Competency Requirements of Pharmaceutical Outcomes & Policy Research Track (POP)
University of Pittsburgh School of Pharmacy

8/12/2021
Page 1 of 6

Theme, Subject and Competency

Exempt if PharmD from ACPE accredited University

Theme, Subject and Competency	Core Courses							Required Courses for Outcomes									Experiences					
Term	F	Sp	F/Sp	F/Sp	Sp	F/Sp	F/Sp	F	F	F	F	Sp	Sp	F	Sp	Sp						
Credits	4	1.5	2/2	3/3	3	1/1	1-2/1-2	1	1	1.5	2	2	1	1	1	1						
	Pharmacology and Ther* PHARM 3028	Found in Clin Drug Dev & Assess PHARM 3077	Grant Writing PHARM 3038/9	Statistical Methods I & II PHARM 3040 & 3045	Applied Multivariate Statistics (PHARM 3073)	Seminar PHARM 3024 or EPIDEM 2260	Journal Club§ PHARM 3303 / 3052	Data Privacy & Security PHARM 3308	Secondary Data Sources, Methods and Tools PHARM 3310	Research Methods PHARM 3304	Intro to SAS± EPIDEM 2185 or equivalent	Pharmacoepidemiology PHARM 2003	U.S. Healthcare System^ PHARM 3306	Research with Biomedical Databases (PHARM 3302)	Data Harmonization PHARM 3305	Secondary Database Applications (PHARM 3301)	Dissert/Thesis Research	Comprehensive Exam	Manuscripts	Presentations at Scientific Conferences		

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

Competency	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
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	X			
Describe the current state of knowledge about a biomedical, clinical, or public health problem.	X		X			X	X	X					X				X		X			
Interpret primary research literature within the pharmaceutical sciences		X		X	X	X	X			X		X										

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

Competency	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Generate a relevant biomedical, clinical, public health, or translational research hypothesis.		X	X	X	X					X		X					X	X				

Competency Requirements of Pharmaceutical Outcomes & Policy Research Track (POP)
University of Pittsburgh School of Pharmacy

8/12/2021
Page 2 of 6

Theme, Subject and Competency *Exempt if PharmD from ACPE accredited University	Core Courses							Required Courses for Outcomes									Experiences					
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Defend the clinical and public health implications of a given research hypothesis.						X	X		X	X		X		X	X	X	X	X				
Appropriately use conceptual models to generate hypotheses and guide study variable selection in outcomes research.							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	X				
Select appropriate observational study design to address policy and outcomes research questions.				X	X					X		X										
Conduct appropriate experiments/analysis to address generated research questions.		X		X	X				X	X		X		X		X	X					
Evaluate possible problems in the design and execution of a study in the pharmaceutical sciences.		X				X	X					X					X	X				
Describe the drug development process.		X					X						X									
Develop appropriate methods to recruit and retain study participants for a selected research design.		X						X												X		

Competency Requirements of Pharmaceutical Outcomes & Policy Research Track (POP)
University of Pittsburgh School of Pharmacy

8/12/2021
Page 3 of 6

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Identify important outcome measures for incorporation into patient oriented clinical trial design.							X			X								X				
Generate a plan for data security/management.								X						X	X							
Identify barriers in translating research discoveries into meaningful changes in human health.						X	X		X					X	X	X	X					
Develop an approach to overcome barriers in translating research to humans.										X							X					
Design appropriate, ethically sound, and hypothesis-driven clinical/outcomes studies.										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				
Select the appropriate statistical approach for the interpretation of preclinical and clinical datasets.				X	X		X			X		X					X	X				
Define bias in clinical and translational research.				X	X		X			X		X										

Competency Requirements of Pharmaceutical Outcomes & Policy Research Track (POP)
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Develop appropriate conclusions based on results from research data.			X		X		X	X			X		X					X	X				

