COURSE SYLLABUS Fall 2011

Updated: September 6, 2011

COURSE TITLE: PREV 633 / CRN 93251
Application of Legal and Regulatory Issues in Clinical Research

CREDITS*:* 1 credit

LOCATION: MSTF 316 (enter through Health Sciences Facility I, take elevator to 5th floor, and take bridge from 5th floor of HSF I to 3rd floor of MSTF)

COURSE MASTER:
School of Medicine
Mary-Claire Roghmann, M.D., M.S.

FACULTY:

School of Medicine
Leslie I. Katzel, M.D., Ph.D.

School of Law
Jack Schwartz, J.D.

John Farley, M.D., M.P.H., Deputy Director of the FDA's Office of Antimicrobial Products, U.S. Food and Drug Administration
Kathleen Palmer, R.N.
Susan Hines, M.S., C.R.N.P.
Debbie Grady, R.N., M.S., C.C.R.C.
Julie Doherty, R.N., M.S., C.C.R.C.

Sponsored by the University of Maryland School of Medicine in conjunction with the UMB SOM General Clinical Research Center (GCRC) and Human Research Protections Office (HRPO).

PRE-REQUISITES: None

COURSE OVERVIEW:
A one-semester, one-credit, multidisciplinary course covering application of legal and regulatory topics critical to performing clinical research including the informed consent process, privacy and confidentiality issues, investigational new drug (IND) applications, financial disclosure and conflict of interest, the institutional review board (IRB) process, recruitment and retention strategies, data safety monitoring plans and quality management and clinical research conduct issues

COURSE OBJECTIVES:
Students will be able to
1. Analyze and apply key points (see below) of specific legal and regulatory topics critical to performing clinical research
2. Demonstrate the ability to apply interdisciplinary resolutions to issues central to clinical research

ACADEMIC INTEGRITY AND CONDUCT:
Students are referred to the following policies regarding academic integrity and conduct: University of Maryland System Policy on Faculty, Students and Institutional Rights and Responsibilities for Academic Integrity and the University of Maryland Graduate Policies and Procedures for Academic Misconduct.

AUDIO-VIDEO TAPING POLICY:
Audio/videotaping requires the permission of each instructor presenting material in this course.

INSTRUCTIONS FOR STUDENT COMMUNICATIONS:
The University and the School of Medicine will use the UMB Text Alert system as the primary means of alerting students to emergencies and giving them instructions on how to respond. Students are strongly encouraged to sign up for the alert system at https://alert.umaryland.edu <https://alert.umaryland.edu/> . Information on the University's status during inclement weather or other emergencies will also be released to local media outlets and be available at the Campus Alerts webpage at www.umaryland.edu/alerts or by calling the Campus Emergency Information Line at 410-706-8622.

WEATHER RELATED CANCELLATIONS:
Information regarding weather related cancellations can be obtained from 410-706-8622.

TEXTBOOK:
None

COURSE REQUIREMENTS:
1. Class participation: Students are required to read assigned papers or textbook reading prior to each class and participate in the case-based discussions.

2. Assignments: In addition to the readings above, students will be expected to independently complete two case-based analyses and perform CITI training. Each paper (of up to 3 pages in an approved format) will provide an analysis of an assigned clinical research case that involves multiple legal and regulatory issues and will include:
    1) identification of the key issues,
    2) an explication of the legal and regulatory requirements and,
    3) a management action plan for issue avoidance or resolution.

   Each of the two papers will be worth 35% of the grade.

EVALUATION AND GRADING:
Case based analyses: 70% (2 papers each worth 35%)
CITI Training: 30% (Basic and GCP modules each worth 15%)

BLACKBOARD –
For accessing Course Information and Documents

WHAT IS BLACKBOARD?
Blackboard is the Web-based communication system for students of the University of Maryland School of Nursing and Graduate School. It includes class announcements, weekly handouts, weekly readings, and similar information. The case based analyses will be submitted via Blackboard.

HOW TO ACCESS BLACKBOARD
The Blackboard website for the University of Maryland Baltimore is
http://blackboard.umaryland.edu/

1. Enter Username and Password to logon. If you do not know your Username / Password, see below.

2. Under My Courses, click on "Fall 2011 PREV633 Legal and Regulatory Issues in Clinical Research"

3. On left side of screen, click on needed folder (announcement, syllabus, course materials). All class handouts and readings are under "Course Materials" and organized by class date.

If you have never used Blackboard, please follow the instructions below:

1. Your Username is identical to your UMB id (usually first initial, first four digits of last name and 3 digit number) – If you do not know your UMB id, please call the campus helpdesk at 6-HELP for assistance.

2. You must now set a password for your Blackboard account.
    a. Click on "Forgot One Card Password?" under Password Tools on the left of the screen
    b. Complete form to identify yourself and click the Submit button.

COURSE SCHEDULE: Tuesdays 4:00 - 5:30 Location: MSTF 316

Class date	Topic	Reading Assignments
9/6/11	Course Overview • Faculty Introductions • Course Expectations • Course Schedule • Assignment of Topics Overview of the Regulatory History of Clinical Research and the Code of Federal Regulations **John Farley**	IRB Human Subjects Training (turn in copy of certificate by end of course)
9/13/11	Controversies in Informed Consent • Define the therapeutic misconception • Discuss the language and literacy controversies in consent forms • List the different models for providing research subjects with **incentives** and explain their rationale **Les Katzel**	• Evans, et al, Bloomberg Markets, 2005 • Muncie, *et al, JAGS* 45 :929-933, 1997 • Paasche-Orlow, *et al, NEJM*, 348 :8, 721-726, 2003 • Dickert, NEJM, 1999
9/20/11	Confidentiality in Clinical Research • Distinguish between Privacy and Confidentiality • Explain the rationale for privacy and confidentiality • List the regulations on privacy and confidentiality • Discuss practical ways to implement protocols in such a way as to maximize privacy and confidentiality **Kathleen Palmer**	No readings required

Class date	Topic	Reading Assignments
9/27/11	The Institutional Review Board (IRB) • List the regulations on IRBs • Describe how our IRB meets them • Describe the AAHRPP Accreditations process • Discuss the future of the local IRB **Les Katzel**	Steinbrook, *NEJM*, 2003
10/4/11	Clinical Research Conduct Case Studies #1 • GCP Considerations • Informed consent process • Source documentation • Separation of clinical and research testing **John Farley/Sue Hines**	CITI GCP Training modules (turn in copy of certificate by end of course)
10/11/11	Clinical Research Conduct Case Studies #2 • Adverse event reporting • Financial disclosure/Conflict of Interest **John Farley/Sue Hines**	As per Clinical Research Conduct Case Studies #1
10/18/11	Maryland Laws affecting Clinical Research • Supplement or extend federal regulations • Resolve issues left to state law by federal regulations • Provide additional safeguards or limitations • Determine when researchers face liability **Jack Schwartz**	Excerpts from the Kennedy-Krieger case at http://biotech.law.lsu.edu/cases/research/grimes_v_KKI_brief.htm

Class date	Topic	Reading Assignments
10/25/11	Research Quality Management **Julie Doherty** **Debbie Grady**	No readings required
11/1/11	Implementing a Clinical Research Study **Mary-Claire Roghmann** **Debbie Grady**	No readings required
11/8/11	Off- Election Day	**Case based papers due. CITI Certificates due. Submit through Blackboard from Assignments.**