Regenerative Medicine, Cell Manufacturing, and Society
Spring 2027

Thursdays 3:00-5:00 Eastern /2:00-4:00 PM Central

This multi-institutional course introduces students working in cell biology and regenerative medicine research to ethical, policy, and social issues relevant to the field of stem cell research and the development of cell therapies. Graduate students at Georgia Institute of Technology (GT), University of Georgia (UGA), University of Puerto Rico – Mayagüez (UPRM) and University of Wisconsin – Madison (UW) who are participating in the NSF Center for Cell Manufacturing Technologies (CMaT) are expected to take it as part of their graduate programs. The course is open to other interested graduate students at each institution.

Instructors	**Office Hours / Contact Information**
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Learning Outcomes: By the end of the course, students will:

1. Understand current and past legal, political, and social issues related to regenerative medicine. This includes laws and regulations, but also an understanding of clinical ethics issues, translational research and commercialization, and emerging novel techniques requiring careful ethical consideration.
2. Understand more about relations of science, the state, and public, particularly around controversial or novel innovations; and learn how best to address emerging controversies and public concerns ethically in their professional careers.
3. Learn the guidelines for the responsible conduct of research for stem cell science and cell manufacturing, where to access regulatory and oversight documents, and how to apply for research protocols with ethics oversight.
4. Gain analytical skills for addressing policy, legal, and social issues through research and writing exercises. Students will also learn analytical and professional presentation skills through classroom interactions and discussion.

Campus-Specific Details:

Campus	Room	Course Number
GT	Virtual	PUBP 8813 – AL
UGA	Boyd Research & Education Center, room 146, Virtual	BIOE 8120
UPRM	Virtual	BING8995-080E
UW	Virtual	CRB 615

The course is designed for the needs of science, engineering and medical students working in stem cell, cellular and molecular biology, and related research as well as social science students interested in learning more about the intersection of biomedical research, ethics and policy. **Note: Basic fundamentals of stem cell science will not be covered**. For those less familiar with stem cell research, background reading is **suggested before the course begins** (e.g. Stem Cell Basics," available at https://stemcells.nih.gov/info/basics/stc-basics)

Instructional Mode: The course combines lecture and discussion. This includes live, real-time interaction with students from other campuses via videoconferencing. Participation is designed to help students engage with students and faculty from other U.S. universities in real-time. Most class sessions will be recorded and available for students to review in case of technical difficulties.

Requirements: Active participation, completion of all readings and assignments, and attendance are required. A student may have no more than 1 unexcused absence (excused absences are defined as those due to illness or exceptional circumstances and should be approved in advance, whenever possible). In addition to in-class work, students will conduct reading, research, and writing outside of class. Evaluation is based on the following: **participation (30%)**, **journal club (20%), international policy project (**i.e. group project 1**) (20%) and a policy/ethics debate (**i.e., group project 2**) (30%).**

Participation evaluation for all students:

▪ Students **must read required material** each week.

▪ Students' input to the discussions should demonstrate engagement with the readings for that day plus material presented in class. We may have lively debates about some topics; this helps to sharpen your skills in identifying issues and arguing a point. At the same time, please be respectful of your colleagues when expressing your point of view.

A = excellent; frequent and thoughtful contributions to discussion; shows engagement with readings; contributes additional insights or critiques

B = good; volunteers summary of readings or offers interpretations; responds to other students' positions or questions

C = minimal; answers questions when directly asked; occasional participation

D = poor; did not participate in discussions or responses reflect that student did not read or engage with readings

F= failure; no participation; does not respond to questions; OR >1 unexcused absence

▪ Students are also expected to contribute to the class Teams site. This is a venue for discussions of class readings among yourselves and your instructors. You can use Teams to raise questions about the reading, highlight news related to class topics, communicate about your group projects, etc. Contributions to the Teams site are one component of your participation in the class. (Students should receive an invitation to the class Teams site the first week of classes.)

Student-Led Journal Club: Most weeks, we will start class with a small group of students leading a journal club discussion on a paper relevant to the class topic. Students will have the opportunity to sign up early in the semester for a week/paper that is of interest. Each group should present the paper including the key questions posed, the methodology used (if appropriate) and the results/conclusions. They should also lead the class in a discussion of the strengths, weaknesses, and implications of the paper as well as how it contributes to or challenges what we have learned in class thus far. Students will be graded on the quality and clarity of the presentation including any presentation materials prepared as well as efforts to promote active engagement among the group in the discussion. Materials (e.g. powerpoint slides or similar) should be uploaded to the class Teams site in advance so other students can download and follow along.

International Policy Project: Students will work in a small group to complete a comparative analysis of the policy environment for stem cell research and cell therapy in a country other than the United States. Students will be assigned to groups and each group will be assigned a country and tasked with researching their policy environment and presenting it to the class. More details will be provided on the class Dropbox site.

Policy / Ethics Debate: Toward the end of the semester, class time will be dedicated to several debates on ethical and policy issues relevant to the advancement of stem cell science, cell therapies and related areas of biomedical innovation. Students will be assigned to a debate topic and side. They will then work with a group of peers to research and develop arguments in favor of their position. In advance of the debate, each group should submit a high-level draft with their key arguments and supporting details. Following the in-class debates, each student will write an individual policy memo, providing a recommended course of action and justifying this recommendation through analysis of the scientific, political, economic, and ethical implications of the decision. More details will be provided on the class Dropbox site.

	Assigned	**Draft Plan**	**Presentation / Debate**	**Final Report**
International Policy Project	February 4	N/A	February 18	February 18
Policy / Ethics Debate	March 11	March 25	April 15 April 22	April 29

Logistics and Communication: All readings are posted on the class Dropbox site**.** The required readings are noted below in the schedule. We will also maintain a class Teams site for discussion of class-related topics, posting of relevant articles, etc. See discussion in "Participation" above.