Introduction to Translational Research in the Health Sciences:

CLRES 3140 (CRN: 19543)
DENT 3111 (CRN: 19438)
HRS 3140 (CRN: 19133)
NUR 3056 (CRN: 19068)
PHARM 3140 (CRN: 19132)
PUBHLT 3000 (CRN: 19338)

Course Summary

The goal of the Clinical and Translational Science Institute (CTSI) common core curriculum is to provide doctor-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 preventative 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/Fail option based on the following:

- Assignments: 10% of final grade
- Mid-Term Multidisciplinary Group Project (Presentation/Written): 20% of final grade
- Mid-Term Peer/Self Evaluation: 5% of final grade
- Final Multidisciplinary Group Project (Presentation/Written): 50% of final 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 point 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 and justify the research:
Defining and justifying the line of research selected

- **Barriers:**
  Identify the current barriers that are limiting the field

- **Overcoming Barriers:**
  Describe (an) approach(es) to overcome barriers

- **Outcomes:**
  Anticipating the outcomes or impact

- **Transdisciplinary Aspects:**
  Discuss how various disciplines can work together to create a more effective and novel transdisciplinary approach to this research

- Final Peer/Self Evaluation: 15% of final grade

**Schedule**

- Fall Term

**Required Texts**

- No required textbooks.
- Please see CourseWeb (http://courseweb.pitt.edu) for the required and supplemental readings for each session.
  - Readings may be downloaded for free online or via the HSLS Library. They are also all available in the course readings folder in the ICRE Library (Parkvale Building, Room 302).
- For the final written group project, software (Microsoft 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 of Falk Library.
- For other software/computer requirements (plug-ins, settings, etc.), please see the Pre-Session 1 section of CourseWeb.

**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 the 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.
Pre-Session 1
Preparing For a Hybrid Course

Objectives

1. Students will prepare their home computers for the technological demands of a hybrid course.

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Focus
Preparation of home computers for technological demands of course.

Pre-Session 1 Content

1. Plug-in Installation
2. Email Preparation

Pre-Session 1 Assignment Due Prior to Session 1

1. Read and complete all bullet points found under Pre-Session 1 in CourseWeb.

Course Introduction
Conceptual Framework for Multidisciplinary and Interdisciplinary Research

Course Introduction 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
Course Introduction

Focus
Course overview and expectations, student introductions and introduction to course project and conceptual framework for multidisciplinary/interdisciplinary research.

Session 1 Content

1. Course overview discussion
2. Guest Speaker: Dr. Joan Lakoski, PhD
   a. “Research Teams of the Future”
Session 1 Assignment Due Prior to Session 2

1. Complete “Survey of Research Interests 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 of this survey will be analyzed by the course instructors and applied to team development.

Readings to be Completed Prior to Session 2


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**Topic 1**

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

**Topic 1 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.

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**Session 2 Online NIH Roadmap and CTSI**

**Focus**

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

**Viewings to be Completed Prior to Session 3**

1. Dr. Elias Zerhouni, Former Director, National Institutes of Health
   a. “Clinical and Translational Research: The NIH Roadmap”
      i. http://content.nejm.org/cgi/content/full/NEJMsb053723/DC1
2. Dr. Sam Poloyac
   a. Recorded presentation on the history and function of the CTSI (Clinical Translational Science institute) and relevance to course projects and future professional research goals

**Readings to be Completed Prior to Session 3**

1. NIH Roadmap for Medical Research
   a. http://content.nejm.org/cgi/content/full/353/15/1621
Supplemental Viewings

1. Dr. Arthur Levine
   a. “The Pathways to Discovery”
      i. http://mediasite.cidde.pitt.edu/mediasite/Viewer/?peid=b11df021-e5af-4b6e-ae5d-255744220183

Assignment Due Prior to Session 3

1. Submit via CourseWeb a brief (maximum 2 pages) written justification of how you think clinical and translational research will evolve from the initial inception by Elias Zerhouni to the current leadership under Francis Collins and future directions for the National Center for Advancing Translational Science.

Topic 2

National and Global Health Care Agendas

Topic 2 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 the 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

Health Issues in All Disciplines

Focus

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 can affect all disciplines. The course project research topics should emerge from discussion. 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.

Viewings to be Completed Prior to Session 4

1. Dr. Linda Siminerio, RN, PhD, CDE
   a. “A Introduction to Translational Research”
      i. http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=a68cadb3-13aa-42b1-9626-8323e8969f33
Assignment Due Prior to Session 6

1. Wiki Review – 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.

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Focus

Local and global health issues and the 10/90 gap and origins.

Viewings to be Completed Prior to Session 5

1. Dr. Stephen Thomas
      i. Video is embedded in Session 4 on CourseWeb.
2. Dr. Ismail Sallam, Former Minister of Health and Population
      i. [http://mediasite.cidde.pitt.edu/mediasite/Viewer/?peid=d9897f11-1414-4576-85d8-82b0c9768de9](http://mediasite.cidde.pitt.edu/mediasite/Viewer/?peid=d9897f11-1414-4576-85d8-82b0c9768de9)

Supplemental Readings

1. Stevens P. Diseases of poverty and the 10/90 gap
2. Garrett L. The challenge of global health. Foreign Affairs 2007;86(Jan/Feb).

