

BIOTECHNOLOGY & THE LAW
HSS404 HONORS- Senior Seminar, 3 Credits, 3 Contact Hours

Fall Term 2024, M, W, 10-11:20, DHRH212

Instructor: M. X. Mitchell, Assistant Professor (she/her or they/them)

mary.mitchell@njit.edu

www.mxmitchell.com

Office Hours:

M, W, 11:30-12:30, Room 322, Cullimore Hall

Prerequisites & Restrictions: ENGL 102 with a grade of C or higher, and 6 credits at the 300-level History and Humanities GER with a grade of C or higher; 3 credits at the 300-level may be taken concurrently as a co-requisite. Registration requires senior standing.

Course Description:

Our world is filled with biotechnologies that offer great hope for human thriving while introducing new risks and dangers. This seminar explores the ways in which biotechnology and the law have intersected in history. Focusing mainly on the United States with some cogent comparisons, we will explore key questions at the intersections between biotechnology and the law in historical context. How have biotechnologies troubled social boundaries such as those between nature and culture, organism and thing, living and unliving, self and society? How have lawmakers and others grappled to leverage the promise of emerging biotechnologies while controlling their risks? How have biotechnologies intervened in, and troubled, property regimes? What value can historical analysis offer to citizens, scientists, and lawmakers working to regulate biotechnologies today?

Rationale & Learning Outcomes:

This course will introduce advanced undergraduate students to questions, topics, and debates about biotechnology and the law in historical perspective. By the end of the course, students will be able to:

- Identify, understand, and engage critically with scholarly and policy debates about the intersections between biotechnology and the law in history.
- Read independently, comprehend, interpret, and discuss peer-reviewed scholarly secondary sources and primary legal and historical sources on the history of biotechnology and the law.
- Demonstrate information literacy through the use of appropriate source material, original research, and the ability to cite properly.
- Develop and execute a capstone research project that uses peer-reviewed secondary sources from the field of history and high-quality primary sources to explore an aspect of the history of biotechnology and the law.

- Work with a group to develop clear, cogent presentations and lead engaging discussions on weekly topics.
- Work independently to develop an effective presentation communicating the key findings of the capstone research project to the class.

Communication:

I can be reached by email. Please use your NJIT email account and send messages directly to my NJIT email account. (I do not read messages generated through Canvas messaging.) I typically reply to emails within two business days. Business days are Mondays through Fridays, 9:00-17:00 EDT. Before writing, please check to make sure your question is not answered in the syllabus/course outline or on the course website.

Course Format:

This course meets in person only. Because this seminar centers on reading and student discussion, our meetings will not be recorded.

This course is organized as an upper-level discussion seminar. By the third and fourth years of university study, students have gained a versatile scholarly skill-set in critical reading and writing, collaborative work, presentation & discussion, and research. This seminar is designed as a “capstone” experience that enables students to hone and refine all of these skills as independent, sophisticated consumers and producers of knowledge.

Our class meetings will be organized around your independent reading and engaged discussion of peer-reviewed historical scholarship and primary legal and historical sources. Although I will supplement our learning with brief lectures to put the readings in broader context, most of our time together will be anchored by student-led discussions of course readings and themes. I will not summarize the readings. Rather, students are expected to learn the “content” of the course by working carefully through the week’s assigned readings before the first class each week.

Over the course of the semester, you will also develop and share your own research with the class. That is, you will become a producer of knowledge about biotechnology and the law in history!! This course format can be challenging, but many students find it intellectually and socially rewarding. This is a chance to develop and flex your scholarly skills while working on what President Lim calls the “power skills” of effective collaboration, analysis, and communication!! These experiences are equally as valuable in the boardroom as they are in the laboratory and library.

Readings:

Each week, students will read assigned peer-reviewed scholarly work about an aspect of biotechnology and the law in history. Many weeks, the scholarly article or articles will be accompanied by a related primary legal or historical source.

All texts will be posted or linked on Canvas. You don’t have to buy anything. Save a tree and some hard-earned cash!

