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

Course instructor:

Introduction to Translational Research in the Health Sciences

Samuel 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:

This is a hybrid course, consisting of nine two-hour live sessions and six 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, and 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 assignments based on the content of web-based lectures (20% of total grade).
- Quality of performance and participation in online/live coursework e.g. chat sessions, group work meetings (30% of grade).
- Development and quality of and individual 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 (at various stages of development) and finally produced as a written report with a maximum length of 10 double-spaced pages in Arial 11 font with no less than 0.5-inch margins. Required elements of the project will be given in the form of a rubric and 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.

Live Class Sessions

Parkvale Building
Room 305
5:00 -- 7:00pm

9/3, 9/17, 10/8, 10/22, 10/29, 11/12, 12/3, 12/10, 12/17

Online Sessions

9/10, 9/24, 10/1, 10/15*, 11/5, 11/19

Please note:

*October 15th is an online session, but student participation is required in an online discussion between 5-7 pm. Please schedule accordingly.

November 26th is Thanksgiving recess-- no online or live session will take place on this date.

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:
Conceptual Framework for Multidisciplinary and Interdisciplinary Research**

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.

Session 1 (Live)

September 3

Focus: Course Overview and expectations, student introductions, and introduction of course project and conceptual framework for multidisciplinary/interdisciplinary research.

Session 1 content:

1. Course overview discussion
2. Guest Speaker: Joan Lakoski, PhD “Research Teams of the Future”

Survey Assignment:

1. Complete “Survey of Research Interest for Multidisciplinary Team Development” in CourseWeb. Student completion of this brief survey will provide the necessary information needed to formulate purposeful and focused multidisciplinary research teams. The results from student answers will be analyzed by the course instructor and applied to team development. **Survey must be completed by September 10th.**

To read:

1. “Life Cycle of Translational Research for Medical Interventions” posted in CourseWeb Session 1.

**Topic 1
Introduction to the National Institutes of Health (NIH) Roadmap and Clinical and Translational Science Institute (CTSI): Resources to Identify and Foster Compelling Research Opportunities to Improve Human Health**

Objectives:

1. Students will be introduced to the history, scope and functions of the NIH Roadmap and CTSI as mechanisms to foster the translation of research to human subjects in populations.
2. Students will study and apply the purpose and themes of the NIH Roadmap and CTSI .
3. Students will be introduced to the conceptual frameworks of different types of translational research.

Focus: The history, scope, purpose and themes of the NIH Roadmap and CTSI as facilitators of translational research.

Session 2 content:

To view:

1. Dr. Elias Zerhouni, Director, National Institutes of Health, "Clinical and Translational Research: The NIH Roadmap," Video clip available at: <http://content.nejm.org/cgi/content/full/NEJMs053723/DC1>
2. Dr. Sam Poloyac, Recorded presentation on the history and function of CTSI (Clinical Translational Science Institute) and relevance to course projects and future professional research goals.

To read:

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.

Survey Assignment:

1. Survey is due September 10th.

Suggested Viewing:

1. Dr. Arthur Levine: "The Pathways to Discovery"

Topic 2 National and Global Health Care Agendas

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.

Focus: (1) Multidisciplinary teams will be assigned and most of the session will be based on a team discussion regarding 1-2 health issues from each member's distinct discipline that can be addressed from multiple perspectives (e.g. policy, genetics, research and development, poverty, etc.) and how those issues affect all disciplines. The course project research topics should emerge from discussion. **(2)** Group Wiki introduction and discussion.

Session 3 content:

1. Group Wiki introduction and application to course project (will be projected in class via CourseWeb).
2. Multidisciplinary team discussions.

Suggested Viewing:

1. Dr. Linda Siminerio: "A Multidisciplinary Approach to Achieving a Healthy People 2010 Goal."

Wiki Review Assignment:

1. Review your team's wiki in CourseWeb and determine how the team will utilize the wiki as an online resource for project development. Communication and accountability among and between team members is crucial to the quality and consistent semester-long development of the course project.

Session 4 (Online)	Local and Global Health Initiatives (Topic 2)	September 24
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Focus: Local and global health issues and the 10/90 gap and origins.

Session 4 Content:

To view:

1. Dr. Stephen Thomas "Healthy Black Families–Pittsburgh: Translate HP2010 goals into culturally appropriate community-based programs"
2. Dr. Ismail Sallam, Former Minister of Health and Population "Setting Public Health Goals: Comparing US and Global Perspectives"

Suggested Readings:

1. Stevens P. Diseases of poverty and the 10/90 gap.url: 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>.

Essay Assignment:

1. Completion of an online brief written essay comparing the Thomas/Sallam local and global health initiatives. Assignment details are provided in CourseWeb.

Session 5 (Online)	Healthy People 2010/2020 (Topic 2)	October 1
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Focus: Healthy People 2010 and the goals of this national health initiative.

Session 5 content:

To view:

1. Sandra Crouse Quinn, PhD, "Healthy People 2010"
2. Michael Yonas and Adrienne Walnoha, "Applying Principles of Community-Based Participatory Research (CBPR): Exploring the Experiences of Individuals Living in a Housing Crisis Through Photovoice"

To read:

1. Healthy People 2010 Home Page (please be sure to read through **all** aspects of the website). URL: <http://www.healthypeople.gov/>. Also, please note there are 28 focus areas in HP 2010. Review the HP 2010 Home Page and review one of the focus areas that relates to your area of research interest.
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>. Also, please review the NCHS website "Fast Stats" section for Pennsylvania trend data that relates to your research area or research interest.