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Focus

Healthy People 2020 and the goals of this national health initiative.

Viewings to be Completed Prior to Session 6

1. Michael Yonas and Adrienne Walnoha
   a. “Applying Principles of Community-Based Participatory Research (CBPR): Exploring the Experiences of Individuals Living in a Housing Crisis Through Photovoice”
      i. MP4 file is embedded in Session 5 on CourseWeb.

Readings to be Completed Prior to Session 6

2. Healthy People 2020 Home Page (please be sure to read through all aspects of the website). Review one of the focus areas that relates to your area of research interest.
3. National Center for Health Statistics (please be sure to read through all aspects of the website with a special emphasis on data). Also, please review the NCHS website “Fast Stats” section for Pennsylvania trend data that relates to your research area or research interest.

Supplemental Readings


Assignment to be Completed Prior to Session 6

1. Submit via CourseWeb a brief (maximum 2 pages) written explanation of how you believe that Healthy People 2020 supports your group project from both a local and global perspective. Note this is an individual assignment, not a group assignment. Please submit original work.

Topic 3
Models of Translational Research

Topic 3 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.

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Focus

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

Session 6 Content

1. Brief lectures on translational research types and how they correlate to the course project.
2. Multidisciplinary teamwork and information about upcoming team presentation that will outline the first phase of course project development. Project rubric will also be distributed and reviewed. Teams will schedule presentation times for Session 9.

Viewings to be Completed Prior to Session 7

1. Dr. Samuel Poloyac
   a. “Type I Translational Research in the Pharmaceutical Sciences”
      i. Narrated Articulate PowerPoint – click link on CourseWeb

2. Dr. Michael Fine
a. “Evidence-Based Approach for the Initial Site of Treatment for Community-Acquired Pneumonia: A Case Study of Type II Translational Research”
   i. Introduction:  
   http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=6f635a93-2fec-41c3-8ef5-0b5a4457c3ed
   ii. The Plan Phase:  
   http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=a23e0b02-e389-4490-87b2-0e589c31af3d
   iii. The Do Phase:  
   http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=74c8d8e1-5d8c-468f-92fd-c9202a9557bd
   iv. The Study Phase:  
   http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=2379694f-487b-47c1-b8e9-4b7c334d38a6
   v. The Act Phase:  
   http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=bda5444b-23c3-4935-a568-2f0f780d777d

Supplemental Reading

   a. http://jama.ama-assn.org/cgi/content/abstract/294/11/1352

Session 7 Models of Translational Research

Focus

Introduces the basic framework of Type 3 translational research.

Session 7 Content

1. Session 7 is an optional live session during which student groups may schedule one-on-one time with the course instructors to work on/discuss their final projects. Groups may also meet independently at a time/location of their own choosing or may choose not to meet.

Viewings to be Completed Prior to Session 8

1. Panel Discussion with Dr. Judy Lave, Dr. Julie Donohue and Dr. Robert Weyant and moderated by Dr. Mark Roberts
      i. http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=47d83f8e-958e-49a2-a00d-5c859e266256

Readings to be Completed Prior to Session 8

   a. http://jama.ama-assn.org/cgi/content/abstract/289/10/1278
   a. http://jama.ama-assn.org/cgi/content/full/297/4/403
Session 8: Health Issues Common to All Disciplines

Focus
Multidisciplinary teamwork on course project.

Session 8 Content

1. Multidisciplinary teams will meet to finalize their mid-term presentation of their project. Instructors will be available to provide assistance and direction.
2. Mid-term presentations next week (Session 9)

Viewings to be Completed Prior to Session 9

1. Dr. Arthur Levine and Dr. Wishwa Kapoor
   a. “Perspectives From Leaders On Translational Research”
      i. http://mediasite.cidde.pitt.edu/mediasite/Viewer/?peid=0c987979-c6fb-4f43-93b9-f886f2ea90c8

Readings to be Completed Prior to Session 9

   a. http://circ.ahajournals.org/content/102/4/368.short
2. National Institutes of Health
   a. “Re-engineering the Clinical Research Enterprise”

Session 8 Assignments to be Completed Prior to Session 9

1. Designate one member of your group to submit via CourseWeb (in Session 9) the final project written material you would like to have graded. Should your group not submit written material by the designated date, the contents of the Group Wiki will be graded in its place.
2. Mid-Term Peer/Self Evaluation due via CourseWeb (in Session 9).

Topic 4
Models of Clinical and Translational Research

Topic 4 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’s Clinical and Translational Science Institute and the resources it can provide to researchers.
Session 9 Applying Methods of Clinical and Translational Research

Focus

Mid-term project presentations.

Session 9 Content

1. Multidisciplinary teams will present the first phase of the course project development (only the first two points on rubric are required). 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.

