</th>
<th>FY20</th>
<th>FY21</th>
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<tr>
<td>Students (Full Time &amp; Part Time)</td>
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<td>25</td>
<td>85</td>
<td>165</td>
<td>218</td>
<td>238</td>
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<tr>
<td>Credit Hours per Full Time Student</td>
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<td>17</td>
<td>15</td>
<td>14</td>
<td>14</td>
<td>14</td>
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<tr>
<td>Total Hours</td>
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<td>1445</td>
<td>2475</td>
<td>3052</td>
<td>3332</td>
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<tr>
<td>Prior 2 year Average Hours</td>
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<td>1960</td>
<td>2763.5</td>
<td>3192</td>
<td>3332</td>
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### Fee Revenue

- **Current OSU Student**
  - FY13: $301
  - FY14: $310
  - FY15: $319
  - FY16: $329
  - FY17: $339
  - FY18: $349
  - FY19: $359
  - FY20: $370
  - FY21: $381

- **New Student**
  - FY13: $389
  - FY14: $401
  - FY15: $413
  - FY16: $425
  - FY17: $438
  - FY18: $451
  - FY19: $464
  - FY20: $478
  - FY21: $493

### Subsidy Revenue

- **Effective Rate (Flat)**
  - FY13: $315.77
  - FY14: $315.77
  - FY15: $315.77
  - FY16: $315.77
  - FY17: $315.77
  - FY18: $315.77
  - FY19: $315.77
  - FY20: $315.77
  - FY21: $315.77

- **Total Subsidy Generated**
  - FY13: 0
  - FY14: $315.77
  - FY15: $315.77
  - FY16: $315.77
  - FY17: $315.77
  - FY18: $315.77
  - FY19: $315.77
  - FY20: $315.77
  - FY21: $315.77

- **Marginal Subsidy**
  - FY13: 0
  - FY14: $315.77
  - FY15: $315.77
  - FY16: $315.77
  - FY17: $315.77
  - FY18: $315.77
  - FY19: $315.77
  - FY20: $315.77
  - FY21: $315.77

- **Tax on Marginal Subsidy**
  - FY13: 0
  - FY14: $315.77
  - FY15: $315.77
  - FY16: $315.77
  - FY17: $315.77
  - FY18: $315.77
  - FY19: $315.77
  - FY20: $315.77
  - FY21: $315.77

### Marginal Revenue from Fees

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<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
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<td>Subsidy Revenue</td>
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<td><strong>Effective Rate (Flat)</strong></td>
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<td><strong>Total Subsidy Generated</strong></td>
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</table>

### Student Services Assessment (SSA)

- **Just "All Students" rate included**
  - FY13: $3.30
  - FY14: $3.50
  - FY15: 3.71
  - FY16: 3.93
  - FY17: 4.17
  - FY18: 4.42
  - FY19: 4.68
  - FY20: 4.96
  - FY21: 5.26

### Fee Revenue

- **Current OSU Student**
  - FY13: $301
  - FY14: $310
  - FY15: $319
  - FY16: $329
  - FY17: $339
  - FY18: $349
  - FY19: $359
  - FY20: $370
  - FY21: $381

- **New Student**
  - FY13: $389
  - FY14: $401
  - FY15: $413
  - FY16: $425
  - FY17: $438
  - FY18: $451
  - FY19: $464
  - FY20: $478
  - FY21: $493

### Tax on Marginal Revenue

- FY13: ($43,272)
- FY14: ($143,121)
- FY15: ($252,492)
- FY16: ($68,204)
- FY17: ($39,925)
- FY18: ($10,819)
- FY19: ($11,143)
- FY20: ($11,478)
- FY21: ($11,478)
## Summary of Marginal Revenue

<table>
<thead>
<tr>
<th></th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
<th>FY17</th>
<th>FY18</th>
<th>FY19</th>
<th>FY20</th>
<th>FY21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marginal Fees</td>
<td>$ -</td>
<td>$180,302</td>
<td>$596,337</td>
<td>$1,052,050</td>
<td>$284,185</td>
<td>$166,355</td>
<td>$45,078</td>
<td>$46,430</td>
<td>$47,823</td>
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<tr>
<td>Marginal Subsidy</td>
<td>$ -</td>
<td>$71,048</td>
<td>$228,144</td>
<td>$319,717</td>
<td>$253,721</td>
<td>$135,307</td>
<td>$44,208</td>
<td>$ -</td>
<td>$ -</td>
</tr>
<tr>
<td>Tax on Marginal Revenue (Return To University)</td>
<td>$ -</td>
<td>$(43,272)</td>
<td>$(160,173)</td>
<td>$(307,247)</td>
<td>$(144,937)</td>
<td>$(100,818)</td>
<td>$(43,292)</td>
<td>$(21,753)</td>
<td>$(11,478)</td>
</tr>
<tr>
<td>Marginal SSA</td>
<td>$ -</td>
<td>$ -</td>
<td>$(834)</td>
<td>$(3,724)</td>
<td>$(4,442)</td>
<td>$(4,038)</td>
<td>$(2,738)</td>
<td>$(1,591)</td>
<td>$(992)</td>
</tr>
</tbody>
</table>

### Total PBA Generation

<table>
<thead>
<tr>
<th></th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
<th>FY17</th>
<th>FY18</th>
<th>FY19</th>
<th>FY20</th>
<th>FY21</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBA Earnings By Program</td>
<td>$137,029</td>
<td>$506,379</td>
<td>$969,223</td>
<td>$454,524</td>
<td>$315,220</td>
<td>$134,355</td>
<td>$67,294</td>
<td>$35,353</td>
<td></td>
</tr>
<tr>
<td>Expenses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personnel</td>
<td>111,461</td>
<td>115,362</td>
<td>119,400</td>
<td>123,579</td>
<td>127,904</td>
<td>132,381</td>
<td>137,014</td>
<td>141,810</td>
<td>146,773</td>
</tr>
<tr>
<td>Infrastructure/PT Lecturers</td>
<td>70,000</td>
<td>72,100</td>
<td>74,263</td>
<td>76,491</td>
<td>78,786</td>
<td>81,149</td>
<td>83,584</td>
<td>86,091</td>
<td>88,674</td>
</tr>
<tr>
<td>Total Program Expense</td>
<td>181,461</td>
<td>187,462</td>
<td>193,663</td>
<td>200,070</td>
<td>206,690</td>
<td>213,530</td>
<td>220,598</td>
<td>227,901</td>
<td>235,447</td>
</tr>
<tr>
<td>Total PBA Generated less Expenses</td>
<td>$(181,461)</td>
<td>$(550,433)</td>
<td>$449,745</td>
<td>$1,412,561</td>
<td>$1,860,466</td>
<td>$2,168,845</td>
<td>$2,296,132</td>
<td>$2,356,122</td>
<td>$2,383,930</td>
</tr>
</tbody>
</table>

SSA = Student Services Assessment, PBA = Present Budget Allocation
Exhibit shows PBA increases only. GFSA (Cash) margin would be settled in first 2 years of program
Revenue assumptions: New Students taking online courses only- $1633/4 credit hour course in FY14
The Ohio State University

Colleges of Nursing, Pharmacy, Medicine, and Veterinary Medicine
Master of Applied Clinical and Preclinical Research

Letters of Support and Concurrence

November 16, 2012

Letters of Support

Bernadette Mazurek Melnyk, PhD, RN, CPNP/PMHNP, FNAP, FAAN
Dean, College of Nursing

Robert W. Brueggemeier, PhD
Dean, College of Pharmacy

Charles J. Lockwood, MD, MHCM
Dean, College of Medicine

Letters of Concurrence

Lonnie J. King, DVM, MS, MPA, ACVPM
Dean, College of Veterinary Medicine

Michael S. Bisesi, PhD
Senior Associate Dean of Academic Affairs, College of Public Health
November 1, 2012

Dr. W. Randy Smith  
Vice Provost for Academic Affairs  
Office of Academic Affairs  
203 Bricker Hall  
190 North Oval Mall

Dear Randy,

I am excited to express our strong support for the new MS in Applied Clinical and Preclinical Research program. This new interdisciplinary program is the result of collaboration between the colleges of Pharmacy, Nursing, Medicine and Veterinary Medicine. The online program will train graduates to be successful researchers involved in both clinical and preclinical research.

Each of the specialization areas, clinical research management, regulatory affairs, safety pharmacology, and clinical pharmacology, will provide highly qualified research professionals for numerous research careers in healthcare and in the pharmaceutical industries. MS graduates with this training are needed for the complexity of research protocols and the growing demand for health practitioners to actualize their innovative ideas for products and processes to improve health.

The faculty in the College of Nursing wholeheartedly approved the MS in Applied Clinical and Preclinical Research program. We are eager to participate in this interdisciplinary program developed by the health sciences colleges.

Warm regards,

Bernadette Mazurek Melnyk, PhD, RN, CPNP/PMHNP, FNAP, FAAN  
Associate Vice President for Health Promotion  
University Chief Wellness Officer  
Dean and Professor, College of Nursing  
Professor of Pediatrics & Psychiatry, College of Medicine
October 30, 2012

Marjorie Neidecker, PhD MEng RN
Clinical Assistant Professor, Colleges of Nursing and Pharmacy
Adjunct Assistant Professor, Dept. of Pharmacology, College of Medicine
The Ohio State University
5197 Graves Hall
333 W. Tenth Ave.
Columbus, OH 43210

Dear Dr. Neidecker,

On behalf of the faculty of the College of Pharmacy, I wish to express our very strongly support for the new professionally-oriented MS in Applied Clinical and Preclinical Research program. This new interdisciplinary program is the result of collaborations of the Colleges of Pharmacy, Nursing, Medicine, and Veterinary Medicine. The online program will train graduates to be successful members involved in clinical and preclinical research. The four areas of specialization in this new MS program are clinical research management, regulatory affairs, safety pharmacology, and clinical pharmacology.

Each of these areas of graduate education will provide highly qualified preclinical and clinical research professionals for numerous research careers in health care and in the pharmaceutical industries. MS graduates with this training are needed for the complexity of clinical research protocols and the global expansion of pharmaceutical product development. Recent discussions with members of our College’s Corporate Advisory Council emphasized the need and career opportunities for MS professionals trained in these specializations.

The graduate faculty of the College of Pharmacy unanimously approved the MS in Applied Clinical and Preclinical Research program. We are excited to participate in this new interdisciplinary program developed by the health sciences colleges.

Sincerely,

Robert W. Brueggemeier, Ph.D.
Dean, College of Pharmacy
Professor, Medicinal Chemistry
November 7, 2012

Dr. W. Randy Smith, Vice Provost for Academic Affairs  
Office of Academic Affairs  
203 Bricker Hall  
190 N. Oval Mall  
Columbus, OH 43210

Dear Dr. Smith:

I strongly support the proposed Masters of Science in Applied Clinical and Preclinical Research. Four courses will be offered by faculty members in our college: Introduction to General Pharmacology, Principles of Clinical Pharmacology, Special Topics in Pharmacogenomics, and the Clinical Pharmacology Capstone experience. The College of Medicine will also provide administrative support for the Clinical Pharmacology specialization.

The new professionally-oriented Masters program will help fill an industry need for highly qualified clinical research professionals who carry out increasingly complex research protocols. Our college’s contribution of the Clinical Pharmacology specialization will provide graduates with the skills necessary to apply the pharmacological principles in clinical research that are required to translate laboratory science into clinical practice. The goals of the Masters of Science in Applied Clinical and Preclinical Research fit into the educational mission of the College of Medicine, by providing unique expertise to a curriculum that has excellent promise in educating much needed professionals. The Masters program and participation in the program was unanimously approved by the faculty of the Department of Pharmacology.

Sincerely,

Charles J. Lockwood, MD, MHCM  
Dean, College of Medicine  
Vice President for Health Sciences  
Professor, Obstetrics and Gynecology  
Leslie H. and Abigail S. Wexner Dean’s Chair in Medicine
October 31, 2012

Dr. W. Randy Smith, Vice Provost for Academic Affairs
Office of Academic Affairs
203 Bricker Hall
190 N. Oval Mall

Dear Dr. Smith:

I am pleased to provide a letter of concurrence for the new proposed Master’s in Applied Preclinical and Clinical Research. Two courses will be offered by faculty members in our college: Comparative Biology for Biomedical Scientists and Animal Modeling in Translational Medicine.

