Engineering Faculty Document No. 22-18
October 26, 2017

**TO:** The Faculty of the College of Engineering

**FROM:** The Faculty of the Weldon School of Biomedical Engineering

**RE:** New Graduate Course, BME 56100, Preclinical and Clinical Study Design

The faculty of the School of Biomedical Engineering has approved the following new course. This action is now submitted to the Engineering Faculty with a recommendation for approval.

**BME 56100** Preclinical and Clinical Study Design
Term Offered: Fall, Lecture 3, Cr. 3
Prerequisite: STAT 51400 or equivalent

**Description:** Medical devices are developed, manufactured, and distributed in a highly regulated environment. This course concerns the preclinical and clinical study design processes for obtaining FDA marketing approval for biomedical devices. Prior to marketing a medical device in the US, specific governmental approval is required dependent on the type of device and the risk associated.

**Reason:** This course will serve as part of a three-course series and includes both an overview and a dive into the specifics of developing a preclinical and clinical strategy that will lead to regulatory approvals necessary for marketing medical devices. This course will fulfill requirements for our professional master's degree and will be listed as recommended courses for our grad tracks for students interested in industry and global health.

George R. Wodicka

George R. Wodicka
Dane A. Miller Head and Professor
Weldon School of Biomedical Engineering

Office of the Registrar
FORM 40G REV. 1/17

# PURDUE UNIVERSITY
## REQUEST FOR ADDITION, EXPIRATION, OR REVISION OF A GRADUATE COURSE (50000-60000 LEVEL)

PRINT

DEPARTMENT: Biomedical Engineering  EFFECTIVE SESSION: Fall 2018

INSTRUCTIONS: Please check the items below which describe the purpose of this request.

- [x] 1. New course with supporting documents (complete proposal form)
- [ ] 2. Add existing course offered at another campus
- [ ] 3. Expiration of a course
- [ ] 4. Change in course number
- [ ] 5. Change in course title
- [ ] 6. Change in course credit/type
- [ ] 7. Change in course attributes
- [ ] 8. Change in instructional hours
- [ ] 9. Change in course description
- [ ] 10. Change in course requisites
- [ ] 11. Change in semesters offered
- [ ] 12. Transfer from one department to another

| PROPOSED: | | EXISTING: | |
|---|---|---|---|
| Subject Abbreviation | BME | Subject Abbreviation | |
| Course Number | 56100 | Course Number | |
| Long Title | Preclinical and Clinical Study Design | | |
| Short Title | Preclinical & Clinical Design | | |

Abbreviated title will be entered by the Office of the Registrar if omitted. (30 CHARACTERS ONLY)

TERMS OFFERED (Check All That Apply): [x] Fall [ ] Spring [ ] Summer

CAMPUS(ES) INVOLVED:
- [ ] Calumet
- [x] Cont Ed
- [ ] Ft. Wayne
- [ ] Indianapolis
- [ ] N. Central
- [ ] Tech Statewide
- [x] W. Lafayette

CREDIT TYPE
1. Fixed Credit: Cr. Hrs. 3
2. Variable Credit Range:
   Minimum Cr. Hrs
   (Check One) To [ ] Or [ ]
   Maximum Cr. Hrs
3. Equivalent Credit: Yes [ ] No [ ]
4. Thesis Credit: Yes [ ] No [ ]

COURSE ATTRIBUTES: Check All That Apply
1. Pass/Not Pass Only [ ]
2. Satisfactory/Unsatisfactory Only [ ]
3. Repeatable [x]
   Maximum Repeatable Credit: [ ]
4. Credit by Examination [ ]
5. Fees [ ] Coop [ ] Lab [ ] Rate Request [ ]
   Include comment to explain fee
6. Registration Approval Type
   Department [ ] Instructor [ ]
7. Variable Title [ ]
8. Honors [ ]
9. Full Time Privilege [ ]
10. Off Campus Experience [ ]

| Schedule Type | Minutes Per Mtg | Meetings Per Week | Weeks Offered | % of Credit Allocated |
|---|---|---|---|---|
| Lecture | 75 | 2 | 16 | |
| Recitation | | | | |
| Presentation | | | | |
| Laboratory | | | | |
| Lab Prep | | | | |
| Studio | | | | |
| Distance | | | | |
| Clinic | | | | |
| Experiential | | | | |
| Research | | | | |
| Ind. Study | | | | |
| Pract/Observ | | | | |

Cross-Listed Courses

COURSE DESCRIPTION (INCLUDE REQUISITES/RESTRICTIONS): (Note: If description will not fit in space provided, please create a separate document and attach to this form.)

