**Document N: Course and Program Development: IMPACT AND APPROVAL SIGNATURES**

See Course and Program Development Policy and Procedures (www.ubalt.edu/provost) for instructions.

---

**SCHOOL:**
- LAW
- MSB
- CAS
- CPA

**CONTACT NAME:** Laurie Beth Harow  
**PHONE:** x4457

**DEPARTMENT/DIVISION:** School of Law  
**DATE PREPARED:** 12/3/14

**PROPOSED SEMESTER OF IMPLEMENTATION:**
- Fall
- Spring  
**YEAR:** 2014

**TYPE OF ACTION:**
- Add (new)
- Deactivate
- Modify
- Other

**LEVEL OF ACTION:**
- Noncredit
- Undergraduate
- Graduate
- Other

**ACTION BEING REQUESTED** (select one category, either Course Actions or Program Actions):
- COURSE ACTIONS
- PROGRAM ACTIONS

**Original Subject Code/Course Number:** LAW 857

**Original Course Title:** Law and Biotechnology

Select one or multiple actions from one of the lists below (review the list of necessary documents and signatures):

**COURSE ACTIONS**
- 1. Experimental Course
- 2. Course Title
- 3. Course Credits
- 4. Course Number
- 5. Course Level
- 6. Pre- and Co-Requisite
- 7. Course Description
- 8. New Course
- 9. Deactivate Course
- 22. Other

**PROGRAM ACTIONS**
- 10. Program Requirements
- 11a. Undergraduate Specialization (Fewer than 24 credits)
- 11b. Master's Specialization (Fewer than 12 credits)
- 11c. Doctoral Specialization (Fewer than 18 credits)
- 12. Minor (add or delete)
- 13. Closed Site Program
- 14. Program Suspension
- 15. Program Reactivation
- 16a. Certificate Program (UG/G) exclusively within existing degree program
- 16b. Certificate Program (UG/G) outside of or across degree programs (12 or more credits)
- 17. Off-Campus Delivery of Existing Programs
- 18a. Undergraduate Concentration (24 or more credits)
- 18b. Master's Concentration (12 or more credits)
- 18c. Doctoral Concentration (18 or more credits)
- 19. Program Title Change
- 20. Program Termination
- 21. New Degree Program
- 22. Other

**ADDITIONAL DOCUMENTATION** (check all appropriate boxes of documents included; review the list of necessary documents):
- Summary proposal (Q)
- Course definition document (P)
- Full five-page MHEC proposal (Q)
- Financial tables (MHEC) (R)
- Other documents as may be required by MHEC/USM (S)
- Other (T)
IMPACT REVIEW (review the list of necessary signatures):

<table>
<thead>
<tr>
<th>Impacted Entity</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Library</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- no impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- impact statement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. OTS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- no impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- impact statement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. University Relations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- no impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- impact statement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Admissions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- no impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- impact statement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Records</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- no impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- impact statement</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

APPROVAL SEQUENCE (review the list of necessary signatures):

<table>
<thead>
<tr>
<th>Approval Level</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Department/Division (Chair)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. General Education (for No. 7, 8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. Final Faculty Review Body Within Each School (Chair)</td>
<td>Michele Shimman</td>
<td>1-21-15</td>
</tr>
<tr>
<td>D. Dean</td>
<td></td>
<td>1-22-15</td>
</tr>
<tr>
<td>E. University Faculty Senate (Chair)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F. University Council (Chair)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>G. Provost and Senior Vice President for Academic Affairs</td>
<td>Arthur T. Anderson</td>
<td>2-18-15</td>
</tr>
<tr>
<td>H. President</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I. Board of Regents (notification only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>J. Board of Regents (approval)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>K. MHEC (notification only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L. MHEC (approval)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M. Middle States Association notification</td>
<td>Required only if the University's mission is changed by the action</td>
<td></td>
</tr>
</tbody>
</table>

1 University Council review (for recommendation to the president or back to the provost) shall be limited to curricular or academic policy issues that may potentially affect the University's mission and strategic planning, or have a significant impact on the generation or allocation of its financial resources.
**Course and Program Development: SUMMARY PROPOSAL**

See Course and Program Development Policy and Procedures (www.ubalt.edu/provost) for instructions.

