

# Cover Sheet: Request 11338

## BME3XXX Clinically-Inspired Engineering Design

### Info

Process	Course New Ugrad/Pro
Status	Pending
Submitter	Theus, Kristin undergrad@bme.ufl.edu
Created	12/7/2016 10:09:18 AM
Updated	3/15/2017 8:56:12 AM
Description of request	In this course, students will be exposed to real clinical problems, thereby learning to communicate with medical professionals in order to identify unmet needs, to develop prototypes and initial concepts for clinical problems, and to critically evaluate potential solutions for clinical problems.

### Actions

Step	Status	Group	User	Comment	Updated
Department	Approved	ENG - Biomedical Engineering 021934001	Rinaldi, Carlos		12/7/2016
No document changes					
College	Approved	ENG - College of Engineering	Caple, Elizabeth		1/26/2017
No document changes					
University Curriculum Committee	Comment	PV - University Curriculum Committee (UCC)	Case, Brandon	Added to the March agenda.	2/27/2017
No document changes					
University Curriculum Committee	Pending	PV - University Curriculum Committee (UCC)			2/27/2017
No document changes					
Statewide Course Numbering System					
No document changes					
Office of the Registrar					
No document changes					
Student Academic Support System					
No document changes					
Catalog					
No document changes					
College Notified					
No document changes					

# Course|New for request 11338

## Info

**Request:** BME3XXX Clinically-Inspired Engineering Design

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**Submitter:** Theus, Kristin undergrad@bme.ufl.edu

**Created:** 3/15/2017 8:55:28 AM

**Form version:** 3

## Responses

**Recommended Prefix**BME

**Course Level** 3

**Number** XXX

**Category of Instruction** Intermediate

**Lab Code** None

**Course Title**Clinically-Inspired Engineering Design

**Transcript Title**CLINICAL ENG DESIGN

**Degree Type**Baccalaureate

**Delivery Method(s)**On-Campus

**Co-Listing**No

**Effective Term** Spring

**Effective Year**2018

**Rotating Topic?**No

**Repeatable Credit?**No

**Amount of Credit**3

**S/U Only?**No

**Contact Type** Regularly Scheduled

**Weekly Contact Hours** 3

**Course Description** In this course, students will be exposed to real clinical problems, thereby learning to communicate with medical professionals in order to identify unmet needs, to develop prototypes and initial concepts for clinical problems, and to critically evaluate potential solutions for clinical problems.

**Prerequisites** BME3060(C)

**Co-requisites** BME4409

**Rationale and Placement in Curriculum** This course will be offered as a junior-level design course that will provide students with an extra design component prior to completing the capstone senior courses. Students will be able to take this course as an elective. The long-term goal is to incorporate this course as a requirement in the BME curriculum. There is no official timeline at this point in time for the change in curriculum to occur. The BME faculty have voted in favor of making this course part of the required curriculum; however, given the marked increase in our enrollment numbers (50 to 100 last year), we are hoping to pilot this course in Spring 2018 and propose official inclusion in the core curriculum in Fall 2018, provided the pilot is successful.

**Course Objectives** Students who complete Clinically-Inspired Engineering Design will learn how to

- Identify medical needs through interactions with healthcare professionals
- Define engineering, regulatory, and economic constraints for the engineering design process in the biomedical industry.

- Develop risk, reliability, and safety assessments
- Understand cost evaluation for potential designs
- Evaluate critical legal issues in intellectual property protection
- Identify, discuss, and resolve potential ethical issues in the development of medical technology

### **Course Textbook(s) and/or Other Assigned Reading** SolidWorks

Title: Biodesign: The Process of Innovating Medical Technologies

Authors: Stefanos Zenios, Josh Makower, Paul Yock, Todd J. Brinton, Uday N. Kumar, Lyn Denend, Thomas M. Krummel

Publication date and edition: 2010, first edition

ISBN number: 978-0521517423

**Weekly Schedule of Topics** Week 1: Course introduction and Professionalism in the medical field

Week 2: Introduction to Solid Works and Prototype Development, Brainstorming Techniques

\*\* HW assignment #1 will be related to creating a solid works draft of a medical/surgical instrument.

Module 1:

Week 3: Introduction to Medical Problem #1

(Introductory Lectures, plus Brainstorming Session with UF medical professional)

Week 4: Identifying unmet medical needs, stakeholder analysis (patient, health care professional, company)

Week 5: Risk, reliability, and safety assessments, Defining engineering design constraints

Week 6: Ethical evaluation of potential designs, Presentation of Module 1 Designs (Product Pamphlet)

\*\* HW assignment #2 will be related to conducting a risk/reliability/safety assessment of their prototype.

