



General Information							
Course Title:	Ethics in the Life Sciences			Course Designation:	IBIOS 591		Credits: 1
Semester:	Spring		Year:	2009			
Department:	Office of Graduate Studies						
Co-Directors:	Michael Verderame, PhD Sheila Vrana, PhD		Phone #	5467 8495	Email:	mverdera@psu.edu svrana@psu.edu	Office Rm # C1712 C1614
Time :	10:15 am to 11:30 am		Days:	Mondays (Jan 26 to April 6)		Location:	C1845

Course Information
<p>Description and/or Overview: This course addresses the important issues of professional ethics in the life sciences: normative standards of conduct and research integrity in diverse but interrelated basic biomedical science disciplines. The course covers the core instructional areas identified by the Office of Research Integrity, U.S. Public Health Service, in its final rule requiring formal training for all persons engaged in federally funded research, whether paid or not from a federal grant or contract. This is a required course for all graduate (Ph.D.) students on the Hershey campus of Penn State University; students usually enroll for this course during their second year.</p>
<p>Goals and/or Objectives: <i>By the completion of this course students will be expected to be able to</i></p> <ul style="list-style-type: none"> describe the guiding principles and rationale for the ethical behavior and normative conduct required of professionals engaged in research in the life sciences. evaluate a situation involving an ethical issue, identify the critical issues and stakeholders, and propose steps to resolve the issue. satisfy the requirements for training in responsible conduct in research mandated for all persons engaged in federally-funded research (with exception of use of animals and human subjects which requires additional training).
<p>Pre-requisites: None</p>
<p>Requirements; course-specific policies and expectations:</p> <p>Format of Sessions: In each session, a faculty facilitator provides an overview (25 minutes) of the topic followed by student-led discussion (50 minutes) of 2–3 case studies illustrating ethical issues related to the session topic. Usually, 2–3 students will be assigned to lead the discussion of each case study: each student will present one case and lead the discussion.</p> <p>Student Expectations: <i>All students are expected to</i></p> <ul style="list-style-type: none"> read the assigned chapter(s) in the text and other relevant material prior to each session. attend each session actively participate in the discussion of the case studies in class. lead the discussion of a case study at least once during the course. actively participate in discussion of issues posted in the course discussion forum. write a concise, critical paper addressing a current ethical issue pertaining to the responsible conduct of science (see below for details). <p>Participation in Class: All students are expected to participate actively in class discussions; the course directors will monitor student participation. The quality of the presentations by students leading the case studies will also be evaluated. Detailed guidelines for case presentation are provided below.</p>

Participation in the Course Discussion Forum:

All students are expected to participate actively in meaningful discussion on the course discussion forum. Meaningful participation includes adding a comment on an issue already posted or posting a new issue for discussion. The amount of participation by each student will be determined at the end of the course.

Required Texts and Resources:

The required textbook is *Scientific Integrity: Text and Cases in Responsible Conduct of Research* (3rd ed.), Francis L. Macrina, ASM Press, Washington, D.C. (2005). This text contains background material and most of the case studies to be used in class. Students are expected to read the assigned chapters prior to the relevant class session. Supplemental material and additional case studies will be distributed in class or via the ANGEL course website, in general one week prior to their use in class.

Electronic Links:

ANGEL will be used to provide online course information. All handouts and other material will be distributed to students via ANGEL. The site contains the course syllabus and schedule, session summaries, case studies, and the course discussion forum. The site also contains links to sites with useful information, including relevant PennState policies, NIH and other ethics sites, recent reports on ethical issues and ethics programs at other institutions (on the ANGEL course site: look under Lessons/Links).

Attendance Policy:

In order to receive a grade of A, a student must attend all ten sessions. One failure to meet the attendance requirement will reduce the grade to a maximum of A-, two to a grade of B, and three to a grade of C. More than 4 breaches in attendance will result in a grade of I or F. It is recognized that legitimate circumstances may on rare occasions prevent attendance at a session; in that case, the student must contact Dr. Verderame or Dr. Vrana at least one week prior to the expected absence and arrange to satisfy the attendance option. The attendance option will usually include the following: (a) reading the relevant chapter(s) in the textbook and (b) preparing a written discussion of a relevant case study provided by the course directors. These assignments must be completed by the next class session.

Examination Policy:

There are no examinations in this course.

Grading Criteria:

Provided that the requirement for attendance has been met, the final course grade will be determined by the course director from the following four components (weighted as indicated): case presentations (15%), classroom participation (25%), participation in the online discussion forum (10%), and the term paper (50%).