**SCHOOL:** LAW

**CONTACT NAME:** Laurie Beth Harow

**PHONE:** x4457

**DEPARTMENT/DIVISION:** School of Law

**DATE PREPARED:** 12/3/14

**PROPOSED SEMESTER OF IMPLEMENTATION:**
- [ ] fall
- [x] spring

**YEAR:** 2014

**ACTION BEING REQUESTED** (select one category, either Course Actions or Program Actions):

- [ ] COURSE ACTIONS
- [x] PROGRAM ACTIONS

**Original Subject Code/Course Number:** LAW 857

**Original Program Title:**

**Original Course Title:**

Law and Biotechnology

Select one or multiple actions from one of the lists below (review the list of necessary documents and signatures):

<table>
<thead>
<tr>
<th>COURSE ACTIONS</th>
<th>PROGRAM ACTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Experimental Course</td>
<td>10. Program Requirements</td>
</tr>
<tr>
<td>2. Course Title</td>
<td>11a. Undergraduate Specialization (fewer than 24 credits)</td>
</tr>
<tr>
<td>3. Course Credits</td>
<td>11b. Master's Specialization (fewer than 12 credits)</td>
</tr>
<tr>
<td>4. Course Number</td>
<td>11c. Doctoral Specialization (fewer than 18 credits)</td>
</tr>
<tr>
<td>5. Course Level</td>
<td>12. Minor (add or delete)</td>
</tr>
<tr>
<td>6. Pre- and Co-Requisite</td>
<td>13. Closed Site Program</td>
</tr>
<tr>
<td>7. Course Description</td>
<td>14. Program Suspension</td>
</tr>
<tr>
<td>✔ 8. New Course</td>
<td>15. Program Reactivation</td>
</tr>
<tr>
<td>9. Deactivate Course</td>
<td>16a. Certificate Program (UG/G) exclusively within existing degree program</td>
</tr>
<tr>
<td>22. Other</td>
<td>16b. Certificate Program (UG/G) outside of or across degree programs (12 or more credits)</td>
</tr>
<tr>
<td></td>
<td>17. Off-Campus Delivery of Existing Programs</td>
</tr>
<tr>
<td></td>
<td>18a. Undergraduate Concentration (24 credits or more)</td>
</tr>
<tr>
<td></td>
<td>18b. Master's Concentration (12 credits or more)</td>
</tr>
<tr>
<td></td>
<td>18c. Doctoral Concentration (18 credits or more)</td>
</tr>
<tr>
<td></td>
<td>19. Program Title Change</td>
</tr>
<tr>
<td></td>
<td>20. Program Termination</td>
</tr>
<tr>
<td></td>
<td>21. New Degree Program</td>
</tr>
<tr>
<td></td>
<td>22. Other</td>
</tr>
</tbody>
</table>

For changes to existing courses:

<table>
<thead>
<tr>
<th>OLD TITLE</th>
<th>SUBJECT CODE/COURSE NO.</th>
<th>CREDITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAMILY LAW CLINIC I</td>
<td>LAW 857</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NEW TITLE</th>
<th>SUBJECT CODE/COURSE NO.</th>
<th>CREDITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAW AND BIOTECHNOLOGY</td>
<td>LAW 857</td>
<td>3</td>
</tr>
</tbody>
</table>
**DESCRIBE THE REQUESTED COURSE/PROGRAM ACTION** (additional pages may be attached if necessary):

**New Course: Law and Biotechnology**

This proposal calls for creating a new upper-level elective course covering topics in law and biotechnology. Planning for this course began in Spring 2014, in conjunction with Dean Weich and Associate Dean Sloan. The course will be sponsored by the Center for Medicine & Law and the Center for the Law of Intellectual Property and Technology, and it should be included as an elective in the Intellectual Property concentration. In providing a foundation for students interested in exploring the intersections between law and science, the course will deepen the University of Baltimore School of Law’s engagement with topics in bioethics, biotechnology, and health law and grow the footprint of both the Center of Medicine & Law and the new Center for the Law of Intellectual Property and Technology. The course may be taught using a variety of assessment tools, including short required papers throughout the term, responses to other students’ written work, and/or a final exam. Each available assessment tool is discussed below.

LAW 857 is currently an inactive course in the catalog.