Viewings to be Completed Prior to Session 10

1. Dr. Wishwa Kapoor
   a. “Translational Research and Quality of Health Care”
      i. [http://www.gmstream.pitt.edu/presentation/wishwa_kapoor/translationalresearchandqualityofhealthcare.html](http://www.gmstream.pitt.edu/presentation/wishwa_kapoor/translationalresearchandqualityofhealthcare.html)

2. Clinical & Translational Science Institute website
   a. [http://www.ctsi.pitt.edu](http://www.ctsi.pitt.edu)

Session 10 Clinical and Translational Research

Focus

Barriers in conducting translational research.

Session 10 Content

1. Students should be able to identify barriers to translation of research within their selected project topics.

Viewings to be Completed Prior to Session 11

1. Panel Discussion with Dr. Sue Manzi, Dr. Charles Sfeir and Dr. Anthony Delitto and moderated by Dr. Sam Poloyac
   a. “Views from Leaders and Senior Investigators in Translational Research: A Discussion about Methods and Working with Multidisciplinary Teams”
      i. [http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=a9652bb2-c887-41c7-838b-2fcfbe2a0081](http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=a9652bb2-c887-41c7-838b-2fcfbe2a0081)

2. Panel Discussion with Dr. Donna Caruthers, Dr. Matthew Rosengart, Dr. Rory Cooper and Ms. Patricia Karausky and moderated by Dr. Judith Erlen
   a. “Barriers in Conducting Clinical and Translational Research: Problems and Solutions”
      i. [http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=06d86557-9e5c-4d45-9fbf-92a2abd20d4f](http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=06d86557-9e5c-4d45-9fbf-92a2abd20d4f)
**Topic 5**

**Drug, Therapeutic and Device Development Process**

**Topic 5 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**

**Research Discoveries and Improved Health Care**

**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 instructors to guide project development.

**Viewings to be Completed Prior to Session 12**

1. Dr. Mark Malandro
   a. “Moving Research Innovations into the Marketplace”
      i. [http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=6a73b739-46e1-47b9-8ecb-219148fb4512](http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=6a73b739-46e1-47b9-8ecb-219148fb4512)

2. Dr. Robert Abraham
      i. [http://www.gmstream.pitt.edu/presentation/robert_abraham/bobabraham_wyeth1.html](http://www.gmstream.pitt.edu/presentation/robert_abraham/bobabraham_wyeth1.html)

3. Dr. Shanta Zimmer
   a. “Vaccinology: A Model of Translational Research from the Bench to the Population and Back Again”
      i. [http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=0ca8ff8-37bd-4ec8-a999-cb2f8a0aa182](http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=0ca8ff8-37bd-4ec8-a999-cb2f8a0aa182)

**Readings to be Completed Prior to Session 12**


**Supplemental Viewing**

1. Dr. Donald S. Burke
   a. “Vaccines: From Development to Public Health Implications”
      i. http://coursecast.icre2.pitt.edu/Panopto/Pages/Viewer/Default.aspx?id=968face3-0bce-4765-b5a6-db52d3ec7e0f

**Supplemental Readings**


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**Session 12**

**Individualized Medicine and Comparative Effectiveness & Academic and Industry Interface**

**Focus**

The process of how therapeutics are compared and/or individualized in clinical practice to improve healthcare outcomes and the academic and industry interface.

**Session 12 Content**

1. Students should consider individualization and/or comparisons of their project interventions against current standard of care.

**Viewings to be Completed Prior to Session 13**

1. Dr. William Evans
   a. “Post-Marketing Surveillance and Individualization of Therapy”
      i. Video is embedded in Session 12 on CourseWeb.

2. Mr. Myron Holubiak, Director at Nastech Pharmaceuticals Company, Inc.
   a. “Development of New Drugs and How to Improve the Pipeline”

**Readings to be Completed Prior to Session 13**

   a. http://www.annals.org/content/148/12/964.full

Supplemental Readings

   a. [http://www.nature.com/nature/journal/v429/n6990/abs/nature02626.html](http://www.nature.com/nature/journal/v429/n6990/abs/nature02626.html)
   a. [http://www.annals.org/content/113/2/147.abstract](http://www.annals.org/content/113/2/147.abstract)

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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 the course project. Please “touch base” with the course instructors during this class session to clarify any details/questions regarding the course project.
2. Final project presentations next two weeks (Session 14 & Session 15).

**Session 13 Assignment to be Completed Prior to Session 14 (12/6)**

1. Designate one member of your group to submit via CourseWeb (in Session 13) a draft of the final written project. This will allow the instructors to better evaluate your oral presentation.

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**Focus**

Multidisciplinary team course project presentations.

**Session 14 Content**

1. Multidisciplinary teams will present their final course projects. See CourseWeb for final project presentation requirements, final paper requirements and grading rubric.

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**Focus**

Multidisciplinary team course project presentations.
Session 15 Content

1. Multidisciplinary teams will present their final course projects. See CourseWeb for final project presentation requirements, final paper requirements and grading rubric.

Final Project Submission

1. Designate one member of your group to submit via CourseWeb prior (in Session 15) your final written project that is to be graded.

NO SESSION 16