

General Information							
Course Title:	Research Ethics for Clinical Investigators			Course Designation: HES 500	Credits: 1		
Semester:	Fall	Year:		2008			
Department:	Public Health Sciences						
Director:	Kevin Gleeson	Phone #	6525	Email:	kgleeson@psu.edu	Office Rm #	H041
Time :	5:30 to 7:00 pm	Days:	Wednesday (10/22/08 - 12/17/08)			Location:	ASB 1101

Course Information
<p>Description and/or Overview:</p> <p>This course will familiarize graduate students with the principles of ethical conduct of clinical research. As such, it is a parallel course to BIOS 591 which is a course structured to teach graduate students the ethical principles that apply primarily to basic science research. As such, the two courses have approximately 40% overlap on the common issues of authorship, collaborative studies, etc. However, the proposed course also deals with the importance of advocacy for human research subjects and teaching both physician and non-physician clinical investigators about the purpose and regulations that apply to Institutional Review Boards (IRBs).</p>
<p>Goals and/or Objectives:</p> <p>This course will teach graduate students fundamental strategies for the evaluation of complex competing interests that are commonplace in the conduct of research. Further, this course covers ethics and collaboration in research, intellectual property rights and it covers current national and institutional approaches to the conduct of clinical research. It also provides a perspective on the obligations of scientists and investigators to the public relation aspects of clinical research.</p>

Pre-requisites:

None

Requirements; course-specific policies and expectations:

The content of the proposed course overlaps that of IBIOS 591 about 40%. However, IBIOS 591 was designed for graduate students doing basic research and the proposed course has been designed for graduate students who will do clinical research. It is anticipated that many graduate students will wish to take both courses.

Required Texts and Resources:

Electronic Links:

Attendance Policy:

Forty percent (40%) of the grade is based on classroom participation so attendance is expected at all sessions.

Examination Policy:

Grading Criteria:

Classroom participation (40%)
Evidence of having completed the assigned reading prior to class (30%)
Written critiques of published studies (30%)

Academic Integrity

Academic Integrity at Penn State is defined by Faculty Senate Policy 49-20 as “the pursuit of scholarly activity in an open, honest and responsible manner”. The University's Code of Conduct states that “all students should act with personal integrity, respect other students' dignity, rights and property, and help create and maintain an environment in which all can succeed through the fruits of their efforts.

Academic integrity includes a commitment not to engage in or tolerate acts of falsification, misrepresentation or deception. Such acts of dishonesty violate the fundamental ethical principles of the University community and compromise the worth of work completed by others”. Academic dishonesty (including, but not limited to cheating, plagiarism, or falsification of information) will not be tolerated and can result in academic or disciplinary sanctions such as a failing (F) grade in the course.

Plagiarism

[For more information, see: <http://tlt.its.psu.edu/suggestions/cyberplag/cyberplagstudent.html>]

Statement on Remediation

The basis for grades, as stated in [Senate Policy 47-20](#), is "...the instructor's judgment of the student's scholastic achievement..." Occasionally, a disagreement arises in the assignment of a grade. A student who wishes to question or challenge the grade assigned in a course must first discuss grading practices and assignments with the instructor. It is expected that the student and instructor will try to eliminate any misunderstandings and will attempt to work out any disagreements over grades.

On the rare occasion that a student and instructor fail to resolve the grade dispute through informal means, the student may request that the head of the academic program offering the course act as a mediator. If this mediation does not resolve the dispute, the student who is a graduate student may request further mediation from the associate dean for graduate studies.

[For more information, see: <http://www.psu.edu/dept/oue/aappm/G-10.html>]

Educator's Code of Conduct

The Penn State Milton S. Hershey Medical Center and Penn State College of Medicine are dedicated to developing and maintaining a strong commitment to ethical teaching practices at all levels of the education process.

