
CLRES 3140
DENT 3111
HRS 3140
NUR 3056
PHARM 3140
PUBHLT 3000

Course instructor:

Introduction to Translational Research in the Health Sciences

Samual M. Poloyac, PharmD, PhD

Course Summary

The goal of the Clinical and Translational Science Institute (CTSI) common core curriculum is to provide doctoral-level graduate students with the knowledge and critical thinking skills they need to engage in clinical or translational research. Introduction to Translational Research in the Health Sciences was developed by the CTSI Education Core and designed to introduce students to the objectives, concepts, models, and processes of clinical and translational research.

The Introduction to Translational Research in the Health Sciences course will provide students with a comprehensive survey of the processes involved in translating research discoveries into practices that promote health and prevent disease. The specific topics to be covered are listed in the lecture schedule and include the implementation of new therapies as standards of care and the application of innovative preventive services. Various research methodologies, including those encompassed in the drug, therapeutic and device development process, will be discussed. The course will offer lectures via electronic media and will use a collaborative learning approach to classroom activities.

Course mechanics:

Six two-hour in-class sessions and nine online sessions, over one semester.

Learning Methods:

Students will be engaged in multiple methods of active learning, including:

- Acquisition of lecture content via an adaptive, hypermedia, Web-based format. Each week, students will be required to review the lecture material before coming to class.
- Participation in classroom sessions that use a collaborative learning format, with instructors serving as class facilitators. Throughout the term, students will be divided into various multidisciplinary working groups.

Course Requirements and Grading:

The course will be offered as a 2-credit course with letter grading or as a Pass or Fail option based on the following:

- Achievement on 1 individual quiz about the content of Web-based lectures (20% of total grade).
- Development of discussion questions for group participation in each session throughout the term (30% of grade).
- Participation in a required group project (50% of total grade). Each group is expected to choose a research project that involves type 1 or type 2 translational research and has the potential to make a major impact on health within the next 10 years. The project is to be presented as a written report whose maximum length is 10 double-spaced pages in Arial 11 font with no less than 0.5-inch margins. Suggested elements include:
 - Defining a health problem.
 - Justifying the line of research selected.
 - Identifying current barriers and suggesting how they can be overcome.
 - Anticipating the outcomes or impact.
 - Identifying the disciplines that need to be involved in this research and why.

6/11/08

Live, In-Class Sessions

Parkvale Building

Room 305

5:00 -- 7:00pm (8/28, 9/4, 9/25, 10/16, 11/13, 12/4)

Online

9/11, 9/18, 10/2, 10/9, 10/23, 10/30, 11/6, 11/20, 12/11

Required Texts:

No required text books.

- See required and suggested readings for each session. All readings will be available on the CourseWeb site.
- For the final written group project, software (MS Office) is available in the University computer labs and is also available for purchase at the PC Center. Web Browsers and Adobe Acrobat Reader are available in the computer labs or may be downloaded for free. Medline is available for use via the Internet or Falk Library.

Student Disability Statement

If you have a disability for which you are or may be requesting an accommodation, you are encouraged to contact both your instructor and the Office of Disability Resources and Services (DRS), 216 William Pitt Union, (412) 648-7890 or (412) 383-7355 (TTY), as early as possible in the term. DRS will verify your disability and determine reasonable accommodations for this course.

Academic Integrity Statement

Students enrolled in any of the Schools of Health Sciences are considered to be professionals and must adhere to the same professional, ethical, and legal standards. It is a violation of the University's code of conduct policy for a student to engage in any act of academic misconduct, such as cheating, plagiarism, deceitful practice, unauthorized collaboration, harassment, or breach of confidentiality. It is also considered to be a violation of the code of conduct policy for a student to tolerate any of the aforementioned acts by other students. Unless authorized by the instructor, use of electronic devices of any kind during examinations is prohibited. Use of a personal digital assistant, palm top computer, cellular telephone, or other electronic device during an examination is considered to be an act of academic misconduct.

Course Introduction		
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Session 1 (Live)	Course Introduction	August 28
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Focus: Course Overview and Expectations.

Objectives:

1. Introduction to course and CourseWeb
2. Student introductions
3. Expectations of the students and of the course
4. Introduction of final project and group work

In-Class Assignment: Group discussion and completed handout on: What are the most pressing health issues in your discipline?

