

Despain, Dezra

From: MacDorman, Karl Fredric
Sent: Thursday, August 20, 2015 11:52 AM
To: Blum, Janice S.
Cc: Despain, Dezra; Jones, Josette F.
Subject: Fwd: Syllabus for Tools and Techniques Fall15
Attachments: Syllabus for Tools and Techniques Fall15.docx; ATT00001.htm

Dear Graduate Affairs Committee,

When the course GRAD G660 Advanced Clinical Research Methods is unavailable, we would like for our doctoral students to be able to substitute GRAD G667 Tools and Techniques in Translational Research in their plan of study. These students are in the PhD in Informatics, Biomedical and Health Informatics specialization.

Best wishes,
Karl MacDorman

Begin forwarded message:

From: "Jones, Josette F." <jofjones@iupui.edu>
Subject: Syllabus for Tools and Techniques Fall15
Date: August 19, 2015 at 10:25:43 PM EDT
To: "Bunge, Elizabeth" <ebunge@iupui.edu>, "MacDorman, Karl Fredric" <kmacdorm@iupui.edu>
Cc: "Wu, Huanmei" <hw9@iupui.edu>

Good Evening,

One of our PhD required courses is GRAD G660 Advanced Clinical Research Methods has no longer openings for our PhD students. The Translational program kindly opened their research course for our students. The syllabus is attached. Do I need to send a substitute form for each student or can we add this course to the list? Your reply is appreciated. Have a great evening.

Josette.

Syllabus

I. Title: Tools and Techniques in Translational Research
Course Number: G-667
Course Director: R. Mark Payne, MD
Schedule: Tuesdays & Thursdays 10 – 11:30 a.m. (Fall semester)
Medical Sciences Building – room B14
Prerequisites: Completion of Preliminary Examinations, or terminal degree (MD, PhD, etc).

II. COURSE DESCRIPTION AND RATIONALE

Translational Research at its most basic definition is the application of basic discovery to human health and disease. This new, but vital, branch of science seeks to characterize the molecular mechanisms of a disease process, determine ways to measure this in the human disease state, and then develop and implement a therapeutic intervention in the clinic. As such, the skills needed to succeed in translational research are diverse and require an understanding of how to manage the multi-disciplinary teams that are a hallmark of translational research.

This course will provide the student and fellow with an understanding of the basic technologies and techniques used in translational research today. Key to this training is understanding how and when to use these technologies, and how to interpret their results and pitfalls. The trainees will also develop an understanding of the components for protecting human subjects, and how to move a novel concept from the lab into a patient. Finally, the student will understand how to identify and measure target endpoints in patients, and how to assemble a multi-disciplinary team to conduct translational research. The course will use a case-based approach whereby specific technologies and problems are demonstrated in readings drawn from the textbook.

Short description: This course is an introduction to translational research and will cover both the basic methodology of molecular research on human disease, as well as the process of moving basic discoveries from the lab into patient care. The course is targeted to the advanced graduate student and clinical or research based postdoctoral fellows.

III. EDUCATIONAL OBJECTIVES

By the completion of this course, the student will be able to:

1. Define translational research and understand how it differs from purely basic or clinical research.
2. Understand the basic concepts and methodology of the multiple techniques used in molecular biology today.
3. Understand the limitations, potential errors, and mistakes that these techniques may have in their application to biology.
4. Be able to interpret and apply data from these techniques.
5. Understand how these techniques are applied to questions of human health and disease.

6. Be able to design a basic molecular strategy to investigate or address a question in human health and disease (bed to bench).
7. Understand the role that the institutional review board (IRB) plays in human studies.
8. Understand the components of a successful IRB application for human studies.
9. Understand how a novel invention or drug moves from bench to bedside.
10. Understand pre-clinical testing and application for an Investigational New Drug application (IND) from the Food and Drug Administration (FDA).
11. Understand the phases of clinical testing: Phase I, II, III, etc., and when to use or apply them.
12. Understand and develop skills in target validation for testing new drugs and inventions in human disease.
13. Understand and develop skills in assembling a multi-disciplinary team in translational research to move a concept from bench to bedside.

IV. Course Content

Weekly readings will be from assignments in the Text, and from distributed articles. The intent of this course is to stimulate discussion and foster interaction among class participants to solve problems in translational research today.