The new academic program is designed to fill an industry need for highly qualified clinical and preclinical research professionals. Furthermore, I believe that the new program will provide courses which will be valuable in broadening the educational opportunities for students in our existing departmental graduate programs.

Sincerely,

Lonnie J. King, DVM, MS, MPA, ACVPM
Dean, College of Veterinary Medicine
November 14, 2012

Dr. W. Randy Smith, Vice Provost for Academic Affairs
Office of Academic Affairs
The Ohio State University
203 Bricker Hall
Columbus, OH 43210

Dear Dr. Smith:

Please accept this letter of concurrence and support regarding the proposed *Master of Science in Applied Clinical and Preclinical Research*. The proposed program with four interdisciplinary specializations is very timely and appropriate for the intended students, including adult learners already with work experience. In addition, I believe that the multidisciplinary and collaborative approach to program development and delivery involving four of the Health Science Colleges is a highlight of the proposed program and will likely contribute toward much success.

Thank you for this opportunity to review and comment.

Sincerely,

Michael S. Bisesi, PhD
Senior Associate Dean, Academic Affairs
OSU College of Public Health
Director, Center for Public Health Practice
Interim Chair & Associate Professor, Division of Environmental Health Sciences
The Ohio State University
Colleges of Nursing, Pharmacy, Medicine, and Veterinary Medicine

Master of Applied Clinical and Preclinical Research

Course Syllabi

November 16, 2012
Revised March 22, 2013

Core Coursework

(1) Nursing 7781    Responsible Conduct of Research
(2) Pharmacology 5600 Introduction to General Pharmacology
(3) Nursing/Pharmacy 7782 Research Design and Methods for Clinical and Preclinical Research
(4) Nursing 7770    Fundamentals of Medical Product Regulatory Affairs
(5) Pharmacy 7784   Data Analysis and Interpretation in Clinical and Preclinical Research
(6) Nursing 7481    Data Management and Informatics in Clinical Trials
(7) Nursing 7405    Clinical Research Operations
(8a) Nursing 7597   Clinical Research Management Capstone
(8b) Nursing/Pharmacy 7598 Regulatory Affairs Capstone
(8c) Pharmacy 7599  Safety Pharmacology Capstone
(8d) Pharmacology 7599 Clinical Pharmacology Capstone

Specialization Coursework

(9) Nursing 7404    Healthcare Project Management
(10) Nursing 7402   Applied Cost-Effectiveness Analysis in Intervention Research
(11) Nursing 7482   Quality Systems and Standards for Medical Products
(12) Pharmacy 7570  Pharmaceutical Safety & Risk Management
(13) Nursing 7460   Technical Writing for the Regulatory Professional
(14) Pharmacy 7572  Federal Regulation of Medical Products
(15) Pharmacy 7580  Principles of Safety Pharmacology
(16) Pharmacy 7582  Organ System Toxicology
(18) Pharmacy 7584  Applied Pharmacokinetics and Pharmacodynamics
(19a) Nursing 7450  Pathophysiology of Altered States
(19b) Health & Rehab. Sc. 5500 Introduction to Pathophysiology
(20) Pharmacology 7600 Principles of Clinical Pharmacology
(21) Pharmacy 7240  Clinical Pharmacogenomics
(22) Pharmacology 7255 Special Topics in Pharmacogenomics
Course Faculty: Kim Arcoleo, PhD MPH

Prerequisite: Graduate or professional student

Course Description: Concepts and policies for the responsible conduct of research (RCOR), Institutional Review Boards and dissemination of findings.

Course Overview: The course is designed to provide a context for the historical evolution of current Human Subjects Protection Programs and the mechanisms developed to guide researchers and protect the rights of research subjects. This course will also provide an in-depth examination of the ethical issues encountered in conducting clinical research including research with vulnerable populations, conflict of interest, and scientific misconduct. The course intent is to provide opportunities for student to develop study protocols, progress reports, journal publications, and scientific presentations.

Objectives:
- Analyze the current global trends for human subject regulations and institutional protection programs by utilizing key historical events and regulatory developments.
- Demonstrate a thorough understanding of the Health Insurance Portability and Accountability Act (HIPAA) and current international privacy guidelines.
- Analyze the trends for Institutional Review Board structure, principles, functions, and composition.
- Critique the challenges and ethical considerations in conducting research with international or other vulnerable populations.
- Explain and discuss research conflict of interest and scientific misconduct and the implications for responsible conduct of research.
- Demonstrate responsible conduct of research standard competency through formulation of an Institutional Review Board protocol, IRB submission packet, and human subject research consent form.

Conduct of the Course: 3 credits didactic. 2.7 hours of classroom content each week. Each class will consist of lecture followed by case study discussion.

Textbooks:

Evaluation:

<table>
<thead>
<tr>
<th>Evaluation Criteria</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance, class participation, and discussion boards</td>
<td>20%</td>
</tr>
<tr>
<td>Individual Final Project Paper/Presentation</td>
<td>40%</td>
</tr>
</tbody>
</table>
Exam #1 Midterm 20%
Exam #2 Final 20%

Grade Equivalents:
A  93-100%  B  83-86%  C  73-76%  D  60-66%
A-  90-93%  B-  80-82%  C-  70-72%  E  59% and below
B+  87-89%  C+  77-79%  D+  67-69%

Content Outline:

<table>
<thead>
<tr>
<th>Week</th>
<th>Topical Content</th>
<th>Readings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>History of Research Administration</td>
<td>Coleman, Ch 1, 2; Kulikowski, Ch 2-4; posted readings</td>
</tr>
<tr>
<td>2</td>
<td>Declaration of Helsinki &amp; the Belmont Report</td>
<td>Coleman Appendices D-F; Kulikowski Ch 45; posted readings</td>
</tr>
<tr>
<td>3</td>
<td>Human Subjects Research - 45 CODE CFR46</td>
<td>Coleman, Ch 3, 6-8, 11, 12, App A; Kulikowski Ch 13, 51, 52; posted readings</td>
</tr>
<tr>
<td>4</td>
<td>HIPAA Privacy Rule; Use &amp; Disclosure of Personal Health Information (PHI)</td>
<td>Coleman, Ch 10; Kulikowski, Ch 53; posted readings</td>
</tr>
<tr>
<td>5</td>
<td>Research w/Vulnerable Populations</td>
<td>Coleman, Ch 9, 13-15; Kulikowski, Ch 55; posted readings</td>
</tr>
<tr>
<td>6</td>
<td>International Issues in Clinical Research</td>
<td>Kulikowski, Ch 32; posted readings</td>
</tr>
<tr>
<td>7</td>
<td>MID-TERM</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Institutional Review Board &amp; Data Safety Monitoring Board (DSMB)</td>
<td>Coleman, Ch 4, 11; Kulikowski, Ch 4, 19, 20; posted readings</td>
</tr>
<tr>
<td>9</td>
<td>Conflict of Interest in Research</td>
<td>Coleman Ch 5; Kulikowski, Ch 49; posted readings</td>
</tr>
<tr>
<td>10</td>
<td>SPRING BREAK</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Scientific Misconduct &amp; Plagiarism</td>
<td>Kulikowski Ch 43, 48, 50, 58; posted readings</td>
</tr>
<tr>
<td>12</td>
<td>Writing a Study Protocol &amp; Research Grant</td>
<td>Kulikowski, Ch 19, 28, 29, 31; posted readings</td>
</tr>
<tr>
<td>13</td>
<td>Structure, quality &amp; interpretation of clinical reports &amp; peer-reviewed manuscripts</td>
<td>Posted readings</td>
</tr>
<tr>
<td>14</td>
<td>FINAL PROJECTS</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>FINAL EXAM</td>
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</tr>
</tbody>
</table>

**Academic and Professional Misconduct:**

Students are subject to the provisions in the “Code of Student Conduct” (copies located in: Student Affairs, Room 240 Newton Hall, Office of Student Life, Room 464 Ohio Union or online at [http://studentaffairs.osu.edu/resource_csc.asp](http://studentaffairs.osu.edu/resource_csc.asp)) and also the Professional Standards (The OSU CON Student Handbook). Failure to comply with these policies will be handled as outlined in the respective documents.
**Students with Disabilities:**
Students requesting accommodation for disability for classroom needs are responsible for notifying the Course Head by the end of the **first week** of the semester to discuss specific needs. Self-identification is the only way to assure that the faculty member can make the appropriate accommodation. Students should provide a letter from the Office for Disability Services (150 Pomerene Hall, 1760 Neil Avenue; (614) 292-3307; TDD: (614) 292-0901) to verify the disability.

Students needing accommodation for temporary physical disabilities or health related reasons should contact the Course Head in order to discuss placement options. Students must be able to perform all job functions as required by the clinical placement site. Students may be asked to provide the Course Head with a letter from their physician indicating physical restrictions or limitations.

**Student Classroom Responsibilities:**
When in the classroom, students are expected to give their complete attention to the course. Cell phones, pagers, and any other type of communication device are to be turned off at the beginning of class. Any cell phones, pagers or other communication devices must be turned off and stored out of sight (book bag, purse, etc). No cell phones, pagers or any other type of communication device will be allowed on the student during any exam.

**Cell Phone and E-transmission Policy**
The use of cell phones is prohibited during class/seminar/clinical with the exception of break times. Students who need to have a cell phone on for emergency purposes should discuss the issue with the designated faculty course head. Students found in violation of this policy should be aware faculty has the option of lowering the course grade and/or reporting the violation to the academic/professional misconduct committee chair. Taking pictures of the College of Nursing/College of Nursing property, clinical sites, and patients using ANY device are prohibited without the written consent of the institution and all parties involved.

Please be aware that electronic transmission of data related to patient specific identifiers and student to student health information obtained in physical assessment labs with student identifiers is a violation of HIPAA.

**Carmen Online Technical Information:**
Web-based components of this course will use The Ohio State University’s course management system, Carmen. Access to this course will require a username and password. Access NXXX at: https://carmen.osu.edu (the same password used to enroll for classes at the Registrar’s website). Carmen requires the use of your UNIVERSITY login and password. Information concerning your University email and login account can be found at https://acctmgt.service.ohio-state.edu/. As part of Carmen, your homepage after you log in will reflect all courses that you are taking across the University. 24 hour technical support can be reached at: Carmen/TELR - Phone: 614-688-4357 (688-HELP) or through the Carmen Help Web page at: https://telr.osu.edu/carmen/help/index.htm
Course content will be available via Carmen.
Grades will be posted via Carmen.

**College of Nursing IT Support**
For technical support and system requirements for these and other systems you will use while enrolled at the College of Nursing, please visit the College of Nursing Technology Guide at [http://go.osu.edu/techguide](http://go.osu.edu/techguide) or e-mail s-help@con.ohio-state.edu.
Course Description:

Introductory course emphasizing the general principles of pharmacology using a systems-based and mechanism-based approach. The course provides a simple overview of the subject.

Prerequisite:

Prior coursework in physiology [EEOB 2520 (232) or PHYSIO 3102 (PHYSIOCB 312)], or permission of instructor.

Objectives:

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

1. Describe factors that affect the pharmacokinetic properties (drug absorption, distribution, metabolization, and elimination in the body) and pharmacodynamics properties (relationship between drug concentration and response in the body) of drugs.
2. Apply basic principles of cell biology, biochemistry, physiology, pathophysiology, and genetics to explain how human diseases are treated with drugs.
3. Identify major drug classifications, and for each identify prototype drug names, indications, mechanism of action, and therapeutic and adverse actions.
4. Identify and demonstrate proficiency using sources of reference material for drug information.