CourseWeb:

1. Discussion board activity.

Topic 1: Introduction to the National Institutes of Health (NIH) Roadmap and the conceptual framework for multidisciplinary and interdisciplinary research.
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Objectives:

1. Students will interpret the unique benefits of multidisciplinary teamwork.
2. Students will identify the barriers to multidisciplinary interaction and develop strategies to lessen the impact of these barriers.
3. Students will recognize the history and scope of the NIH Roadmap.
4. Students will study the purpose and themes of the NIH Roadmap.

Session 2 (Live)	Multidisciplinary Research and Teamwork (Topic 1)	September 4
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Focus: In this session we will view a presentation by Dr. Joan Lakoski on multidisciplinary team work. The class will also break-out into multidisciplinary groups to discuss Session 1 in-class assignment and brainstorm final project ideas.

Assignments:

To be viewed:

1. Dr. Elias Zerhouni, Director, National Institutes of Health, "Clinical and Translational Research: The NIH Roadmap," Videoclip available at: <http://content.nejm.org/cgi/content/full/NEJMs053723/DC1>
2. Dr. Arthur Levine, Dean, University of Pittsburgh School of Medicine, "The New Pathways to Discovery."

Readings:

1. NIH Roadmap for Medical Research. Available at: <http://nihroadmap.nih.gov/>.
2. Zerhouni EA. Translational and clinical science—time for a new vision. *NEJM* 2005;353:1621 Available at: <http://content.nejm.org/cgi/content/full/353/15/1621>.
3. Woolf, SH. The Meaning of Translational Research and Why It Matters. *JAMA* 2008;299(2):211-213.

Topic 2: Objectives at the national level in *Healthy People 2010 / 2020* and at the global level as proposed or designed by organizations such as the World Health Organization.

Objectives:

1. Students will examine the origins of the *Healthy People* initiative.
2. Students will identify the two primary goals of the *Healthy People* initiative.
3. Students will identify major sources of data for measuring *Healthy People* objectives (MEPS, BRFSS, NHANES, and others)
4. Students will describe the 10/90 gap and its origins.
5. Students will identify public health issues within minority communities both locally and abroad.
6. Students will be introduced to issues in healthcare that affect all disciplines and can be viewed from multiple perspectives.
7. Students will be able to relate to issues and recognize new perspectives related to health issues that affect their discipline.

Session 3 (Online)

Healthy People 2010/2020 (Topic 2)

September 11

Focus: Healthy People 2010 and the goals of this national health initiative.

Assignments:

To be viewed:

1. Sandra Crouse Quinn, PhD, Graduate School of Public Health, University of Pittsburgh, "Nuts and Bolts: Definitions, Terminology, Major Goals, and Objectives of HP2010"
2. Dr. Linda Siminerio, "A Multidisciplinary Approach to Achieving a Healthy People 2010 Goal"
3. Stephen Thomas, PhD, Graduate School of Public Health, University of Pittsburgh, "Healthy Black Family Project: Translating HP2010 goals into culturally appropriate community-based programs"

Readings:

1. Healthy People 2010 Home Page (please be sure to read through all aspects of the website). url: <http://www.healthypeople.gov/> --
2. National Center for Health Statistics (please be sure to read through **all** aspects of the website with a special emphasis on data). url: <http://www.cdc.gov/nchs/hphome.htm>

Session 4 (Online)

Global Health Initiatives (Topic 2)

September 18

Focus: Session 4 introduces students to global health issues and the 10/90 gap and its origins.

Assignments:

To be viewed:

2. Dr. Ismail Sallam, Former Minister of Health and Population "Setting Public Health Goals: Comparing US and Global Perspectives"

Readings:

1. Stevens P. Diseases of poverty and the 10/90 gap.url: [http://www.fightingdiseases.org/pdf/Diseases of Poverty FINAL.pdf](http://www.fightingdiseases.org/pdf/Diseases_of_Poverty_FINAL.pdf)
2. Garrett L. The challenge of global health. Foreign Affairs 2007;86(Jan/Feb). Available at: <http://www.foreignaffairs.org/20070101faessay86103/laurie-garrett/the-challenge-of-global-health.html>.
3. Doyal L. Gender and the 10/90 gap in health research. 2004. Bull World Health Organ; 82

Session 5 (Live)	Health Issues in all Disciplines (Topic 2)	September 25
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Focus: Session 5 is an in-class session that will include a discussion and group work about the 1-2 health issues from your distinct discipline that can be addressed from multiple perspectives (eg. policy, genetics, research and development, poverty, etc.) and how those issues affect all disciplines.