\*\* Presentation #1 will be the creation of a product pamphlet for their prototype along with product specifications and simulated terms of use (instruction manual). The written material will be assessed for the student's ability to address stakeholder needs, insure a safe and reliable system, meet defined design constraints, and ethically meet medical treatment standards.

Module 2:

Week 7: Introduction to Medical Problem #2

(Introductory Lectures, plus Brainstorming Session with UF medical professional)

Week 8: Regulatory constraints – FDA regulation of Medical Devices and Drugs

Week 9: Regulatory constraints – 510(k) vs. PMA, Clinical Trial Design

Week 10: Ethical evaluation of potential designs, Presentation of Module 2 Design (Poster Session)

\*\* HW assignment #3 will be related to identifying an FDA path for their 2nd prototype.

\*\* Presentation #2 will be the creation and presentation of a poster. Posters will be presented in a simulated entrepreneur's event, with teams evaluating the prototypes path to commercialization, as well as its ability to meet stakeholder needs, insure a safe and reliable system, meet defined design constraints, and ethically meet medical treatment standards.

Module 3:

Week 11: Introduction to Medical Problem #3

(Introductory Lectures, plus Brainstorming Session with UF medical professional)

Week 12: Intellectual property protection – patents, copyrights, and trade secrets

Week 13: Cost assessment, Time value of money

Week 14: Ethical evaluation of potential designs, Historical cases of ethical dilemmas in biomedical engineering design

Week 15: Final Presentations of Module #3 Designs (Oral Presentation)

\*\* HW assignment #4 will be related to identifying a financial plan for their 3rd prototype based on traditional BME startup funding mechanisms (venture capital, SBIR, STTR, etc.)

\*\* Presentation #3 will be an oral and written presentation of a business plan for their 3rd prototype. Presentations will simulate a venture capital interview, with teams evaluating the prototypes path to commercialization and financial stability of the theoretical firm, as well as the product's ability to meet stakeholder needs, insure a safe and reliable system, meet defined design constraints, and ethically meet medical treatment standards.

### **Links and Policies**

<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>

<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>

<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>

<https://www.dso.ufl.edu/drc>

<https://evaluations.ufl.edu/evals>

<https://evaluations.ufl.edu/results/>

<https://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/>

<http://registrar.ufl.edu/catalog0910/policies/regulationferpa.html>

<http://www.counseling.ufl.edu/cwc>

<http://www.police.ufl.edu/>

<https://www.crc.ufl.edu/>

<http://cms.uflib.ufl.edu/ask>

<https://teachingcenter.ufl.edu/>

<https://writing.ufl.edu/writing-studio/>

[https://www.dso.ufl.edu/documents/UF\\_Complaints\\_policy.pdf](https://www.dso.ufl.edu/documents/UF_Complaints_policy.pdf)

<http://www.distance.ufl.edu/student-complaint-process>

### **Grading Scheme A: 90-100**

B+: 84-86

A-: 87-89

B: 81-83

B-: 78-80

C+: 75-77

C: 72-74

C-: 69-71

D+: 66-68

D: 63-65

D-: 60-62

Fail: <60

**Instructor(s)** To be determined

## Clinically-Inspired Engineering Design

BME 3XXX Section XXXX

**Class Periods:** TBA, **Location:** TBA, **Academic Term:** Spring 20XX

### **Instructor:**

TBD

TBD

TBD@bme.ufl.edu

Office Hours: TBD

### **Teaching Assistants:**

Please contact through the Canvas website

- TBD

### **Course Description**

In this course, students will be exposed to real clinical problems, thereby learning to communicate with medical professionals in order to identify unmet needs, to develop prototypes and initial concepts for clinical problems, and to critically evaluate potential solutions for clinical problems.

### **Course Pre-Requisites / Co-Requisites**

Pre-Requisites: BME3060(C)

Co-Requisites: BME4409

### **Course Objectives**

Students who complete Clinically-Inspired Engineering Design will learn how to

- Identify medical needs through interactions with healthcare professionals
- Define engineering, regulatory, and economic constraints for the engineering design process in the biomedical industry.
- Develop risk, reliability, and safety assessments
- Understand cost evaluation for potential designs
- Evaluate critical legal issues in intellectual property protection
- Identify, discuss, and resolve potential ethical issues in the development of medical technology

### **Professional Component (ABET):**

This design course will teach students to develop engineering prototypes and design criteria by communicating with medical professionals.