Course Topics:

Unit 1: Principles of Drug Therapy
1. Pharmacokinetics
2. Drug-Receptor Interactions and Pharmacodynamics

Unit 2: Drugs Affecting the Autonomic Nervous System
3. The Autonomic Nervous System
4. Cholinergic Agonists
5. Cholinergic Antagonists
6. Adrenergic Agonists
7. Adrenergic Antagonists

Unit 3: Drugs Affecting the Central Nervous System
8. Neurodegenerative Diseases
9. Anxiolytic and Hypnotic Drugs
10. Central Nervous System Stimulants
11. Anesthetics
12. Antidepressants
13. Antipsychotic Drugs
14. Opioids
15. Epilepsy

Unit 4: Drugs Affecting the Cardiovascular System
16. Heart Failure
17. Antiarrhythmics
18. Antianginal Drugs
19. Antihypertensives
20. Blood Drugs
21. Hyperlipidemias
22. Diuretics

Unit 5: Drugs Affecting the Endocrine System
23. Pituitary and Thyroid
24. Insulin and Other Glucose-Lowering Drugs
25. Estrogens and Androgens
26. Adrenal Hormones

Unit 6: Drugs Affecting Other Organs
27. Respiratory System
28. Gastrointestinal and Antiemetic Drugs
29. Erectile Dysfunction, Osteoporosis, and Obesity

Unit 7: Chemotherapeutic Drugs
30. Principles of Antimicrobial Therapy
31. Cell Wall Inhibitors
32. Protein Synthesis Inhibitors
33. Quinolones, Folic Acid Antagonists, and Urinary Tract Antiseptics
34. Antimycobacterials
35. Antifungal Drugs
36. Antiprotozoal Drugs
37. Anthelmintic Drugs
38. Antiviral Drugs
39. Anticancer Drugs
40. Immunosuppressants

Unit 8: Anti-inflammatory Drugs and Autacoids
41. Anti-inflammatory Drugs
42. Autacoids & Autacoid Antagonists
43. Toxicology
THE OHIO STATE UNIVERSITY
GRADUATE SCHOOL
DEPARTMENT OF NURSING
Nursing 7782
Pharmacy 7782
Research Design and Methods for Clinical and Preclinical Research
3 Credits

Course Description:
Assessment of ethical design and methods used in clinical and preclinical research. Measurement issues in conducting research across diverse populations; reliability, validity, bias, and confounding; and appropriate statistical measurement and analysis for given study designs.

Prerequisite:
Admission to the Master’s program in Applied Clinical and Preclinical Research or permission of the instructor.

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

1. Critically evaluate published epidemiological, clinical trial, and other clinical research study designs (e.g. adaptive trial designs) and outcome analyses.
2. Compare and contrast the strengths and limitations of various epidemiological, clinical trial, and adaptive study designs that apply to health research.
3. Summarize and explain the measurement concerns that need to be considered when conducting research across diverse populations.
4. Appraise and apply measures that enhance the reliability and validity of research tools and methods to insure an accurate outcome of the proposed research.
5. Analyze, synthesize, critically evaluate and interpret selected research issues related to sampling, statistical conclusions and internal and external validity.
6. Analyze and determine the level of research data in order to apply critically appropriate statistical measurements in quantitative research.
7. Integrate ethical principles of human subjects’ research into the design of clinical trials.
8. Assess potential threats to the validity of epidemiological and clinical study designs, including sources of bias, confounding, and misclassification.
9. Synthesize course content through the development of a clinical trial protocol integrating principles of ethical research.

Course Topics:

- Specific Aims
- Research Questions and Hypotheses
- Construct Mapping and Logic Models
- Experimental Designs and Participant Flow
- Quasi and Non-Experimental Designs
- Sampling, Recruiting, and Retention
• Measurement Reliability and Validity
• Data Collection Mapping
• Fidelity
• Data Management and Analysis
• Effect Size and Power
Course Description:

Function of clinical research in medical product development and the regulatory process of new medical products. Laws and regulations concerning the development, testing, commercialization, and total product life cycle for medical products. Regulations governing the conduct of clinical research, including study sponsors, investigators, and Institutional Review Boards.

Prerequisite:

Admission to the Master’s program in Applied Clinical and Preclinical Research or permission of the instructor.

Objectives:

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

1. Appraise the United States and international regulatory systems and agencies governing the commercialization of medical products and the conduct of clinical trials.
2. Analyze the structure of the Food and Drug Administration (FDA) and the functions of each major component of the organization.
3. Evaluate the regulatory impact of the Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA) and state and local authorities, and the Federal Communications Commission (FCC) and the Federal Trade Commission (FTC).
4. Discuss the conduct of ethical clinical research and the associated regulations during the product development process.
5. Investigate the consequences of failure to comply with regulatory policies.
6. Compare and contrast the types of approvals and characteristics of each pathway for regulated products.
7. Analyze the importance of audits and the inspectional process and the subsequent reporting requirements.
8. Summarize the membership requirements, ethical obligations, and regulatory oversight of an Institutional Review Board (IRB).
9. Explain the role of FDA Advisory Committees in the review of products and in Agency policy decisions.
10. Defend the contribution of quality systems in each stage of product development and production.

Course Topics:

- Overview of medical product development and regulation
- History of Food and Drug Administration (FDA) laws to present time
- Device vs. drug, safety and effectiveness
• FDA Organization
• The role of clinical research in product development
• Phases of new product trials
• Definitions: sponsor, investigator, monitor, Contract Research Organization (CRO), Clinical Research Center (CRC), Data and Safety Monitoring Board (DSMB)
• Research site management: study feasibility, recruitment, forms
• Regulation of new medical devices:
  o Premarket Notification 510(k), Premarket Approval (PMA), Investigational Device Exemption (IDE)
  o Device classification, registration and listing
• Regulatory submissions for medical devices
• Regulation of new pharmaceutical drugs
  o New Drug Application (NDA), Investigational New Drug (IND) application,
  o Generic products, Over the Counter (OTC) drugs
  o Drug development pathway, Critical Path Institute (C-PATH)
• Regulatory Submissions for Drug products
  o Monographs, NDA, IND, bioequivalence studies
• Regulation of biologic products, foods, supplements, cosmetics, orphan products, combination products
• Manufacturing, inspections, quality systems, audits
• Advertising, Food and Drug Administration (FDA), Federal Trade Commission (FTC), Federal Communications Commission (FCC)
• Good Clinical Practices (GCPs), Investigational Review Boards (IRB), legal issues, event reporting, human subject protection, site regulatory documents
• FDA Advisory Committee Role-Process, preparation for a panel meeting
Course Description:

Introduction to the principles of biostatistical methods used in biomedical and public health research. Analysis of clinical trials data and interpretation of statistical results in biomedical studies.

Prerequisite:

Prerequisite or Corequisite: NURSING/PHR 7782 (Research Design and Methods for Clinical and Preclinical Research), or permission of instructor.

Objectives:

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

1. Perform simple statistical calculations.
   a. Calculate descriptive statistics in biomedical and public health research problems.

2. Demonstrate competency using a statistical software package to perform statistical calculations given a data set.
   a. Employ Excel and SPSS to calculate descriptive statistics.
   b. Employ SPSS to make inference on data drawn from discrete and continuous probability distributions.
   c. Employ SPSS to estimate key parameters from a sample to a population by constructing and interpreting both point estimates and confidence intervals.
   d. Employ SPSS to make an inference from a sample to a population using hypothesis tests.
   e. Employ SPSS to perform a simple linear regression.
   f. Employ Excel and SPSS to produce plots and graphs to visually present data.

3. Interpret statistical information presented in biomedical journal articles.
   a. Describe the relationship between two variables by interpreting SPSS output of
      - multivariable linear regression,
      - multivariable logistic regression,
      - ANOVA, and
      - survival analysis.

4. Prepare a simple draft of a biomedical manuscript using professional biomedical writing style, proper content structure, and correct reference techniques.
   a. Identify the basic sections of a biomedical manuscript.
   b. Compile a literature review of a topic to provide background information.
   c. Describe the statistical analysis plan to provide the methods information.
   d. Report the results of an analysis.
   e. Interpret and discuss the relevance of the findings.
   f. Demonstrate professional biomedical writing style.
Course Topics:

- Introduction
- Study Designs
- Quantifying the Extent of Disease
- Summarizing Data Collected in the Sample
- The Role of Probability
- Confidence Interval Estimates
- Hypothesis Testing Procedures
- Power and Sample Size Determination
- Multivariable Methods
- Nonparametric Tests
- Survival Analysis
- Data Analysis Plan
- Writing a biomedical journal article
Course Description:

Introduction to database design, data management, quality assurance, and technology assessment in clinical research administration.

Prerequisite:

Prerequisite: NURSING 7782 (Research Design and Methods for Clinical and Preclinical Research), or permission of instructor.

Objectives:

Upon completion of the course, students will be able to:

1. Estimate the staff and money required for the data entry, management, and analysis portions of a regulated clinical trial.
2. Appraise the methods for tracking study participants, reporting sample attrition, and implications for the generalizability of the findings.
3. Synthesize the course content related to forms and database design, technology assessment, data quality, and security by designing a data management and analysis plan.
4. Assess the complexities of ethical data management and integration from multi-site clinical trials domestic and international.
5. Summarize the documenting, reporting, and public use dataset requirements for clinical trials.

Course Topics:

- Resource requirements for data entry management systems
- Pre-planning through data lock process
- Management information system (MIS) & tracking study participants, exception handling, retention
- Database design, electronic data capture (EDC), multi-site data integration;
- Clinical Data Interchange Standards Consortium (CDISC), case report form development, survey design, data collection forms, test procedures
- Issues surrounding data management and security in internet-based and computer-assisted data collection
- Technology assessment tools, methods, trends
- Data security & confidentiality, HIPAA, Health Level 7 (HL7)
- Data management & analysis plan
- Intention-to-treat, sub-group, and regression analyses
- Interim, monitoring, and stopping rules
• Auditing for continuous quality improvement (CQI), data safety monitoring boards, monitoring, study closure, working w/clinical research organizations
• Documentation & reporting of clinical trials: Consolidated Standards of Reporting Trials (CONSORT), Common Technical Document (CTD), Inter-university Consortium for Political and Social Research (ICPSR)
Course Description:
Operational planning of clinical trials including budgeting, study timeline, site evaluation and selection, study initiation, content and timing of monitoring visits, quality assurance, study closure procedures.

Prerequisite:
Prerequisite: NURSING 7782 (Research Design and Methods for Clinical and Preclinical Research), or permission of instructor. Pre- or Corequisite: NURSING 7481 (Data Management and Informatics in Clinical Trials), or permission or instructor.

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

1. Formulate the budget for a regulated clinical trial to include study personnel, consultants, equipment, travel, patient care, marketing/advertising, contractual agreements, and indirect costs.
2. Appraise the methods for selecting and evaluating potential clinical research trial sites.
3. Compare and contrast the roles and responsibilities of the clinical research site and sponsor, and the appropriate communication between each.
4. Analyze standard research industry contracts including form, function, and trouble shooting.
5. Generate a plan for clinical trial enrollment, recruitment, and retention of study participants.
6. Compose an operational implementation timeline including procedures for FDA audits and reporting, cash flow analysis, and study closure procedures.
7. Communicate the clinical monitoring activities required to comply with FDA regulations.
8. Synthesize the key components from a clinical trial for post-study reporting and dissemination of clinical trial results.

Course Topics:
- Introduction and overview of clinical trials
- The FDA and clinical trials
- Society, politics, and ethics
- Regulatory Affairs
- Clinical Research Project Management
- Financial considerations in clinical research
- Site qualification and selection
- Post study regulated reporting, closure and publication of results
• Daily conduct and operations of clinical trials
• Study start-up
• Clinical trial monitoring
• Study close-out and final reporting
Course Description:

Capstone project or internship for students in the Clinical Research Management specialization of the MS Applied Clinical and Preclinical Research program. Culminating learning activity integrating core and specialization coursework. Capstone project or internship performed at an organization involved with clinical research administration with the oversight of a faculty advisor and site mentor.

Prerequisite:

Completion of all required clinical research management courses in the MS Applied Clinical and Preclinical Research program, or permission of the program director.

Objectives:

For students choosing to do a culminating project, upon completion of the course, students will be able to:

1. Demonstrate knowledge of basic clinical research project management principles, tools, practices, ethics, and industry trends through the completion of the capstone project.
2. Design a clinical trial project management plan including components for development, implementation, and evaluation of the plan.
3. Formulate an evidence-based quality improvement process plan through a critical assessment of the clinical trials process.
4. Synthesize and apply basic clinical research project management principles, regulations, and best practices in solving common operational and implementation issues.
5. Disseminate clinical trial results to key stakeholders.