Grading Scheme Overview & Deadlines:

ASSIGNMENT	%	DEADLINE
Attendance & Participation	15	whole term
Group Preso & Reading Discussion Leadership	10	variable
Group “Connections” Discussion Leadership	10	variable
Project Topic & Annotated Bib.	10	10/11/2024, 17:00 EDT Canvas
Paper Draft	5	11/17/2024, 17:00 EDT Canvas
Peer Review	5	11/22/2024, 17:00 EDT Canvas
Research Project Presentation	10	variable – last two weeks of class
Final Project Paper	35	12/14/2024, 17:00 EDT Canvas

Grading Scale:

A= 90 to 100

B+= 88 to 89

B= 80 to 87

C+= 78 to 79

C= 70 to 77

D= 60 to 69

F= 59 to 0

Overview of Graded Course Components:Attendance & Participation (15%)

Let’s make this an exciting space to connect and share ideas! Nobody wants to sit around in silence! (Folks probably don’t want to listen to me drone on either!) A seminar is only as good as the discussion it generates. I expect all students to prepare for class by doing the readings, to attend class, and to participate meaningfully in discussion throughout the term. You will be marked on your participation in class exercises and discussions, including, where applicable, written components, such as discussion board posts or reading assessments completed during class. It is not possible to participate if you do not attend. Attendance is therefore essential and is included as a component of the participation grade. Unexcused absences will negatively affect your mark. During class, discussion contribution quality counts as much as quantity. Each week, ask yourself whether you are engaging with your classmates’ ideas, speaking up in class, and engaging respectfully.

Group Presentation & Reading Discussion Leadership (10%) & Group “Connections” Discussion Leadership (10%)

During one class period, you will be tasked with presenting on the week’s theme and readings and leading class discussion as a part of a small group. These presentations and discussions will typically occur on our Monday meetings. During one class period in a different week, you will be tasked with researching the connections and resonances between the week’s themes and present-day problems, questions, and events. With your small-group companions, you will

develop plans to lead discussions on these connections. These presentations and discussions will typically occur on our Wednesday meetings. Here is your chance to connect history to today's debates, laws, and emerging research!

There are two components to these assessments:

- 1) The students must prepare and give a short, ~5 minute presentation. Presentations will be assessed on accuracy, relevancy, clarity, and keeping with the time limit.
- 2) The students will lead and facilitate discussion. Group members may wish to prepare discussion questions or plan short exercises. Discussion leadership will be assessed on team members' actions and contributions to spark broader conversation. Here, remember that the class as a whole can help everyone earn good marks! When you are an audience member, help your classmates out by engaging!

Further details will be discussed in class. We will conduct sign-up to sort students into groups.

Absent exceptional circumstances, everyone in the group will receive the same marks. If there is an issue with a teammate's lack of participation, it is essential that you let me know as soon as possible. I expect everyone to share the load and to work together. Because this is a group project tied to a particular class meeting, I will not be able to grant extensions.

These assessments have a few purposes. First, one of the best ways to learn is by teaching. In preparing and presenting advances students' their facility with the subject matter. Second, presenting is an essential skill in the "real world". Becoming accustomed to presenting will pay dividends in the long run. Third, working together with colleagues is good practice for life after university and offers additional opportunities for deepening one's understandings of the material through discussion with group members.

Project Topic & Annotated Bibliography (10%)

The focus of your writing this term will be a ~5,000 word (about 20 pages) (inclusive of notes and references) research paper analyzing some aspect of the intersections between biotechnology and the law in historical context. There are so many exciting technologies, laws, events, and debates that we will not have a chance to cover in class. Here is your opportunity to research and write about something we did not get a chance to cover! Each student must submit a proposed plan for the final project along with an annotated bibliography of high-quality primary and peer-reviewed, scholarly secondary sources.

This step is intended to enable me to provide helpful feedback on your plans before you begin the in-depth work on your projects. I will provide further details and leave ample time for discussion in class.

