BIOE 3000:
Bioengineering Ethics and Entrepreneurship (1,0)
Spring 2022

Meeting Times:
Fridays 12:20pm – 1:10pm
Kinard 101

Instructor:
Tyler Harvey, PhD
Lecturer of Bioengineering
313 Rhodes Engineering Research Center
Email: tgharve@clemson.edu
Office Hours: By Appointment (https://tgharve.youcanbook.me)

Teaching assistant:
Pantrika Krisanarungson
Email: pkrisan@g.clemson.edu

Modality: In-person synchronous

Course Objectives:
Students who are successful in this course will demonstrate the ability to:

1. evaluate current and historical ethical issues relevant to biomedical engineering practice and medicine, including the use of animal and human subjects in research.

2. explain the legislation, agencies, and regulations relevant to the field of biomedical engineering.

3. identify opportunities for the translation of biomedical research and innovation to the commercial marketplace.

4. apply basic business concepts utilized by medical technology companies and entrepreneurs.

Grading:
This course is a Pass/No Pass course. A grade of Pass will be earned with a final grade of 70% or above and submission of all course materials.

Participation[1]: 15%
Assignments[2] (3 at 10% each): 30%
Online compliance exams (2 at 15% each): 30%
Professional development activities[3]: 25%

[1]**Participation:** While we will not meet synchronously every week, all students are expected to participate in the course content each week. The form this take will vary from week to week (participation in group discussions on class, posting on the Canvas discussion board, uploading short reflections to materials assigned for viewing outside class, etc.) Each week you do not engage with the course, without a valid excuse, will result in a 1% reduction in your course grade.

Specific COVID-19 related information:
For a student who reports testing positive or is being asked to quarantine/isolate because of exposure to the virus, it will be up to the student to inform the instructor that they will be moving to online only instruction for at least the next two weeks. Students are directed to use the Notification of Absence link in Canvas to initiate this notification, which can be found under the "Help" button on the left navigation. (For courses where Canvas is not used, the direct link to the Notification of Absence form can be found through the Division of Student Affairs site.) Additional communication via email is encouraged; students should follow-up with the instructor to develop a continued plan of study for each course. Students cannot be penalized in their grade for needing to move to online instruction.

[2]**Assignments:** All assignments should be submitted through Canvas by 11:59pm on the date listed in the schedule. For group assignments, only one member of the group is required to submit, but the names of each group member should be clearly listed.

[4]**Professional Development Token Sheet:** You are required to attend professional development events, hold leadership roles, or impact your community in some way in order to succeed in this course. Each token counts as 2.5% of your final grade for a max of 25%. The attached sheet should be completed and turned in by 11:59pm on the last day of class.

Grading Scheme:
Pass: >=70%**
Fail: <70%

==**ALL ASSIGNMENTS, COMPLIANCE EXAMS, AND TOKEN SHEETS MUST BE SUBMITTED IN ORDER TO PASS THIS COURSE. ANY MISSING ITEMS WILL RESULT IN AN AUTOMATIC FAIL.==

Academic Grievances
Academic grievances are handled by Dr. Jeffrey Appling in Undergraduate Studies. Students are advised to visit the Ombudsman's Office prior to filing a grievance.

Accepting Late Work
While you should endeavor to turn all assignments in on time, I recognize that sometimes circumstances arise that makes this a challenge. Therefore, late work (exclusive of quizzes) will be accepted via Canvas or in person up until the point where the assignment has been graded and grades entered to Canvas.

Beyond this, late work will not be accepted unless there are extenuating circumstances. Email your instructor if you have a special case that requires turning work in late.

Communicating with Your Instructor
You have numerous ways of communicating with your instructor: phone, email, and in-office meetings by appointment.

- If you have a personal concern (such as a question about a grade), send a message to your instructor through your Clemson email account or through Canvas.
- I am here to help you, so please ask questions and seek clarification as early and as often as needed. Delay will only hinder your learning.

Minimum Technical Skills
Students are expected to have a minimum working knowledge of computers and a word processing suite to be successful in this class. You must be comfortable with your computer system and willing to deal with any problems that may arise. Lack of technical knowledge can greatly interfere with your learning a new subject. You should be able to do the following computer tasks:

- Get your password and login to your class before the semester begins (if available)
- Attach files to email messages
- Word processing tasks (type, cut, paste, copy, name, save, rename, etc.)
- Download information from the Internet
- Use a Web browser

Students are expected to be comfortable accessing the Canvas course site and downloading files such as Microsoft Office documents, YouTube videos, and PDFs. In addition, students should be able to use Microsoft Office to compose written documents, spreadsheets, and PowerPoint presentations.

General Policies & Procedures
Students are expected to adhere to all policies and procedure outlined by Clemson University at: http://www.clemson.edu/administration/student-affairs/studenthandbook/universitypolicies/index.html.

The Clemson University Academic Integrity Statement
As members of the Clemson University community, we have inherited Thomas Green Clemson's vision of this institution as a "high seminary of learning." Fundamental to this vision is a mutual commitment to truthfulness, honor, and responsibility, without which we cannot earn the trust and respect of others. Furthermore, we recognize that academic dishonesty detracts from the value of a Clemson degree. Therefore, we shall not tolerate lying, cheating, or stealing in any form.

