

## Syllabus – 8-17-2016

### 1. Course Title: GMS 6847, Section 28C7 – Translational Research and Therapeutics: Bench, Bedside, Community, & Policy

Classroom: Tuesdays 1:00-3:00pm & Thursdays 1:00-2:00pm – ARB Room R5-265 (Department of Pharmacology & Therapeutics Conference Room)

Course Director:

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Section Leaders

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### 2. Office hours: By appointment

### 3. Course Objectives

This course is for students to gain an insight into clinical research and clinical application, for clinical researchers to gain insight into the basic science required to reach clinical trials, and for all researchers to gain insight into the importance of industry, regulation, marketing, and acceptance into medical practice, which constitutes the endpoint of translational research. The course meets during the Fall semester for three hours per week, and includes guest lecturers with varied expertise in the principles of translational research. The course will emphasize understanding and applying the steps in the multi-T phase process of translational research. It will utilize multimodal teaching technique combining didactic lectures, reading assignments, and multidisciplinary team-based learning.

This course will introduce and explore in-depth the multi-T-phase concept of translational research. It will emphasize moving knowledge and discovery gained from basic science research at the bench to its application in clinical and community settings, and finally into national health policy. This course will explore the breadth of T0 research in the identification of opportunities and approaches to health problems as it relates to small molecules, biologics, diagnostics, and devices. It will elucidate the important aspects of T1-T2 translational health research as it relates to Phase I - Phase III clinical trials that take observational studies to evidenced-based guidelines for treatments. Finally, the course will explore T3 & T4 research that includes dissemination and implementation of research from clinical trials to health practices, evaluation of their impact and the potential integration into population health policy.

*General Course Learning Objectives:*

- a. Describe the process of identifying potential connections between scientific discoveries and human conditions (aging, injury, fatigue, pain, *etc.*) or diseases (diabetes, cancer, hypertension, infection, *etc.*).
- b. Describe the process of identifying an unmet medical need (*i.e.*, review knowledge of human conditions/diseases and their treatment and vice versa; this should include a discussion of benefit/risk/limitations of current treatments).
- c. Identify how scientific knowledge or discoveries might be used to improve upon existing therapies (compare benefit and risk of current versus proposed therapies).
- d. Describe the major steps in the process where basic scientific discoveries are applied towards solving medical problems in patients and society (T0-T4).
- e. Discuss the different types of knowledge or expertise that are required to move between steps T0-T4 (*i.e.*, formal sciences vs. natural sciences vs. social sciences; a priori knowledge vs. post priori knowledge) and the importance of team science.

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### Specific Course Learning Objectives for Sections T0, T1, T2, T3, and T4

#### Section T0: Identification of opportunities and approaches to health problems: Envisioning a path between bench and bedside.

- a. Describe how small molecules, biologics, devices, and diagnostics can be used to treat human conditions or diseases.
- b. Discuss how different model systems are used to approximate molecular, cellular, or physiologic aspects of the human environment (*i.e.*, in vitro biochemical or cellular models, animal models, *etc.*) and the advantages/limitations of each approach.
- c. Discuss what type of benchmark findings need to be obtained before preclinical studies can be moved into human trials (*i.e.*, standards underlying preclinical evaluation, regulatory requirements).
- d. Define therapeutic modalities and describe how they can be used.
- e. Contemplate other real-world considerations that influence the impact of a healthcare innovation including cost, insurance coverage, its accessibility to patients, and market size.

#### Section T1: Discovery of Candidate Health Applications: The Journey from Laboratory to the Clinic

- a. Explain how intellectual property is protected and why this is important
- b. Recognize governmental and institutional requirements which must be met to initiate clinical studies
- c. Discuss the purpose and design of Phase I and 0 clinical trials (what type of information is obtained from these studies and how is this used to guide future translational studies)
- d. Identify and surmount roadblocks frequently encountered in Phase I trials and how these might be avoided by the implementation of Phase 0 trials

#### Section T2: Health application – to evidence-based practice guidelines: From the Bedside Back to the Bench

- a. Describe the value of evidence-based medicine in evaluating the effectiveness of new therapeutic applications.
- b. Discuss the purpose and design of a phase 2 clinical trial and how it differs from a phase 1 clinical trial.
- c. Describe what type of information is typically obtained from a phase 2 study and how this information is used to guide future translational studies (*i.e.*, phase 3 trials).
- d. Describe the review and approval process required to initiate a phase 2 clinical trial.
- e. Discuss and give examples of how surrogate endpoints can be used to predict clinical outcome.
- f. Describe the review and approval process required to progress from a phase 2 into a phase 3 clinical trial.
- g. Discuss the process of obtaining a New Drug Application (NDA), a Biologics License Application (BLA), or a 510(k) Medical Device Application.
- h. Discuss how evidence-based medicine uses information from Phase 2/3 clinical trials to optimize and establish new practice guidelines

#### Section T3: Practice Guidelines to Health Practices

- a. Describe the disseminating of new discoveries to communities and populations.
- b. Identify examples of evidence-based clinical best practices that when implemented result in known health disparities.
- c. Describe the steps to implement a new health benefit (*i.e.*, device, drug) and track population-level access.
- d. Describe the social determinants of Population Health

#### Section T4: Practice to Population: Health Impact

- a. Discuss the factors and interventions that influence the health outcomes of populations
- b. Describe how to measure the health outcomes of populations
- c. Discuss the need for economic evaluation, its different forms, and current issues and controversies.
- d. Discuss issues related to quality of life measurement and patient reported outcomes.
- e. Identify the steps to critical appraisal of evaluation studies.