The foundation for this Educator's Code of Conduct is provided by the Penn State University Graduate School Statement on Teaching Ethics (1). The development of this Graduate School statement was based on a special issue of the journal, *New Directions for Teaching and Learning*. In this special issue, entitled *Ethical Dimensions of College and University Teaching: Understanding and Honoring the Special Relationship between Teachers and Students* (2), several authors provided theoretical and practical guidelines for honing ethical college teaching skills. Some of the authors' recommendations have been used to formulate the Educator's Code of Conduct provided herein. Some of these recommendations were modified to specifically fit the needs of both educators and students at the Hershey Medical Center and the Penn State College of Medicine. Both the Unified Campus Commitment to Excellence of the Hershey Medical Center and Penn State College of Medicine (3) and the Code of Ethical Behavior of the Hershey Medical Center, Policy A-20 HAM (4) were also consulted in preparing this Educator's Code of Conduct.

Four Norms to Govern Teaching

Honesty

Honesty and integrity must be practiced during all aspects of the education process.

Promise-Keeping

Promise keeping requires the educator to fulfill the "promises" made at the beginning of the semester or any other learning activity. Syllabi, assignments, grading principles, and class and office hour schedules each involve promises that are made to students and that must be adhered to under normal circumstances.

Respect for Persons

The educator must approach the learner with personal respect. In addition, the educator ought to encourage mutual respect among students. In particular, respect for race, religion, sexual orientation, disability gender, age, marital status, cultural differences, and political conviction should be supported and encouraged in all aspects of the educational process. Additionally, educators ought to show respect and common courtesy for students both during interpersonal interactions and in responding promptly to students' need for guidance and feedback. An environment free from harassment and discrimination, verbal abuse, physical violence, and intimidation in any form must also be provided for all learning activities.

Fairness

Recognizing the inherent subjectivity involved in grading, an educator ought to ensure that their grading practices are as objective as possible by creating and adhering to unambiguous criteria.

Principles of Ethical College and University Teaching

Content Competence

An educator maintains a high level of subject matter knowledge and ensures that the content of the educational experience is current, accurate, representative, and appropriate to the position of the learning experience within the students' program of study. The educator must be capable of approaching each learner with a commitment to meeting his or her educational needs.

Pedagogical Competence

A pedagogically competent educator communicates the objectives of the educational experience to students, is aware of alternative instructional methods or strategies, and selects methods of instruction that are effective in helping students to achieve the course objectives.

Dealing with Sensitive Topics

Topics that students are likely to find sensitive or discomfiting are dealt with in an open, honest, and positive way.

Student Development

The overriding responsibility of the educator is to contribute to the intellectual development of the student, at least in the context of the educator's own area of expertise, and to avoid actions such as exploitation and discrimination that detract from student development.

Dual Relationship with Students

To avoid conflict of interest, an educator does not enter into dual-role relationships with students that are likely to detract from student development or lead to actual or perceived favoritism on the part of the educator. The establishment of a romantic/sexual relationship between an educator and a student should be reported to the immediate supervisor of the educator. Such relationships should be dealt with consistent with Penn State Administrative Policy AD41 — Sexual Harassment (5).

Student Confidentiality

Student grades, letters of evaluation, attendance records, and private communications are treated as confidential materials and are released only with student consent, for legitimate academic purposes, or if there are reasonable grounds for believing that releasing such information will be beneficial to the student or will prevent harm to the student or to others.

Patient Privacy and Confidentiality

Educators who utilize patient information as part of any educational experience must follow patient privacy and confidentiality guidelines as outlined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Respect for Colleagues

An educator respects the dignity of his or her colleagues and works cooperatively with colleagues in the interest of fostering student development.

Valid Assessment of Students

An educator is responsible for taking adequate steps to ensure that the assessment of a student's performance is valid, open, fair, and congruent with the course/educational experience objectives. An educator must be aware that such assessments are important in students' lives and in the development of their careers.

