Course Information

Course Number/Section: HCS 6399
Course Title: SCIENTIFIC INTEGRITY AND RESEARCH ETHICS
Term: Maymester
Days & Times: May 20-25, 2012 9:30-4:30

Professor Contact Information

Professor: Emily A. Tobey
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1966 Inwood Road
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Office Hours: By appointment

Course Description

This course will cover critical issues associated with scientific integrity, data handling and management, authorship, peer review, conflicts of interest, research fraud and misconduct, issues in animal and human research (i.e., protections for research subjects), ownership of data and intellectual property, responsibilities of principal and co-principal investigators, and financial disclosures.

Student Learning Objectives/Outcomes

At the conclusion of this course, students will be able to:

* discuss the factors underlying the informed consent process.

* review appropriate forms for human protection.

* complete the on-line training provided by the Office of Human Research Protection.

* watch the working safely with nonhuman primate video tape and provide a personal statement attesting your completion.

* Complete assignments associated with the Office Of Research Integrity (ORI) interactive video, “The Lab” http://ori.hhs.gov/TheLab/

* describe the events leading to the Nuremberg Code and Belmont Report.
*debate issues concerning scientific integrity.

*define examples of research fraud and misconduct.

*describe federal and state guidelines for ownership of intellectual properties.

*participate in discussions regarding scientific responsibility.

*understand copyright rules and regulations.

*review and use current guidelines for data collection and management.

*recognize the important factors underlying authorship.

*navigate the internet to locate valuable resource tools.

*locate on routine basis, updates to the Federal Register.

Objectives provided in italics will be used to evaluate program effectiveness in association with the University of Texas at Dallas SACS accreditation process.

REQUIRED MATERIALS AND REFERENCES

Websites:

NIH guideline to Responsible Conduct of Research,  
http://phrp.nihtraining.com/users/login.php
May be accessed through the UTD Office of Sponsored Research website.

http://ohsr.od.nih.gov/guidelines/belmont.html

http://ohsr.od.nih.gov/guidelines/nuremberg.html

World Medical Association Declaration of Helsinki.  Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964. Amended by the 29th World Medical
Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; and the 41st World Medical Assembly, Hong Kong, September 1989.
http://www.wma.net/e/policy/b3.htm

**Working safely with nonhuman primates.**
http://grants.nih.gov/grants/olaw/TrainingVideos.htm

**UTD Faculty Handbook**
http://provost.utdallas.edu/

**Judicial Affairs: The University of Texas at Dallas' Handbook of Operating Procedures Title V**
http://utdallas.edu/judicialaffairs/
Maintaining academic integrity
How does scholastic dishonesty affect you?
What can you do to help?
READINGS


Siva, N. (2011). Nature group journal retracts two papers after cancer researcher was found to have falsified data. *BMJ, 343*, d5218.


Grading Policy and Assignments

• All students will be expected to read the assigned readings, complete class projects and participate in class discussions and activities.

• The format for the course will include lectures, small group discussions, and project activities. Students will work in small groups to research problems related to information covered by the lectures and panel discussions.

• All students will be required to complete materials satisfactorily (passing grades) to receive course credit. A passing grade will require students satisfactorily develop a portfolio which will include a TAKE-HOME FINAL EXAMINATION DUE JUNE 25, AT 5:00 PM.

• In addition, all students will need to print out documentation that they have completed the computer on-line courses assigned in class and include this information in your portfolio.

Required Assignments for “The Lab—Thoughts for You to Consider”

The Lab: Avoiding Research Misconduct is a virtual interactive video learning program available through the auspices of the Office of Research Integrity. The program is located at http://ori.hhs.gov/TheLab/. Your assignments are based on watching and making decisions on the possibilities of research misconduct. You will play different characters and play different roles. You will be asked to make different decisions.

The class assignments ask you to: First, complete the assignment making decisions as you would make them—NOT as you think the video wants you to make them. It is important to explore how you feel about the situations, what you might need to ask about the choices of right from wrong, better or worse, etc. Think about what you would decide to do and then, make a decision to carry out your intention by making a selection. No one is tracking what you decide, how you decide, or what you do. The exercise is to think through options and explore your decision making.