Attached

*COURSE LEARNING OUTCOMES: (Note: If course learning outcomes will not fit in space provided, please create a separate document and attach it to this form.)

Attached

| | | | | | |
|---|---|---|---|---|---|
| Calumet Department Head | Date | Calumet School Dean | Date | Calumet Director of Graduate Studies | Date |
| Fort Wayne Department Head | Date | Fort Wayne School Dean | Date | Fort Wayne Director of Graduate Studies | Date |
| Indianapolis Department Head | Date | Indianapolis School Dean | Date | IUPUI Associate Dean for Graduate Education | Date |
| North Central Department Head | Date | North Central School Dean | Date | North Central Director of Graduate Studies | Date |
| George R. Wodicka 11/17/17 | | | | | |
| West Lafayette Department Head | Date | West Lafayette College/School Dean | Date | Date Approved by Graduate Council | Date |
| Graduate Area Committee Convener | Date | Graduate Dean | Date | Graduate Council Secretary | Date |
| | | | | West Lafayette Registrar | Date |

OFFICE OF THE REGISTRAR

## Form 40G Course Description and Learning Outcomes for BME 56100

**Course Description:**

**Prerequisite:** STAT 51400 or equivalent

Medical devices are developed, manufactured, and distributed in a highly regulated environment. This course concerns the preclinical and clinical study design processes for obtaining FDA marketing approval for biomedical devices. Prior to marketing a medical device in the US, specific governmental approval is required dependent on the type of device and the risk associated.

This course is part of a three-course series dealing with various aspect of regulatory science. Regulatory science considers the scientific and technical foundations that support the practical testing and regulations that ensure the safety and effectiveness of medical devices. This course covers the responsible conduct of clinical and pre-clinical research, including evaluation of device tissue interactions and how they may be studied with pre-clinical animal models to predict safety and performance in human clinical trials that are necessary to gain regulatory approval for marketing. In the section on ethics we will cover several topics related to responsible conduct of clinical and pre-clinical research, including informed consent, risk assessment and ethical decisions, IRB oversight and ethical study design.

**Course Learning Outcomes:**

1. Students will more thoroughly understand and apply the various considerations and perspectives in designing and implementing a preclinical and clinical study strategy that will successfully lead to the marketing approval by a regulatory authority (e.g. FDA).
2. Students will be able to follow a structured, iterative decision-making process for moral reasoning to reach a supported-conclusion regarding ethical dilemmas in engineering design and testing.

# Detailed Graduate Course Proposal for Academic Review

**To:** Purdue University Graduate Council

**From:** Faculty Member: Lyn Freeman
Department: BME
Campus: WL

**Date:** 6/8/2017

**Subject:** Proposal for New Graduate Course

**Contact for information if questions arise:**
Name: Tammy Siemers
Phone: 60294
Email: tsiemers@purdue.edu
Address: MJIS 1021

**Course Number:** BME 56100
**Course Title:** Preclinical and Clinical Study Design
**Short Title:** Preclinical & Clinical Design

**Course Description:**

Medical devices are developed, manufactured, and distributed in a highly regulated environment. This course concerns the preclinical and clinical study design processes for obtaining FDA marketing approval for biomedical devices. Prior to marketing a medical device in the US, specific governmental approval is required dependent on the type of device and the risk associated.

This course is part of a three-course series dealing with various aspect of regulatory science. Regulatory science considers the scientific and technical foundations that support the practical testing and regulations that ensure the safety and effectiveness of medical devices. This course covers the responsible conduct of clinical and pre-clinical research, including evaluation of device tissue interactions and how they may be studied with pre-clinical animal models to predict safety and performance in human clinical trials that are necessary to gain regulatory approval for marketing. In the section on ethics we will cover several topics related to responsible conduct of clinical and pre-clinical research, including informed consent, risk assessment and ethical decisions, IRB oversight and ethical study design.