Term Paper

The term paper provides students with the opportunity to explore an ethical issue in the life sciences in greater depth. Papers should be organized into 4 sections:

- "The Ethical Issue" - select a topic on a current ethical issue in the life sciences
- "Analysis" - analyze the issue in depth
- "Stakeholders" - evaluate the positions of different stakeholders
- "Conclusion" - reach a well-argued conclusion supported by your analysis

Students must select the topic for their term paper and inform Dr. Verderame or Dr. Vrana by **February 9, 2009**. The paper (minimum 1,500 words) is due by **5pm on March 23, 2009**. Students must upload an electronic file to a drop box on the course ANGEL site. The term paper will be graded based on the student's insight into the topic selected and clarity of expression, as expressed in.

Sample topics are listed below:

- Assisted fertilization and/or assisted reproduction
- Financial conflicts of interest and objectivity in research
- Gene therapy
- Genetic testing
- Offensive biological warfare research
- Ownership of genes and gene sequences
- Privacy and confidentiality
- Protection of human subjects in research
- Restrictions on marketing on genetically engineered plants and plant products
- Restrictions on research using transplanted somatic cell nuclei
- Right of the public and public interest groups to unpublished data
- Sale of organs for transplantation
- Teaching evolution and creationism in the public schools
- Universal DNA fingerprinting
- Use of animals in research
- Use of data obtained illegally or unethically
- Use of fetal tissue and stem cells in research
- Use of inactive placebos in clinical studies
- Xenotransplantation

Presentation of Case Studies

The cases in each session will usually be presented by two or three students who will share the responsibilities of presenting the case to the class, identifying the key issues, and moderating the discussion. Students are encouraged to use alternative formats to present the case study, including acting out the scenario. After the case presentation, the presenters should wait a few moments before beginning discussion, in order to allow the discussants some time to think about the problem. The presenters should *facilitate* the discussion, which may include offering one or more solutions (to stimulate discussion, not all of the solutions need be practical or appropriate), and the rationale used in reaching those solutions. Following presentation of the study, the floor is open for general participation by the students. Class members may offer their analysis, challenge the solutions presented by others, pose relevant questions or make other comments pertaining to the case study. During this dialog, the presenters of the case study act as moderators and facilitators of the discussion.

The goal is to reach, through discussion, one or more acceptable resolutions to the issues being presented.

Cases studies will contain uncertainties and ambiguities -- students are urged to clarify and respond in the face of such uncertainties. It is acceptable for the discussants to clarify or to make assumptions about a case (or part of a case) and then to continue discussion aimed at solving it in this clarified context. However, keep in mind that the developing a solution may be context sensitive. If clarifying assumptions are made, the case discussion is followed through to closure based on those assumptions. Further discussion of the case study with other clarifying assumptions may lead to different resolutions.

Many times a unique or consensus resolution will not emerge. There may be several "right answers," all of which are acceptable to a greater or lesser degree. Ranking such answers by merit as part of the case discussion may be desirable and useful, but usually is not necessary. Students should reflect on the underlying principle when consensus is reached: was consensus based upon a rule of 'rightness', the practical consideration of benefit and utility, or

compliance with a law or regulation?

Although there may be several acceptable resolutions for the issues raised by the case study, there are clearly "wrong answers." Responses in this category would consist of obvious violations of specific standards, guidelines, or rules and regulations. In addition, "wrong answers" would be inconsistent with the written or unwritten ethical standards for scientific conduct generally accepted by the profession. The resolution to the case study should be ethically and legally defensible.

Resolutions to the issues posed by the case study should be consistent with standards related to global considerations (e.g., issues related to plagiarism, human rights, etc.). If the case study involves issues in which there are differences between the "legal" and the "ethical" determination, the presenter should alert the discussants to this dichotomy.

Some questions that apply to most case studies are:

- What are the ethical issues? How should they be resolved?
- Who is affected by the action and who is affected by the outcome?
- What are those effects?
- What steps, if any, should be taken to prevent a problem described in a case study from happening again?

In general, the discussion of a case study should lead to self-discovery as the participants examine explicit and implicit codes and apply personal and professional values in striving to reach a resolution to the issues being posed. Arriving at a resolution and understanding how the resolution was arrived at are both important goals of the learning process afforded by case study analyses.

A case discussion usually lasts 10-15 minutes or longer. It is preferable to discuss one case thoroughly than to try to cover a set number superficially. The presenters of the case study should bring the discussion to closure at the appropriate point. Some scheduled case studies may not be presented, but these are good topics for the electronic forum.

