Instructor Name: Catherine Striley, PhD, MS, MPE
Room Number: CTRB 2004 Mowry Road 4237
Phone Number: 352-273-5359
Email Address: cstriley@ufl.edu
Office Hours: Each Friday at noon; via zoom or office by prearrangement
Preferred Course Communications (e.g. email, office phone): Email

May 11, 2023 11:00 AM
May 18, 2023 11:00 AM
May 25, 2023 11:00 AM
Jun 1, 2023 11:00 AM
Jun 8, 2023 11:00 AM
Jun 15, 2023 11:00 AM

Please download and import the following iCalendar (.ics) files to your calendar system.
Weekly: https://ufl.zoom.us/meeting/tJMsd--gqjkuE93SFREGbOnMpa97- CRJYajj/ics?icsToken=98tyKuCrvzssEtCXtBCORowEBYIgM_zwiHpajj_0OrznXJgduRw3bJsMbz9cWvLp

Join Zoom Meeting
https://ufl.zoom.us/j/97106842499?pwd=ZVdXaU1MSm8wN01qdXNaZE5wbngyZz09

Meeting ID: 971 0684 2499
Passcode: 634163
One tap mobile
+13052241968,,97106842499# US
+13092053325,,97106842499# US

Prerequisites
Advanced graduate student (doctoral level), PhD candidacy, or permission of the instructor.

PURPOSE AND OUTCOME

Course Overview
This course in ethics for those enrolled in graduate programs in epidemiology, health-related programs, or research-intensive graduate programs, provides students with provides systematic instruction on ethical issues and principles in the practice of science covering the DHHS- and NIH-mandated curriculum in the Responsible Conduct of Research.

Relation to Program Outcomes
This is the required ethics course and course in responsible research conduct for PhD students. It specifically addresses the PhD competency of:
   Recognize potential ethical issues and implement the concepts of ethical conduct of research in epidemiology studies.
It also helps to meet the competency of:
   Become an independent researcher in the field of epidemiology.

Course Objectives and/or Goals
Upon successful completion of the course, students should be able to:

1. Apply the federal definition of research misconduct and UF responsible conduct policies to cases of questionable conduct.
2. Explain the procedure for reporting misconduct and investigating misconduct as well as possible sanctions for misconduct.
3. Exhibit highly developed ethical reasoning skills in an analysis of a case of questionable research conduct by providing alternative behaviors by specific actors that could and should have stopped or mitigated the ethical breach.
4. Compare and contrast responsible and questionable research conduct in relation to study design, implementation, dissemination of findings and peer review of grants and manuscripts.
5. Synthesize commonalities in questionable conduct in research.
6. Establish skills needed to lead an interprofessional team in the application of ethical standards to research conduct.
7. Prepare a research proposal to answer a specified research question pertaining to responsible research conduct.

Instructional Methods
This course will consist of in-person, synchronous online and asynchronous zoom recordings with group based and other online activities, depending on the section. Students are expected to engage with the course material regardless of timing of participation.

In-Class Sessions: Sessions will include a combination of lecture, ethical case critical analyses and discussion of ethical principles. Students are responsible for all the material presented in the course and assigned readings. Students are responsible for presenting ethical cases and their analysis using a presented framework.

Assessments: Assessments will include participation, multiple ethical case analyses, presentation of an ethical case and analysis and research design for an ethical study.

What is expected of you: You are expected to participate in class sessions and complete all readings, participate in discussions and assignments. You are expected to actively engage in the course throughout the semester. Your participation fosters a rich experience for you and your peers that facilitates overall mastery of the course objectives. You are also expected to develop expertise to lead other students in ethical analysis.

Topical Outline/Course Schedule

**Week 1 May 13**

Topics:

- Integrity in Research vs. Misconduct and Questionable Research Practice
- Ethical frameworks for ethical decision making; Regulations and professional standards of public health practice and research
- Mentorship
- Team Science

Objectives

1. Describe some skills needs to be an effective team scientist.
2. Explain the “common rule.”
3. Within an ethical case, define at least 5 kinds of questionable conduct through group work.
4. Describe the SFNO framework for ethical analysis and decision making
5. Analyze the role of the mentor and mentee as they relate to responsible research conduct

**Required Readings (due by start of class)**

Text *(National Academies of Science (NAS)) Chapters 1 and 2*


For Supplemental Reading:


**Activities**

In class: SFNO Case Workup (Example)

On own: The Lab Simulation

**Assignments Due**

Each week, you will be responsible for posting to **Discussion Boards (Assignment 1)**. You may also be scheduled for your **Case Analysis Presentation (Assignment 2)** depending on your pre-arranged due dates with the instructor.