## A. Justification for the Course

### Justification of the need for the course

This course is part of a three-course series and includes both an overview, and a dive into the specifics of developing a preclinical and clinical strategy that will lead to regulatory approvals necessary for marketing medical devices. Topics include: risk assessment, integrating with marketing and commercialization strategies, selecting appropriate bench and preclinical testing, following GLP and GCP guidelines, selecting study populations, endpoints, and sample size, managing study logistics, communicating findings, and performing post-market monitoring. A student who successfully fulfills the course requirements should be able to demonstrate a functional understanding of risk assessment, and preclinical and clinical study design for biomedical devices.

### Justification that course will be taught at a graduate level

Students will study several topics related to responsible conduct of clinical and pre-clinical research, including informed consent, risk assessment and ethical decisions, IRB oversight and ethical study design. Time will be spent on the topics of increasing ethical awareness and developing ethical reasoning skill within the context of medical device design and testing.

Students will analyze case studies – both historic and new cases – that focus on emerging technologies. Students will use a framework for analyzing ethical dilemmas particularly fitting within the context of engineering. This methodology, Reflexive Principlism, is based on a set of common moral principles as ethical starting places for this analysis. In this framework the common ethical principles are applied in an iterative process of analysis and decision making that is similar to the engineering design process. Skill in ethical reasoning is essential for engineers, and these skills are gaining greater visibility as industries, professional organizations, and funding agencies begin to recognize their value to ethical professionalism.

The course employs the learning strategies of reading, reviewing, discussing, writing, and presenting. This course is a CRITICAL THINKING class.

### Justification of the demand for the course

- Anticipated enrollment
  - Undergraduate 10
  - Graduate 20

**Justification for online delivery**

This course will also be offered online as it fulfills requirements for the Biomedical Concentration for the MSE degree offered through Engineering Professional Education and the Biomedical Device Design professional master's available through the Weldon School of Biomedical Engineering. The EPE degree is for working professionals and needs to be taught online where the professional master's degree requires students to take courses while on internship.

## B. Learning Outcomes and Methods of Assessment

1. Students will more thoroughly understand and apply the various considerations and perspectives in designing and implementing a preclinical and clinical study strategy that will successfully lead to the marketing approval by a regulatory authority (e.g. FDA).

2. Students will be able to follow a structured, iterative decision-making process for moral reasoning to reach a supported-conclusion regarding ethical dilemmas in engineering design and testing.

| Learning Outcomes | Assessment Methods |
|---|---|
| Students will be able to follow a structured, iterative decision-making process for moral reasoning to reach a supported-conclusion regarding ethical dilemmas in engineering design and testing. | • Quizzes |
| Students will more thoroughly understand and apply the various considerations and perspectives in designing and implementing a preclinical and clinical study strategy that will successfully lead to the marketing approval by a regulatory authority (e.g. FDA). | • Papers and Projects |

| | |
|---|---|
| Students will be able to follow a structured, iterative decision-making process for moral reasoning to reach a supported-conclusion regarding ethical dilemmas in engineering design and testing. | • Class Participation |

- *Quizzes-*
  - Quizzes are in an online format. Quizzes will be accessible by noon (EST) on Friday in the online learning environment, Blackboard Learn, and should be completed by noon (EST) on the following Tuesday. Once the quiz attempt is started, a student has 30 minutes to complete it. A student who misses a quiz deadline will lose the point value of that particular quiz. The online quizzes are not re-opened for missed deadlines. There will be approximately 10 quizzes.
- *Papers and Projects—*
  - *Ethics Case Reports--* These assignments will be completed in teams of 4-5 students. The case reports are designed to encourage discussion and interaction with your team about differing perspectives on each case.
  - *Statistics Study Design Problem-* A statistics problem that relates to designing a clinical research project will be assigned. The problem will address estimating sample size and power and the likelihood of making type I (false-positive) and type II (false-negative) errors. The problem will be open book and will be completed individually.
- *Class Participation—*
  - *Biography and Pre-assessment knowledge—* The first component is the completion and submission of the class biography assignment, which is valued at 5 points.
  - *Participation in online discussions--* When all the reports are posted in Blackboard Learn in the Discussion area, then the class can compare these decisions for a larger view of how complex ethical decisions can be resolved.