---

**SET FORTH THE RATIONALE FOR THIS PROPOSAL:**

The proposed course significantly expands classroom opportunities for students to engage with topics touching health law and the intersections between science, biotechnology in particular, and the law. The School of Law’s existing offerings include a course entitled “Health Care Law,” taught most recently by Greg Dolin and Marie Vasbinder. The proposed course, however, differs from and complements the course presently offered. Health Care Law primarily addresses topics related to the definition, evaluation, and distribution of health care as a resource. The proposed course addresses distinct topics related to law and biotechnology, including vaccination and medical treatment for communicable diseases, experimentation involving humans, and ownership and exploitation of genetic data. These topics currently are not assigned or discussed in any existing law school course.
<table>
<thead>
<tr>
<th><strong>1. DATE PREPARED</strong></th>
<th>12/3/2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. PREPARED BY</strong></td>
<td>Laurie Harow</td>
</tr>
<tr>
<td><strong>3. DEPARTMENT/DIVISION</strong></td>
<td>School of Law</td>
</tr>
<tr>
<td><strong>4. COURSE NUMBER(S) with SUBJECT CODE(S)</strong></td>
<td>LAW 875</td>
</tr>
<tr>
<td><strong>5. COURSE TITLE</strong></td>
<td>Law and Biotechnology</td>
</tr>
<tr>
<td><strong>6. CREDIT HOURS</strong></td>
<td>3</td>
</tr>
<tr>
<td><strong>7. CATALOG DESCRIPTION</strong></td>
<td>This course examines the impact of advancements in the biosciences on a variety of legal and policy issues. The course will engage with new challenges, such as intellectual property in the body, human subjects research, and the medical and forensic uses of genetic information. A background in biotechnology is not necessary for this course.</td>
</tr>
<tr>
<td><strong>8. PREREQUISITES</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>9. COURSE PURPOSE</strong></td>
<td>Elective</td>
</tr>
<tr>
<td><strong>10. GENERAL EDUCATION AREA</strong></td>
<td>This course should be associated with a concentration in intellectual property, as one of the courses offered, but not required, for the concentration. In addition, when a health law concentration is developed and authorized, this course should be associated with that concentration as well.</td>
</tr>
<tr>
<td><strong>11. COURSE TYPE/COMPONENT</strong></td>
<td>Lecture</td>
</tr>
</tbody>
</table>

Summer 2010
12. FACULTY QUALIFIED TO TEACH COURSE

Responsibility for the course will reside with Professors Natalie Ram and Greg Dolin, respectively the associate director and co-director of the Center for Medicine & Law. Professor Ram holds an undergraduate degree in public policy focusing on bioethics and writes principally about the intersection between law and science. In addition, Professor Ram began to discuss and plan this proposal with Dean Welch and Associate Dean Sloan even before accepting a position with the law school. Professor Dolin also is available and prepared to teach this course. Professor Dolin holds a medical degree as well as a law degree and writes principally about the health law and intellectual property. This course is well within Professor Ram and Professor Dolin's areas of expertise.

13. CONTENT OUTLINE

This upper level elective course focuses on current issues at the intersection of law and biotechnology, and so the topics covered likely will change somewhat over time. Core subjects to be covered, however, will include (1) food and drug regulation, (2) biotechnology and intellectual property rights, (3) medical treatment and prevention, (4) human subjects research and informed consent, and (5) matters related to genetic information. Additional topics may also be introduced, including stem cell research, embryo selection and manipulation for reproductive purposes, and neuroscience and neuroethics.

14. LEARNING GOALS

For students to gain familiarity with a variety of legal and policy issues at the forefront of advancements in biotechnology.

15. ASSESSMENT STRATEGIES

This course may be administered using a variety of assessment tools. Grades will be assigned based on the overall participation in all aspects of the course and the quality of the work presented and submitted. This may include five short discussion papers submitted in response to assigned readings over the course of the term, as well as five online discussion responses to the work of others in the class. An exam also may supplement or replace discussion papers for purposes of assessment.

16. SUGGESTED TEXT(S) and MATERIALS (e.g. textbooks, equipment, software, etc., that students must purchase)

GOODWIN, PARIS, & TU, BIOTECHNOLOGY, BIOETHICS & THE LAW (expected spring 2015); if this casebook is not available in time, alternative materials will be provided via TWEN.

17. SPECIAL GRADING OPTIONS (if applicable)

n/a

18. SUGGESTED CLASS SIZE

Open

19. LAB FEES (if applicable)

n/a
Fall Semester, 2014, Room 3750
Thurs 3.30pm – 6.30pm

Professor Michele Goodwin,
Chancellor's Professor of Law

Office: Room 4800S
Tel: 949.824.3897
mgoodwin@law.uci.edu

Grading:
1. Final (Paper) 50%
2. Policy Position Papers 50%

Position Papers:
Write a one to two page position paper articulating the public policy you believe should govern the issue under discussion. The purpose of the paper is to have students reflect on and take a preliminary position on the public policy issue under consideration.