### **Relation to Program Outcomes (ABET):**

Outcome	Coverage*
a. Apply knowledge	High
b1. Conduct experiments	Low
b2. Statistical design of experiments	Low
c. Design	High
d. Function on teams	High
e. Solve problems	High
f. Professional and ethical responsibility	High
g. Communicate	High
h1. Economic impact	High
h2. Global, societal, and environmental impact	High
i. Lifelong learning	Low
j. Contemporary issues	Low
k. Techniques, skills, and tools for degree program	Medium

\*Coverage is given as high, medium, or low. An empty box indicates that this outcome is not part of the course.

## **Required Textbooks and Software**

- SolidWorks
- Title: Biodesign: The Process of Innovating Medical Technologies  
Authors: Stefanos Zenios, Josh Makower, Paul Yock, Todd J. Brinton, Uday N. Kumar, Lyn Denend, Thomas M. Krummel  
Publication date and edition: 2010, first edition  
ISBN number: 978-0521517423

## **Course Schedule**

\*\* This course will follow a problem-based learning approach using 3 separate 4 week modules. At the beginning of each module, the students will be introduced to a medical problem by a UF medical professional. Students will then draft potential solutions in teams, evaluating critical design components. At the end of the module, students will present their concepts in teams.

Week 1: Course introduction and Professionalism in the medical field

Week 2: Introduction to Solid Works and Prototype Development, Brainstorming Techniques

\*\* HW assignment #1 will be related to creating a solid works draft of a medical/surgical instrument.

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\*\* Presentation #3 will be an oral and written presentation of a business plan for their 3<sup>rd</sup> prototype. Presentations

will simulate a venture capital interview, with teams evaluating the prototypes path to commercialization and financial stability of the theoretical firm, as well as the product's ability to meet stakeholder needs, insure a safe and reliable system, meet defined design constraints, and ethically meet medical treatment standards.

**Attendance Policy, Class Expectations, and Make-Up Policy**

Attendance is mandatory. Class notes will not be provided to absent students, unless they have excused absences. Excused absences are consistent with university policies in the undergraduate catalog (<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>) and require appropriate documentation.

Unless prior arrangements have been made with the instructor, students will be deducted 2 letter grades for late coursework (grading will start at 75% [C]). The deduction occurs at the time the work is due. After 1 week, a zero will be assigned on homework.

**Evaluation of Grades**

Assignment	Percentage of Final Grade
Module #1 Presentation	30%
Module #2 Presentation	30%
Module #3 Presentation	30%
Homework (4)	10%
	100%

**Grading Policy**

A: 90-100    B+: 84-86    C+: 75-77    D+: 66-68    Fail: <60  
A-: 87-89    B: 81-83    C: 72-74    D: 63-65  
              B-: 78-80    C-: 69-71    D-: 60-62

For information on current UF grading policies for assigning grade points, please visit: <https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>.

A C- will not be a qualifying grade for critical tracking courses. In order to graduate, students must have an overall GPA and an upper-division GPA of 2.0 or better (C or better). Note: A C- average is equivalent to a GPA of 1.67, and therefore, it does not satisfy this graduation requirement. More information on UF grading policy may be found at: <https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>.

**Students Requiring Accommodations**

Students with disabilities requesting accommodations should first register with the Disability Resource Center (352-392-8565, <https://www.dso.ufl.edu/drc>) by providing appropriate documentation. Once registered, students will receive an accommodation letter which must be presented to the instructor when requesting accommodation. Students with disabilities should follow this procedure as early as possible in the semester.

**Course Evaluation**

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at <https://evaluations.ufl.edu/evals>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu/results/>.

**University Honesty Policy**

UF students are bound by The Honor Pledge which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: "On my honor, I have neither given nor received unauthorized aid in doing this assignment." The Honor Code (<https://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/>) specifies a

number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

### ***Software Use***

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

### ***Student Privacy***

There are federal laws protecting your privacy with regards to grades earned in courses and on individual assignments. For more information, please see:

<http://registrar.ufl.edu/catalog0910/policies/regulationferpa.html>

### ***Campus Resources:***

#### ***Health and Wellness***

#### **U Matter, We Care:**

If you or a friend is in distress, please contact [umatter@ufl.edu](mailto:umatter@ufl.edu) or 352 392-1575 so that a team member can reach out to the student.

**Counseling and Wellness Center:** <http://www.counseling.ufl.edu/cwc>, and 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies.

#### **Sexual Assault Recovery Services (SARS)**

Student Health Care Center, 392-1161.