For students choosing to do an internship/field experience, upon completion of the course, students will be able to:

1. Summarize the organization’s mission, goals, objectives and activities and its role within the clinical research industry.
2. Research the body of knowledge related to the internship topic area.
3. Synthesize clinical research management principles and practice during application to a case.
4. Critique operational plans to conduct clinical research using best practices learned throughout the program.
Course Topics:

The clinical research management capstone is an individual, faculty-approved project or internship. It is designed as a culmination project which synthesizes and applies the basic concepts learned in clinical research management coursework:

- Clinical research principles, ethics, and regulations,
- Clinical trial design and implementation,
- Data management and statistical analysis,
- Project management methodologies, tools, and processes
- Dissemination of clinical trial results.

Course topics may vary at the discretion of the capstone advisor to meet the needs of the student's capstone topic.
Course Description:

Capstone project or internship for students in the Regulatory Affairs specialization of the MS Applied Clinical and Preclinical Research program. Culminating learning activity integrating core and specialization coursework. Capstone project or internship performed at an organization involved with the regulation of medical products with the oversight of a faculty advisor and a site mentor.

Prerequisite:

Completion of all required regulatory affairs courses in the MS Applied Clinical and Preclinical Research program, or permission of the program director.

Objectives:

For students choosing to do a culminating project, upon completion of the course, students will be able to:

1. Assess current regulations that focus on public health, quality and safety, considering the origin and significance of related laws and regulations and their impact on public health.
2. Critique regulatory submissions evaluating the product life cycle to include product design, manufacturing, testing and post-market surveillance.
3. Lead an evidence-based scientific review team, using sound principles of project management to critically analyze a product risk mitigation plan.
4. Examine regulatory science submissions to judge adherence to valid research methods and principles of ethical conduct of research.
5. Examine quality systems and standards and their impact on public safety.
6. Optimize technology-enabled regulatory science strategies and practices.

For students choosing to do an internship/field experience, upon completion of the course, students will be able to:

1. Summarize the organization’s mission, goals, objectives and activities and its role within the regulatory area.
2. Research the body of knowledge related to the internship topic area.
3. Synthesize regulatory principles and practice during application to a case.
4. Critique cases using the ELSI (Ethical, Legal, Social Implications) framework.

Course Topics:

The regulatory affairs capstone is an individual, faculty-approved project or internship. It is designed as a culmination project which synthesizes and applies the basic concepts learned in regulatory affairs coursework:
• Laws and regulations related to public health, quality and safety, and their impact on public health.
• Regulatory submissions evaluating the product life cycle: product design, manufacturing, testing and post-market surveillance.
• Leadership of an evidence-based scientific review team; sound principles of project management.
• Product risk mitigation plan.
• Regulatory science submissions.
• Adherence to valid research methods and principles of ethical conduct of research.
• Quality systems and standards and their impact on public safety.
• Technology-enabled regulatory science strategies and practices.
• The ELSI (Ethical, Legal, Social Implications) framework.

Course topics may vary at the discretion of the capstone advisor to meet the needs of the student’s capstone topic.
Course Description:

Capstone project or internship for students in the Safety Pharmacology specialization of the MS Applied Clinical and Preclinical Research program. Culminating learning activity integrating core and specialization coursework. Capstone project or internship performed at an organization involved with preclinical research studies with the oversight of a faculty advisor and a site mentor.

Prerequisite:

Completion of all required didactic safety pharmacology courses in the MS Applied Clinical and Preclinical Research program, or permission of the program director.

Objectives:

For students choosing to do a culminating project, upon completion of the course, students will be able to:

1. Demonstrate knowledge of basic safety pharmacology principles, tools, practices, and ethics, through the completion of the capstone project.
2. Design a safety pharmacology evaluation project including components for development, implementation, and evaluation of the plan.
3. Formulate an evidence-based safety pharmacology evaluation process through critical assessment of the process.
4. Synthesize and apply safety pharmacology principles, regulations, and best practices in solving common operational and implementation issues.
5. Disseminate safety pharmacology results to key stakeholders.

For students choosing to do an internship/field experience, upon completion of the course, students will be able to:

1. Summarize the organization’s mission, goals, objectives and activities and its role within the pre-clinical safety pharmacology industry.
2. Research the body of knowledge related to the internship topic area.
3. Synthesize safety pharmacology principles and practice during application to a case.
4. Critique operational plans to conduct safety pharmacology research using best practices learned throughout the program.

Course Topics:

The safety pharmacology capstone is an individual, faculty-approved project or internship. It is designed as a culmination project which synthesizes and applies the basic concepts learned in safety pharmacology coursework:

- Principles of safety pharmacology
- Organ system toxicology
- Applied pharmacokinetics and pharmacodynamics, and
- Clinical pharmacogenomics, animal modeling in translational medicine, or comparative biology

Course topics may vary at the discretion of the capstone advisor to meet the needs of the student’s capstone topic.
Course Description:

Capstone project or internship for students in the Clinical Pharmacology specialization of the MS Applied Clinical and Preclinical Research program. Culminating learning activity integrating core and specialization coursework. Capstone project or internship performed at an organization involved with clinical research drug studies with the oversight of a faculty advisor and a site mentor.

Prerequisite:

Completion of all required didactic clinical pharmacology courses in the MS Applied Clinical and Preclinical Research program, or permission of the program director.

Objectives:

For students choosing to do a culminating project, upon completion of the course, students will be able to:

1. Demonstrate knowledge of basic clinical pharmacology, pharmaceutical, or drug-development research principles, tools, practices, ethics, and industry trends through the completion of the capstone project.
2. Design a first-in-humans clinical trial including a study protocol, informed consent form, and other associated regulatory documents.
3. Formulate an evidence-based quality improvement process plan through a critical assessment of the clinical trials process.
4. Synthesize and apply basic clinical pharmacology or pharmaceutical research principles, regulations, and best practices in solving common operational and implementation issues.
5. Disseminate clinical trial or pharmacology research results.

For students choosing to do an internship/field experience, upon completion of the course, students will be able to:

1. Summarize the organization’s mission, goals, objectives and activities and its role within the clinical pharmacology or pharmaceutical research industry.
2. Research the body of knowledge related to the internship topic area.
3. Synthesize clinical pharmacology principles and practice during application to a particular case, trial, or study.
4. Critique operational plans to conduct clinical pharmacology or pharmaceutical research using best practices learned throughout the program.
**Course Topics:**

The clinical pharmacology capstone is an individual, faculty-approved project or internship. It is designed as a culmination project which synthesizes and applies the basic concepts learned in clinical pharmacology coursework:

- Clinical pharmacology research principles, ethics, and regulations,
- Clinical trial design and implementation,
- Data management and statistical analysis,
- Project management methodologies, tools, and processes
- Dissemination of clinical trial results.

Course topics may vary at the discretion of the capstone advisor to meet the needs of the student’s capstone topic.
Course Description:

Principles of project management, strategic planning, and leadership in clinical research and regulatory settings.

Prerequisite:

Prerequisite: NURSING 7782 (Research Design and Methods for Clinical and Preclinical Research), or permission of instructor. Pre- or Corequisite: NURSING 7481 (Data Management and Informatics in Clinical Trials), or permission or instructor.

Objectives:

Upon completion of this course, students will be able to:

1. Differentiate between ongoing project operations and project management.
2. Appraise who project stakeholders are and how to manage stakeholder relationships.
3. Communicate the roles of the project manager and the skills needed to perform successfully.
4. Integrate the principles of the project management body of knowledge (PMBOK) to successfully manage project scope, time and cost issues, project quality, human resources, communications, and project risks.
5. Demonstrate proficiency in using project management software such as Microsoft Project to manage and integrate all the components of a successful project.

Course Topics:

- Defining Project Management and the Global Project
- Strategic Planning and Process Management
- The Triple Constraint
- Quality in Organizations
- Leadership, Human Resources, & Performance Management
- Case Study
- Managing the Healthcare Project
Course description: Introduction to cost-effectiveness analysis, including evaluating costs and health effects, ethics, using results to inform resource allocation, interpretation, and decision analysis in health care.

Prerequisite: Graduate or professional student

Objectives:
2. Summarize the role of contingent valuation and discounting in cost-effectiveness analysis (CEA).
3. Communicate the principles of CEA including framing, health and cost inputs, cost-effectiveness ratios, uncertainty, and quality-adjusted life years (QALYs).
4. Interpret various measures of health status and quality of life used in CEA.
5. Express principles of decision analysis (DA), including decision trees to illustrate options and their consequences.

Course Topics:
- Overview of cost-effectiveness analysis
- Cost analysis and measuring costs in cost-utility analysis (CUA)
- Decision trees using TreeAge Pro
- Cost issues in CUA: productivity costs & survivor consumption goods
- Assessing effectiveness in CEA and outcomes in CUA
- Measures of health status and quality of life used in CEA/CUA
- Cost-effectiveness analysis using TreeAge Pro CUA and healthcare policy
- Contingent valuation
- Valuing human life and quality-adjusted life years (QALYs)
- Discounting in CEA
- Medical decision making and decision-analytic models
- Markov models using TreeAge Pro
- Capturing uncertainty in CEAs
- Sensitivity analysis using TreeAge Pro
- Reporting standards for CEA studies
Nursing 7482
Quality Systems and Standards for Medical Products
3 Credits

Course Description:

Concepts and application of total quality management for federal regulation of medical products including drugs and medical devices.

Prerequisite:

Prerequisite: NURSING 7770 (Fundamentals of Medical Product Regulatory Affairs), or permission of instructor.

Objectives:

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

1. Summarize the Food and Drug Administration (FDA) regulatory environment for drugs and medical devices; explain key general concepts underlying modern quality management systems.
2. Formulate relevant documentation and audit and record-retention procedures for compliance to various regulations.
3. Develop in-house training procedures for company personnel to ensure regulatory compliance in the context of a certain drug or medical device.
4. Analyze the relevant quality systems that are involved in regulatory compliance for a specific drug or medical device
5. Synthesize processes to make improvements in quality based on findings from data/audits and quality systems regulations (QSR) or good manufacturing practices (GMP) requirements.
6. Design systems to monitor product performance/failure trends, including failure mode effects analysis (FMEA);
7. Critique documentation supporting any proposed changes to products or processes, including contractual obligations/agreements to ensure regulatory compliance of medical products
8. Assess validation of product software and quality systems software; equipment and manufacturing processes/procedures;
9. Plan for the use of valid statistical tools and methods – including risk management and total quality management (TQM) – throughout the product life cycle

Course Topics:

- Total quality management (TQM) systems;
- Audit and record-keeping procedures
- Current good manufacturing practices
- Quality systems regulations promulgated by the Food and Drug Administration (FDA)
• Data handling (including statistical evaluation)
• Assessing compliance and corrective actions
• Identification of methods to validate quality of manufacturing and software in the quality context
The Ohio State University

PHARMACEUTICAL SAFETY AND RISK MANAGEMENT
Pharmacy 7570
3 semester credit hours

Course Description:

Comprehensive investigation of pharmacovigilance initiatives and pharmaceutical safety regulation. Pharmaceutical risk management in premarket testing and development, recognition of safety signals, post-approval experience, drug production, risk mitigation, and administration of pharmaceuticals.

Prerequisites:

Prerequisite: NURSING 7770 (Fundamentals of Medical Product Regulatory Affairs), or permission of instructor.

Course Objectives:

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

1. Examine key components of a safety analysis for pharmaceuticals during clinical trials (phase I, phase II, and phase III in most cases) and factors that limit the likelihood of detecting serious adverse drug reactions in the clinical trial setting.
2. Critique the quality of medical products' safety studies and identify factors that influence the overall quality of these studies.
3. Evaluate the quality of advertising and labeling safety messages for pharmaceutical agents for all levels of health literacy.
4. Compare and contrast perceived and real conflicts of interest and ethical concerns associated with pharmacovigilance initiatives.
5. Formulate strategies for evaluating safety of follow-on products.
6. Examine off-label use of medical products and appropriate regulatory responses to off label safety concerns.
7. Differentiate the factors leading up to, and related processes associated with, recalls, warnings, and adverse event reporting requirements.
8. Evaluate the potential and realities of pharmacogenomics and drug safety.
9. Critique the breadth and depth of the existing pharmacovigilance initiatives.
10. Investigate drug-drug interactions as part of safe drug development.
11. Analyze the quality of existing safe drug administration, storage, and supply chain management.
12. Appraise legal and regulatory considerations related to drug safety.

