

SYLLABUS
Ethics for Translational Sciences (BMSC 6218)

COURSE DESCRIPTION:

BMSC 6218 is a new graduate course that has been adapted from the existing BMSC 8218 “Careers in Science: Ethics and Grantsmanship”, which is offered to first year IBS graduate students. In collaboration with Dr. Hirshfield, BMSC 6218 has been tailored to graduate students enrolled in the new Master’s program in Anatomical and Translational Sciences (M-ATS). Therefore, the chief objective of BMSC 6128 is to provide a solid foundation in ethics for translational sciences by focusing on ethical issues relevant to the design and conduct of translational research, such as data management, human-based research, conflict of interest, responsible use of animals in phase T1 of clinical trial. Graduate students in the M-ATS program will share lectures on ethical issues delivered by world-renowned ethicists with IBS graduate students enrolled in BMSC 8218. Furthermore, they will have additional in class case-based assignments. They will have to debate two contemporary cases on the Presidential Commission on Moral Science: protecting participants in human subject research (lectures 11 and 12) and ethical issues in clinical trials involving vulnerable patient population” A clinical Drug Study at the University of Minnesota Department of Psychiatry: the Dan Markingson case (lectures 14 and 15) and write in-depth analysis on each case.

LEARNING OBJECTIVES:

- 1) Define ethics of translational scientific investigation.
- 2) List the three R’s involving the use of animals in research.
- 3) Recognize the principles and ethical obligations in areas such as data management, conflicts of interests, and human participant research as expected for physicians and scientists in the US.
- 4) Explain the history and practice of the social responsibilities of physicians and scientists in training.

CREDIT HOURS: 2

PREREQUISITE: Permission of Instructor

LECTURE CONTACT TIME/HOURS: one lecture per week from 1:45-2:00 pm on Tuesdays in Ross Hall 237.

METHOD OF ASSESSMENT: Grades will be calculated from Examination (40%), two Class Presentations (30%), and two in-depth written analyses (3-5 single space pages) on the Presidential Commission and the Dan Markingson case (30%).

For the discussion sessions on the Presidential Commission for the study of bioethical issues, scheduled on March 22nd and March 29th (lectures 11 and 12), students will be responsible to read the entire full executive summary and will choose to discuss (15 minute-long oral presentation) one of the eight Commission Recommendations detailed in chapter 3 of the document and write a 3-page long written analysis (single space) to be turned in on April 12th no later than 4:00 pm to Dr. Hirshfield.

For the discussion sessions on the Clinical Drug Study at the University of Minnesota Department of Psychiatry: the Dan Markingson case, scheduled on April 12th and April 19th (lectures 14 and 15), students will be responsible to read the provided two documents and encouraged to expand their readings from searches on the internet and will choose to discuss an ethical issue that is raised by the case from the provided list and write a 3-page long written analysis (single space) to be turned in on **April 29th** no later than 4:00 pm to Dr. Hirshfield.

NOTE: IN ACCORD WITH UNIVERSITY POLICY, IF A FINAL EXAM IS GIVEN, THE FINAL EXAM WILL BE GIVEN DURING THE FINAL EXAM PERIOD AND NOT THE LAST WEEK OF THE SEMESTER

FACULTY:

1) Linda Werling, Ph.D. (Course Director)

Professor, Department of Pharmacology and Physiology
Associate Dean for Graduate Studies
Director of the Institute for Biomedical Sciences
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2) Anne Hirshfield, Ph.D. (Course Co-Director)

Professor, Department of Anatomy and Regenerative Biology
Ross Hall 402a, anh@gwu.edu
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REQUIRED TEXTS:

Texts

- 1) "Introduction to the Responsible Conduct of Research" by Steneck, Nicholas (See readings handout for web address) on web
- 2) "An Introductory Course with cases" (3rd or 4th ed.) by Macrina, Frank
- 3) "The Ethical Dimensions of the Biological and Health Sciences" (2nd ed.) by Bulger, Heitmann and Reiser