Project Draft (5%)

Students must submit a full draft (~75% complete) of the research paper. Details to follow.

The deadline on this component is inflexible because lateness would affect your peer review partner's ability to complete their evaluation of your draft. Because of this, I will not be able to grant extensions on this component of the assignment.

The purpose of this assessment is to give students a chance to improve their research and writing before the final version is due. While we've certainly all probably done a fair bit of "last minute" work, large research projects tend to get stronger with sustained attention over time. Including a draft gives an incentive to students to work steadily over the course of the term. Moreover, the exercises will give everyone a chance to give and receive peer feedback to improve the final product.

Peer Review (5%)

Each student will be paired with a colleague. The two students will give detailed, actionable feedback on their partner's project draft. More details to follow.

Because feedback is only useful if there is time to incorporate it into the final paper, I will not be able to grant extensions on this component of the assessment.

This assignment is intended to give everyone a chance to benefit from having a "fresh" set of eyes on their project. Often, one gets so close to one's work, it becomes difficult to see areas that might be clarified or improved. An outside reader can add tremendous value. Being an outside reader for someone else, moreover, helps readers develop a critical eye and distance that can aid in revising one's own work.

Research Project Presentation (10%)

Every student will prepare and deliver a short presentation on their project during the last two weeks of class. The exact time limit is TBD, depending on how many students are enrolled in the course. Our presentations will take place during the last two class periods of the term. Students will need to submit slides, if used, no later than 5PM the day prior to the presentation so that I can assemble a slide deck for the day.

Because everyone will present on one of those days, and we need to space the presentations across those two periods, the deadline on this component of assessment is not flexible. I will not be able to grant extensions.

This component is intended to give everyone a chance to share all the hard work they have done throughout the course! This is a time to engage deeply with each other's research and ideas. Although presenting can be anxiety-producing for some individuals, it is a valuable life and work-place skill. Moreover, many individuals find that doing presentations over time helps to reduce this stress. Since we will be collaborating as a group all semester, I hope that this will be a comfortable space to share work and practice presentation skills. Let's celebrate all you have accomplished!

Research Paper (35%)

As noted, the capstone assessment of the term will be a ~5,000 word research paper. More details to follow. This is a scaffolded assignment. The final paper will be the product of work you have done on interim steps throughout the term.

The purpose of this assessment is to give every student a chance to do research on a relevant topic that is of interest to them, but which we did not have a chance to explore during class. Doing in-depth research helps to improve skills in finding and evaluating the quality of primary and secondary sources, and in developing a tailored research question. These skills are valuable within the university, but also extend to many workplaces.

Time Management, Deadlines, Late Work:

It is often the case that having more time to study or to revise an assignment would lead to better work product. Yet it is also true in university and working life that you will be asked to complete a great many tasks under time constraints. Working to deadline is one transferable skill that university coursework is intended to help students develop. Timeliness is part of the criteria I use to assess the quality of a particular piece of work product.

Since timeliness is part of our assessment criteria for written work, late work submitted after class date and time deadlines (or after a properly granted extension) may be marked down by 5% per calendar day up to a 40% deduction, after which the work will not be accepted. By way of example, if an assignment is due on Tuesday at noon and you hand it in at 13:00EDT that day, it will be marked down by 5%. If you hand it in anytime on Wednesday it will be marked down by 10% and so forth.

If you are experiencing difficulties completing your coursework or if you need to seek accommodation for illness, disability, death in family, religious reasons, etc., under university policy, you must inform the Dean of Students Office. Instructors can only accommodate a student at the direction of the Dean's Office. Their office is a wonderful resource!! They can help you plan a course of action and decide if you want to seek an accommodation. They also help in communicating with your instructors and connecting you with other resources on campus for help with your situation.

Copyright Rights & Prohibition on Distribution & Recording:

Lectures and course materials prepared by the instructor are considered to be an instructor's intellectual property. You may not publish, distribute, or otherwise sell course materials in any form including on any website. You may not record class sessions.