In-class assignment:

1. Group discussion.

Assignment:

1. Identify 1-2 health issues from your distinct discipline that can be addressed from multiple perspectives (eg. policy, genetics, research and development, poverty, etc.) and how those issues affect all disciplines. Minimum 1 page, double-spaced, Arial 11 point font. To be placed in digital dropbox in CourseWeb by Monday, September 22nd.

Topic 3: Examine Models of translational research
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Objectives:

1. Students will be introduced to the conceptual frameworks of different types of translational research.
2. Students will describe and provide examples of T3 translational research.
3. Students will analyze the methods of T3 translational research.
4. Students will begin to recognize barriers to conducting T3 translational research and improving health policy.
5. Students will analyze the methods of and barriers to T1, T2 and T3 translation.
6. Students will assess and defend the relevance of translational research with respect to the NIH and WHO initiatives.

Session 6 (Online)	Models of Translational Research (Topic 3)	October 2
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Focus: Session 6 introduces students to the basic framework of Type 1 and Type 2 translational research.

In-class assignment:

1. Group discussion on assignment.

Assignments:

To be viewed:

1. Dr. Samuel Poloyac, "Type I Translational Research in the Pharmaceutical Sciences."

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2. Dr. Yvette Conley, "Type I Translational Research: A Genomics Perspective"
3. Dr. Michael Fine, "Evidence-Based Approach for the Initial Site of Treatment for Community-Acquired Pneumonia: A Case study of Type II Translational Research"

Readings:

1. Lenfant C. Clinical Research to Clinical Practice: Lost In Translation. *NEJM* 2003;349:868-74.
2. Zerhouni EA. US Biomedical Research: Basic, Translational, and Clinical Sciences. *JAMA* 2005;294:1352-58.

Session 7 (Online)	Models of Translational Research (Topic 3)	October 9
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Focus: Session 7 introduces students to the basic framework of Type 3 translational research.

Assignments:

To be viewed:

1. Panel Discussion, "The Conceptual Framework of Type 3 Translational Research"

Readings:

1. Sung NS, Crowley WF Jr, Genel M, et al. Central Challenges Facing the National Clinical Research Enterprise. *JAMA* 2003; 289:1278-87.
2. Westfall JM, Mold J, Fagnan. Practice-Based Research - "Blue Highways" on the NIH Roadmap. *JAMA* 2007;297:403-406
3. Primary Care Practice-based Research Networks: Working at the Interface between Research and Quality Improvement. *Annals of Family Medicine* 3;S1:S12-S20.

CourseWeb:

1. Web-based review (Date of review TBA) for October 16th in class mid-term quiz via online virtual discussion.

Session 8 (Live)	Models of Translational Research (Topic3)	October 16
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Focus: In this session students will discuss methods in translational research.

In-Class Assignment:

1. Group discussion.
2. Mid-term quiz.

Topic 4: Methods of Clinical and Translational Research
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Objectives:

1. Students will recognize the methods of T2 and T3 translation, including methods related to changing provider behavior, using informatics, changing patient and population behavior, and changing public policy.
2. Students will examine issues concerning the manner in which clinical and translational research leads to innovation and discovery, including issues related to technology transfer.
3. Students will be introduced to the Clinical and Translational Science Institute and the resources it can provide to researchers.

Focus: In this session students will learn about issues in clinical and translational research from institutional leaders and senior investigators.

Assignments:

To be Viewed:

1. Dr. Arthur Levine and Dr. Wishwa Kapoor discussion, “Perspectives From Leaders On Translational Research”
2. Dr. Wishwa Kapoor, “Translational Research and the Quality of Health Care”

Readings:

1. Lenfant C. Training the next generation of biomedical researchers: challenges and opportunities. *Circulation* 2000;102:368-70.
2. National Institutes of Health. Re-engineering the Clinical Research Enterprise. Available at: <http://nihroadmap.nih.gov/clinicalresearch/overview-translational.asp>.