The role of the faculty member is to offer occasional clarification, to keep the discussion of the case study focused, and to assist the presenters in assuring that all students have the opportunity to participate in the dialog. Ideally, the faculty member will have minimum engagement during the discussion of a case study.

Acknowledgement

The original format of this course was designed by Dr. Gaylen Bradley (Dept of Pharmacology). Dr. Bradley also wrote the session summaries and has given permission for their continued use in the course. The current course directors for this course are grateful for Dr. Bradley's many contributions to the teaching of scientific ethics both at Penn State and elsewhere.

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

In particular, the papers must be entirely a student’s own work: all sources must be referenced and any verbatim text from another source must be placed in quotations and referenced. Students are also discouraged from lightly paraphrasing text from other sources. In addition to ethical concerns, the papers provide an opportunity for students to improve their writing skills: therefore, it is in a student’s best interests to use his or her own words, particularly for students for whom English is not their native language. Plagiarism in a paper will result in a reduced or zero score for the paper.

[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:		Ethics in the Life Sciences	Course Designation:		IBIOS 591
Course Co-Directors:		Michael Verderame & Sheila Vrana			
Time :	10:15 am to 11:30 am	Days:	Mondays (Jan 26 to April 6)	Location:	C1847
Date	Lecture #	Instructor Last, First	Instruction Typ (Lecture or Lab)	Projected Lecture Topic - This list is an approximate guide to lecture topics. Titles and content are subject to change	
Jan 26	1	Verderame, Michael	Lecture	Introduction: Ethics & Professionalism	
Feb 2	2	Verderame, Michael	Lecture	Mentoring	
Feb 9	3	Vrana, Kent	Lecture	Data Acquisition and Management	
Feb 16	4	Wilson, Ronald	Lecture	Use of Animals in Research	
Feb 23	5	Gleeson, Kevin	Lecture	Use of Human Subjects in Research	
Mar 2	6	Courtney, Richard	Lecture	Peer Review and Authorship	
Mar 9				SPRING BREAK	
Mar 16	7	Snyder, Alan	Lecture	Ownership & Intellectual Property	
Mar 23	8	Vrana, Sheila	Lecture	Research Misconduct	
Mar 30	9	Milner, Robert	Lecture	Collaborative Research	
Apr 6	10	Vrana, Sheila	Lecture	Conflicts of Interest & Commitment	

Contact Information

Faculty / Title	Department	Phone #	EMAIL	Office Room #	Mail Code
Michael Verderame, PhD Course Co-director	Medicine and Graduate Education	5467	mverdera@psu.edu	C1712	H109
<i>Comments: (i.e. preferred method of contact, contact hrs.)</i>	<i>Contact by email first.</i>				
Sheila Vrana, PhD Course Co-director	Pharmacology and Research Affairs	8495	svrana@psu.edu	C1614	H138
<i>Comments: (i.e. preferred method of contact, contact hrs.)</i>	<i>Contact by email first.</i>				
Richard Courtney, PhD	Microbiology and Immunology	6521	rcourtney@psu.edu	C6800	H107
<i>Comments: (i.e. preferred method of contact, contact hrs.)</i>	<i>Contact by email first.</i>				
Kevin Gleeson, MD	Medicine	6525	kxg4@psu.edu	C5860	H041
<i>Comments: (i.e. preferred method of contact, contact hrs.)</i>	<i>Contact by email first.</i>				
Alan Snyder, PhD	Surgery	7068	asnyder@psu.edu	C4864	H151
<i>Comments: (i.e. preferred method of contact, contact hrs.)</i>	<i>Contact by email first.</i>				
Ronald Wilson, DVM	Comparative Medicine	8460	rwilson@psu.edu	CG722B	H054
<i>Comments: (i.e. preferred method of contact, contact hrs.)</i>	<i>Contact by email first.</i>				
Kent Vrana, PhD	Pharmacology	8285	kvrana@psu.edu	C7710	H078
<i>Comments: (i.e. preferred method of contact, contact hrs.)</i>	<i>Contact by email first.</i>				
Robert Milner, PhD	Neural and Behavioral Sciences	6407	rmilner@psu.edu	C3802C	H109
<i>Comments: (i.e. preferred method of contact, contact hrs.)</i>	<i>Contact by email first.</i>				
Kathy Simon, Course Secretary	Graduate Student Affairs	8892	ksimon@psu.edu	C1712	H170