Description:
This course is a systematic examination of the ethical concepts and standards of responsible conduct of research in biomedical science and clinical investigation. Its aim is to provide postdoctoral trainees and junior faculty in biomedical clinical research a framework in which to recognize, examine, resolve, and prevent ethical questions and conflicts in their professional work and prepare them for independent research and mentoring of others.

Objectives:
Upon successfully completing this class, students will be able to:
1) Trace the historical development of standards of good research practice and concepts of scientific integrity and research ethics – including legal and socio-religious influences – in biomedical science and clinical investigation;
2) Recognize, identify, and analyze questions central to the ethical problems in biomedical science and clinical research using relevant professional standards and regulatory policies on human and animal research; conflict of interest; data collection, management, and sharing; authorship and publication, peer review; collaboration; and mentor-trainee relations;
3) Formulate recommendations for promoting responsible conduct and preventing and/or resolving ethical conflict in biomedical science and clinical research, reflecting regulations, formal codes, and professional standards as appropriate; and
4) Identify the appropriate institutional resources for addressing questions related to ethics and integrity in biomedical science and clinical research in academic and nonacademic settings.

Reading Assignments:
The course will start with a discussion of the popular novel Intuition by Allegra Goodman, which depicts the personal and professional pressures and rewards in academic biomedical research and sets the stage for sessions. Other required reading includes sections of the textbook Scientific Integrity, 4th ed., by Francis Macrina (American Society for Microbiology Press, 2014). It is available as a paperback or pdf from the VU Bookstore or online. The syllabus lists URLs for all other readings. As supplemental reading, ORI Introduction to Responsible Conduct of Research, (Nicholas Steneck, Office of Research Integrity, 2004), is available at http://ori.hhs.gov/ori-intro.

Students are encouraged to bring articles on research from the lay press and medical literature to discuss in class. The Health and Science sections of the New York Times (www.nytimes.com) typically have lots to offer, as do JAMA, Science, and Nature. Local news is especially welcome.

Evaluation:
This is a condensed schedule, and attendance in class is required. If you need to miss class please contact Dr. Heitman as much in advance as possible. Substantive, informed participation in discussion and small group work in class accounts for 50% of the course grade (10% per session). Fifty percent (50%) of the course grade will be based on a comprehensive final exam consisting of short essay questions and analysis of a case. The exam will be an open-book, open-notes time-limited take home exam. A score of 80% will be considered the threshold for a passing grade (B).
<table>
<thead>
<tr>
<th>DATE/ROOM</th>
<th>TOPIC and READINGS (● = required; ○ = optional/supplemental)</th>
</tr>
</thead>
</table>
| Tuesday, May 5 | 12:30 – 3 PM  
411AB Light Hall | Integrity, Misconduct, and Research Policy  
● Intuition (all) |
| Tuesday, May 19 | 12:30 – 3 PM  
411 AB Light Hall | Responsible Authorship, Publication, and Peer Review  
● Macrina, Scientific Integrity, chapters 1 and 4  
   ○ ICMJE Recommendations for …Scholarly Work in Medical Journals [Link]  
   ○ NIH Policy: Maintaining Confidentiality in NIH Peer Review [Link] |
| Thursday, May 23 | 12:30 – 3 PM  
411AB Light Hall | Academic Research and Industry: Conflicts of Interest and Integrity of Data  
● Macrina, Scientific Integrity, chapter 7  
● Vanderbilt University Conflict of Interest and Commitment Policy [Link]  
● PhRMA. Principles on conduct of clinical trials and communication of clinical trial results. 2011 [Link] |
| Tuesday, May 26 | 12:30 PM – 3 PM  
411AB Light Hall | Voluntariness, Vulnerability, and Disparities in Research with Human Participants  
● Vanderbilt University Institutional Review Board Policy, IVA-E (and subparts)  
   ○ Informed Consent Process [Link]  
   ○ IRB Guidebook: Chapter 6 - Special Classes of Subjects [Link]  
   ○ Trinidad et al., Research practices and participant preferences. Science 2011; 331: 277-88 [Link]  
   ○ NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Trials [Link]  
   ○ NIH Inclusion Enrollment Form (rev.8/12) [Link]  
| Thursday, May 28 | 1 PM – 4 PM  
411AB Light Hall | The Clinical Research Community: Students, Teachers, Mentors, and Collaborators  
● Macrina, Scientific Integrity, chapter 3 & 8  
● The Singapore Statement on Research Integrity [Link]  
● The Montreal Statement on Collaborative Research [Link]  
● Coustou, How to swim with sharks. Thoracic Surgical Clinics 2011; 21: 441–442 [Link] |
| Individually scheduled | FINAL EXAM - TAKE HOME |

April 2015