### Course Change Proposal

**Form A**

<table>
<thead>
<tr>
<th>Academic Group (College):</th>
<th>Academic Organization (Department):</th>
<th>Date:</th>
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<tbody>
<tr>
<td>Natural Sciences and Mathematics</td>
<td>Biological Sciences</td>
<td>10/30/09</td>
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**Type of Course Proposal:**
- New _X_  Change ___  Deletion ___

**Department Chair:**
- Rose Leigh Vines

**Submitted by:**
- Tom Peavy

**Does this course fulfill a requirement for single-subject or multiple subject credential students?**
- Yes ___  No _X_

**For Catalog Copy:**
- Yes _X_  No ___

**CCE (Extension):**
- Yes _X_  No ___

**Semester Effective:**
- SUMMER 2010

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This course replaces experimental course Subject Area (prefix) and Catalog Nbr (course number):

If changing an existing course, should new version be considered a repeat of the original version? If so, the same Course ID will be maintained. If not, a new Course ID will be assigned. Note: In PeopleSoft terminology, the Course ID is the unique system identifier, not the Catalog Nbr.

<table>
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<tr>
<th>Change from:</th>
<th>Change to:</th>
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<tr>
<td><strong>Subject Area (prefix) &amp; Catalog Nbr (course no.):</strong></td>
<td><strong>Subject Area (prefix) &amp; Catalog Nbr (course no.):</strong></td>
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<tr>
<td></td>
<td><strong>Title:</strong> Stem Cell Biology and Manufacturing Practices</td>
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<td><strong>Units:</strong> 1.0</td>
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**JUSTIFICATION:**

The Department of Biological Sciences has recently established a non-thesis MA degree program which was formerly approved at the CSU-level. The culminating project for the MA degree is either a grant proposal project, or a research internship project (at a participating UC Davis Stem Cell Program laboratory). It is imperative that graduate students in this research internship track become knowledgeable about stem cell biology and the rigorous stem cell culture process which includes the regulatory procedures. This proposed course will not only educate the students about the basic biology, cell culture, therapeutic uses, and regulatory procedures related to stem cells, but will also enhance their practical skills for their internships and careers in stem cell research.

**NEW COURSE DESCRIPTION:** (Not to exceed 80 words, and language should conform to catalog copy. See http://www.csus.edu/umandl/acad_cms.htm - Guidelines for Catalog Course Description)

Graduate level introductory course in human stem cell biology with specific emphasis on adult, embryonic and induced pluripotent stem cells. Topics will include how stem cells are isolated or generated, how they are cultured, and how they are used for regenerative therapies. In addition, students will learn about Good Manufacturing Practice (GMP) and how to manufacture human stem cells. Prerequisite: Graduate status or instructor permission. Only open to students in the Stem Cell Track. Units: 1.0.

**Note:**
- Prerequisite: Department Chair and Instructor permission
- Enforced at Registration: Yes  No _X_

**Corequisite:**
- Enforced at Registration: Yes  No
- Graded: Letter _X_  Credit/No Credit
- Instructor Approval Required? Yes _X_  No ___

**Course Classification (e.g., lecture, lab, seminar, discussion):**
- C4
- Title for CMS (not more than 30 characters)
- Stem Cell Biology

**Cross Listed?**
- Yes ___  No _X_
- If yes, do they meet together and fulfill the same requirement, and what is the other course.

**How Many Times Can This Course be Taken for Credit?**
- _1_

**Can the course be taken for Credit more than once during the same term?**
- Yes ___  No _X_
FOR NEW COURSE PROPOSALS OR SUBSTANTIVE CHANGES ONLY:

**Description of the Expected Learning Outcomes:** Describe outcomes using the following format: “Students will be able to: 1), 2), etc.” See the example at http://www.csus.edu/aacf/example.htm

Students will be able to:
- Discern the differences between embryonic, induced pluripotent, and adult stem cells
- Explain stem cell culture techniques and applications
- Identify current therapies for human diseases using stem cells
- Describe relevant stem cell Federal regulations and Good Manufacturing Practice (GMP)
- Explain the Quality Control and Quality Assurance processes of the stem cell manufacturing process

**Attach a list of the required/recommended course readings and activities [Note: it is understood that these are updated and modified as needed by the instructor(s).] This attachment should be forwarded only to your Dean's office, not Academic Affairs.**

**Assessment Strategies:** A description of the assessment strategies (e.g., portfolios, examinations, performances, pre-and post-tests, conferences with students, student papers) which will be used by the instructor to determine the extent to which students have achieved the learning outcomes noted above:

Students will be assessed based on the following:
- Attendance and participation in the course
- Two exams

**For whom is this course being developed?**

Majors in the Dept X  Majors of other Depts  Minors in the Dept  General Education  Other  

Is this course required in a degree program (major, minor, graduate degree, certificate)? Yes X No  

If yes, identify program(s): Master of Art: Stem Cell Internship track

Does the proposed change or addition cause a significant increase in the use of College or University resources (lab room, computer facilities, faculty, etc.)? Yes X No  

If yes, attach a description of resources needed and verify that resources are available.

Indicate which department or programs will be affected by the proposed course (if any). **None**

*The Department Chair’s signature below indicates that affected programs have been sent a copy of this proposal form.*

**Approvals:** If proposed change, new course or deletion is approved, sign and date below. If not approved, forward without signing to the next reviewing authority, and attach an explanatory memorandum to the original copy.

