University of Pittsburgh | School of Pharmacy

Competency Requirements for a PhD in Pharmaceutical Sciences – Clinical Pharmaceutical Science (CPS)

Reviewed 5.30.24 BT

Theme, Subject and Competency		Required core courses							Required courses for the CPSP track										Required reinforcing experiences					
	Term	F	F	S	F/Sp	F	F/Sp	F/Sp	Sp	F	F	F	Sp	Su	F	Su	F	F						
	Credit	1	4	4	2/2	3	1-2/ 1-2	1/1	4	3.5	1	4	2	3	1	1	1	1						
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Learning Outcome from the Graduate Program Assessment Matrix: Acquire expert knowledge of biological, chemical, and analytical processes related to pharmaceutical sciences. Master a field of scholarship related to a specific research topic.																								
LITERATURE REVIEW AND EVALUATION																								
Extract literature from appropriate bibliographic sources.					X		X	X			X		X						X	X	X			
Critique clinical and scientific evidence derived from literature.					X	X	X	X			X		X						X	X	X			
Describe the current state of knowledge about a biomedical, clinical, or public health problem.			X		X		X	X			X								X		X			
Interpret primary research literature within the pharmaceutical sciences					X		X	X		X	X	X	X								X	X		

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Learning Outcome from the Graduate Program Assessment Matrix: Use the scientific method to generate, analyze, and interpret scientific data relevant to the identification, analysis, and use of therapeutic agents. • Generate mechanistic hypotheses based on prior evidence • Derive specific predictions that are hypothesis-driven • Plan detailed experimental procedures that test specific predictions • Gather data via experimentation • Appropriately analyze and interpret data																								
HYPOTHESIS GENERATION																								
Generate a relevant biomedical, clinical, public health, or translational research hypothesis.					X								X						X	X				
Defend the clinical and public health implications of a given research hypothesis.								X					X						X	X	X		X	
RESEARCH METHODS AND STUDY DESIGN																								
Design appropriate experiments to address generated research questions in the pharmaceutical sciences.				X	X				X				X	X					X	X				
Conduct appropriate experiments to address generated research questions.				X	X				X				X	X	X				X					

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Evaluate possible problems in the design and execution of a study in the pharmaceutical sciences.			X	X		X	X	X		X	X	X	X					X	X				
Describe the drug development process.			X					X	X		X												
Develop appropriate methods to recruit and retain study participants for a selected research design.												X		X				X	X			X	
Identify important outcome measures for incorporation into patient oriented clinical trial design.										X		X	X					X	X			X	
Generate a plan for data security/management.												X	X	X								X	
Identify barriers in translating research discoveries into meaningful changes in human health.			X							X		X	X	X				X	X				

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Develop an approach to overcome barriers in translating research to humans.													X	X				X					
Design appropriate, ethically sound, and hypothesis-driven clinical studies.												X	X	X	X			X	X			X	
STATISTICAL METHODS AND DATA EVALUATION																							
Apply fundamental principles of statistical analysis, such as power analysis, correlation, causation, regression, and summary statistics.				X	X	X				X	X				X	X	X	X	X	X			
Select the appropriate statistical approach for the interpretation of preclinical and clinical datasets.					X	X					X		X					X	X	X	X		
Define bias in clinical and translational research.					X								X	X	X							X	
Develop appropriate conclusions based on results from research data.			X	X		X	X	X				X	X	X				X	X	X	X	X	

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Learning Outcome from the Graduate Program Assessment Matrix: Communicate scientific facts, research results and ideas in a clear and compelling way in both oral and written form. • Write a scientific paper of sufficient quality to be published in a nationally recognized peer reviewed journal • Apply knowledge and understanding of ethical research practices (e.g., ownership of data, authorship, falsification and misrepresentation of data, ethical use of animals in research, use of copyrighted material, plagiarism) • Prepare a lecture or seminar that has focus and depth, and that presents information in a clear and informative way • Write a meritorious grant proposal (i.e., one that is hypothesis-driven, scientifically justified, and appropriately analyzed and interpreted)																								
GRANTSMANSHIP																								
Identify federal and non-federal agencies and programmatic initiatives aimed at translating research to clinical care of patients.					X								X						X					
Defend a written research proposal describing specific aims, significance, innovation, and approach.					X								X						X	X				
Defend a written research proposal that describes specific research aims, significance, innovation, and approach for a human clinical trial.					X								X						X	X			X	

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PREPARATION AND DELIVERY OF ORAL AND WRITTEN SCIENTIFIC INFORMATION																								
Develop presentations describing proposed research, research in progress, or research findings.							X	X			X		X						X	X		X		
Assess the clinical implications of scientific information.							X	X			X		X						X	X	X			
Prepare publication/presentation quality abstracts, posters and manuscripts.					X			X											X	X	X	X		
Develop an appropriate response to constructive criticism of oral and written presentations.					X			X											X	X	X	X		

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SCIENTIFIC LEADERSHIP, MANAGEMENT, AND CROSS-DISCIPLINARY TEAMWORK																								
Demonstrate professionalism, interpersonal skills and collegial approaches to teamwork.							X	X		X	X		X								X	X		X
Mentor students in research, clinical, or professional activities.																								X
Develop a therapeutic protocol/guideline for medication related issues or management.																							X	
Recognize the strengths and limitations of personal research skills.								X											X	X	X			

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ETHICAL CONDUCT OF RESEARCH																								
Recognize scientific misconduct and conflict of interest.					X										X						X		X	
Demonstrate knowledge of the standards of professional and ethical conduct established to guide researchers in protecting the rights, well-being, and dignity in the recruitment and retainment of human subjects in clinical research.													X	X	X					X			X	
Give examples of the informed consent process including an understanding of the risk/benefit criteria and its impact on the patient/volunteer.													X	X	X								X	

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Appendix – Descriptions and expectations of Experiences to achieve CPSP competencies

Comprehensive exam

- The comprehensive exam committee asks questions during the oral examination which will test the student's ability and knowledge in the responsible conduct of clinical research.
- CPSP graduate students must propose a clinical study and address human subject protections in their written proposal.

Dissertation/Thesis Research

- CPSP graduate students conduct research that meets the NIH definition of clinical research:
  "Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies".

Institutional Review Board (IRB)

- All CPSP graduate students serve as an investigator on an IRB-approved protocol and are encouraged to serve as Principal Investigators with faculty oversight in accordance with University of Pittsburgh IRB policies.

Preparation and Review of Manuscripts

- CPSP graduate students are expected to prepare manuscripts of their dissertation and other research and submit them for peer reviewed publication in collaboration.
- Published literature in the student's area of research is reviewed on an ongoing basis (individually by the student and through journal clubs). CPSP graduate students should also have the opportunity to review unpublished manuscripts submitted to peer-reviewed journals with their faculty major advisor.