**Week 2 May 18**

**Topics: Keeping Research Safe**

- **Human Subjects Research**
  - IRBs
  - Deviations
  - SAEs
- **Animal Care**
  - IACUCs
- **Laboratory Safety**
  - Civility issues (bullying, harassment, and inappropriate behavior)
- **Whistleblowing**

**Objectives**

1. Apply the basic principles in human subjects’ research to the consent process and to a simulated clinical research situation

2. Describe the basic principles in animal subjects’ research
3. Compare and contrast reporting SAEs versus Deviations

Required Reading (due by start of class)

Text (Steneck) Chapter 3 and 4 https://ori.hhs.gov/ori-introduction-responsible-conduct-research


Kalichman M. Whistleblowing. Resources for Research Ethics Education. 2001. Available at: https://nationalethicscenter.org/resources/7418


Activities

In and out of class: Team case analysis preparation

Out of class and on own: https://ori.hhs.gov/research-clinic

Assignments Due

Each week, you will be responsible for posting to Discussion Boards (Assignment 1). You may also be scheduled for your Case Analysis Presentation (Assignment 2) depending on your pre-arranged due dates with the instructor.

Week 3 May 25

Topics: Specific Populations Then and Now

Conflict of interest

Vulnerable and Federally Protected Populations

Recruitment and Remuneration

Objectives

1. Compare and contrast vulnerable populations and federally protected populations;
2. Critically analyze recruitment, retention and remuneration from a population perspective;
3. Describe limits to confidentiality and plans for intervention;
4. Define and provide examples of both institutional and individual conflict of interest.

Required Reading

Text (Steneck) Chapters 5 and 6


Activities

In-class and on-own: Willowbrook case using SFNO

In-class: Guatemala Case

Student case presentations

Assignments Due

Each week, you will be responsible for posting to Discussion Boards (Assignment 1). You may also be scheduled for your Case Analysis Presentation (Assignment 2) depending on your pre-arranged due dates with the instructor.

Week 4 June 1

Topics:

International Law and Ethics; Decolonialization

Authorship and Peer Review

Inventorship and Intellectual Rights

Collaboration

Objectives,

1. Define and describe plagiarism from the US federal perspective and UF honor code and apply the definitions to 3 cases.
2. Identify 3 methods to clarify expectations among different stakeholders.
3. Compare and contrast different expectations of populations, institutions and funders for rights and permissions.
4. Recommend 3 ways to reduce disputes between stakeholders and to increase collaboration.

Required Reading (due by start of class)

Text (Steneck) Chapter 8 & 9 & 10.


Reference:
Activities

Hypothetical Case followed by Instructor presented case: Havasupi Tribe vs. Arizona State University

Assignments Due

Each week, you will be responsible for posting to Discussion Boards (Assignment 1). You may also be scheduled for your Case Analysis Presentation (Assignment 2) depending on your pre-arranged due dates with the instructor.

Week 5 June 8

Topics: Research Data and Dissemination

Data Ownership and Management

Community Collaboration

Research vs. Surveillance

Required Reading (due by start of class)


Activities

Student case presentations

Research plan preparation

Assignments Due

Each week, you will be responsible for posting to Discussion Boards (Assignment 1). You may also be scheduled for your Case Analysis Presentation (Assignment 2) depending on your pre-arranged due dates with the instructor.

Week 6 June 15

Topics: Contemporary Ethical Issues

- Genetics
- Artificial Intelligence
  - Privacy and confidentiality
  - Virtual Reality
- Rigor and Reproducibility
- Creative forms of predation in publishing

Objectives

1. Identify at least 3 current ethical quandaries in AI and provide a suggestion for how each can be managed.
2. Analyze an ethical case with conflicting interest between those whose privacy/confidentiality may be impacted and those who could profit or benefit from the use of data shared through social media to highlight how specific interests may conflict and may undermine (a) social media and (b) research enterprise.