**Signatures:**

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<tr>
<th>Department Chair:</th>
<th>Date</th>
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<td>11/16/09</td>
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<tr>
<th>College Dean or Associate Dean:</th>
<th>Date</th>
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CPSP (for school personnel courses ONLY)

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<tr>
<th>Associate Vice President and Dean for Academic Programs</th>
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**Distribution:** Academic Affairs (original), Department Chair and College Dean. Dean’s office to send original after approval to Academic Affairs, at mail zip 6016. An electronic copy must also be sent.

9/19/08
Stem Cell Biology and Manufacturing Practices
BIO 225

Instructor: TBA
Contact Info: TBA
Office Hours: TBA
Class time: 1 meeting per week during an 8 week summer session

Course Format: This course will meet for two 50 min blocks per week over a 8-week summer session. The course will be graded and students will receive 1 Unit for completing the course.

Course Materials: Course readings will be provided by the instructor. Reference texts may be recommended.

Course Content and Objectives: BIO 225 is a graduate level introduction to human stem cell biology with specific emphasis on adult, embryonic and induced pluripotent stem cells. Topics will include how stem cells are isolated or generated, how they are cultured, and how they are used for regenerative therapies. In addition, students will learn about Good Manufacturing Practice (GMP) and how to manufacture human stem cells. 1 unit class; graded.

Learning Objectives:
- Discern the differences between embryonic, induced pluripotent, and adult stem cells
- Learn stem cell culture techniques and applications
- Explore current therapies for human diseases using stem cells
- Become familiar with Federal regulations and Good Manufacturing Practice (GMP)
- Learn about product manufacturing within a GMP facility

Course Requirements

a. Class Participation: Attendance and participation in each of the class sessions is expected. Failure to do so will result in the loss of points at the instructor’s discretion.

b. Grading will be based on the result of two exams and attendance/participation

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<th>Evaluation</th>
<th>Points</th>
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<tr>
<td>2 Exams (100 points each)</td>
<td>200</td>
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<tr>
<td>Attendance/Participation</td>
<td>25</td>
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<tr>
<td>Total Points</td>
<td>225</td>
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Course Policies:

a. Make-Up Exam/Quiz Policy: If, due to personal illness or emergency, you are unable to take the scheduled exam, you must contact the instructor by the end of the day the exam is scheduled. Documentation of the emergency will be required prior to rescheduling the exam.

b. Adding/Dropping the Course: It is important that you evaluate whether you have the necessary time to devote to this course. The 8-week summer schedule is compressed and thus a student must drop the course prior to the end of the second week so as not to receive an WU or F in the class.

c. Classroom Conduct: To learn we must strive to keep our attention on the task. Be mindful of potential distractions that you can prevent. Electronic devices should be off, or, if necessary, set to vibrate. If you arrive late or need to leave early please take a seat near a door.
d. Cheating and Plagiarism: Evidence of cheating or plagiarism, will be reported to the Department Chair and the Dean of Students, and the student may be dismissed from the course with a grade of “F”. Other possible lesser actions may be the loss of all points for the exam and/or reduction of the students final grade. All exams are closed book and notes. Plagiarism is defined by the University as “the use of distinctive ideas or works belonging to another person without providing adequate acknowledgement of that person’s contribution.” The university’s policy on plagiarism is provided on the web at http://www.csus.edu/admbus/umanual/ump14150.htm. The CSUS library web site also has a number of documents addressing integrity and plagiarism: http://library.csus.edu/content2.asp?pageID=360.

e. Disabilities: If you have a disability, please let the instructor know as soon as possible so as to make accommodations to facilitate your full participation. Every attempt to maintain confidentiality will be made.

TENTATIVE SCHEDULE (SUBJECT TO CHANGE):
(Each class meeting is 100 min)

Week 1: Introduction to Human Stem Cells and Adult Stem Cells
What are stem cells? What kind of human stem cells do exist, how do we define them?
What are adult stem cells, what kind of human adult stem cells do we know, and what is their biology?.

Week 2: Cell Culture of Adult Stem Cells and Introduction to Human Embryonic Stem Cells and Induced Pluripotent Stem Cells
What are the culture systems for adult stem cells, and what can we do with such culture systems?
What are human embryonic stem cells (hESCs), and what is their biology? What are induced pluripotent stem cells (iPSCs), and how do we generate them?

Week 3: Culture Systems and In Vivo Models for Human Stem Cells
What are the culture systems for hESCs and iPSCs, what can we do with such culture systems?
What are the current in vivo models for stem cell applications and translational medicine, how do they work, and what can we do with them?

Week 4: Therapies for Human Diseases Using Stem Cells and Review for Exam 1
What kind of human stem cell therapies exist already, and what are researchers planning for the future?

Week 5: Exam 1 and Introduction to Good Manufacturing Practice (GMP)
Exam 1 (50 min test)
The history of GMP, regulations by the Federal Government, definitions of current Good Manufacturing Practice (cGMP).

Week 6: The actual environment – first experiences inside the GMP Facility
How to enter, work in, and exit a GMP Facility? How to observe GMP rules, personnel, product and waste flow, and how to document these items?

Week 7: Sterile and controlled product manufacturing within the GMP Facility.

Week 8: Exam 2
RESOURCE STATEMENT FOR BIO 225:

BIO 225 is a required course for the students in the M.A. Stem Cell track. Because of the nature of the stem cell track, Bio 225 needs to be taught during the summer before students begin an internship program at the Center for Regenerative Medicine at the U.C. Davis Medical Center. Since this will be offered during the summer, the course will be administered through CCE at no cost to the Department. Students will be supervised by a faculty mentor in the M.A. Stem Cell Program who will also have the opportunity to be trained as a part of this program.