The papers are due by 4pm each WEDNESDAY. Please submit papers electronically to mgoodwin@law.uci.edu. PLEASE COPY: mali@law.uci.edu

Final Paper:
FINAL PAPERS DUE: THURSDAY, DECEMBER 11, 2014

Part I: Overview

Welcome to Biotechnology & The Law. This is a survey class, examining issues ranging from drug regulation, clinical trials, assisted reproductive technology, telemedicine, and stem cell development/regulation to the commercialization of the human body. For this class we will use the Biotechnology, Bioethics, & The Law Casebook (in development). This course requires substantial reading, preparation, organization, and the ability to analyze subtle nuances between various judicial decisions, legislative enactments and the legal rules, which sometimes may seem in conflict. This area of law, however, is complicated by the fact that there isn’t the same type of common law tradition that one finds in Torts, Contracts, or Constitutional Law. Rather, what you will find are problems in need of solutions. We will examine whether the various issues emerging from biotechnology conflicts are best resolved by regulation, judicial intervention, or private

Continued....
negotiation. Professor Goodwin encourages robust dialogue in her courses. Students are to come prepared with their ideas, intuitions, and opinions—their analysis should demonstrate a grasp of the materials. Students are expected to discuss the materials, act responsibly toward their peers, as well as conduct themselves in a professional manner. There are no prerequisites for this course. However, students must be prepared for rigorous discussions and substantial reading assignments. This course is a building block for the other courses in a law and science curriculum, including Patents, Food & Drug Law, Health Regulations, and Bioethics. The core competencies expected in this class are critical thinking and the application of social, legal, moral, and economic reasoning.

Much of the reading assigned for class will be covered during discussion. However, some assigned readings will not, given limited class time. Students are nonetheless responsible for this material. This class balances the theoretical with the practical. Students are expected to consider context, social and political policy in their deliberation about cases and the rules. The readings include excerpts from medical journals, regulations, cases, newspapers, and social science periodicals.

**Part II: Course Goals**

The goals of this course are to:

- Introduce students to the study of health policy, biotechnological developments, and ethics;
- Familiarize students with the medical and legal literature on the topic;
- Engage students with practical as well as theoretical ideas in biotechnology law;
- Stimulate intellectual curiosity about the subject matter;
- Inspire critical thinking and thoughtful analysis;

**Part III: Grading**

**Class Paper/Grade:**

Students will write a weekly position paper of one to two pages. Students will use footnotes in these assignments as well as the final paper. The position papers are due each Wednesday at 4pm. Please email the position papers to Professor Goodwin and also copy her faculty assistant, Mr. Mohammed Ali: mali@law.uci.edu.

The position papers will count for 50% of the student’s grade. The final paper will count for 50% of the final grade.

For the final, students will write a substantive research paper of approximately 25-30 double-spaced pages on a subject related to biotechnology and the law. Professor Goodwin will meet with students to agree upon and advise an appropriate topic for the paper. The class papers will be presented and discussed at the end of class.

**Additional information:**
Paper guidelines: Papers must be typed, 12 point font, and double-spaced. Please use footnotes rather than endnotes. The Blue Book must be used for citation.

Papers are to be written independently. Students will be graded on analysis, comprehension of material, research, format, clarity, and use of legal principals and rules.

Students are required to submit an abstract of their paper on or before Monday, October 13, 2014. The abstract should be 250-500 words.

The papers should be thoroughly researched and well written. Plagiarism is not acceptable and any student violating the law school honor code shall be asked to withdraw. Students caught cheating will also be subject to the law school's disciplinary code.

Class participation and attendance will be taken into consideration when evaluating a student's final grade. Students' grades may be enhanced by thoughtful, analytical participation. A student's grade may also be affected or a student may be withdrawn from this class by failure to come to class and/or coming to class unprepared or late.

Academic Integrity Policy: Academic integrity is essential to a positive teaching and learning environment. All students enrolled in University courses are expected to complete coursework responsibilities with fairness and honesty. Failure to do so by seeking unfair advantage over others or misrepresenting someone else's work as your own, can result in disciplinary action.

Within this course, a student responsible for scholastic dishonesty can be assigned a penalty up to and including an "F" for the course. If you have any questions regarding the expectations for a specific assignment or exam, please ask.