3. Explain how national/cultural context may affect researchers’ views of intellectual property and data ownership.

4. Compare and contrast the importance of 5 practices to help ensure the rigor and reproducibility of research.

**Required Readings (due by start of class)**


For Supplemental Reading:


**Activities**

In class and out of class: Group work on AI ethical challenges

On-own: NIGMS Clearinghouse for Training Modules to Enhance Data Reproducibility: Modules 1 – 4

**Assignments Due**

Each week, you will be responsible for posting to Discussion Boards (Assignment 1). You may also be scheduled for your Case Analysis Presentation (Assignment 2), depending on your pre-arranged due dates with the instructor.

*Assignment 4 Due June 19, 2023*

**Course Materials and Technology**

**Required Textbooks:**


All additional readings will be available for download on CANVAS or through a provided internet link.

**Additional Resources**

To help find possible cases:

The Scientist, for instance https://www.the-scientist.com/news-opinion/nature-science-retractions-connected-to-research-misconduct-65735

Retraction Watch, https://retractionwatch.com/

The Office for Research Integrity, https://ori.hhs.gov/content/case_summary

Supplemental reading:


For technical support for this class, please contact the UF Help Desk at:

- learning-support@ufl.edu
- (352) 392-HELP - select option 2/ (352) 392-4357
- https://elearning.ufl.edu/
- https://helpdesk.ufl.edu/
### Assignments and Grading

<table>
<thead>
<tr>
<th>Assignment #/ Points (%)</th>
<th>Requirement</th>
<th>Date Due</th>
<th>Details on assignment and grading criteria</th>
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<tbody>
<tr>
<td>1. 35 pts (35%)</td>
<td><strong>Team Case Analysis Presentation.</strong> Please do not use classic ethics cases. Use the ORI web page for cases or use other sites. Case Summaries</td>
<td>As scheduled with instructor</td>
<td>Teams will be composed in the 2nd class based on class section and topic choice. Topics of case may include: conflict of interest, data fabrication or manipulation; publication; genetics; clinical trials – equipoise or informed consent; clinical trials- placebo; clinical trial eligibility; protected human population; community or population harm; lack of consent; lack of human subjects protection; plagiarism; other (team defined). Once the team is composed based on the topic, students should choose a case of research misconduct/ethical violation from 2000 or more recently. All team members will need to go through the SFNO framework on their own, and then meet to prepare a presentation for the class based on the joint review. Points of contention should be included. Please try to limit the presentation to less than 12 slides. Refer students to references if possible. The case presentation should cover (as much as possible): a timeline of alleged events; all facts known; stakeholders; germane norms, values, regulations and ethical standards; options that could have/should have been considered, and possible solutions from any point in the timeline.</td>
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<tr>
<td>2. 30 pts (30%)</td>
<td><strong>Discussion Boards: Shared Application of Learning</strong> Application of readings, lectures and case presentations to ethical discussions through posting to the class listserv.</td>
<td>Weekly</td>
<td>This discussion board will require the student to create posting and respond to other student’s postings. Canvas metrics track time of the site and participation. While no numeric standard will be followed, students should post or respond to another student’s posting at least one time per week and for the major activity of each week. Postings will be graded on the basis of responsiveness to discussion assignment prompt, application of assigned readings, and responsiveness to fellow students’ postings. (See Rubric, below)</td>
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<tr>
<td>3. 35 pts (35%)</td>
<td><strong>Concept paper for a simple one aim research proposal.</strong> Students should outline a research question related to public health ethics or the responsible conduct of research, and map out a basic approach to answer the question.</td>
<td>June 20, 2022</td>
<td>The Concept Paper should include question, approach you would take to answer it (may include hypothesis, sample, measures, intervention (if relevant), and planned analysis) such as one might send to a possible Program Officer to discuss submission of a full proposal. 2 page maximum. NIH has resources to such as <a href="https://nida.nih.gov/sites/default/files/conceptpapers.pdf">https://nida.nih.gov/sites/default/files/conceptpapers.pdf</a> NSF refers to these as Concept Outlines and has a formal submission process. It is not necessary to choose a grant mechanism. You also don’t need to know who you might collaborate with to conduct this study, but feel free to pick people you would like to include (without talking to them about this class exercise, this is hypothetical only). (Students should put paper through Turnitin).</td>
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<tr>
<td>Criteria</td>
<td>Excellent</td>
<td>Good</td>
<td>Fair</td>
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<tr>
<td>Responsiveness to discussion assignment prompt 50 points</td>
<td>All components of discussion prompt addressed in initial posting 50 – 46 points</td>
<td>Up to 90% of the prompt components addressed in one or more postings 45 – 40 points</td>
<td>Up to 75% of the prompt components addressed in one or more postings 39-35 points</td>
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<tr>
<td>Application of assigned reading(s) 25 points</td>
<td>Very clear that readings were understood by incorporation into postings 25 – 24 points</td>
<td>Readings were understood and incorporated 23 – 21 points</td>
<td>Somewhat clear that readings were understood by incorporation into postings 20 – 18 points</td>
</tr>
<tr>
<td>Responsiveness to fellow students’ posting 25 points</td>
<td>Responsiveness to group discussion and at least two additional replies with multiple points from multiple participants clearly built upon/refuted in postings 25 – 24 points</td>
<td>At least one point from multiple participants clearly built upon/refuted in postings 23 – 21 points</td>
<td>One or more points from one or more participants only vaguely built upon/refuted in postings 20 – 18 points</td>
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<td>Total points 5</td>
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This course is graded Satisfactory/Unsatisfactory. S/U grades do not affect GPA points. A passing grade requires 80/100 points.