A simple definition of plagiarism is when someone presents another person's words, visuals, or ideas as his or her own. The instructor will deal with plagiarism on a case-by-case basis. The most

serious offense within this category occurs when a student copies text from the Internet or from a collective file. This type of academic dishonesty is a serious offense that will result in a failing grade for the assignment as well as the filing of a formal report to the University.

See the Undergraduate Academic Integrity Policy website for additional information about academic integrity and Clemson procedures and policies regarding scholastic dishonesty.

Email Communication
Because of privacy regulations, University faculty and staff may email students only through Clemson email. Therefore, you must use your Clemson email account in this course for all email communications. Check your Clemson account at least three times per week for important messages.

COVID-19 related information for in-person classes:
While on campus, face coverings are required in all buildings and classrooms. Face coverings are also required in outdoor spaces where physical distance cannot be guaranteed. Please be familiar with the additional information on the Healthy Clemson website, such as the use of wipes for in-person classes. If the instructor does not have a face covering or refuses to wear an approved face covering without valid accommodation, students should notify the department chair. If a student does not have a face covering or refuses to wear an approved face covering without valid accommodation, the instructor will ask the student to leave the academic space and may report the student's actions to the Office of Community & Ethical Standards as a violation of the Student Code of Conduct. If the student's actions disrupt the class to the extent that an immediate response is needed, the instructor may call the Clemson University Police Department at 656-2222.

Student Disability Services
Student Disability Services coordinates the provision of accommodations for students with disabilities in compliance with Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990.

Reasonable and specific accommodations are developed with each student based on current documentation from an appropriate licensed professional. All accommodations are individualized, flexible, and confidential based on the nature of the disability and the academic environment. Housing accommodations for a disability or medical condition are also coordinated through this office.

Visit the Student Disability Services website for location, contact information, as well as official policies and procedures. You can also visit this link for additional details: http://www.clemson.edu/campus-life/campus-services/sds/about.html

Students requiring an accommodation can call Student Disability Services (SDS): sdsl@ clemson.edu or 864-656-6848 or visit http://www.clemson.edu/campus-life/campusservices/sds/about.html.

Academic Support Services

Students may access a variety of academic support services to support your learning in the classroom. Here are links to services available:

- Academic Success Center http://www.clemson.edu/asc/staff.html
- The Writing Centerhttp://www.clemson.edu/centers-institutes/writing/
- Clemson Online Library Guides http://libguides.clemson.edu/distanced
- Online Library Resourceshttp://www.clemson.edu/library/
- Academic Advising http://www.clemson.edu/academics/advising/index.html
- Registrar http://www.registrar.clemson.edu/html/indexStudents.htm

Copyright Notice

The Clemson University Title IX (Sexual Harassment) Statement

Clemson University is committed to a policy of equal opportunity for all persons and does not discriminate on the basis of race, color, religion, sex, sexual orientation, gender, pregnancy, national origin, age, disability, veteran's status, genetic information or protected activity (e.g., opposition to prohibited discrimination or participation in any complaint process, etc.) in employment, educational programs and activities, admissions and financial aid. This includes a prohibition against sexual harassment and sexual violence as mandated by Title IX of the Education Amendments of 1972. The University is committed to combatting sexual harassment and sexual violence. As a result, you should know that University faculty and staff members who work directly with students are required to report any instances of sexual harassment and sexual violence, to the University's Title IX Coordinator. What this means is that as your professor, I am required to report any incidents of sexual harassment, sexual violence or misconduct, stalking, domestic and/or relationship violence that are directly reported to me, or of which I am somehow made aware. There are two important exceptions to this requirement about which you should be aware:

> Confidential Resources and facilitators of sexual awareness programs such as "Take Back the Night and Aspire to be Well" when acting in those capacities, are not required to report incidents of sexual discrimination.
>
> Another important exception to the reporting requirement exists for academic work. Disclosures about sexual harassment, sexual violence, stalking, domestic and/or relationship violence that are shared as part of an academic project, a research project, classroom discussion, or course assignment, are not required to be disclosed to the University's Title IX Coordinator.

This policy is located at http://www.clemson.edu/campus-life/campus-services/access/title-ix/. Ms. Alesia Smith is the Executive Director for Equity Compliance and the Title IX Coordinator. Her office is located at 223 Holtzendorff Hall, phone number is 864.656.3181, and email address is alesias@clemson.edu.

Tentative Schedule:

Date	Topic	Assignment(s) Due
1/14/22	Course Introduction	
1/21/22	Module 1: Biomedical ethics	
1/28/22	Case Studies	
2/4/22	Human and Animal Research	
2/11/22	Module 2: Intellectual Property	Assignment 1
2/18/22	NO CLASS - COMPLIANCE EXAM	Compliance Exam 1
2/25/22	Regulatory Landscape	
3/4/22	NO CLASS - COMPLIANCE EXAM	Compliance Exam 2
3/11/22	Medical Reimbursement	
3/18/22	Module 3: Business concepts	Assignment 2
3/25/22	NO CLASS – SPRING BREAK	
4/1/22	Guest Speaker	
4/8/22	NO CLASS - ASSIGNMENT PREP	
4/15/22	Group Presentations (Assignment 3)	
4/22/22	Group Presentations (Assignment 3)	
4/29/22	Licensure and Course Wrap-up	Course Evaluation PD Token Sheet