Focus: In this session students will be introduced to barriers in conducting translational research.

Assignments:

To be Viewed:

1. Panel Discussion, “Views from Leaders and Senior Investigators in Translational Research: A Discussion about Methods and Working with Multidisciplinary Teams.”
2. Panel Discussion, “Barriers in Conducting Clinical and Translational Research: Problems and Solutions.”

Topic 5: Drug, Therapeutic and Device Development Process
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Objectives:

1. Students will describe and analyze the process of drug and therapeutic development from pre-clinical discovery through clinical studies.
2. Students will identify the unique drug development and public health issues associated with vaccine development.
3. Students will describe and analyze each step of the drug development process from preclinical discovery through clinical studies and postmarketing surveillance.
4. Students will debate the potential benefits and risks of early screening of compounds for drug development.
5. Students will recommend future interventions that may improve patient care through drug therapy individualization.
6. Students will discuss the importance of postmarketing optimization and individualization of drug therapy.

Focus: In this session students will be introduced to the process of how new drugs, therapeutics and devices are discovered and their implications on improved health care.

Assignments:

To be Viewed:

1. Dr. Mark Malandro, "Moving Research Innovations Into the Marketplace."
2. Dr. Robert Abraham, "New Drug Discovery: Preclinical to Clinical Drug Development"
3. Dr. Donald S. Burke, "Vaccines: From Development to Public Health Implications"

Readings:

1. Burke DS. Human Trials of Experimental HIV Vaccines. *AIDS* 1995;9(suppl A):S171-80.
2. Lin JH, Sahakian DC, de Morais SM, Xu JJ, Polzer RJ, Winter SM. The Role of Absorption, Distribution, Metabolism, Excretion, and Toxicity in Drug Discovery. *Current Topics in Medicinal Chemistry* 2003;3:1125-54.
3. Amidon GL, Lennernas H, Shah VP, Crison JR. A Theoretical Basis for a Biopharmaceutic Drug Classification: The Correlation of In Vitro Drug Product Dissolution and In Vivo Bioavailability. *Pharm Res* Mar 1995;12(3):413-420.
4. Wu CY, Benet LZ. Predicting Drug Disposition Via Application of BCS: Transport / Absorption / Elimination Interplay and Development of a Biopharmaceutics Drug Disposition Classification System. *Pharm Res* Jan 2005;22(1):11-23.

Focus: This in class session will include a discussion about the previous online readings and viewings you have completed to date. The latter half of the session will be devoted to questions and direction regarding the final group project.

Assignments:

To be viewed:

1. Dr. Sam Poloyac, "Pharmacokinetic and Drug Metabolism Considerations in Drug Development"
2. Dr. William Evans, "Postmarketing Surveillance and Individualization of Therapy"

Readings:

1. Evans WE, Relling MV. Pharmacogenomics: Moving Toward Individualized Medicine. *Nature* 2004;429:429:464-8.
2. Evans WE, McLeod HL. Pharmacogenomics: Drug Disposition, Drug Targets, and Side Effects. *NEJM* 2003;248:538-49.

Session 13 (Online) Therapeutic Development Process (Topic 5) November 20

Focus: All viewings and readings within Topic 5 must be completed by December 2, 2008. Small group assignments will be given during the next live session (December 4th). These assignments will serve to reinforce your understanding of Topic 5 materials and share your perspectives with classmates from other disciplines.

Assignments:

To be viewed:

1. Mr. Myron Holubiak Director, at Natestch Pharmaceuticals Company Inc. "Development of new drugs and how to improve the pipeline."

Group project:

1. Continued work.

Session 14 (Live) Therapeutic Development Process (Topic 5) December 4

Focus: Small group assignments to reinforce understanding of Topic 5 materials and share perspectives with classmates from other disciplines.

In-Class Assignment

1. Small group work.

Assignments:

Group project:

1. Continued work.

Topic: Final Project

Session 15 (Online) Therapeutic Development Process December 11

Focus: Final project due today. This project must be submitted via the CourseWeb digital dropbox by 5 pm on December 11, 2008.