Academic Integrity:

Academic Integrity is the cornerstone of higher education and is central to the ideals of this course and the university. Cheating is strictly prohibited and devalues the degree that you are working on. As a member of the NJIT community, it is your responsibility to protect your educational investment by knowing and following the academic code of integrity policy that is found at: [NJIT Academic Integrity Code](#).

Please note that it is my professional obligation and responsibility to report any academic misconduct to the Dean of Students Office. Any student found in violation of the code by cheating, plagiarizing or using any online software inappropriately will result in disciplinary action. This may include a failing grade of F, and/or suspension or dismissal from the university. If you have any questions about the code of Academic Integrity, please contact the Dean of Students Office at dos@njit.edu

Generative Artificial Intelligence Prohibition:

Use of generative AI intelligence tools or apps is strictly prohibited in this class. Use of any such tools in our assignments, and especially representing AI-generated ideas or expressions as one's own, may be considered an academic offense. This course is intended to provide an opportunity for students to work on skills of independent critical reading, synthesis, analysis, and expression. These skills will remain incredibly important regardless of the continual development of AI. I'm interested in what's on your mind, not what's on a language processing model's mind!!!

Further to this policy, students will be required to submit their original written work online on canvas in the specified file formats. Student work will be subject to review by tools furnished by the administration to NJIT instructors and used to detect plagiarism, AI use, and irregularities in sourcing and citation of the written word and claims. Plagiarism, use of AI, and/or other irregularities may result in disciplinary procedures or failure of the assignment or course.

Inclusive Learning Environment & Accessibility:

My goal is to facilitate the learning of all students in our course. Students with diverse learning styles and needs are welcome. If you have an accommodation need, you should register with NJIT's Student Disability Services (SDS), <http://www.njit.edu/counseling/services/disabilities.php>. SDS will assess your situation, develop an accommodation plan with you, and support you in requesting accommodation for your course work. Remember that the process of accommodation is private: SDS will not share details of your condition with any instructor.

Learning Community:

Together we will strive to create an intentional, respectful learning community. Building such a community requires safety and trust. When you speak, please exercise care and think about how your comment might resonate with others having experiences and identities different from yours. Please also try to ensure that your mode of engagement invites and creates space for others to speak. All of us, from time to time (including me!), may express ourselves incompletely, or inadvertently say something someone else finds hurtful. Handling these moments is an important part of the learning process. If you are finding discussion difficult, feel unwelcome to express your views, or find a particular discussion or comment to be hurtful, please come talk to me. I will do my utmost to make everyone feel welcome, safe, and able to express their considered viewpoints.

A Note on Violence:

This course covers acts of violence and discrimination against racialized persons and others who have been marginalized socially, politically, and legally. If you think you may be upset by readings or discussions of these topics, please make an appointment with me at your earliest convenience to discuss the course content and the syllabus and to decide whether the class is a good fit for your interests.

**** I reserve the right to make changes to the syllabus as needed. ****

READING SCHEDULE

Week 1 (9/4/2024) – Introductions

This week we will begin to think about biotechnology as we get to know one another. Please come ready to introduce yourself and your interests and to work with your classmates.

Week 2 (9/9/2024 & 9/11/2024) – Defining Terms

Last week, we thought a bit about biotechnology. This week, we turn to law and history. What is law anyway? How do different layers of law and regulation intersect? What are some sources of law and how can they be read and analyzed? What do legal historians do and how do they make claims? How is historical research on law and science relevant today? How do historians think about present-day concerns as they assemble historical claims? When is a focus on the present a legitimate way of making historical knowledge and when might it be problematic?

David Armitage, “The Impulse of the Present,” *Historical Transactions: The Royal Historical Society Blog*, available at: <https://blog.royalhistsoc.org/2023/07/26/the-impulse-of-the-present/>

Orin Kerr, “How to Read a Legal Opinion,” *The Green Bag* 11 (2007): 51-63.