NOTE: I USE THE WORD, “YOU”, THIS IS A PROJECT THAT SHOULD REFLECT YOUR OWN PERSONAL VIEWS.

Play each character as many ways as you can to explore the options of decisions and outcomes. The questions below should be typed, single-spaced and sent to me electronically by the due dates. The answers to the questions should not be longer than 1 page per question—thus, if there are 2 questions, you should turn in no more than 2 pages—if there are 4 questions, you should turn in no more than 4 pages.

Kim Park—Due June 4, 2012 by 5:00 pm
1. What should be your role as a graduate student in a laboratory?
2. How will you maximize your professional engagement to avoid research misconduct situations?
3. Would you, as an individual, ever consider retaliation to another person in your laboratory? If yes, why? If not, why?

Aaron Hutchinson—Due June 8, 2012 by 5:00pm

1. As a future mentor and lab leader, what represents a balance of life to you?
2. What are your personal life goals?
3. What steps would you take to address Kim’s concerns?
4. What is the problem from your perspective with “always?”
5. How would you handle a lab member who cut corners?

Hardik Rao—Due June 14, 2012 by 5:00 pm

1. How do you strike a balance between your personal life and your laboratory responsibilities?
2. What can you personally do to promote honesty and ethical practices in your laboratory?
3. Can you think of a time when you “cut corners?” How would you alter your behavior to do it differently in the future?

Beth Ridgley—Due June 18, 2012 by 5:00 pm

1. What information should you prepared to share with a research integrity officer?
2. What information should you be responsible for in a laboratory?
3. What does integrity mean to you and how does it influence your decisions?
Take-Home Final Examination—Each Question worth 25 points

Please prepare a 2-page, double-space response for each response. Email your examination to Dr. Tobey at: etobey@utdallas.edu. Responses are due on JUNE 25 at 5:00 pm.

1. Here is an example used to train publication ethics at UT Southwestern Medical Center. Read the example and answer one of the possible scenarios described in 1a-1e.

You are the editor of the esteemed scientific journal, Clinical Research Today (CRT). In your position you are responsible for assigning blind peer reviewers to submitted manuscripts, and then take editorial action (publish, reject, advice to revise and resubmit) based on the peer reviews and your own editorial judgment. Despite CRT’s excellent reputation, submissions have fallen off lately, and the editorial board and publisher have noted lackluster sales, and your overall citation rate from the Institute for Scientific Information (ISI) has fallen a point in the past year. You consider several incidents:

1a: You have referred a manuscript back to the author for revisions and resubmission, but the first author, a distinguished senior scientist in his field, has called you and offered to "resubmit if you don't re-send to Reviewer B, who obviously doesn’t know what he’s talking about". What do you say?

1b: You receive a promising paper offering a potentially important finding for a rare disease. Two potential, qualified referees have refused the paper because they’re "too busy", and a third potential referee says "I believe the convention here is for me to be appointed to the journal’s Editorial Board in order to be a reviewer." What next?

1c: An author of a paper has returned the galley proofs for the manuscript, accompanied by a note saying that in the re-review of their data, 12 of their cohort of 88 confessed to suicidal ideation on their survey forms, which the investigators did not pick up on their original computer scan of the data. The data are now a year old, but the investigators followed up on this subgroup and could find no information on 5 of the 12, and only one report of a suicide attempt which was not completed. The author wants to know if it is still OK to publish as is. What should they do?

1d: An expert in her field has called you about your request to review a blinded manuscript. She says she thinks she may have advised one of the authors about the study design about a year ago, and is not sure she should review the manuscript. Setting this issue aside, you consider her the best qualified reviewer for this manuscript. What should you say/do?
1. You, the editor, receive negative comments from three reviewers, concerning the same reviewer-blinded manuscript. What are the qualities of these reviews that support fair-minded review, and what aspects of these reviews may be unfair? How would you weigh the reviews in terms of influencing your final decision? Which reviewers would you use again? Why or why not? How might you counsel referees towards a fairer, valid review process?

