

CALIFORNIA STATE UNIVERSITY CHANNEL ISLANDS

COURSE MODIFICATION PROPOSAL

Courses must be submitted by October 15, 2010, and finalized by the end of the fall semester to make the next catalog (2011-12) production

DATE (CHANGE DATE EACH TIME REVISED): 9-20-2010; REV 10.25.10

PROGRAM AREA(S): BIOLOGY

Directions: All of sections of this form must be completed for course modifications. Use **YELLOWED** areas to enter data. All documents are stand alone sources of course information.

1. Course Information.

[Follow accepted catalog format.] (Add additional prefixes i f cross-listed)

OLD

Prefix BIOL Course# 503 Title BIOTECHNOLOGY
LAW AND REGULATION Units (3)

3 hours lecture per week

hours blank per week

Prerequisites:

Consent of Instructor Required for Enrollment

Corequisites:

Catalog Description (Do not use any symbols): Individual and organizational responsibility in R&D and commercial aspects of biotechnology. Topics include: intellectual property, privacy, government and industrial regulation, liability, ethics, and policy responses to societal concerns in the U.S. and abroad. Case studies involving gene therapy, cloning, and biomaterials in the medical and health sector, and farming and crop modification in the agricultural sector will be explored in detail.

NEW

Prefix BIOL Course# 503 Title BIOTECHNOLOGY
LAW AND REGULATION Units (3)

3 hours lecture per week

hours blank per week

Prerequisites:

Consent of Instructor Required for Enrollment

Corequisites:

Catalog Description (Do not use any symbols): Individual and organizational responsibility in R&D and commercial aspects of biotechnology. Topics include: intellectual property, privacy, government and industrial regulation, liability, ethics, **responsible conduct of research**, and policy responses to societal concerns in the U.S. and abroad. Case studies involving gene therapy, cloning, and biomaterials in the medical and health sector, and farming and crop modification in the agricultural sector will be explored in detail.

General Education Categories
 Lab Fee Requested
 Course Level:
 Undergraduate
 Post-bac/Credential
 X Graduate

Graded
 CR/NC
 X A - F

Repeatable for up to units
 Total Completions
 Multiple Enrollment in same semester

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 X A - F

Repeatable for up to units
 Total Completions
 Multiple Enrollment in same semester

2. Mode of Instruction (Hours per Unit are defaulted)

Hegis Code(s) _____
(Provided by the Dean)

Existing

Proposed

	Units	Hours Per Unit	Benchmark Enrollment	Graded		Units	Hours Per Unit	Benchmark Enrollment	Graded	CS No. (filled out by Dean)
Lecture	3	1	15	x	Lecture	3	1	30	x	
Seminar		1			Seminar		1			
Lab		3			Lab		3			
Activity		2			Activity		2			

Field Studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Field Studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Indep Study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Indep Study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other blank	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other blank	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Course Attributes:

☐ **General Education Categories:** All courses with GE category notations (including deletions) must be submitted to the GE website: <http://summit.csuci.edu/geapproval>. Upon completion, the GE Committee will forward your documents to the Curriculum Committee for further processing.

A (English Language, Communication, Critical Thinking)

- ☐ A-1 Oral Communication
- ☐ A-2 English Writing
- ☐ A-3 Critical Thinking

B (Mathematics, Sciences & Technology)

- ☐ B-1 Physical Sciences
- ☐ B-2 Life Sciences – Biology
- ☐ B-3 Mathematics – Mathematics and Applications
- ☐ B-4 Computers and Information Technology

C (Fine Arts, Literature, Languages & Cultures)

- ☐ C-1 Art
- ☐ C-2 Literature Courses
- ☐ C-3a Language
- ☐ C-3b Multicultural

D (Social Perspectives)

E (Human Psychological and Physiological Perspectives)

UDIGE/INTD Interdisciplinary

Meets University Writing Requirement

Meets University Language Requirement

☐ **American Institutions, Title V Section 40404:** ☐ Government ☐ US Constitution ☐ US History

Refer to website, Exec Order 405, for more information: <http://senate.csuci.edu/comm/curriculum/resources.htm>

☐ **Service Learning Course** (Approval from the Center for Community Engagement must be received before you can request this course attribute).

4. Justification and Requirements for the Course. *[Make a brief statement to justify the need for the course]*

OLD

This course is required element of the core curriculum for the proposed Professional Science Masters degree in Bioinformatics.

x Requirement for the Major/Minor

☐ Elective for the Major/Minor

☐ Free Elective

NEW

This course is required element of the core curriculum for the proposed Professional Science Masters degree in Bioinformatics.

x Requirement for the Major/Minor

☐ Elective for the Major/Minor

☐ Free Elective

Submit Program Modification if this course changes your program.

5. Student Learning Outcomes. (List in numerical order. You may wish to visit resource information at the following website: <http://senate.csuci.edu/comm/curriculum/resources.htm>)

Upon completion of the course, the student will be able to:

OLD

- Describe Federal laws governing biotechnological issues and the associated regulatory agencies
- Describe California laws governing

Upon completion of the course, the student will be able to:

NEW

- Describe Federal laws governing biotechnological issues and the associated regulatory agencies
- Describe California laws governing

biotechnological issues and the associated regulatory agencies

- Discuss current issues and debates in cloning, gene therapy, and crop modification.
- Outline the technology transfer process for commercially valuable biotech products

biotechnological issues and the associated regulatory agencies

- Discuss current issues in bioethics and responsible conduct of research and debates in cloning, gene therapy, and crop modification.
- Outline the technology transfer process for commercially valuable biotech products

6. Course Content in Outline Form. (Be as brief as possible, but use as much space as necessary)

OLD

Biotechnology: History and Trends (Evolution of biotech industry, agricultural and food products, pesticides and herbicides, drugs, medical products, GMOs)
Public policy and ethical issues
Regulation of Biotechnology (Food and Drug Administration, US Department of Agriculture, U.S. Environmental Protection Agency, International)
Protecting Biotechnology Products (property rights, technology transfer, patents)
Liability Risks

NEW

Biotechnology: History and Trends (Evolution of biotech industry, agricultural and food products, pesticides and herbicides, drugs, medical products, GMOs)
Public policy, ethical issues and responsible conduct of research
Regulation of Biotechnology (Food and Drug Administration, US Department of Agriculture, U.S. Environmental Protection Agency, International)
Protecting Biotechnology Products (property rights, technology transfer, patents)
Liability Risks

Does this course content overlap with a course offered in your academic program? Yes ☐ No ☒

If YES, what course(s) and provide a justification of the overlap.