**Final Grading Criteria**

| Assessment Methods (should match method types in the previous table) | Weight Toward Final Course Grade |
|---|---|
| Exams and Quizzes | 80 points |
| Papers and Projects | 45 points |
| Class Participation | 25 points |

**Methods of Instruction**

| Class Hrs/Week | Method of Instruction | Contribution to Outcomes |
|---|---|---|
| 3 | Lecture | Use expert industry speakers to explain the different roles in designing a pre-clinical and clinical study. |

## C. Prerequisite(s)

- Statistics 51400 or equivalent

## D. Course Instructor(s)

| Name | Rank | School, dept., or center | Graduate Faculty or expected date |
|---|---|---|---|
| Lynetta Freeman | Associate Professor | BME and BMS | Yes |
| Dianne Little | Assistant Professor | BME and BMS | Yes |
| Andrew Brightman | Assistant Head, Associate Professor of Practice | BME | Yes |
| Jennifer Kerr | President, Cook Research, Inc. | Cook Group | No |

## E. Course Schedule or Outline

***Option 1: Schedule Format***

| Week | Topic(s) |
|---|---|
| 1 | Overview and Unmet Needs Analysis |
| 2 | Opportunity and Outcomes and Reimbursement |
| 3 | Regulatory Strategy |
| 4 | Ethical Decision Making and Animal Welfare |
| 5 | Protection of Human Subjects and Bioethics |
| 6 | Risk Management and Risk Analysis |
| 7 | Preclinical Evaluation Strategy |
| 8 | Clinical Testing on Animals |
| 9 | Designing the Clinical Strategy |
| 10 | Implementing the Clinical Strategy |
| 11 | Integrating Study Data Into Regulatory Submissions |
| 12 | Imaging Modalities |
| 13 | Post Market Safety Guidelines and SAGES Guidelines |
| 14 | Outsourcing and Global Considerations |
| 15 | Combination Devices |
| 16 | Not applicable |

## F. Reading List (including course text)

### Primary Reading List

- Biodesign. The Process of Innovating Medical Technologies. 2nd edition. Zenios, Makower, Yock, (eds.) Cambridge University Press. 2015. ISBN 987-1-107-08735-4

## G. Library Resources

| Name of journal, proceedings, book, video, or other acquisition | Already in Libraries? |
|---|---|
| Not Applicable | [type yes or no)] |

## H. Course Syllabus (now required)

## Preclinical and Clinical Study Design

**Course Description:**

Medical devices are developed, manufactured, and distributed in a highly regulated environment. This course concerns the preclinical and clinical study design processes for obtaining FDA marketing approval for biomedical devices. Prior to marketing a medical device in the US, specific governmental approval is required dependent on the type of device and the risk associated.

This course is part of a three-course series dealing with various aspect of regulatory science. Regulatory science considers the scientific and technical foundations that support the practical testing and regulations that ensure the safety and effectiveness of medical devices. This course covers the responsible conduct of clinical and pre-clinical research, including evaluation of device tissue interactions and how they may be studied with pre-clinical animal models to predict safety and performance in human clinical trials that are necessary to gain regulatory approval for marketing. In the section on ethics we will cover several topics related to responsible conduct of clinical and pre-clinical research, including informed consent, risk assessment and ethical decisions, IRB oversight and ethical study design.

**Time/On-Campus Location:** Mondays & Wednesdays, 4:30 pm – 5:45 pm, WANG 2599
**Credit Hours:** 3
**Prerequisites:** Statistics 51400 or equivalent

**Course Coordinators:**

**Lynetta Freeman, DVM, MS** Associate Professor of Small Animal Surgery & Biomedical Engineering

Contact Info: (765) 337-4280; ljfreema@purdue.edu

Office hours: By email/appointment - Lynn Hall G602

**Jennifer Kerr, MS, CCRA, RAC,** President, Cook Research, Inc.

Contact info: (765) 463-7537; Jennifer.kerr@cookmedical.com

Office hours: By email/appointment – Cook Research, Inc., 1 Geddes Way, West Lafayette, IN 47906

**Recommended Text:** Biodesign. The Process of Innovating Medical Technologies. 2nd edition. Zenios, Makower, Yock, (eds.) Cambridge University Press. 2015. ISBN 987-1-107-08735-4

**Learning Outcomes***:* The following specific learning outcomes will direct the course …

1. Students will more thoroughly understand and apply the various considerations and perspectives in designing and implementing a preclinical and clinical study strategy that will successfully lead to the marketing approval by a regulatory authority (e.g. FDA).
2. Students will be able to follow a structured, iterative decision-making process for moral reasoning to reach a supported-conclusion regarding ethical dilemmas in engineering design and testing.