Course Topics:

- Key methods of assessing safety of pharmaceutical products
  - Definitions; Code of Federal Regulation definition of a drug;
  - Risk/benefit analysis; typical drug safety concerns; phases of drug testing; toxicity
- Advertising, labeling, and promotion of pharmaceuticals
- Additional indications for existing drugs
- Safety signals; evaluating safety data
- Study bias, execution, auditing, and subject selection (e.g., testing drugs on homogenous populations)
- Influence of direct-to-consumer marketing
- Post approval studies to evaluate products
  - Studies and ethical considerations in the evaluation of safety
  - Studies designed to complement marketing campaigns
- Development and approval of follow-up product
  - Review of follow-up products
- Off-label use
  - Case studies
- Rare, unexpected side effects
  - How safe is safe? exploring risk
  - Globalization of data sharing
  - Biosimilars
- Recalls, Warnings, Reporting requirements
  - Risk evaluation and mitigation strategies (REMS);
  - Black box warnings, dear doctor letters, Medwatch, mandatory and voluntary recalls, classification of recalls
- Pharmacogenomics
  - Personalized medication, regulatory issues, compounding, quality control
- Pharmacovigilance
  - Data monitoring, reporting requirements and guidelines
  - Critical Pathway
  - QT syndrome, hepatic symptoms
- Drug-Drug interactions
  - Sentinel events
  - Special patient groups: pregnancy and teratogenesis, pediatrics, geriatrics, obesity
- Safe administration of drug products
  - Error avoidance, new technologies, production, storage, compliance, expiration dating
- Legal and Regulatory Issues
  - Mass Tort litigation, liability, and regulatory issues related to pharmaceutical safety
Course Description:

Writing and presentation skills critical for regulatory professionals in the medical products industry.

Prerequisite:

Prerequisite: NURSING 7770 (Fundamentals of Medical Product Regulatory Affairs), or permission of instructor.

Objectives:

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

1. Construct coherent written regulatory documents using “Plain Language” techniques.
2. Synthesize valid, scientific information to support regulatory decisions.
3. Appraise supporting regulatory documents and exhibits (e.g. laboratory records, adverse event reports) for appropriate use in argument development.
4. Defend conclusions which have been developed for use in a mock FDA advisory panel using practiced oral and written “Plain Language” techniques.
5. Constructively critique written documents and oral presentations.
6. Evaluate and revise content and organization of written documents and oral presentations.

Course Topics:

- Plain language approach to creating regulatory documents
- Analyzing the purpose and audience for the document or presentation
- Information gathering and support, use of exhibits
- Plain language techniques (writing, revising and editing)
- Avoiding common pitfalls; jargon; proper use of acronyms; common errors
- Preparing, presenting and defending a presentation
- Writing standard operating procedures (SOPs), policies and procedures
- Creating formal letters and responses
- Reports and scientific reviews
- Creating tables, graphs and other visual aids
- Preparation of documents for Mock FDA Panel Meeting
- Enact mock FDA Panel Meeting
Course Description:

Examination of the regulation of medical products (drugs, medical devices, and biologics) by the Food and Drug Administration (FDA). Consumer protection laws and regulations affecting the traditional pharmaceutical industry and emerging biotechnology and genomics industries. Special consideration of regulations which apply to life science companies or medical research institutions.

Prerequisite:

Admission to the Master’s program in Applied Clinical and Preclinical Research or permission of the instructor.

Objectives:

Upon completion of this course, the student will demonstrate an understanding of:

1. FDA jurisdiction of medical products and licensure of new drugs.
2. Regulation of medical products, including prescription drugs, over-the-counter drugs, vitamin and mineral supplements, biologics and blood products, organ and tissue transplants, medical devices, and new biotechnologies.
3. Regulation of physician prescribing.
4. State regulation of drugs and medical devices.

Topics:

- Introduction to Food & Drug Law
- FDA Jurisdiction and Human Drugs
- General Requirements and FDA Licensure of New Drugs
- Regulation of Over-the-Counter Drugs
- Regulation of Physician Prescribing
- Biologics and Blood Products
- Organ and Tissue Transplants
- Medical Device Amendments
- Regulation of Carcinogens
- Regulation of New Biotechnologies
- Regulation of Vitamin- Mineral Supplements
- State Regulation of Drugs and Devices
- FDA Enforcement
- FDA Practice and procedure
Course Description:

Introduction to organ system studies of current experimental models, risk assessment, and regulatory guidelines for evaluating drug candidates in various organ systems.

Prerequisite:

Admission to the Master’s program in Applied Clinical and Preclinical Research or permission of the instructor.

Objectives:

Upon completion of the course, the student will be able to:

1. Identify undesirable pharmacodynamic properties of a substance that may have relevance to its human safety.
2. Evaluate adverse pharmacodynamic and/or pathophysiological effects of a substance observed in toxicology and/or clinical studies.
3. Understand the concentration-response relationship for any effect on major physiological systems that may be predictive of adverse events in animals and humans.
4. Appraise possible mechanism of an observed and/or suspected adverse pharmacodynamic effect.

Course Topics:

- In vivo and in vitro experimental models
- Data analysis and risk assessment
- Animal welfare concerns
- Regulatory guidelines of the United States
- Fundamentals of processes and procedures of safety pharmacology
- Fundamentals of Good Laboratory Practice (GLP)
The Ohio State University

ORGAN SYSTEM TOXICOLOGY
Pharmacy 7582

3 semester credit hours

Course Description:

Actions of drugs on the nervous, cardiovascular, and pulmonary systems, in both normal and disease conditions. Principles of physiology and pharmacology as they relate to adverse and unanticipated drug effects.

Prerequisite:

Admission to the Master’s program in Applied Clinical and Preclinical Research or permission of the instructor.

Objectives:

Upon completion of the course, the student will be able to:

1. Understand the basic principles and applications within the science of toxicology.
2. Understand basic principles of function of the nervous system, cardiovascular system, and pulmonary system.
3. Understand the effects of selected toxicants on the nervous system, cardiovascular system, and pulmonary system.
4. Recognize different populations at risk based on past history, age, geography, and occupational and environmental exposures.

Course Topics:

Principles of toxicology

- Basic cell biology
- Mechanisms by which proper cell function can be disturbed

Nervous system:

- Basic biology of neurons
- Synaptic physiology
- Pharmacological targets:
  - Voltage-gated channels and their effect on action potential generation and propagation
  - Central GABAergic systems
  - Central noradrenergic and serotonergic systems
  - Central dopaminergic systems
  - Central opiate systems
  - Central cholinergic and glutamatergic systems
  - Peripheral cholinergic and noradrenergic systems

Cardiovascular system:
• Basic anatomic and physiological principles of the cardiovascular system
• Neuro-hormonal as well as metabolic control of cardiovascular function
• Pathophysiology of various cardiovascular diseases
• Pharmacology and pharmacotherapy of agents used in management of cardiovascular disease
• Effects of toxins on the cardiovascular system

Pulmonary system:
• Function and structure of the respiratory system
• Ventilation, diffusion, and exchange of respiratory gases
• Blood flow and metabolism in lungs
• Ventilation-perfusion relationships in the lungs
• Neural control of breathing
• Autonomic pharmacology as it relates to the respiratory system
  o Fundamentals of pulmonary pathologies
Course description: This course will provide a solid foundation in efficiently, effectively, and ethically using animal models to investigate the safety of novel medical products and devices.

Target audience: Graduate students (distance) engaged in safety pharmacology research using various laboratory animal species

Course format: Lecture (online access to course materials)

Course frequency: Online (at student’s pace) within a 14-week semester

Instructor(s):
- Leader: Co-leaders (ULAR representative and VBS representative)
- Instructors: Veterinary Biosciences [VBS] - multiple
  University Laboratory Animal Resources [ULAR] - multiple

Course objectives: This course will provide a solid foundation in efficiently, effectively, and ethically using animal models to investigate the safety of novel medical products and devices.

Students who pass the course will have demonstrated their understanding of animal modeling as a tool for safety pharmacology, emphasizing such topics:

- Review basic principles of safety pharmacology
- Introduce concepts of comparative biology, medicine, and pathology as embodied in various animal models used in biomedical research
- Learn how to design, conduct, analyze, and interpret safety pharmacology studies in animals
- Understand the criteria for selecting the most appropriate animal model

Course Topics

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4 *Comparative Biology of Laboratory Animals*
- Biology of Laboratory Animals
- Comparative Pharmacology of Animals and Humans
- Genetics of Laboratory Animals
- Environmental Influences on Laboratory Animals
- Microbiology of Laboratory Animals

5 *Basic Procedures for Animal Care*
- Marking/Handling/Experimental Methods
- Fertility/Immunizations
- Humane Endpoints and Euthanasia
- Anesthesia and Surgery

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| 7     | *Animal Modeling in Safety Pharmacology* |
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|       | Basic Safety Pharmacology Methods: Function |
|       | Basic Safety Pharmacology Methods: Structure |
|       | Advanced Safety Pharmacology Techniques |
|       | Statistical Design in Safety Pharmacology |
|       | Reporting Safety Pharmacology Data      |

| 8     | *Primary Concerns in Safety Pharmacology* |
|       | Cardiovascular Dysfunction               |
|       | Central Nervous System                    |
|       | Digestive System                          |
|       | Immune System                             |
|       | Respiratory System                        |
|       | Urinary System                            |
|       | Other Topics                              |

**TOTAL COVERAGE**
The Ohio State University

APPLIED PHARMACOKINETICS AND PHARMACODYNAMICS
Pharmacy 7584

3 semester credit hours

Course Description:

Introduction to basic and advanced concepts in pharmacokinetics, pharmacodynamics, and pharmacology for clinical investigators and other research professionals participating in the conduct of clinical trials.

Prerequisite:

Prior coursework in pharmacology. Not open to students with credit for Pharmacy 731, 732, 733; Pharmacy 802; Pharmacy 7310 and 7320; or Pharmacy 8020.

Objectives:

To provide course participants with an understanding of:
1. the role of pharmacokinetics (PK) in clinical drug development,
2. the relationship between PK and in vivo drug activity and efficacy (i.e. pharmacodynamics, PD),
3. drugs based on their clearance, volume of distribution, bioavailability, mechanism of elimination, and protein binding,
4. primary clinical pharmacokinetic literature,
5. individualized drug therapy in patient populations given PK estimates for that population and knowledge of the disease state,
6. drug concentration-time data and the ability to make recommendations regarding dosage regimens.

Course Topics:

a. The role of PK analysis in clinical drug development
b. Use of pre-clinical PK and PD information in early clinical trials
c. PK and PD modeling
d. Hepatic and renal clearance
e. Protein binding
f. Dosing schedules – effect on activity and toxicity
g. Drug metabolism and metabolite PK
h. Drug interactions
i. Pharmacologic response
j. Pharmacogenetics
THE OHIO STATE UNIVERSITY
GRADUATE SCHOOL
Department of Nursing
Nursing 7450
Pathophysiology of Altered Health States
Fall Semester, 2012
4 Credit Hours – Hybrid format

Faculty:

Teaching Associate:

Prerequisites: Grad standing in Nursing or permission of Instructor

Course Description: Analysis of theories and research regarding alterations of health states across the life span, with an emphasis on pathophysiological processes.

The AACN Essentials of Master’s Education for Advanced Nursing Practice (2011) were used to guide course development.

Course Objectives: The student will be able to:
1. Analyze the relationship between normal physiology and pathophysiological phenomena produced by altered health states across the life span.
2. Synthesize the current state of knowledge regarding the pathophysiological changes in selected disease states.
3. Describe the developmental physiology, normal etiology, pathogenesis and clinical manifestations of specific altered health states.
4. Articulate the relationship between the pathophysiologic processes and advanced nursing and/or pharmacologic interventions for disease states across the life span.