Week 3 (9/16/2024 & 9/18/2024) – Experimental Bodies

Last week, we considered the ways in which the present affects historians’ research, claims-making, and analysis. We thought critically and analytically about how people in history used claims of oldness and newness in support of their own aims and interests. And we considered how historians craft claims of oldness and newness; relevancy and irrelevancy. This week, we will explore two scholarly articles about how human beings and bodies have been used as research resources. Pay careful attention to how the authors of each respective article think about the past and the present. What evidence do they use in support of their claims? What are their arguments about time? How does time play into the construction of legal, moral, and historical claims?

Susan C. Lawrence & Susan E. Lederer, "Medical Specimens and the Erasure of Racial Violence: The Case of Harriet Cole," *Medical Humanities* 49 (2023): 457-467.

Nancy D. Campbell & Laura Stark, "Making Up 'Vulnerable' People: Human Subjects & the Subjective Experience of Medical Experiment," *Social History of Medicine* 28 (2015): 825-848.

Week 4 (9/23/2024 & 9/25/2024)– Vaccination

Last week, we considered humans as research subjects. This week, we move on to one of the earliest and most important classes of therapeutic medical biotechnology: vaccines. These biotechnologies raised and continue to raise important questions about the reach of state power into humans' biological bodies, and arguments about the body as a boundary that state power ought not to transgress. According to Willrich, how did the legal landscape surrounding vaccines change in the Progressive Era United States? What factors does he identify as important? What evidence does he draw upon to substantiate his claims? How did the Supreme Court articulate its reasoning relating to the reach of state power in Jacobson v. Massachusetts?

Michael Willrich, "'The Least Vaccinated of Any Civilized Country': Personal Liberty and Public Health in the Progressive Era," *Journal of Policy History* 20 (2008): 76-93.

Jacobson v. Massachusetts, 197 U.S. 11 (1905), excerpts TBA.

Week 5 (09/30/2024 & 10/02/2024) – Making Historical Knowledge

You are not just consumers of historical knowledge. You are also producers! (Or will be soon!) This week we will think about our own interests as budding historians. On MONDAY 9/30, we will go over to the Rutgers library to hear a presentation on research. Wednesday, we will discuss how historical questions are framed and researched.

Week 6 (10/07/2024 & 10/9/2024) – Body Products

Previously, we examined how vaccination policy engaged questions of bodily liberty and autonomy. When can the state force a biotech into someone's body? This week, we ask what happens when pieces of a human body become biotechnologies. What makes something a part of one's body? When does part of a body stop being part of the person from which it was removed? What does it mean when part of a person who will someday die is made immortal? Who owns these immortal pieces of people?

Hannah Landecker, *Culturing Life: How Cells Became Technologies* (Cambridge: Harvard University Press, 2010), "Immortality", 68-106.

Moore v. Regents of the University of California, 793 P.2d 479 (Cal. 1990), excerpts TBA.

Week 7 (10/14/2024 & 10/23/2024) – Grappling with Change

We have examined important moments of scientific and technological change throughout our time together. This week, we will explore how do scientists, lawyers, and technicians work to govern fast-paced technological change—especially when new biotechs introduce risk and hazard. How should risk and benefit be balanced? Who should decide—government, experts, members of the public? The setting of our inquiry is the 1975 Asilomar conference, where scores of microbiologists and a few lawyers gathered to decide how the new technology of recombinant DNA should be regulated. The conference and principles it generated, however, also became a historical tool. Why was Asilomar important in its time? How has it been important afterwards? Thinking back to our second week of class, what do the many meanings of Asilomar reveal about the types and uses of history in the present?

J. Benjamin Hurlbut, “Remembering the Future: Science, Law, and the Legacy of Asilomar,” in *Dreamscapes of Modernity: Sociotechnical Imaginaries and the Fabrication of Power*, eds. Sheila Jasanoff and Sang-Hyun Kim (Chicago: University of Chicago Press, 2015), 126-151.