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4. Course Schedule:

Translational Research & Therapeutics: Bench, Bedside, Community, & Policy Fall 2016		
	2-hour sessions (1:00-3:00 pm)	1-hour sessions (1:00-2:00 pm)
Intro (3)	Tue, Aug 23 <b>Drs. Martens/Dr. McCormack</b> Intro T0-T4 steps, unmet medical need (BRCA), teams, needs for T transitions; Homework: unmet medical need worksheet	Thu, Aug 25 Teams identify unmet medical needs
T0 (7)	Tue, Aug 30 <b>Dr. Harrison</b> T0 intro lecture Case Study – Small Molecules, Dr. Lee Sweeney	Thu, Sep 1 Case Study Studies: Biologics, Dr. Edgar Rodriguez
	Tue, Sep 6 T0 TBL Session	Thu, Sep 8 Team meeting: apply T0 to unmet medical need
	Tue, Sep 13 Brief T0 Team Reports	Thu, Sep 15 <b>Dr. Law</b> T1 intro lecture – Dr. Brian Law
T1 (7)	Tue, Sep 20 Pharmacokinetics in Phase 1 Trials BM Transplant Trials – Dr. John Wingard	Thu, Sep 22 Case study
	Tue, Sep 27 T1 TBL Session Team meeting: apply T1 to unmet medical need	Thu, Sep 29 Brief T1 Team Reports
T2 (6)	Tue, Oct 4 <b>Dr. Rowe</b> T2 intro lecture – Dr. Tom Rowe Phase 2/3 Clinical Trials – Dr. Priya Gopalan	Thu, Oct 6 Drug Metabolism in Clinical Trials – Dr. Margaret James
	Tue, Oct 11 T2 TBL Session Team meeting: apply T2 to unmet medical need	Thu, Oct 13 Brief T2 Team Reports
	Tue, Oct 18 Tour CTSI Clinical Research Facilities	Thu, Oct 20 <b>Dr. Barnett</b> T3 intro lecture – Dr. Tracey Barnett
T3 (7)	Tue, Oct 25 Health Disparities – Dr. Tracey Barnett Identifying disparities using big data – Dr. Travis Gerke	Thu, Oct 27 Phase 4 Clinical Trials – Dr. Thom George
	Tue, Nov 1 T3 TBL Session Team meeting: apply T3 to unmet medical need	Thu, Nov 3 Brief T3 Team Reports
T4 (8)	Tue, Nov 8 <b>Faculty</b> T4 Intro lecture – TBD	Thu, Nov 10 Topic pending faculty confirmation
	Tue, Nov 15 Health Economics- Dr. Ramzi Salloum Public Health/Global Medicine – Pending faculty confirmation.	Thu, Nov 17 UF HealthStreet – Speaker: TBE
	Tue, Nov 22 T4 TBL Session	Thu, Nov 24 Thanksgiving Holiday
	Tue, Nov 29 Team meeting: Work on final reports	Thu, Dec 1 Team meeting: Work on final reports
	Tue, Dec 6 Final Team Reports including T4 Team Reports	

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### 5. Methods of Evaluation and Grading

Students will be evaluated based on their performance on TBL readiness assurance tests (50% of grade) and on team presentations (50% of grade).

Exams (50% of grade): There will be five team-based learning sessions, each of which will include an individual readiness assurance test (IRAT) and team readiness assurance test (TRAT), consisting of the same questions. These tests will consist of multiple choice type questions based on content in assigned reading materials and immediately preceding lectures. The relative weight of the IRAT and TRAT will be determined by student voting.

Team Activities and Presentations (50% of grade): Student participation in the team activities and presentations will be assessed by the course faculty and by peer evaluation as outlined below.

T0-T4 Team Reports	20% each (faculty evaluation)
Final Team Report	25% (faculty evaluation)
Participation/Attendance	5%

The following grading scale will be used for this course:

A	93-100%	C	74-76%
A-	90-92%	C-	70-73%
B+	87-89%	D+	67-69%
B	84-86%	D	64-66%
B-	80-83%	D-	60-63%
C+	77-79%	F	< 60%

At the end of the semester the final letter grade cut-offs may be adjusted lower, but will not be adjusted higher.

**6. Attendance:** Requirements for class attendance and make-up exams, assignments and other work in this course are consistent with university policies that can be found at:

<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>

### 7. Accommodations for students with disabilities:

Students requesting classroom accommodation must first register with the Dean of Students Office. The Dean of Students Office will provide documentation to the student who must then provide this documentation to the Instructor when requesting accommodation.

**8. Required and recommended textbooks:** Lecture materials will be provided in pdf format. There is no required textbook.

**9. Information on current UF grading policies:** please consult the following website:

<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>

**10. Evaluation process:** Students are expected to provide feedback on the quality of instruction in this course based on 10 criteria. These evaluations are conducted online at <https://evaluations.ufl.edu>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at:

<https://evaluations.ufl.edu>

**11. Materials, Supplies, Fees:** not applicable