More information on UF grading policy may be found at: https://catalog.ufl.edu/graduate/?catoid=10&navoid=2020#grades

**Policy Related to Make up Exams or Other Work**

Please contact me as quickly as possible if you are late handing in an assignment or need to make up work. Late work may result in loss of up to 5% of the points given, if delay is not due to a reason consistent with the university policy, below. Students with personal health or family health emergencies will be given an appropriate extension of deadline with no loss of points.

**Policy Related to Required Class Attendance**

Please note all faculty are bound by the UF policy for excused absences. Excused absences must be consistent with university policies in the Graduate Catalog (https://catalog.ufl.edu/graduate/?catoid=10&navoid=2020#attendance). Additional information can be found here: https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies/.

**STUDENT EXPECTATIONS, ROLES, AND OPPORTUNITIES FOR INPUT**

Expectations Regarding Course Behavior
As a classroom of scholars and a learning community, the instructor will treat students with respect and expects respect in return. The classroom climate will be supportive, encouraging and open. To this end, no one should be taking calls or texts or using their laptops for other purposes than taking notes while the class is in session, except in the case of emergency. Electronic items must be turned off if they appear to detract from classroom discussion and attention. Please listen attentively; participation is required. When opinions differ, please listen first, and then prepare to comment. If you feel you have been treated disrespectfully by any member of the scholastic community involved in this course, please bring this to the instructor’s attention privately for remediation.

Communication Guidelines

Communications on-line or in-person must reflect integrity and respect.

Academic Integrity

Students are expected to act in accordance with the University of Florida policy on academic integrity. As a student at the University of Florida, you have committed yourself to uphold the Honor Code, which includes the following pledge:

“We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honesty and integrity.”

You are expected to exhibit behavior consistent with this commitment to the UF academic community, and on all work submitted for credit at the University of Florida, the following pledge is either required or implied:

“On my honor, I have neither given nor received unauthorized aid in doing this assignment.”

It is your individual responsibility to know and comply with all university policies and procedures regarding academic integrity and the Student Honor Code. Violations of the Honor Code at the University of Florida will not be tolerated. Violations will be reported to the Dean of Students Office for consideration of disciplinary action. For additional information regarding Academic Integrity, please see Student Conduct and Honor Code or the Graduate Student Website for additional details: https://sccr.dso.ufl.edu/process/student-conduct-code/ http://www.graduateschool.ufl.edu/graduate-life/student-life/

Please remember cheating, lying, misrepresentation, or plagiarism in any form is unacceptable and inexcusable behavior.