2. Issues regarding informed consent. Select one of the questions below.

Journalists often observe people without their knowledge or consent and write about their observations. Journalists also intrude in to the privacy of people by interviewing them after they or their relatives are involved in an accident or tragedy of some sort. If journalists may engage in such actions, is it not also permissible for social science researchers to do the same?

Is there some type of research involving human subjects that should not to be done? If you think so, specify the features of such research and why prohibition would be justified. If you think not, indicate how the rights and welfares of research subjects can be adequately protected (especially vulnerable subjects)?

3. You have been asked to speak to a high school class regarding an academic career in a university. Describe how scientific integrity and research ethics shape a faculty member and lead to their roles as citizens in their communities.

4. One of your peers, Dr. Oops, tends to be disorganized in his data collection. You have noted on several occasions his failure to record the protocol's data on the sponsors approved forms. Instead, Dr. Oops writes down the data on scrap paper or even his wrist on occasion, later transferring the data to the sponsor's forms. You are concerned that Dr. Oops may be making data collection errors on the basis of his sloppy data-recording habit. How would you handle this situation?

5. Do you believe it is necessary to treat virtual patients or participants ethically? How might your view change the current construct of ethical treatment?

6. What importance can you attached to Marston and his concepts?
Student Conduct & Discipline
The University of Texas System and The University of Texas at Dallas have rules and regulations for the orderly and efficient conduct of their business. It is the responsibility of each student and each student organization to be knowledgeable about the rules and regulations which govern student conduct and activities. General information on student conduct and discipline is contained in the UTD publication, A to Z Guide, which is provided to all registered students each academic year. The University of Texas at Dallas administers student discipline within the procedures of recognized and established due process. Procedures are defined and described in the Rules and Regulations, Series 50000, Board of Regents, The University of Texas System, and in Title V, Rules on Student Services and Activities of the university’s Handbook of Operating Procedures. Copies of these rules and regulations are available to students in the Office of the Dean of Students, where staff members are available to assist students in interpreting the rules and regulations (SU 1.602, 972/883-6391).

A student at the university neither loses the rights nor escapes the responsibilities of citizenship. He or she is expected to obey federal, state, and local laws as well as the Regents’ Rules, university regulations, and administrative rules. Students are subject to discipline for violating the standards of conduct whether such conduct takes place on or off campus, or whether civil or criminal penalties are also imposed for such conduct.

Academic Integrity
The faculty expects from its students a high level of responsibility and academic honesty. Because the value of an academic degree depends upon the absolute integrity of the work done by the student for that degree, it is imperative that a student demonstrate a high standard of individual honor in his or her scholastic work.

Scholastic dishonesty includes, but is not limited to, statements, acts or omissions related to applications for enrollment or the award of a degree, and/or the submission as one’s own work or material that is not one’s own. As a general rule, scholastic dishonesty involves one of the following acts: cheating, plagiarism, collusion and/or falsifying academic records. Students suspected of academic dishonesty are subject to disciplinary proceedings.

Plagiarism, especially from the web, from portions of papers for other classes, and from any other source is unacceptable and will be dealt with under the university’s policy on plagiarism (see general catalog for details). This course will use the resources of turnitin.com, which searches the web for possible plagiarism and is over 90% effective.

Email Use
The University of Texas at Dallas recognizes the value and efficiency of communication between faculty/staff and students through electronic mail. At the same time, email raises some issues concerning security and the identity of each individual in an email exchange. The university encourages all official student email correspondence be sent only to a student’s U.T. Dallas email address and that faculty and staff consider email from students official only if it originates from a UTD student account. This allows the university to maintain a high degree of confidence in the identity of all individual corresponding and the security of the transmitted information. UTD furnishes each student with a free email account that is to be used in all communication with university personnel. The Department of Information Resources at U.T. Dallas provides a method for students to have their U.T. Dallas mail forwarded to other accounts.