Paul Berg, David Baltimore, Sydney Brenner, Richard O. Roblin III, & Maxine F. Singer, “Summary Statement of the Asilomar Conference on Recombinant DNA Molecules, *PNAS* 72 (1975): 1981-1984.

Week 8 (10/21/2024 & 10/23/2024) – Check-in & Tune-up!

This week, we will not meet as a class. Rather, Mitchell will use the class-time to meet one-on-one with students to discuss their research plans, troubleshoot any obstacles, and brain-storm. Sign-up procedures will be discussed in class.

Week 9 (10/28/2024 & 10/30/2024) – Products of Nature

In past weeks, we considered the ways in which human bodies (living and dead) are utilized as biotechnologies. We began to explore difficult questions of who, if anyone, owns human tissues. This week, we dig even deeper into the engineering of life-forms, bringing the discussion into the laws governing intellectual property—i.e. patents. Tracing the emergence and contestation of categories of invention that US lawmakers have deemed unpatentable, we will examine how litigants and lawmakers construct the line between things that are natural and things that are human-made. How do we distinguish nature from technology? What are the historical policy reasons for these distinctions? How have emerging techniques and technologies troubled existing legal frameworks?

Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe* (Chicago: University of Chicago Press, 2017), Chapter 2, 51-80.

Diamond v. Chakrabarty, 447 U.S. 303 (1980), excerpts TBA.

Week 10 (11/04/2024 & 11/6/2024) – Reading the Book of Life

Last week, we considered the causes and consequences of developing engineered life-forms as technology and seeking intellectual property rights in them. In other words, we explored whether particular classes of engineered living things could be the subject of patent rights. This week, we move even further beneath the surface to trace debates over gene patents—patent claims in sequences of DNA and cDNA within human beings. When is a gene information and when is it a thing? How do claims of patent rights in life forms differ from claims of patent rights in human genes? How do these debates implicate different questions of law, policy, and morality than the question of patenting engineered living organisms?

Robert Cook-Deegan, “Gene Patents,” in Mary Crowley, ed., *From Birth to Death and Bench to Clinic* (Garrison, NY: The Hastings Center, 2009): 69-72.

Shobita Parthasarathy, *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care* (Cambridge: MIT Press, 2007), Chapter 3, 115-144.

Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013), excerpts TBA.

Week 11 (11/11/2024 & 11/13/2024) – Identity, Culture, & Biotechnology

Last week, we explored property rights in DNA and cDNA sequences. This week, we zoom out to the level of distinct social communities to ask how and why culture matters in relation to the use of genetic materials as biotechnological research tools. Examining a dispute over the collection and use of Native American (Havasupai) tissue samples in research, we will think critically about the cultural embeddedness of regulatory and property regimes. We will consider arguments that one-size-fits-all regulation is inappropriate in the context of interactions with Native American communities. Are there other communities whose histories and experiences might counsel special consideration or different sets of legal rules? If so, why? If not, why not? Does considering the Havasupai community’s arguments make you think differently about the Moore or Association of Molecular Pathologists cases or the HeLa cell line discussed earlier in the term? Why or why not?

Rebecca Tsosie, “Cultural Challenges to Biotechnology: Native American Genetic Resources and the Concept of Cultural Harm,” *The Journal of Law, Medicine, and Ethics* 35 (2007): 396-411.

Appellants’ Opening Brief, Tilousi et al. v. Arizona Board of Regents, No. 1 CA-CV 07-0801 (Jan. 7, 2007).

Week 12 (11/18/2024 & 11/20/2024) – Peer Review Week

No class!! Take the time to carefully review your partner’s draft paper and to consider their feedback on your paper.

Week 13 (11/25/2024 & 11/27/2024) – Movie Night & Discussion!

The themes we have been exploring all semester are the topic of many creative works that consider the rewards and especially the risks of emerging biotechnologies. This week, we will have some fun screening a movie selected by the class and discussing its intersection with class themes.

Week 14 (12/2/2024 & 12/4/2024) – Research Symposium Presentations

Week 15 (12/9/2024 & 12/11/2024) – Research Symposium Presentations