Carmen Online Technical Information: All course content, including grades, will be available via Carmen, The Ohio State University’s course management system, at: http://carmen.osu.edu. Carmen requires the use of your UNIVERSITY login and password (lastname.#). After you log in, your homepage will display a list of all your registered courses for the quarter. Select ’N 7450’ to enter the course. Information concerning your University email and login account can be found at https://acctmgt.service.ohio-state.edu/.
As part of Carmen, your homepage after you log in will reflect all courses that you are taking across the University. 24 hour technical support can be reached at: Carmen/TEL R - Phone: 614-688-4357 (688-HELP) or through the Carmen Help Web page at: http://telr.osu.edu/carmen/help/index.htm

**Conduct of Courses:** This is a mixed media course that is presented through the use of mixed media. The course will consist of a 2-2 ½ hour recorded lecture twice per week that can be accessed through Carmen. **Students are expected to attend class, listen to all recorded powerpoints, participate in 2 case studies, take all 4 midterms and final exam.**

**Textbook:**

**Required:**

**Evaluation:**

A. **Case studies (2) – short answers/video** 10% each = 20%

This is a small group assignment in which each member of the group will receive the same score. You will choose one case study from the 2 choices presented for each assignment. **You are to work in groups of 4.** You can choose different group members for each case study. Feel free to discuss the cases between groups, but do not copy responses from one group to the next. There will be 4 main questions for each cast study. The first question will be worth 20 points, the remaining 3 questions will be worth 25 points each and APA format is worth 5 points.

First Case Study Due:  
Second Case Study Due:

**Requirements for each paper: Page 1:** title page that includes a list of the group members; **Pages 2 & 3:** answer(s) to questions - double-spaced following APA format (6th edition-2010); **Page 4:** reference list - citations should be used throughout the paper. You are expected to review the current literature, cite published articles and use a variety of resources including current guidelines. Submit each Case Study in the dropbox on the course website by the due date. **One submission for each group for each case study. Do not exceed the page limit.** Save the file as your groupname.case # (e.g. GoBucks.case 1). **DO NOT SUBMIT THE ACTUAL CASE STUDY.**

ISWAT: Videos of a pt/NP discussion will be made by each group in the lab in the basement. Details regarding this project will be shared after the start of class.
Papers will be submitted on time unless previous arrangements have been made with the faculty instructor. Late papers without previous arrangement will receive 5 percentage point deductions for each day late.

C. Midterm Exam  \[15\% \times 4 \text{ exams}=60\%\]
In Class Room 172 Newton, Dates TBA

D. Final Exam  \[20\%\]
In Class Room 172 Newton, Date TBA

The midterms and final exams will be paper/pencil exams that will be taken at the College of Nursing. Each exam will consists of a combination of multiple choice, True/False and matching questions.

F. Bonus Case Study – individual assignment \[1\%\]
Choose and sign up for a content area from choices listed on course website. NO pediatric case studies are accepted. Develop case study. Compose and answer a minimum of 3 questions that demonstrate your knowledge of the topic – answers should relate to the case study. The first question should ask for differential diagnoses (other diseases/conditions that might be responsible for the patient’s presentation and what signs/symptoms rule out the various differential diagnoses).

Requirements: Page 1: Title page; Page 2: Case Study; Page 3: Short answers; Page 4: References. APA format.

Grades will be assigned as follows:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>93-100</td>
</tr>
<tr>
<td>A-</td>
<td>90-92</td>
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<tr>
<td>B+</td>
<td>87-89</td>
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<td>B</td>
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<td>D</td>
<td>60-66</td>
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<td>E</td>
<td>&lt;59</td>
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</table>

Academic and Professional Misconduct:
Students are subject to the provisions in the “Code of Student Conduct” (copies located in: Student Affairs, Room 236 Newton Hall, Office of Student Life, Room 464 Ohio Union or online at [http://studentaffairs.osu.edu/resource_csc.asp](http://studentaffairs.osu.edu/resource_csc.asp)) and also the Professional Standards (The OSU CON Student Handbook). Failure to comply with these policies will be handled as outlined in the respective documents.

Students with Disabilities:
Students requesting accommodation for disability or health reasons are responsible for notifying the Course Head by the end of the first week of the quarter to discuss specific needs. Self-identification is the only way to assure that the faculty member can make the appropriate accommodation. Students should provide a letter from the Office for Disability Services (150 Pomerene Hall, 1760 Neil Avenue; (614) 292-3307; TDD: (614) 292-0901) to verify the disability. If you have not previously contacted the Office of Disability Services, I encourage you to do so at (614) 292-3307 (V) or (614) 292-0901 (TDD)
<table>
<thead>
<tr>
<th>Week Date</th>
<th>Topic/Lectures</th>
<th>Textbook Readings/Articles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1 Day 1</td>
<td>Structure of Human Cell, Tissue biology, cellular environment</td>
<td>Text p. 1-125 Current article</td>
</tr>
<tr>
<td>Week 1 Day 2</td>
<td>Genes and Gene environment/interaction</td>
<td>Text p. 126-182 Current article</td>
</tr>
<tr>
<td>Week 2 Day 1</td>
<td>Inflammation and Immunity Alterations in inflammation/immunity</td>
<td>Text p. 183-292 Current article</td>
</tr>
<tr>
<td>Week 2 Day 2</td>
<td>Principles of Infection</td>
<td>Text p. 293-335 Current article</td>
</tr>
<tr>
<td>Week 3 Day 1</td>
<td>Stress and Disease</td>
<td>Cancer online Text p. 336-395 Current article</td>
</tr>
<tr>
<td>Week 3 Day 2</td>
<td>Midterm #1 Neurological disorders</td>
<td>Text p. 442-280 Current article</td>
</tr>
<tr>
<td>Week 4 Day 1</td>
<td>Neurological disorders, con’t Hormonal regulation</td>
<td>Text p. 696-780 Current article</td>
</tr>
<tr>
<td>Week 4 Day 2</td>
<td>Pain, Temperature, Sleep</td>
<td>Text p. 481-524, Current article</td>
</tr>
<tr>
<td>Week 5 Day 1</td>
<td>Pain, Temperature, Sleep, con’t</td>
<td>Current article</td>
</tr>
<tr>
<td>Week 5 Day 2</td>
<td>Hematologic System Hematologic Disorders</td>
<td>Text p. 952-1061 Current article</td>
</tr>
<tr>
<td>Week 6 Day 1</td>
<td>Midterm #2 Alteration in Neurobiology</td>
<td>Text p. 624-664 Current article</td>
</tr>
<tr>
<td>Week 6 Day 2</td>
<td>Alteration in Neurobiology, con’t</td>
<td>Current article</td>
</tr>
<tr>
<td>Week 7 Day 1</td>
<td>Renal &amp; Urologic Systems</td>
<td>Text p.1344-1401 Current article</td>
</tr>
<tr>
<td>Week 7 Day 2</td>
<td>Digestive Systems</td>
<td>Text p.1420-1515 Current article</td>
</tr>
<tr>
<td>Week 8 Day 1</td>
<td>Musculoskeletal System and Dysfunction</td>
<td>Text p.1540-1617 Current article</td>
</tr>
<tr>
<td>Week 8 Day 2</td>
<td>Midterm #3 Alterations in Cardiovascular System</td>
<td>Text p. 1644-1679, Chpt 29 Current article</td>
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<tr>
<td>Week 9 Day 1</td>
<td>Alterations in Cardiovascular System, con’t</td>
<td>Text Chpt 29-30 NEJM EKG practice strips</td>
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<tr>
<td>Week 9</td>
<td>Alterations in Pulmonary System: NEJM CXR interpretation Text Chpt 32-33 Current article</td>
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<td>Day 2</td>
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<td>Week 10</td>
<td>Alterations in Pulmonary Function: con’t</td>
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<tr>
<td>Day 1</td>
<td>Text Chpt 32-33 Current article</td>
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<tr>
<td>Week 10</td>
<td>Alterations in Digestive Function</td>
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<tr>
<td>Day 2</td>
<td>Text Chpt 38-39 Current article</td>
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<tr>
<td>Week 11</td>
<td>Alterations in Neurologic System</td>
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<tr>
<td>Day 1</td>
<td>Text Chpt 14,16,17 Current article</td>
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<tr>
<td>Week 11</td>
<td>Alterations in Sensory Function</td>
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<tr>
<td>Day 2</td>
<td>Text Chpt 15 Current article</td>
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<tr>
<td>Week 12</td>
<td>Midterm #4</td>
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<tr>
<td>Day 1</td>
<td>Current article</td>
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<tr>
<td>Week 12</td>
<td>Alteration in Musculoskeletal System:</td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>Breast cancer online, Chpt 11 Text Chpt 41-42 Current article</td>
<td></td>
</tr>
<tr>
<td>Week 13</td>
<td>Alterations of Female and Male Reproductive Systems:</td>
<td></td>
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<tr>
<td>Day 1</td>
<td>*Case study #2 Text Chpt 22-23 Current article</td>
<td></td>
</tr>
<tr>
<td>Week 13</td>
<td>Sexually Transmitted Infections: HIV/AIDS</td>
<td></td>
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<tr>
<td>Day 2</td>
<td>Text Chpt 24, p. 318-325 Current article</td>
<td></td>
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<tr>
<td>Week 14</td>
<td>Alterations in Skin Function</td>
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<tr>
<td>Day 1</td>
<td>Text Chpt 44 Current article</td>
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<tr>
<td>Week 14</td>
<td>Multiple Organ Dysfunction</td>
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<tr>
<td>Day 2</td>
<td>Text Chpt 46 Current article</td>
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<tr>
<td>Finals week</td>
<td>Final Exam</td>
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</tbody>
</table>
SCHOOL OF HEALTH AND REHABILITION SCIENCES
PATHOPHYSIOLOGY 5500,
FIRST SEMESTER SESSION, 2012

4 Credits

Optional, Recitation Class Meeting, One Per Week, Atwell Hall, Room 327, Fridays, 2:20 to 3:40pm

Faculty; Steve G. Moon, M.S., FAMI, CMI, Instructor, Medical Illustrator; www.moonmedart.com
Office, 543 Atwell Hall, 614-292-0442; Email, Stephen.Moon@osu.edu or smoon25@msn.com
Office Hours; Tuesday, Wednesday, Thursday 1 to 4pm or by Appointment, times can be arranged to accommodate student schedules

Require Web: Functional Access to CARMEN "Desire to Learn", site

Because of the technical language of pathophysiology, students will often need to use Anatomy, Medical Dictionary and Terminology Texts, Some suggestions include:


Medical Terminology text reference- "Medical Terminology, An Illustrated Guide", Cohan; Lippincott
"Medical language", Allan, Lockyer; McGraw-Hill

Prerequisites: Semester Equivalent for Physiology, Permission of Instructor, only given with higher level courses than required completed
(SHRS Majors, suggested, not required, preparatory courses include; Human Anatomy, Medical Terminology for best preparation

Class Modules; Weekly Recitation; Quizzes-Clinical Studies/ Example Examinations, Examinations, available from CARMEN site, Use of material on Carmen is described later in this syllabus

Course Description: How disrupting normal structures and functions of the human body leads to development of disease processes from the cellular to the multi-system level. Explanation of the major concepts of pathophysiology including etiology, signs, symptoms, diagnosis, treatment and complications of major body system disorders.

Course Overview: Pathophysiology 5500 is designed to give the student whose career goal is dealing with the healthcare of people, directly or indirectly, background in the basic pathological mechanisms that cause illness. The vocabulary of pathology and a basic understanding of fundamental disease mechanisms is something that all health professionals share in common. The course will provide an elementary and broad understanding of major body system disorders as related to the etiology, signs, symptoms, diagnosis, treatment and complications of these disorders.

Course Objectives:
1. Based on prerequisite knowledge of normal structure and functioning of the human body, identify and describe abnormal physiological disorders in the human population, using associated terms
2. Explain how disease affects and is manifested in the interrelated systems of the human organism.
3. Explain the physiological basis for the etiology, pathology, signs, symptoms, diagnostic procedures, treatments, and common complications of selected disease conditions
4. Think critically about the human body.

QUIZZES and CASE STUDIES:
Students are expected to take all Quizzes / Case Studies online as scheduled. They can be found during their open times in the Quizzes / Case studies folders in Carmen. (Please see Evaluation and Grading Scale for grading specifics and Course Calendar and for quiz dates and times.) Students may NOT make up quizzes / Case Studies for any reason.
If a student is unable to take these online for any reason (including but not limited to technology problems, family emergency, and illness) the problem will be evaluated individually.