Suggested Reading:

1. Doyal L. Gender and the 10/90 gap in health research. 2004. Bull World Health Organ; 82

Assignment:

To read:

1. Lenfant C. Clinical Research to Clinical Practice: Lost In Translation. *NEJM* 2003;349:868-74. This article is posted in CourseWeb, Session 5 and provides background information for the October 8th brief lecture.

Topic 3 Models of Translational Research

Objectives:

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

Focus: The basic framework of Type 1 and Type 2 translational research.

Session 6 content:

1. Brief lecture: Translational research types and how they correlate to course project.
2. Multidisciplinary teamwork and information about upcoming team presentation (October 22nd) that will outline the first phase of course project development. Project rubric will also be distributed and reviewed. Teams will schedule presentation times for next week's class session.

Assignment:

To view:

1. Dr. Samuel Poloyac, "Type I Translational Research in the Pharmaceutical Sciences."
2. Dr. Michael Fine, "Evidence-Based Approach for the Initial Site of Treatment for Community-Acquired Pneumonia: A Case study of Type II Translational Research."

Suggested reading:

1. Zerhouni EA. US Biomedical Research: Basic, Translational, and Clinical Sciences. *JAMA* 2005; 294:1352-58.

Session 7 (Online Discussion)	Models of Translational Research (Topic 3)	October 15
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Focus: Introduces the basic framework of Type 3 translational research.

Session 7 Content:

1. Session 7 will include an online discussion of course topics and content covered up to and including this session. Discussion will focus on the relation of online course content to the course project. Students will be divided into two groups so the online chat session can be managed more efficiently by the instructor. Each session will be an hour in length and will be scheduled between 5-7pm.

Assignment(s):

To view:

1. Panel Discussion, "The Conceptual Framework of Type 3 Translational Research" with Drs. Lave, Donohue and Weyant moderated by Dr. Mark Roberts

To read:

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.

Focus: Multidisciplinary team presentations.

Session 8 Content:

1. Multidisciplinary teams will be presenting the first phase of course project development. This presentation will be informal and about 10-15 minutes in length. The instructor and peers will ask questions and provide constructive comments and suggestions to further course project development.

Assignment(s):

To view:

1. Dr. Arthur Levine and Dr. Wishwa Kapoor discussion, "Perspectives From Leaders On Translational Research"

To read:

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>.

<p>Topic 4 Methods of Clinical and Translational Research</p>

Objectives:

1. Students will recognize the methods of T1, 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 University of Pittsburgh Clinical and Translational Science Institute and the resources it can provide to researchers.

Focus: Multidisciplinary teamwork on course project with application of course content and peer review suggestions to ongoing project development.

Session 9 Content:

1. Multidisciplinary team discussions to refine or reorganize initial work of course project.

Assignment:

To view:

1. Dr. Wishwa Kapoor, “Translational Research and Quality of Health Care”
2. Clinical & Translational Science Institute website: <http://www.ctsi.pitt.edu>

Session 10 (Online)	Clinical and Translational Research (Topic 4)	November 5
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Focus: Barriers in conducting translational research.

Session 10 Content:

To View:

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.”

Assignment(s):

None

<p style="text-align: center;">Topic 5 Drug, Therapeutic and Device Development Process</p>

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 post-marketing 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 post-marketing optimization and individualization of drug therapy.

Session 11 (Live)	Research Discoveries and Improved Health Care (Topic 5)	November 12
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Focus: Multidisciplinary teamwork on course project with application of course content and peer review suggestions to project development.

Session 11 Content:

1. Ongoing multidisciplinary team course project development and informal meeting with course instructor to guide project development.

Assignment(s):

To view:

1. Dr. Mark Malandro, "Moving Research Innovations into the Marketplace."
2. Dr. Robert Abraham, "New Drug Discovery: Preclinical to Clinical Drug Development"
3. Dr. Shanta Zimmer, "Vaccinology: A Model of Translational Research From the Bench to the Population and Back Again."

To read:

1. Burke DS. Human Trials of Experimental HIV Vaccines. *AIDS* 1995;9 (suppl A):S171-80.

Optional Viewing:

1. Dr. Donald S. Burke, "Vaccines: From Development to Public Health Implications"

Session 12 (Online)	Surveillance and Individualization of Therapy (Topic 5)	November 19
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Focus: The process of how drug therapeutics are optimized and individualized in clinical practice to improve healthcare.

Session 12 content:

To view:

1. Dr. William Evans, "Post-marketing Surveillance and Individualization of Therapy"

Suggested 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 (Live)	Academic and Industry Interface (Topic 5)	December 3
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Focus: (Ongoing) Multidisciplinary teamwork on course project with application of course content and peer review suggestions to project development.

Session 13 content:

1. Multidisciplinary teams will discuss final work (edits, updates) to complete course project. Please “touch base” with course instructor during this class session to clarify any details/questions regarding the course project during this class session.

Assignment(s):

To view:

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

Other:

1. **Course projects are due during the next two sessions** and will be presented by teams.

Session 14 (Live)	Final Class/Project Presentations	December 10
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Multidisciplinary team course project presentations and paper version of overall project development due today.

Session 15 (Live)	Final Class/Project Presentations	December 17
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Multidisciplinary team course project presentations and paper version of overall project development due today.