Withdrawal from Class
The administration of this institution has set deadlines for withdrawal of any college-level courses. These dates and times are published in that semester's course catalog. Administration procedures must be followed. It is the student's responsibility to handle withdrawal requirements from any class. In other words, I cannot drop or withdraw any student. You must do the proper paperwork to ensure that you will not receive a final grade of "F" in a course if you choose not to attend the class once you are enrolled.

Student Grievance Procedures
Procedures for student grievances are found in Title V, Rules on Student Services and Activities, of the university’s Handbook of Operating Procedures. In attempting to resolve any student grievance regarding grades, evaluations, or other fulfillments of academic responsibility, it is the obligation of the student first to make a serious effort to resolve the matter with the instructor, supervisor, administrator, or committee with whom the grievance originates (hereafter called “the respondent”). Individual faculty members retain primary responsibility for assigning grades and evaluations. If the matter cannot be resolved at that level, the grievance must be submitted in writing to the
Incomplete Grade Policy
As per university policy, incomplete grades will be granted only for work unavoidably missed at the semester’s end and only if 70% of the course work has been completed. An incomplete grade must be resolved within eight (8) weeks from the first day of the subsequent long semester. If the required work to complete the course and to remove the incomplete grade is not submitted by the specified deadline, the incomplete grade is changed automatically to a grade of F.

Disability Services
The goal of Disability Services is to provide students with disabilities educational opportunities equal to those of their non-disabled peers. Disability Services is located in room 1.610 in the Student Union. Office hours are Monday and Thursday, 8:30 a.m. to 6:30 p.m.; Tuesday and Wednesday, 8:30 a.m. to 7:30 p.m.; and Friday, 8:30 a.m. to 5:30 p.m.
The contact information for the Office of Disability Services is:
The University of Texas at Dallas, SU 22
PO Box 830688
Richardson, Texas 75083-0688
(972) 883-2098 (voice or TTY)
Essentially, the law requires that colleges and universities make those reasonable adjustments necessary to eliminate discrimination on the basis of disability. For example, it may be necessary to remove classroom prohibitions against tape recorders or animals (in the case of dog guides) for students who are blind. Occasionally an assignment requirement may be substituted (for example, a research paper versus an oral presentation for a student who is hearing impaired). Classes enrolled students with mobility impairments may have to be rescheduled in accessible facilities. The college or university may need to provide special services such as registration, note-taking, or mobility assistance.
It is the student’s responsibility to notify his or her professors of the need for such an accommodation. Disability Services provides students with letters to present to faculty members to verify that the student has a disability and needs accommodations. Individuals requiring special accommodation should contact the professor after class or during office hours.

Religious Holy Days
The University of Texas at Dallas will excuse a student from class or other required activities for the travel to and observance of a religious holy day for a religion whose places of worship are exempt from property tax under Section 11.20, Tax Code, Texas Code Annotated.
The student is encouraged to notify the instructor or activity sponsor as soon as possible regarding the absence, preferably in advance of the assignment. The student, so excused, will be allowed to take the exam or complete the assignment within a reasonable time after the absence: a period equal to the length of the absence, up to a maximum of one week. A student who notifies the instructor and completes any missed exam or assignment may not be penalized for the absence. A student who fails to complete the exam or assignment within the prescribed period may receive a failing grade for that exam or assignment.
If a student or an instructor disagrees about the nature of the absence [i.e., for the purpose of observing a religious holy day] or if there is similar disagreement about whether the student has been given a reasonable time to complete any missed assignments or examinations, either the student or the instructor may request a ruling from the chief executive officer of the institution, or his or her designee. The chief executive officer or designee must take into account the legislative intent of TEC 51.911(b), and the student and instructor will abide by the decision of the chief executive officer or designee.

Off-Campus Instruction and Course Activities
Off-campus, out-of-state, and foreign instruction and activities are subject to state law and University policies and procedures regarding travel and risk-related activities. Information regarding these rules and
regulations may be found at the website address given below. Additional information is available from the office of the school dean. (http://www.utdallas.edu/BusinessAffairs/Travel_Risk_Activities.htm)

These descriptions and timelines are subject to change at the discretion of the Professor.