**University Police Department** at 392-1111 (or 9-1-1 for emergencies), or <http://www.police.ufl.edu/>.

#### ***Academic Resources***

**E-learning technical support**, 352-392-4357 (select option 2) or e-mail to [Learning-support@ufl.edu](mailto:Learning-support@ufl.edu).  
<https://lss.at.ufl.edu/help.shtml>.

**Career Resource Center**, Reitz Union, 392-1601. Career assistance and counseling. <https://www.crc.ufl.edu/>.

**Library Support**, <http://cms.uflib.ufl.edu/ask>. Various ways to receive assistance with respect to using the libraries or finding resources.

**Teaching Center**, Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.  
<https://teachingcenter.ufl.edu/>.

**Writing Studio, 302 Tigert Hall**, 846-1138. Help brainstorming, formatting, and writing papers.  
<https://writing.ufl.edu/writing-studio/>.

**Student Complaints Campus:** [https://www.dso.ufl.edu/documents/UF\\_Complaints\\_policy.pdf](https://www.dso.ufl.edu/documents/UF_Complaints_policy.pdf).

**On-Line Students Complaints:** <http://www.distance.ufl.edu/student-complaint-process>.





**From:** [Allen, Kyle](#)  
**To:** [Theus, Kristin](#)  
**Subject:** FW: External consultation request for new BME course  
**Date:** Tuesday, March 14, 2017 5:20:37 PM

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I guess attach the email? I will meet with him to discuss the rest.

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**From:** Fantone, Joseph C, III  
**Sent:** Tuesday, March 14, 2017 2:53 PM  
**To:** Allen, Kyle <kyle.allen@bme.ufl.edu>  
**Subject:** RE: External consultation request for new BME course

Hi

Happy to support this innovative course. There is no overlap with current COM courses. I think there will be significant interest in participating by COM faculty. I wonder if it could be listed as a 5000 course to make it attractive to both COE students as well as COM professional and graduate students. Alternatively maybe a separate 5000 level course could be developed co-sponsored by both Colleges with integration with students in the 3000 level course.

Happy to discuss.

Joe

Joseph C. Fantone, M.D.  
Professor, Department of Pathology  
Senior Associate Dean for Educational Affairs  
University of Florida College of Medicine  
tel: 352-273-7925  
fax: 352-273-7899

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**From:** Allen, Kyle  
**Sent:** Monday, March 13, 2017 12:17 PM  
**To:** Fantone, Joseph C, III <[jfantone@ufl.edu](mailto:jfantone@ufl.edu)>  
**Cc:** Theus, Kristin <[undergrad@bme.ufl.edu](mailto:undergrad@bme.ufl.edu)>  
**Subject:** External consultation request for new BME course

Dr. Fantone –

Our department is in the process of developing a new junior design curriculum called ‘Clinically-Inspired Engineering Design’. Recently, the first syllabus (attached) was reviewed by the College of Engineering curriculum committee and the University curriculum committee. There was a request at the University level that we “upload a letter of support/consult from COM, possibly from Dr. Fantone?”

Given I am fairly new in this position, I'm hoping you can provide me some guidance here. Based on conversations, I'm assuming the letter is to discuss overlap with COM classes. In brief, our course is designed as follows:

Week 1-2: Solid Works Modules.

Week 3-6: Engineering Constraints

Week 7-10: Regulatory Constraints

Week 11-15: Economical and Intellectual Property Constraints

The course is formatted to be problem-based learning, where we are hoping to recruit 3 college of medicine faculty per semester to propose a medical problem for our student to work on virtually (prototype design and evaluation on a computer). This would be a minimal time commitment by the COM faculty member - 1 lecture (50 minutes) to introduce a medical problem is all that is required. If the faculty member is willing, a 2<sup>nd</sup> block of time to evaluate student designs (though not required). Perhaps, this is also why the letter is required.

Currently, we are in the pilot phase for this program because it is a new junior-level course. Though long term (and if successful), we hope to have 2 semesters of this program in our curriculum, requiring 6 medical problems over the course of the year. Again, given the virtual nature of this program, we believe this will be minimal effort for COM faculty. But, we are also hopeful that this will sprout ideas and design projects for our senior design teams, offer a unique resource to design oriented faculty in COM, and really leverage the unique colocalization of resources at the University of Florida.

Please let me know if you'd like to discuss more or can provide me additional guidance here.

Kyle D. Allen

External Consultation Results (departments with potential overlap or interest in proposed course, if any)

Department	Name and Title
_____	_____
Phone Number	E-mail
_____	_____
Comments	

Department	Name and Title
_____	_____
Phone Number	E-mail
_____	_____
Comments	

Department	Name and Title
_____	_____
Phone Number	E-mail
_____	_____
Comments	