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

Theme, Subject and Competency		Pharmacology and Ther*	Found in Clin Drug Dev & Assess	Grant Writing	Statistical Methods I & II	Applied Multivariate Statistics	Seminar	Journal Club§	Data Privacy & Security	Secondary Data Sources	Research Methods	Intro to SAS±	Pharmacoepidemiology	U.S. Healthcare System^	Research with Biomedical Databases	Data Harmonization	Secondary Database Applications	Dissert/Thesis Research	Comprehensive Exam	Manuscripts	Presentations		
Identify federal and non-federal agencies and programmatic initiatives aimed at translating research to clinical care of patients.				x														X					
Defend a written research proposal describing specific aims, significance, innovation, and approach.				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				

PREPARATION AND DELIVERY OF ORAL AND WRITTEN SCIENTIFIC INFORMATION

Competency Requirements of Pharmaceutical Outcomes & Policy Research Track (POP)
University of Pittsburgh School of Pharmacy

8/12/2021
Page 5 of 6

Theme, Subject and Competency *Exempt if PharmD from ACPE accredited University*	Core Courses							Required Courses for Outcomes									Experiences					
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Develop presentations describing proposed research, research in progress, or research findings.						X	X										X	X		X		
Assess the clinical implications of scientific information.						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		
SCIENTIFIC LEADERSHIP, MANAGEMENT, AND CROSS-DISCIPLINARY TEAMWORK																						
Demonstrate professionalism, interpersonal skills and collegial approaches to teamwork.						X																
Mentor students in research, clinical, or professional activities.																						
Develop a therapeutic protocol/guideline for medication related issues or management.																						

Competency Requirements of Pharmaceutical Outcomes & Policy Research Track (POP)
University of Pittsburgh School of Pharmacy

8/12/2021
Page 6 of 6

Theme, Subject and Competency *Exempt if PharmD from ACPE accredited University		Core Courses							Required Courses for Outcomes									Experiences					
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Recognize the strengths and limitations of personal research skills.							X											X	X	X			
ETHICAL CONDUCT OF RESEARCH																							
Recognize scientific misconduct and conflict of interest.									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				
Give examples of the informed consent process including an understanding of the risk/benefit criteria and its impact on the patient/volunteer.									X														

Competency Requirements of Pharmaceutical Outcomes & Policy Research Track (POP)
University of Pittsburgh School of Pharmacy

8/12/2021
Page 7 of 6

Appendix – Descriptions and expectations of Experiences to achieve POP competencies

Distribution of courses across outcomes competencies:

Course Distribution	Credit Hours
Statistics*	13
Methods & Epidemiology	4.5
Data programming and visualization	6
U.S Healthcare Policy	1
Data Privacy & Security	1
Databases and applications	2
Foundations	1.5
Journal Club	4
Grant writing	4
Seminar	4
Research practicum	8(TBD)‡
Electives#	8(TBD)‡
Dissertation	15(TBD)‡
TOTAL	**72 required**

± An alternative statistical software introductory course is EPIDEM 2186 Introduction to R
§ Alternative Journal Clubs are listed below
^ Alternative courses for Intro to US Healthcare System are listed below
‡ minimum number of credits but could be more
*In addition to PHARM 3040, 3045, and 3073, students will be required to take Applied Survival Analysis (Fall, BIOST 2066) and Longitudinal and Clustered Data Analysis (Fall, BIOST 2050). Other Advanced Methods Classes listed below can be substituted for these courses as needed.
Elective options listed below

Comprehensive exam
- Pharmaceutical outcomes & policy (POP) graduate students must propose a novel and relevant study in comparative effectiveness or pharmaceutical policy research. The proposal should demonstrate mastery in: (1) epidemiology, (2) biostatistics, (3) outcomes/policy research methods, and (4) U.S. health care and pharmaceutical policy.
- The comprehensive exam committee asks questions during the oral examination which will test the student's ability and knowledge in the responsible conduct of outcomes and policy research.