Materials:

Students will be provided access to electronic materials and cases that can be downloaded. Folders will be maintained on TWEN. No assignment is due on the first day of class.

Disability Services:

The University of California is committed to providing equitable access to learning opportunities for all students. The DSC (Disability Services Center) offers a wide range of services for UC Irvine students with disabilities that are individually tailored to the needs of each student. Contact DSC at (949) 824-7494, TDD: (949) 824-6272, disability.uci.edu.
Civility Policy:
Laptop Usage
Please refrain from instant messaging, e-mailing, surfing the Internet, playing games, writing papers, doing homework, etc. during class time. Inappropriate laptop use can become a distraction for the class. Failure to follow this guideline will affect a student’s final grade.

Emailing:
“There are four ways, and only four ways, in which we have contact with the world. We are evaluated and classified by these four contacts: what we do, how we look, what we say, and how we say it.”
- Dale Carnegie (1888-1955)

Please maintain professionalism in all your communications, including email messages. Please compose all emails in professional language. In all your emails, consider them as legal memos or correspondences. Include a subject in the subject line, your name in the signature line, a formal greeting line or salutation to the professor (including the professor’s name), and a concise statement about the question or comment you wish to convey. Please use your law.uci.edu email account or an account that identifies your name to avoid the filter sending your email to the SPAM folder. Please refrain from sending emails to the professor that do not meet the standards identified here. Emails that do not follow these guidelines will not be returned.

Suggested Resources:
How To Email A Professor: http://mleddy.blogspot.com/2005/01/how-to-e-mail-professor.html
Email Etiquette – Adapated For Academia, http://science.kennesaw.edu/hmattord/email.htm
Emails as Professional Correspondence, http://www.clarku.edu/departments/socsci/docs/KA_Email_Etiquette.pdf
Part IV: Assignments

NOTE: Several reading assignments span two classes. The readings may be modified and that will be announced at class or with a revised syllabus. Each week, class will involve readings and class discussion. Students will also view documentaries, perform group assignments, and engage current topics. The first group assignment is below.

#1) August 21, 2014: (FIRST CLASS) (Introduction)  
Video: TBA-Regarding Assisted Reproduction  
LAB: Draft Model ART Law

Thursday, August 28, 2014: Present Model ART Law

#2) Regulating Scientific Development:  
Chapter I: Why The Law Regulates Scientific Development

#3) September 4, 2014:  
Chapter II: Food Law: Regulation & Statute

A. Early History  
B. Regulating Food  
C. Genetically Modified Foods  
D. Fraud

Read pp 1-47

#4) September 11, 2014:  
Chapter II continued...

Read pp 47-end of chapter

#5) September 18, 2014:  
Chapter III: Drug Law

A. Drug Regulation  
B. Drug and Pharmaceutical Development  
C. Drug Accessibility  
D. Drug Testing and Trials  
E. Gender and Drug Trials  
F. Race and Drug Trials  
G. Drug Liability


Read pp 1-48 [recommended reading through end of chapter]
#6) September 25, 2014:
Read pp 1-50
Chapter IV: Biotechnology and Intellectual Property Rights
  A. History: Patent Law and the Regulation of Biotechnological Development
  B. Patent Regulation in The United States
  C. Europe and Patent Regulation
  D. GATT-TRIPS
  E. Patents in Developing Countries
  F. The Convention on Biological Diversity

#7) October 2, 2014:
Read pp 51-90

October 9, 2014: NO CLASS-MID SEMESTER REVIEW WEEK

#8) October 16, 2014:
Chapter V: Disease and Biotechnology
  A. Vaccine Law
  B. AIDS
  C. Tuberculosis
Read pp 1-52

#9) October 23, 2014:
Chapter VI: Human Experimentation
  A. Organ Transplantation
  B. Xenotransplantation
  C. Transgenic Animals

#10) October 30, 2014:
Reading 1: Goodwin, Black Markets: The Supply & Demand of Human Body Parts (Cambridge University Press, 2006)
Read Introduction, chapters 1, 3, and 6

#11) November 6, 2014:
Chapter VII: DNA & The Law
  A. DNA in The Courts
  B. Genetic Testing in Educational Settings
  C. Workplace Discrimination
  D. Insurance
Read pp 1-35

#12) November 13, 2014:
Chapter VII: DNA & The Law -
A. DNA in The Courts
B. Genetic Testing in Educational Settings
C. Workplace Discrimination
D. Insurance

Read pp 36-52

#13) November 20, 2014:
Students present final papers to class