BIOTECHNOLOGY AND THE LAW
BINF 4191/5191
SYLLABUS – SPRING, 2015

Instructor: 228B PORTAL building
Office Phone: (704) 687-8016
Office Hours: by appointment
Class Hours: Tuesday and Thursday 12:30 – 1:45 (3 credit hours)
Email: cmahler@uncc.edu

A. COURSE DESCRIPTION

Biotechnology and the Law: At the intersection of biotechnology and the law, an intricate body of law is forming based on constitutional, case, regulatory and administrative law. This body of legal knowledge is interwoven with ethics, policy and public opinion and continues to change as technology advances and society adapts and develops new norms. The class is designed to provide the student with a working knowledge of US law as it currently applies to the life sciences with sufficient background to understand the policy, legislative decisions, and debates that are likely to impact careers in biotechnology and the life sciences in coming years.

The course is divided into two approximately equal sections. The first half of the semester provides an overview of the historical sources of law, various aspects of law as it now exists in the United States (contracts, torts, property, corporate forms, etc.), and the roles of the legislative, executive, and judicial branches plus administrative agencies in creating, enforcing, and interpreting the law. The second half focuses on how various aspects of the law directly affect individuals working in the life sciences with an emphasis on regulations pertaining to research and to the delivery of healthcare.

The course meets in Room 301 of the Bioinformatics Bldg.

B. PRE- OR CO-REQUISITES

Prerequisite: Admission to a graduate program or junior or senior status in a scientific/technical course of study or if in a non-biological/technical or scientific program, special permission of the instructor.

C. OBJECTIVES OF THE COURSE

Upon completion of Biotechnology and the Law, students will be able to:

• Recognize distinct types of law pertaining to biotechnology and healthcare
• Articulate various historical sources of current law
• Understand how codified law is created and enforced
• Become familiar with intellectual property rights, corporate forms, laws affecting start-up companies, and regulation of research and commercial activity in the life sciences.
• Be exposed to case law and the litigation process
• Develop critical thinking skills and communication skills necessary to convey positions on issues
• Develop an appreciation to the challenges of policymaking / legislative agendas around biotechnology and healthcare

D. INSTRUCTIONAL METHOD

The course integrates lectures, presentations, and discussions.

E. GRADING

100% quizzes and class participation. Excessive absenteeism will affect a student’s grade. Quizzes will be given approximately every 2 to 3 weeks with advance notice.
F. **Specify policies that apply to this course:**
   The following policies apply to students in BINF 4191/5191

1. **University Integrity**
   All students are required to read and abide by the Code of Student Academic Integrity. Violations of the Code of Student Academic Integrity, including plagiarism, will result in disciplinary action as provided in the Code. Definitions and examples of plagiarism are set forth in the Code. The Code is available online at: [http://legal.uncc.edu/policies/up-407](http://legal.uncc.edu/policies/up-407).

2. **Attendance**
   Class attendance is required, although exceptions will be made for reasons such as illness or family emergency.
   If the instructor is late, students are required to wait 20 minutes after the start of class before leaving to avoid being counted absent. If written instructions are left, they are to be followed.

3. **Grading Policy**
   Grades will be assigned on the following scale:
   - A=93-100%
   - B=85-92%
   - C=77-84%
   - D=70-77%
   - F=0-70%

4. **Additional Policies**
   UNC Charlotte is committed to access to education. If you have a disability and need academic accommodations, please provide a letter of accommodation from Disability Services early in the semester. For more information on accommodations, contact the Office of Disability Services at 704-687-0040 or visit their office at Fretwell 230.

   The use of cell phones, pagers, PDAs, or other communication devices is disruptive and prohibited during class. Individuals using such devices, unless for class activities or emergency, are to leave the class and will receive an unexcused absence. Students are permitted to use computers during class for note-taking and other class-related work only.

G. **Textbook**
   There is no one textbook. A collection of current readings and chapters will be assigned.
H. Schedule of Topics (Subject to Change)

Jan 9 Sources of the Law I (Hammurabi, Mosaic Law, Roman Law, trial by ordeal)
Jan 14 Sources of the Law II (Church Law, Common Law, Code Napoleon)
Jan 16 Branches of the Law I (Criminal, Tort, Contract)
Jan 21 Branches of the Law II (Property/Inheritance, Tax, Procedure)
Jan 23 US Legal System (Constitution and Treaties; State, Federal, Local)
Jan 28 Legislative Process; Judicial Process I (jurisdiction, forum, venue, trials)
Jan 30 Judicial Process II (appeals, supreme court, inferior courts); Administrative Law
Feb 4 IP Basics I (Trademark, Trade Secret, Secrecy Agreements)
Feb 6 IP Basics II (Patents, Material Transfer Agreements)
Feb 11 IP Basics III (Data rights, Licensing IP)
Feb 13 Corporate Forms (Corporate Personhood, Requirements for Maintaining Corporate Personhood, Piercing the Corporate Veil)
Feb 18 Instructor out, guest speakers on copyrights
Feb 20 Instructor out, guest speaker on practical aspects of starting new companies
Feb 25 Open Source Software – basis and varieties; Databases Final date for Approval of Topics for Papers (if applicable)
Feb 27 Patenting Life and DNA; Product Liability
March 4 – Spring Break
March 6 – Spring Break
March 11 Midterm Exam – 25%
March 13 Drug Discovery, IP Protection, Consideration of Drug Names, Therapeutic Windows, Safety and Efficacy
March 18 Regulation of Drugs and Medical Devices I (Thalidomide, ethics, history of FDA)
March 20 Regulation of Drugs and Medical Devices II (FDA Regulations, Classes of Drugs and Devices, 510k Equivalence and 510k “creep”)
March 25 Biosafety, IACUC’s and Animal Care – the basics
March 27 Human Subjects and IRB’s (Introduction and History) Outlines of Papers Due (if applicable)
April 1 IRB’s, IACUC’s, and Animal Care – The Rubber Hits the Road (Panel Discussion)
April 3 Conflicts of Interest
April 8 GMO’s, Safety, Labeling, Factory farms
April 10 Types and Regulation of Medical Treatment (Allopathy, Homeopathy, Naturopathy, Chiropractic, Podiatry, Faith Healing/children)
April 15 Economics of Healthcare, Disparities of Research and Treatment (females, elderly, minorities), drug pricing
April 17 Insurance (what it is, how it works, emphasis on aspects of health insurance) and Reimbursement (DRG’s, ICD’s and the economic importance of Medicare/Medicaid)
April 22 – The Affordable Care Act and Alternative Healthcare Systems (French, British, German, Canadian)
April 24 – subject chosen by class Papers Due (if applicable)
April 29 – subject chosen by class
May 8 Final Exam (25%)