Online Faculty Course Evaluation Process

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via https://ufl.bluerap.com/ufl/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/.

Policy Related to Guests Attending Class:

Only registered students are permitted to attend class. However, we recognize that students who are caretakers may face occasional unexpected challenges creating attendance barriers. Therefore, by exception, a department chair or his or her designee (e.g., instructors) may grant a student permission to bring a guest(s) for a total of two class sessions per semester. This is two sessions total across all courses. No further extensions will be granted. Please note that guests are not permitted to attend either cadaver or wet labs. Students are responsible for course material regardless of attendance. For additional information, please review the Classroom Guests of Students policy in its entirety. Link to full policy: http://facstaff.phhp.ufl.edu/services/resourceguide/getstarted.htm

SUPPORT SERVICES

Accommodations for Students with Disabilities
If you require classroom accommodation because of a disability, it is strongly recommended you register with the Dean of Students Office [http://www.dso.ufl.edu](http://www.dso.ufl.edu) within the first week of class or as soon as you believe you might be eligible for accommodations. The Dean of Students Office will provide documentation of accommodations to you, which you must then give to me as the instructor of the course to receive accommodations. Please do this as soon as possible after you receive the letter. Students with disabilities should follow this procedure as early as possible in the semester. The College is committed to providing reasonable accommodations to assist students in their coursework.

**Counseling and Student Health**

Students sometimes experience stress from academic expectations and/or personal and interpersonal issues that may interfere with their academic performance. If you find yourself facing issues that have the potential to or are already negatively affecting your coursework, you are encouraged to talk with an instructor and/or seek help through University resources available to you.

- The Counseling and Wellness Center 352-392-1575 offers a variety of support services such as psychological assessment and intervention and assistance for math and test anxiety. Visit their web site for more information: [https://counseling.ufl.edu/](https://counseling.ufl.edu/). On line and in person assistance is available.

- You Matter We Care website: [https://umatter.ufl.edu/](https://umatter.ufl.edu/). If you are feeling overwhelmed or stressed, you can reach out for help through the You Matter We Care website, which is staffed by Dean of Students and Counseling Center personnel.

- The Student Health Care Center at Shands is a satellite clinic of the main Student Health Care Center located on Fletcher Drive on campus. Student Health at Shands offers a variety of clinical services. The clinic is located on the second floor of the Dental Tower in the Health Science Center. For more information, contact the clinic at 392-0627 or check out the web site at: [https://shcc.ufl.edu/](https://shcc.ufl.edu/)

- Crisis intervention is always available 24/7 from:
  Alachua County Crisis Center:
  (352) 264-6789
  [https://www.alachuacounty.us/DEPTS/CSS/CRISISCENTER/Pages/CrisisCenter.aspx](https://www.alachuacounty.us/DEPTS/CSS/CRISISCENTER/Pages/CrisisCenter.aspx)

Do not wait until you reach a crisis to come in and talk with us. We have helped many students through stressful situations impacting their academic performance. You are not alone so do not be afraid to ask for assistance.

**Inclusive Learning Environment**

Public health and health professions are based on the belief in human dignity and on respect for the individual. As we share our personal beliefs inside or outside of the classroom, it is always with the understanding that we value and respect diversity of background, experience, and opinion, where every individual feels valued. We believe in, and promote, openness and tolerance of differences in ethnicity and culture, and we respect differing personal, spiritual, religious and political values. We further believe that celebrating such diversity enriches the quality of the educational experiences we provide our students and enhances our own personal and professional relationships. We embrace The University of Florida’s Non-Discrimination Policy, which reads, “The University shall actively promote equal opportunity policies and practices conforming to laws against discrimination. The University is committed to non-discrimination with respect to race, creed, color, religion, age, disability, sex, sexual orientation, gender identity and expression, marital status, national origin, political opinions or affiliations, genetic information and veteran status as protected under the Vietnam Era Veterans’ Readjustment Assistance Act.” If you have questions or concerns about your rights and responsibilities for inclusive learning environment, please see your instructor or refer to the Office of Multicultural & Diversity Affairs website: [https://multicultural.ufl.edu/](https://multicultural.ufl.edu/)