Does this course content overlap a course offered in another academic area? Yes ☐ No ☒

If YES, what course(s) and provide a justification of the overlap.

Overlapping courses require Chairs' signatures.

7. Cross-listed Courses (Please note each prefix in item No. 1)

- A. List cross-listed courses (Signature of Academic Chair(s) of the other academic area(s) is required).
- B. List each cross-listed prefix for the course:
- C. Program responsible for staffing:

8. References. [Provide 3-5 references]

OLD Biotechnology, Law, Business and Regulation. Michael J. Malinowski, Beth E. Arnold, eds. Aspen Law & Business Publications, 1999.

Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology. Thomas H. Murray, Maxwell J. Mehlman, eds. New York : John Wiley & Sons, 2000.

Biotechnology and the Federal Circuit. Kenneth J. Burchfield. BNA Books, 1995.

Valuation and Pricing of Technology-Based Intellectual Property. Richard Razgaitis, Wiley, John & Sons. 2002.

NEW Biotechnology, Law, Business and Regulation. Michael J. Malinowski, Beth E. Arnold, eds. Aspen Law

& Business Publications, 1999.
 Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology. Thomas H. Murray, Maxwell J. Mehlman, eds. New York : John Wiley & Sons, 2000.
 Biotechnology and the Federal Circuit. Kenneth J. Burchfield. BNA Books, 1995.
 Valuation and Pricing of Technology-Based Intellectual Property. Richard Razgaitis, Wiley, John & Sons. 2002.

Bioethics: Principles, Issues, and Cases by Lewis Vaughn. Publisher: Oxford University Press, USA; 1 edition (March 13, 2009)

Bioethics: Health Care Law and Ethics. Barry R. Furrow, Thomas L. Greaney, Sandra H. Johnson, Timothy S. Jost, Robert L. Schwartz. Publisher: West; 6 edition (July 28, 2008)

9. Tenure Track Faculty qualified to teach this course.
 Biology faculty

10. Requested Effective Date or First Semester offered: F2011

11. New Resource Requested: Yes ☐ No ☒
 If YES, list the resources needed.

- A. Computer Needs (data processing, audio visual, broadcasting, other equipment, etc.) ☐
- B. Library Needs (streaming media, video hosting, databases, exhibit space, etc.) ☐
- C. Facility/Space/Transportation Needs: ☐
- D. Lab Fee Requested: Yes ☐ No ☐ (Refer to the Dean's Office for additional processing)
- E. Other. ☐

12. Indicate Changes and Justification for Each. [Check all that apply and follow with justification. Be as brief as possible but, use as much space as necessary.]

- | | |
|--|--|
| <input type="checkbox"/> Course title | <input checked="" type="checkbox"/> Course Content |
| <input type="checkbox"/> Prefix/suffix | <input checked="" type="checkbox"/> Course Learning Outcomes |
| <input type="checkbox"/> Course number | <input checked="" type="checkbox"/> References |
| <input type="checkbox"/> Units | <input type="checkbox"/> GE |
| <input checked="" type="checkbox"/> Staffing formula and enrollment limits | <input type="checkbox"/> Other <input type="checkbox"/> |
| <input type="checkbox"/> Prerequisites/Corequisites | <input type="checkbox"/> Reactivate Course |
| <input checked="" type="checkbox"/> Catalog description | |
| <input checked="" type="checkbox"/> Mode of Instruction | |

Justification: Responsible conduct of research is a key topic of bioethics and maintaining scientific integrity in research is essential for all the students in the MS in Biotechnology and Bioinformatics to learn. Both the National Institutes of Health and National Science Foundation require applicants for their grants to be trained in this area. Hence, clearly describe this topic in the course description, the course content and student learning outcomes is required.

13. Will this course modification alter any degree, credential, certificate, or minor in your program? Yes ☐ No ☒
 If, YES attach a program update or program modification form for all programs affected.
 Priority deadline for New Minors and Programs: **October 4, 2010** of preceding year.
 Priority deadline for Course Proposals and Modifications: **October 15, 2010**.
 Last day to submit forms to be considered during the current academic year: **April 15th**.

Ching-Hua Wang

Proposer(s) of Course Modification
 Type in name. Signatures will be collected after Curriculum approval.

7.6.10 km2

9-20-2010

Date

Approval Sheet

Course: BIOL 503

If your course has a General Education Component or involves Center affiliation, the Center will also sign off during the approval process.

Multiple Chair fields are available for cross-listed courses.

Program Chair		
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Signature

Date

Program Chair		
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Signature

Date

Program Chair		
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Signature

Date

General Education Chair		
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Signature

Date

Center for Intl Affairs Director		
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Signature

Date

Center for Integrative Studies Director		
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Signature

Date

Center for Multicultural Engagement Director		
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Signature

Date

Center for Civic Engagement and Service Learning Director		
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Signature

Date

Curriculum Chair		
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Signature

Date

Dean of Faculty		
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Signature

Date