Additional Readings for Lectures 11, 12, 14, and 15

(see attached four pdf documents)

FACULTY:

- 1) Dr. Ruth Ellen Bulger, Emeritus Professor, Department of Anatomy, Physiology, and Genetics, USUHS, Bethesda, Maryland
- 2) Dr. Kayleen Gloor, Veterinarian, GWU SMHS
- 3) Dr. Linda Werling, Professor of Pharmacology and Physiology, GWU SMHS
- 4) Mr. Edward You, Supervisory Special Agent, FBI Weapons of Mass Destruction Directorate, Biological Countermeasures Unit

5) Dr. Anne Hirshfield, Professor of Anatomy and Regenerative Biology, GWU SMHS

CLASS POLICIES

Attendance policy: mandatory

Late work: accepted with permission, penalty may be incurred if unduly late as determined by instructor

Religious Holidays: will be accommodated if requested

[NOTE: for university policies on teaching, see <http://www.gwu.edu/~academic/Teaching/main.htm>]

ACADEMIC INTEGRITY

I personally support the GW Code of Academic Integrity. It states: “Academic dishonesty is defined as cheating of any kind, including misrepresenting one's own work, taking credit for the work of others without crediting them and without appropriate authorization, and the fabrication of information.” For the remainder of the code, see: <http://www.gwu.edu/~ntegrity/code.html>

SUPPORT FOR STUDENTS OUTSIDE THE CLASSROOM

DISABILITY SUPPORT SERVICES (DSS)

Any student who may need an accommodation based on the potential impact of a disability should contact the Disability Support Services office at 202-994-8250 in the Marvin Center, Suite 242, to establish eligibility and to coordinate reasonable accommodations. For additional information please refer to:

<http://gwired.gwu.edu/dss/>

UNIVERSITY COUNSELING CENTER (UCC) 202-994-5300

The University Counseling Center (UCC) offers 24/7 assistance and referral to address students' personal, social, career, and study skills problems. Services for students include:

- crisis and emergency mental health consultations
- confidential assessment, counseling services (individual and small group), and referrals

<http://gwired.gwu.edu/counsel/CounselingServices/AcademicSupportServices>

SECURITY

In the case of an emergency, if at all possible, the class should shelter in place. If the building that the class is in is affected, follow the evacuation procedures for the building. After evacuation, seek shelter at a predetermined rendezvous location.

LECTURE TOPICS:

Week	Date	Topic (Instructor)
1	Jan 12:	Principles of Scientific Responsibility (Bulger)
2	Jan 19:	Play “The Lab” in lieu of Class Meeting
3	Jan 26:	Authorship Principles (Bulger)
4	Feb 2:	Data Management (Bulger)

- 5 Feb 9: Conflicts of Interest, Commitment and Industry Relations (Bulger)
- 6 Feb 16: Student short presentations of an ethical problem in research
- 7 Feb 23: Human Participant Research (Bulger)
- 8 Mar 1: Responsible Use of Animals in Research (Gloor)
- 9 Mar 8: The Scientist and Society (Bulger)
- 10 Mar 15: Spring Break
- 11 Mar 22: Student presentations on the Presidential Commission for the study of Bioethical Issues
“Moral Science: Protecting participants in human subjects research” (Hirshfield)
- 12 March 29: Student presentations on the Presidential Commission for the study of Bioethical Issues
“Moral Science: Protecting participants in human subjects research” (Hirshfield)
- 13 Apr 5: Dual Use (You)
- 14 Apr 12: Modern Ethics Case Review: The Dan Markingson Case - Student presentations
(Hirshfield)
- 15 Apr 19: Modern Ethics Case Review: The Dan Markingson Case - Student presentations
(Hirshfield)
- 16 Apr 26: Reading Day
- 17 May 3: Final Exam