Dissertation/Thesis Research
- POP graduate students conduct research that meets the adapted definition from the Agency for Healthcare Research & Quality:

Competency Requirements of Pharmaceutical Outcomes & Policy Research Track (POP)
University of Pittsburgh School of Pharmacy

8/12/2021
Page 8 of 6

"Pharmaceutical outcomes & policy (POP) research evaluates the impact of medications, health care policies, and pharmacy interventions on health outcomes of patients and populations. POP research emphasizes health problem- (or disease-) oriented evaluations of care delivered in general, real-world settings; multidisciplinary teams; and a wide range of outcomes, including mortality, morbidity, functional status, mental well-being, costs of care, and other aspects of health-related quality of life. POP research may entail any in a range of primary data collection methods and secondary (or "synthetic") methods that combine data from primary studies."

Collaborative Institutional Training Initiative (CITI Program)

- All POP graduate students will need to complete appropriate CITI Program training courses and modules prior to conducting any research, even for deidentified data

Preparation and Review of Manuscripts

- POP 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). POP graduate students should also have the opportunity to review unpublished manuscripts submitted to peer-reviewed journals with their faculty major advisor.

§ Options for Journal Clubs (each journal club can be taken twice)

PHARM 3052	Topics and Methods in Pharmaceutical Outcomes and Policy Research	1
PHARM 3034	Topics in Translational Research	1
HPM 3000	Doctoral Research and Professional Development Seminar	1
EPIDEM 2950	Epidemiology of Aging Workshop	1

^ Options for Intro to US Healthcare System

HPM 2001	Health Policy and Management in Public Health	3
HPM 2105	Introduction to the US Healthcare Delivery System 1	1
HPM 2216	Health Insurance: Financing Health Care	3

* Options for Advanced Methods Courses

EPIDEM 2230	Advanced Topics in Epidemiological Methods	2
HPM 3505	Advanced Empirical Microeconomics Methods with Applications for Healthcare Research	3
PIA 3004	Seminar in Research Design and Methods	3
PIA 2032	Advanced Quantitative Methods: Causal Inference for Policy Analysis	3
PIA 2033	Advanced Methods Casual Inference	3
PSYED 3472	Causal Inference in Educational Research	3
PSYED 3408	Hierarchical Linear Modeling	3

Options for Electives

Competency Requirements of Pharmaceutical Outcomes & Policy Research Track (POP)
University of Pittsburgh School of Pharmacy

8/12/2021
Page 9 of 6

Code	Course	Credits
PHARM 5834	Python for Data Management and Analytics	3
PHARM 3011	Principles of Biochemistry	1
PHARM 3071	Foundations in Pharmaceutical Sciences	4
BIOST 2063	Bayesian Data Science	3
BIOST 2093	SAS for Data Management and Analysis	2
BIOST 2094	Advanced R Computing	2
BIOST 2062	Clinical Trials: Methods and Practice	3
BIOST 2066	Applied Survival Analysis: Methods and Practice	2
HPM 2028	Microeconomics Applied to Health	3
HPM 2005	Current Issues in Health Law	1
PSYED 3408	Hierarchical Linear Modeling	3
CLRES 2120	Cost Effctvns Anal Hlth Care	1
CLRES 2121	Clinical Decision Analysis	1
CLRES 2122	Computer Methods in Decision and Cost-Effectiveness Analysis	1
PIA 3004	Seminar in Research Design and Methods	3
EPIDEM 2250	Seminar in Epidemiology	1
EPIDEM 2221	Geospatial Mapping and Spatial Analysis in Epidemiology	2
EPIDEM 2981	Epidemiology of Aging-Methods	2
PHARM 3140	Introduction to Translational Research	3
BIONF2018	Introduction to R Programming for Scientific Research	3
CMPINF 2100	Data-Centric Computing (python)	3
CMPINF 2110	Managing, Querying, and Preserving Data (SQL)	
CMPINF 2120	Applied Predictive Modeling	
CMPINF 2100	Data Visualization	
CMPINF 2999	Data and Society in the Internet Age	
Pharm 5834	Python	3
Pharm 5916	Predictive Analytics	1.5
Pharm 3300	Advanced Pharmacoeconomics	1