Respect for Institution and Profession

In the interest of student development, an educator is aware of and respects the educational goals, policies, and standards of the institution in which he or she teaches and the profession which he or she represents.

Citing Sources of Educational Material

An educator acknowledges and documents, as appropriate, the sources of information and other materials used for teaching.

Violations of the Educator's Code of Conduct

Should a learner experience conduct that is inconsistent with the Educator's Code of Conduct, he/she is encouraged to first address the issue with either the educator responsible for the inconsistency or the director of the course in which the educator teaches. Should this attempt to resolve the problem fail, or if the nature of the inconsistency is such that the learner does not feel comfortable addressing the issue with either the educator or the course director, the student may consult other individuals. These individuals may include but are not limited to: faculty advisor, student ombudsman, departmental chair, the Vice Dean for Educational Affairs, and the Vice Dean for Faculty and Administrative Affairs. The decision of who to contact may be dependent on the educational program of the learner and/or type of violation that was encountered.

References:

- (1) <http://www.gradsch.psu.edu/research/ethics.html#teaching>)
- (2) <http://cte.uncwil.edu/et/br030697.htm>
- (3) Unified Campus Commitment to Excellence of the Penn State Milton S. Hershey Medical Center and College of Medicine; 05/11/01
- (4) Code of Ethical Behavior of the Hershey Medical Center, Policy A-20 HAM; Effective Date October, 2001
- (5) <http://guru.psu.edu/POLICIES/Ad41.html>

Developed by the Unified Campus Academic Team Endorsed by Teams Council — May 21, 2003

Course Schedule					
Course Title:		Research Ethics for Clinical Investigators	Course Designation:	HES 500	
Course Director:		Kevin Gleeson, M.D.			
Time :	5:30pm to 7:00pm		Days:	Wednesday 10/22/08 - 12/19/08	Location: ASB 1101
Date	Lecture #	Instructor (Last name, First name)	Instruction Type (Lecture or lab)	Projected Lecture Topic - This list is an approximate guide to lecture topics. Titles and content are subject to change	
10/22/08	1	Gleeson, Kevin	Lecture	Human Subjects Protection 1: Why all the fuss:	
10/29/08	2	Milner, Robert	Lecture	Ethics of Authorship	
11/05/08	3	IRB Committee	Monthly Committee Meeting	Attendance at a session of the IRB	
11/12/08	4	Gleeson, Kevin Hay, Kathy Gifford, Kathie	Mini-Lectures Group Discussions	Structured group reviews of three IRB protocols of varying levels of risk.	
11/19/08	5	Vrana, Sheila	Lecture	Conflicts of Interest	
11/26/08	THANKSGIVING BREAK - NO CLASS				
12/3/08	6	Gleeson, Kevin	Lecture	Human Subjects Protection 2: Why all the trouble?	
12/10/08	7	Snyder, Alan	Lecture	Ethics of Ownership/Intellectual Property	
12/17/08 FINALS WEEK	8	Gleeson, Kevin Manlove, Megan	Lecture	The Public Relations of Clinical Research: What are the investigators responsibilities?	
		Gleeson, Kevin	Class Presentations	Three class study groups do in-class presentations on the model informed consent and IRB protocols that they have created.	

Contact Information					
Faculty / Title	Department	Phone #	EMAIL	Office Room #	Mail Code
Kathy Simon, Adm. Asst.	Graduate Student Affairs	6608	ksimon@psu.edu	1712	H170
Kevin Gleeson, M.D.	Medicine	6525	kgleeson@psu.edu	Pgr 0115	H041
Thomas Lloyd, Ph.D.	HES	6258	Tal3@psu.edu	ASB 2200	A210
Robert Milner, Ph.D.	Neural & Behavioral Science	6407	rmilner@psu.edu	C3802C	H108
Mardi Sawyer Program Administrator	Health Evaluation Sciences	1286	Mds21@psu.edu	ASB 2200	A210