Students are strongly urged to plan ahead and to take all quizzes / Case Studies regardless of current circumstances. Students should take all quizzes / Case Studies on a secure, high-speed web connection on campus to avoid technology problems. If disrupted due to campus-wide CARMEN or server problems, the open time will be extended, Instructor will know when this happens.

Think of the quizzes / Case Studies as learning tools, not just as assessment tools. You are encouraged to work together and use notes and the text. Quiz and Exam difficulty are similar. Use the quizzes as a way to gage your understanding of content. Preparing for a quiz as you would for an exam will help you know whether you are studying adequately and gaining an appropriate understanding prior to taking an exam. Also PLEASE DO NOT FORGET TO GO OVER AND UNDERSTAND THE “SAMPLE EXAM”, provided in each Exam Module on Carmen. The Sample Exam is very comprehensive in depth of difficulty and breath of material covered. Use the Sample exam as a measure of your understanding by printing a copy and take out the answers provided, as you go through the Sample Exam. Since the Sample Exam has the same Multiple Choice format as the actual exam that will be taken, it is advisable to understand why the incorrect choices are INCORRECT and NOT just know the correct answer.

Each quiz and Sample Exam will cover all topics listed on the course calendar since the previous exam.

**EXAMINATIONS, DATES, ALL EXAMS TAKEN ON CARMEN, ON DATES INDICATED:**

**PLEASE NOTE THAT MATERIAL MAY BE REARRANGED, FROM EXAM TO EXAM, BUT EXAMS DATES CAN NOT BE CHANGED, EXAMINATIONS ARE ONCE EVERY TWO WEEKS, TOTAL OF 8 EXAMINATIONS**

**EXAM MODULE I, TIME/DATE: SEPT. 7, 8:00AM TO 11:30PM, ON CARMEN SITE**
COVERS CHAPTERS 2, 3, 4; – RECITATIONS AVAILABLE.
THE CARMEN CHAPTER- MP QUIZZES, CASE STUDIES, AND ORGAN/SYSTEMS DISEASE ANALYSIS MUST BE FINISHED BEFORE THE EXAMINATIONS ARE TAKEN ON CARMEN

**EXAM MODULE II, TIME/DATE: SEPT. 21, 8:00AM TO 11:30PM, ON CARMEN SITE**
COVERS CHAPTERS 6, 7, 8; – RECITATIONS AVAILABLE.
THE CARMEN CHAPTER- MP QUIZZES, CASE STUDIES, AND ORGAN/SYSTEMS DISEASE ANALYSIS MUST BE FINISHED BEFORE THE EXAMINATIONS ARE TAKEN ON CARMEN

**EXAM MODULE III, TIME/DATE: OCT. 5, 8:00AM TO 11:30PM, ON CARMEN SITE**
COVERS CHAPTERS 10, 11, 12; – RECITATIONS AVAILABLE.
THE CARMEN CHAPTER- MP QUIZZES, CASE STUDIES, AND ORGAN/SYSTEMS DISEASE ANALYSIS MUST BE FINISHED BEFORE THE EXAMINATIONS ARE TAKEN ON CARMEN

**EXAM MODULE IV, TIME/DATE: OCT. 19, 8:00AM TO 11:30PM, ON CARMEN SITE**
COVERS CHAPTERS 13, 14 15; – RECITATIONS AVAILABLE.
THE CARMEN CHAPTER- MP QUIZZES, CASE STUDIES, AND ORGAN/SYSTEMS DISEASE ANALYSIS MUST BE FINISHED BEFORE THE EXAMINATIONS ARE TAKEN ON CARMEN

**EXAM MODULE V, TIME/DATE: NOV. 2, 8:00AM TO 11:30PM, ON CARMEN SITE**
COVERS CHAPTERS 16, 18, 19 – RECITATIONS AVAILABLE.
THE CARMEN CHAPTER- MP QUIZZES, CASE STUDIES, AND ORGAN/SYSTEMS DISEASE ANALYSIS MUST BE FINISHED BEFORE THE EXAMINATIONS ARE TAKEN ON CARMEN

**EXAM MODULE VI, TIME/DATE: NOV. 16, 8:00AM TO 11:30PM, ON CARMEN SITE**
COVERS CHAPTERS 20, 22, 23; – RECITATION AVAILABLE.
THE CARMEN CHAPTER- MP QUIZZES, CASE STUDIES, AND ORGAN/SYSTEMS DISEASE ANALYSIS MUST BE FINISHED BEFORE THE EXAMINATIONS ARE TAKEN ON CARMEN

**EXAM MODULE VII, TIME/DATE: NOV. 30, 8:00AM TO 11:30PM, ON CARMEN SITE**
COVERS CHAPTERS 25, 29, 30 – RECITATION AVAILABLE.
THE CARMEN CHAPTER- MP QUIZZES, CASE STUDIES, AND ORGAN/SYSTEMS DISEASE ANALYSIS MUST BE FINISHED BEFORE THE EXAMINATIONS ARE TAKEN ON CARMEN

**EXAM MODULE VIII, TIME/DATE: DEC. 11, 8:00AM TO 11:30PM, ON CARMEN SITE**
COVERS CHAPTERS 32, 37, 39/40 – RECITATION AVAILABLE.
THE CARMEN CHAPTER- MP QUIZZES, CASE STUDIES, AND ORGAN/SYSTEMS DISEASE ANALYSIS MUST BE FINISHED BEFORE THE EXAMINATIONS ARE TAKEN ON CARMEN
THE QUIZ, CASE STUDY, ORGAN/SYSTEMS DISEASE ANALYSIS, AND EXAMINATION GRADES WILL BE AVAILABLE ON CARMEN WHEN STUDENT FINISHES EACH SECTION EXAMINATION MODULE

Students are expected to take all quizzes and exams as scheduled on Carmen. Students are strongly urged to take all exams regardless of current circumstances. If a student is suspected of cheating during an exam, he/she may be asked to change seats. For further policies on cheating, see Academic misconduct.

CARMEN INSTRUCTIONAL MODEL:
PLEASE BE AWARE THAT Pathophysiology 5500 is nor a COURSE ABOUT HOW TO USE CARMEN. CARMEN IS A NECESSARY COMMUNICATION MEDIA AND NOT AN ELEMENT OF STUDY AND EXAMINATION. THEREFORE CARMEN WILL BE UTILIZED AS NEEDED. THE STUDENT SHOULD SPEND AS MUCH TIME AS POSSIBLE STUDING THE PORTH TEXT, STUDY GUIDES, PRACTICE EXAMS, QUIZZES AND CASE STUDIES.

To be successful in using the Carmen courses, it is important that you use a fully supported browser and meet basic system requirements identified on the following link— http://telr.osu.edu/carmen-help/common/terms/browsers.htm. Help for using common Carmen tools is available through the links in the “Student Guide” available on http://elearning.osu.edu/carmen help/students/index.htm

Students need reliable access to the CARMEN course management system. Students also need recent version of Adobe Reader to download and access PDF documents. If you have problems accessing any files on CARMEN, always call the CARMEN Help Line. They can answer any CARMEN-related questions.

The Quizzes and Case Studies are taken on Carmen, by the dates indicated by Examination module.

The Structure of Required Learning Material available from Carmen, Study procedure:
I. ALL MATERIAL FOR EACH EXAM IS UNDER “EXAMINATION MODULE, (I TO VIII), INCLUDING:
   A. PRINT OUT THE “STUDY GUIDES” FOR EACH CHAPTER IN EACH EXAMINATION MODULE
   B. FINISH EACH QUIZ AND CASE STUDY FOR EACH EXAMINATION MODULE
   C. REVIEW AND UNDERSTAND THE SAMPLE EXAM FOR EACH EXAMINATION MODULE

STUDY INTERACTION REQUIREMENTS AND EVALUATION
Each of the Examination Modules is comprised of two graded activities. The student must successfully complete the online Quizzes and Case Studies, and Exams to achieve a passing grade.

1. Three chapters comprise each of the Eight Examination Modules, with each Exam Module having two graded activities -
   The 8 Quizzes are 25 points each Examination Module, Total 200 points
   The 8 Case Studies are 15 points each Examination Module, Total 120 points
   The 8 Examinations are 60 points each Examination Module, Total 480 points
   Total Number of Points is, 800, divided by to get the % and letter grade

2. Eight exams are given on Specific Days ONLY, as listed on page 2

   NOTE: Each exam will be available on the scheduled date ONLY.

There will be no make-up exams. The only exception, at the instructor’s discretion, will be arranged with the instructor PRIOR to the scheduled exam date, and ONLY if the student has a valid excuse. Each of the 8 exams consists of multiple choice questions, 60 total selected from the chapters of study, study guides and word lectures. The form of the Examinations is exactly as the Sample Exam is structured. Questions will be taken from the Porth text chapters, as outlined by the Chapter Study Guide and Word Lectures. ANY “MAKE-UP” EXAMINATIONS WILL BE TAKEN IN ROOM 543 AT A TIME ARRANGED. EXAMS WILL NOT BE REACTIVATED ON THE HRS 5500 CARMEN SITE. STUDENTS RESCHEDULING EXAMS WILL TAKE EXAMS FROM THE COMPUTER TERMINAL IN ROOM 543.

Grade breakdown:

Carmen Examination Modules:
Quizzes, 8  
25 X 8 = 200 Points
Case Studies, 8  
15 X 8 = 120 Points
Examinations, 8  
60 X 8 = 480 Points
TOTAL  
800 Points

* SAMP LOWEST PASSING GRADE

Grading Scale:

A  
93 – 100%
A-  
90 – 92%
B+  
87 – 89%

B  
83 – 86% Grad.
B-  
80 – 82%
C+  
77 – 79%
C  
73 – 76%

C-  
70 – 72%
D+  
67 – 69%
D  
63 – 66%
D-  
60 – 62%
E  
59% & below
FINAL TOTAL POINTS DIVIDED BY 8 TO CALCULATE FINAL SCORE AND LETTER GRADE: EXAMPLE: TOTAL SCORE IS 658, TO FIGURE %, LETTER GRADE: DIVIDED BY 8 = 82.25, B-, (82.9999, IS STILL B-) THERE WILL BE NO “ROUNDING OFF” OF NUMERIC SCORE, FINAL SCORE TAKEN TO 00.00 PLACE

INSTRUCTOR

Steve G. Moon, M.S., C.M.I., F.A.M.I. received his Bachelor of Science Degree in Medical Illustration from The Ohio State University College of Medicine and his Master of Science Degree in Medical and Biological Illustration from the University of Michigan. His career in medical illustration began in the Department of Anatomy at the University of Arkansas, and then at Spenco Medical Corporation in Texas. Mr. Moon returned to The Ohio State University to teach and coordinate for the Medical Illustration Program in the Division of Biomedical Communications, the School of Allied Medical Professions, the College of Medicine. Tenure was granted in 1987. In recent years, with Medical illustration, Mr. Moon has also been teaching courses in pathophysiology and anatomy and medical terminology in the School of Health and Rehab. Sciences.

STUDENTS RESOURCES

1. Allied Med Homepage - amp.osu.edu
2. E-mail Activation, Management and Forwarding- https://acctmgt.service.ohio-state.edu/
3. Master Schedule of Classes - www.ureg.ohio-state.edu/courses
5. OSU WebMail- https://webmail.osu.edu/

STUDENTS WITH DISABILITIES

If you need an accommodation based on the impact of a disability, contact your instructor to discuss your specific needs. The Office for Disability Services is located in 150 Pomerene Hall, 614-292-0567, http://ods.osu.edu/. This office coordinates reasonable accommodations for students with documented disabilities.

ACADEMIC MISCONDUCT POLICY

Students are expected to maintain standards of professionalism in regard to academic performance and are expected to protect the integrity of their work at all times. Academic misconduct will not be tolerated. The University defines academic misconduct as any activity that tends to compromise the academic integrity of the institution or subvert the educational process. Examples of academic misconduct include, but are not limited to violation of course rules, providing or receiving information during quizzes and examinations, and submitting plagiarized work for an academic requirement. It is very important to submit your own work. The Internet presents temptation to “borrow” others words so be careful to appropriately reference the work of others. Alleged academic misconduct will be referred to the University’s Committee on Academic Misconduct. This committee is charged with maintaining the academic integrity of the University by establishing procedures for and investigating all reported cases of alleged academic misconduct by students and determining suitable disciplinary action if necessary. Visit http://oaa.osu.edu/coam.html for more information.