Date		Topic	Faculty / Dept.
August	25	Introduction to Translational Research	R. Mark Payne, M.D.
August	27	Assembly of Multi-disciplinary Teams - The Role of the Clinical Nurse Coordinator in Translational Research	Lucy Miller, R.N., B.S.N., CCRC
September	1	Clinical & Translational Sciences Institute and Project Development Teams	Tammy Sadjyk, Ph.D.
	3	Funding	Alicia Gahimer (Research Development Specialist - Office of VP Research)
	8	Mentorship	Kurt Kroenke, MD
	10	Model Based Analysis	TBD
	15	Case Studies in Faculty Innovators Translating Their Work into Commercial Entities	Mervin Yoder, M.D.
	17	The Do's & Don'ts for Submitting IRB Applications	Christine Caldwell, , JD, MA, CIP
	22	Health Disparities	Sarah Wiehe, MD, MPH
	24	Institutional Review Boards & Human Studies - Current Controversies in Human Subjects Research	Christine Caldwell, , JD, MA, CIP
	29	Translational Research Ethics	Eric Meslin, Ph.D.
October	1	Intellectual Property	Brion St. Amour, JD & Jeremy Schieler, Ph.D.
	6	Use and Regulation of Animals in Research (IACUC issues)	Debra Hickman, DVM, MS, DACLAM
	8	Comparative Human / Animal Studies	TBD
	13	Community Engagement	Sarah Wiehe, MD, MPH
	15	Basic Methodologies in Molecular Biology of Human Disease & Health I (Earlier Techniques)	Stephen R. Dlouhy, Ph.D.
	20	Fall Break - NO CLASS	
	22	Basic Methodologies in Molecular Biology of Human Disease & Health I (Contemporary Techniques)	Stephen R. Dlouhy, Ph.D.
	27	Genome Wide Association Studies	Tatiana Foroud, Ph.D.
	29	Whole Exome Sequencing Studies	Tatiana Foroud, Ph.D.
November	3	Introduction to Flow Cytometry	Edward Srour, Ph.D.
	5	Bioinformatics	Yunlong Liu, Ph.D.
	10	Microarray and next generation sequencing technology	Yunlong Liu, Ph.D.
	12	Translational Clinical Cognitive Neuroscience: A psychologist's perspective	Bill Hetrick, PhD
	17	A Story of Translational Research Success	Michael Sturek, Ph.D.
	19	Drug Development: Non-viral Gene Therapy	R. Mark Payne, M.D.
	24	Drug Development: Goin' to the FDA	Gretchen Bowken
	26	Thanksgiving - NO CLASS	
December	1	International Drug Development Regulatory Sciences	Carl Garner, Ph.D.
	3	Drug Development: Moving from the Lab to the Patient - Operational Translation: From Chemicals to Drugs	Chris Dunwiddie, Ph.D.
	8	Drug Discovery: Preclinical Development - Contemporary Issues with Xenobiotic Drug Discovery	Carl Garner, Ph.D.
	10	Business of Life Science	George Telthorst, M.B.A.
	15	Final (10:30 - 12:30)	

Modified: August 21, 2015

V. RECOMMENDED TEXTS

Recommended:

Schuster, D. P., & Powers, W. J. (2005). *Translational and experimental clinical research*. Philadelphia: Lippincott Williams & Wilkins.

Ream, W., & Field, K. G. (1998). *Molecular biology techniques: An intensive laboratory course*. San Diego, CA: Academic Press.

Suggested Reading:

1. Littman, B.H., Di Mario, L., Plebani, M., & Marincola, F.M. (2007). What's next in translational medicine? *Clin Sci (Lond)* 112:217-227.
2. Birmingham, K. (2002). What is translational research? *Nat Med* 8:647.

V. EVALUATION AND GRADING

This class is intended to be highly interactive. Students and fellows are expected to attend and to participate actively in at least 80% of the class sessions. (e.g., if 25 sessions are scheduled, absences should be 5 or less). Most class sessions will have advance reading assignments from required textbooks, journal articles or handouts. Some sessions will also have problems, cases or questions to complete in advance of the class. Students and fellows will be expected to be prepared to discuss any assigned readings. In addition to the didactic lectures, highlights from readings will be addressed, questions will be posed, and additional material to augment the readings will be presented. Thus, dialogue and critical thinking on the part of the student will be emphasized. Students and fellows are encouraged to have “balanced” participation. Neither silence during the entire semester nor consistently “dominating” the class discussion are desirable.

Students and fellows in the class will be graded as follows: 30% of the grade from lecture evaluations and forum discussions, 30% from attendance, homework, and participation, and 40% from the final exam. Exam will consist of a combination of short answer / fill in the blank questions, and short essay questions. Objective covered in the lectures will be the source of all examination questions.

Final Course Exam. This exam will cover information throughout the semester, and will consist of short answers and short essay. Participants will have 2 hrs. to complete the exam.

Grading Scale:

Letter grade	Percentage
A	93-100
A-	90-92.99
B+	87-89.99
B	75-86.99
C	60-74.99
D	50-59.99
F	<50

Note that grades of C and lower are not passing grades in graduate level courses.

VI. CHEATING AND PLAGIARISM:

Students are instructed to make themselves aware of University regulations concerning plagiarism, the maintenance of academic honesty and the definitions of unacceptable behavior and cheating. Academic misconduct of any sort will not be tolerated and will be dealt with as outlined in the ***IU/IUPUI Code of Student Rights, Responsibilities, and Conduct***, which can be viewed at:

http://www.life.iupui.edu/help/docs/Part_3all.html

Examples of misconduct include but are not limited to:

1. Cheating

A student must not use or attempt to use unauthorized assistance, materials, information, or study aids in any academic exercise

2. Fabrication

A student must not falsify or invent any information or data in an academic exercise including, but not limited to, records or reports, laboratory results, and citations to the sources of information.

3. Plagiarism

A student must not adopt or reproduce ideas, words, or statements of another person without appropriate acknowledgment. A student must give credit to the originality of others and acknowledge an indebtedness whenever he or she does any of the following:

- a. Quotes another person's actual words, either oral or written
- b. Paraphrases another person's words, either oral or written
- c. Uses another person's idea, opinion, or theory; or
- d. Borrows facts, statistics, or other illustrative material, unless the information is common knowledge.

4. Interference

- a. A student must not steal, change, destroy, or impede another student's work.
- b. A student must not give or offer a bribe, promise favors, or make threats with the intention of affecting a grade or the evaluation of academic performance.

Potential consequences for academic misconduct:

If the instructor has information that one of his/her students committed an act of academic misconduct, the faculty member will hold an informal conference with the student. The conference will be prompt and private. If the faculty member concludes that the student is responsible for the misconduct, then the faculty member will impose an appropriate academic sanction (i.e., lower or failing grade on the assignment, assessing a lower or failing grade for the course).

VII. AMERICANS WITH DISABILITIES ACT:

Students needing accommodations because of a disability will need to register with Adaptive Educational Services (AES) and complete the appropriate forms issued by AES before accommodations will be given. The AES office is located in Taylor Hall, UC 100. You can also reach the office by calling 274-3241. Visit <http://aes.iupui.edu/> for more information.