FEEDBACK AND CONTINUOUS QUALITY IMPROVEMENT

Students are encouraged to provide feedback throughout the quarter in order that we may continually fine-tune the coverage level and the teaching/learning processes used in our courses. As the instructor, my goal is to stimulate an atmosphere that encourages self-directed learning. I welcome the opportunity to meet to discuss your learning needs during office hours or schedule a meeting.
THE USE OF CARMEN COMPONENTS FOR EXAMINATION STUDY AND COMPLETION OF THE QUIZZES AND CASE STUDIES WILL BE PRESENTED IN LECTURE AS FOLLOWS:

I. IN CARMEN, SHRS 5500, STUDY IS ORGANIZED INTO EIGHT SECTIONS TERMED, "EXAMINATION MODULES"

II. EACH EXAMINATION MODULE CONTAINS ALL THE INFORMATION NEEDED TO DIRECT YOUR TEXT STUDY FOR EACH EXAMINATION, EXAMINATION MODULES ARE ORGANIZED AS FOLLOWS:
   A. A "STUDY GUIDE", THAT OUTLINES THE SPECIFIC MATERIAL COVERED ON EACH EXAMINATION, FROM YOUR TEXT READINGS WITH EXAM DATE, TIME, COVERING THE THREE CHAPTERS EACH
   B. QUIZ, CASE STUDY AND QUIZ COMPLETION
   C. SAMPLE EXAM
   D. WORD FILE OF THE POWERPOINT LECTURE MATERIAL, YOU NEED TO TAKE NOTES AS YOU READ THE TEXT

THE PORTH TEXT AND EXAMINATION MODULE "STUDY GUIDE"

I. THE STUDY GUIDE OUTLINING THE MOST IMPORTANT CONCEPTS IN THE PORTH TEXT ARE TO BE USED IN CONCERT, IN THE FOLLOWING MANNER:
   A. PRINT OUT THE STUDY GUIDE AND REVIEW THE WORD LECTURES FOR EACH CHATER
   B. READ THE PORTH TEXT CHAPTERS WITH THE STUDY GUIDE, NOTE HOW THE STUDY GUIDE OUTLINES THE MOST RELEVANT CONCEPTS, PROCESSES AND TERMS.
   1. PLEASE NOTE THAT YOU SHOULD NEVER ONLY READ THE STUDY GUIDE WITHOUT THE PORTH TEXT AT HAND, THE EXAM MATERIAL REQUIRES YOU TO UNDERSTAND THE MATERIAL WITH THE FULL DESCRIPTIONS, TEXT ILLUSTRATIONS, TABLES, ETC.
   2. THE MATERIAL THAT IS NOT OUTLINED SPECIFICALLY WILL NOT BE COVERED ON THE EXAMS. OFTEN THE MATERIAL NOT INCLUDED IS INDICATED BY "SUBJECT TITLE - NOT COVERED", PHRASE

II. MATERIAL IN TEXT IS FOLLOWED PAGE BY PAGE IN THE STUDY GUIDES, BUT SINCE SOME MATERIAL IS NOT COVERED, MATERIAL FOR THE EXAMS IS INDICATED BY SUBJECT / TITLE NOT ALWAYS BY PAGE NUMBERS

III. THE TEXT, STUDY GUIDE AND WORD LECTURES HAVE MATERIAL FOR THE EXAMINATIONS. YOU WILL NEED TO BE FAMILIAR WITH THE TEXT MATERIAL AS OUTLINED IN THE STUDY GUIDES. THE STUDY GUIDES ONLY OUTLINE THE TEXT MATERIAL, LIST THE "TOPICS" TO BE COVERED ON EACH EXAM. YOU MUST UNDERSTAND THE TEXT DETAILED DESCRIPTIONS OF THE "TOPICS" LISTED ON THE STUDY GUIDES. THE MATERIAL "TOPICS" NOT LISTED ON EACH STUDY GUIDE WILL NOT BE ON THE EXAMS. ALSO FURTHER DESCRIPTIONS OF THE TEXT MATERIAL LISTED IN THE STUDY GUIDES ARE IN THE WORD LECTURES. YOU SHOULD REVIEW THESE WORD LECTURES FOR FLOW CHARTS AND ILLUSTRATIONS THAT ARE NOT IN YOUR TEXT. THESE ARE ADDED FOR BETTER UNDERSTANDING OF THE TEXT MATERIAL COVERED ON THE EXAMS.

NOTES:
Course Description:

Introduction and review of basic and advanced concepts in pharmacology for clinical pharmacologists. Overview of pharmacologic principles underlying the individualization of drug therapy and contemporary drug development. Fundamentals of clinical pharmacology for the development, evaluation, and clinical use of pharmaceutical products.

Prerequisite:

Pharmacology 5600 Introduction to General Pharmacology. Admission to the Master's program in Applied Clinical and Preclinical Research or permission of the instructor.

Objectives:

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

1. Articulate the role of pharmacokinetics in clinical drug development.
2. Recognize the relationship between pharmacokinetics and in vivo drug activity and efficacy.
3. Understand drugs based on their clearance, volume of distribution, bioavailability, mechanism of elimination, and protein binding.
4. Appraise primary clinical pharmacokinetic literature.
5. Devise individualized drug therapies in patient populations given pharmacokinetics estimates for that population and knowledge of their disease state.
6. Interpret drug concentration-time data and propose recommendations regarding dosage regimens.
7. Design the synopsis for a phase 1 (first-in-human) drug trial, synthesizing preclinical drug study outcomes and considerations for expected toxicity and intended patient populations.

Course Topics:

1. Introduction

MODULE 1: PHARMACOKINETICS
2. Clinical pharmacokinetics
3. Compartmental analysis of drug distribution
4. Drug absorption and bioavailability
5. Effects of renal disease on pharmacokinetics
6. Kinetics of hemodialysis and hemofiltration
7. Effects of liver disease on pharmacokinetics
8. Noncompartmental vs. compartmental approaches to pharmacokinetic analysis
9. Distributed models of drug kinetics
10. Population pharmacokinetics

MODULE 2: DRUG METABOLISM AND TRANSPORT
11. Pathways of drug metabolism
12. Biochemical mechanisms of drug toxicity
13. Chemical assay of drugs and drug metabolites
14. Equilibrative and concentrative transport
15. Pharmacogenetics
16. Drug interactions

MODULE 3: ASSESSMENT OF DRUG EFFECTS
17. Physiological and laboratory markers of drug effect
18. Dose response and concentration response analysis
19. Kinetics of pharmacologic effect
20. Disease progression models

MODULE 4: OPTIMIZING AND EVALUATING PATIENT THERAPY
21. Sex differences in pharmacokinetics and pharmacodynamics
22. Drug therapy in pregnant and nursing women
23. Drug therapy in neonates and pediatric patients
24. Drug therapy in the elderly
25. Clinical analysis of adverse drug reactions
26. Quality assessment of drug therapy

MODULE 5: DRUG DISCOVERY AND DEVELOPMENT
27. Project management
28. Drug discovery
29. Pre-clinical development
30. Animal scale up
31. Phase I studies
32. PK and PD considerations in the development of biotechnology products and large molecules
33. Design of clinical development programs
34. Good design practices for clinical trials
35. Role of the FDA in guiding drug development
Clinical Pharmacogenomics
Pharmacy 7240
2 Credit Hours
Autumn Semester 2012

Course Description:
This course will cover the principles and techniques necessary to understand the role of genetic variation in the pharmacokinetics and pharmacodynamics of drugs and therapeutic management of disease.

Course Directors: Jeffrey S. Johnston, Ph.D., Office: 236 Parks Hall
Telephone: 292-2607; E-Mail: johnston.14@osu.edu

Dr. Daren L. Knoell, F.A.C.C.P., Office: 405A Davis HLRI
Professor of Pharmacy and Internal Medicine
Telephone 292-0075; E-Mail: daren.knoell@osumc.edu

Instructors: Claire Murphy, Pharm.D.
Wolfgang Sadee, Ph.D.
Thomas Schmittgen, Ph.D.
Jeffrey Johnston, Ph.D.
Daren Knoell, Pharm.D., F.A.C.C.P.
Quan Li, Pharm.D.,BCOP,BCPS
Leigha Senter, MS, CGC.

Meeting Times:
Tuesdays and Thursdays; (2:30-3:20)

Textbook:
No Required Textbook
Suggested Textbook Pharmacogenomics: Applications to Patient Care (Reserved copy available in library)

Course Objectives: To understand the genetic factors that cause differences in efficacy or toxicity of drugs and treatment protocols in different individuals with different disease states. The primary focus will be on the genetic basis and corresponding biological mechanisms responsible for hypo- and hyperresponsitivity to pharmacologic agents. To evaluate genomic methods in drug design, development, and therapy. To assess the contributions of genetic factors to interindividual variability in drug response, and the potential for optimizing individual therapy.
Course Policies:
Attendance is mandatory. Unexcused absences may result in a loss of points as determined by the course instructor and coordinators.

Grading:
Your final grade in the course will be determined by your performance (scores) on three midterm examinations. However, some instructors may administer in class or take home assignments that will be counted toward the midterm grade(s)

Midterm 1  33.3%
Midterm 2  33.3%
Midterm 3  33.3%

Grading Scale:
93 or above    A
90-92.9        A-
87-89.9        B+
83-86.9        B
80-82.9        B-
77-79.9        C+
73-76.9        C
70-72.9        C-
67-69.9        D+
60-66.9        D
59 or below    E

Examination policy:
There is no rounding (i.e. a grade of 92.9 results in an A-)! Lobbying for points will not be tolerated!
All students must take exams at the time and date specified by the course coordinator(s). Failure to take the exam at the time and date specified will result in a zero for that exam. Any exceptions to exam times/dates must be approved in advance by the course director(s).
Acceptable reasons for missing the exam may include a death in the family, hospitalization, or some other calamity. Weather is not an acceptable reason to miss an exam unless a Level 3 snow emergency is declared in your county of academic year residence.

Honor Code for Doctor of Pharmacy Students
The Honor Code for Doctor of Pharmacy Students is available on the College’s web site (www.pharmacy.ohio-state.edu) and applies to all PharmD students. It addresses issues relating to misconduct by students associated with academic and experiential activities. The Honor Code dictates that “PharmD students are honor bound to respond to suspected Honor Code violations. Students are expected to take definite measures to confront unethical actions or practices on the part of a colleague by directly advising that person or reporting such actions and practices. They may report such violations to the faculty member for the course involved or directly to the Honor Council.”
Disability Statement:
Any student who feels she or he may need an accommodation based on the impact of a disability should contact the course instructor(s) privately to discuss specific needs and contact the Office of Disability Services, Room 150 Pomerene Hall, 1760 Neil Avenue (614-292-3307) to coordinate reasonable accommodations for a documented disability.
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<th>Week #</th>
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The final exam will be held during finals week and will be scheduled by the College Registrar.
Course Description:

Seminar on current issues in pharmacogenomics. Presentation and discussion of research and recent advances in pharmacogenomics.

Prerequisite:

Admission to the Master's program in Applied Clinical and Preclinical Research or permission of the instructor. This course is to be taken concurrently with PHR 7240 Clinical Pharmacogenomics.

Objectives:

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

1. Interpret findings in original research articles in the current pharmacogenomics literature and articulate significant clinical applications.

Course Topics:

Course topics will vary. Examples include:

- Polymorphisms & population genetics
- Genotyping, mRNA expression assays, haplotype analysis, emerging technologies
- Pharmacogenetics of transporters and clinical relevance
- Pharmacogenetics of Phase I and II metabolism; predictive biomarker panels
- Pharmacogenomics of receptors; relevance in psychiatry
- Beta-blockers in heart failure, genetics of adrenergic signaling
- Implementation of pharmacogenomics in medical practice
- Pharmacogenomics of protein kinases, and individualized cancer therapy
- Ethical issues in pharmacogenomics