This course includes both an overview, and a dive into the specifics of developing a preclinical and clinical strategy that will lead to regulatory approvals necessary for marketing medical devices. Topics include: risk assessment, integrating with marketing and commercialization strategies, selecting appropriate bench and preclinical testing, following GLP and GCP guidelines, selecting study populations, endpoints, and sample size, managing study logistics, communicating findings, and performing post-market monitoring. A student who successfully fulfills the course requirements should be able to demonstrate a functional understanding of risk assessment, and preclinical and clinical study design for biomedical devices.

In the section on ethics, students will study several topics related to responsible conduct of clinical and pre-clinical research, including informed consent, risk assessment and ethical decisions, IRB oversight and ethical study design. Time will be spent on the topics of increasing ethical awareness and developing ethical reasoning skill within the context of medical device design and testing.

Students will analyze case studies – both historic and new cases – that focus on emerging technologies. Students will use a framework for analyzing ethical dilemmas particularly fitting within the context of engineering. This methodology, Reflexive Principlism, is based on a set of common moral principles as ethical starting places for this analysis. In this framework the common ethical principles are applied in an iterative process of analysis and decision making that is similar to the engineering design process. Skill in ethical reasoning is essential for engineers, and these skills are gaining greater visibility as industries, professional organizations, and funding agencies begin to recognize their value to ethical professionalism.

**Learning Strategies:** The course employs the learning strategies of reading, reviewing, discussing, writing, and presenting. This course is a CRITICAL THINKING class. It's imperative that students attend, participate, and complete assignments in the method appropriate to the learning format of the course section – in-class or at a distance.

**Assessments:** The final grade is based on points earned from a variety of learning activities and assessments. Please see the grid at the end of the syllabus for a breakdown of point values for the various assignments and activities.

**Quizzes:** Quizzes are in an online format. Quizzes will be accessible by noon (EST) on Friday in the online learning environment, Blackboard Learn, and should be completed by noon (EST) on the following Tuesday. Once the quiz attempt is started, a student has 30 minutes to complete it. A student who misses a quiz deadline will lose the point value of that particular quiz. The online quizzes are not re-opened for missed deadlines.

**Ethics Case Reports:** These assignments will be completed in teams of 4-5 students.

The case reports are designed to encourage discussion and interaction with your team about differing perspectives on each case. The end goal is to generate a consensus decision regarding the ethical dilemma(s) or question(s) related to the case and then report your decision back to the class with a justification that makes clear the "why and how" the decision was reached. Teams will be encouraged to continue to use the reasoning process of Reflexive Principlism as a framework for discussions and for the report. When all the reports are posted in Blackboard Learn in the Discussion area, then the class can compare these decisions for a larger view of how complex ethical decisions can be resolved.

**Statistics/Study Design Problem Assignment:** A statistics problem that relates to designing a clinical research project will be assigned. The problem will address estimating sample size and power and the likelihood of making type I (false-positive) and type II (false-negative) errors. The problem will be open book and will be completed individually.

**Class Participation:** This course has on-campus and at-a-distance (online) sections which have been merged into one online course environment in Blackboard Learn. The participation grade has two components. The first component is the completion and submission of the class biography assignment, which is valued at 5 points. The second component is attending class (or viewing of the recorded lectures by distance students) and taking the quizzes associated with the material presented.

| **Date of Class** | **Class** | **Main Topic** | **Instructor** | **Assignments Due** |
|---|---|---|---|---|
| Aug 22 | 1 | **Overview – Biomedical Device Development and Regulatory Pathways** | Kerr | Suggested Reading Assignment: *Biodesign,* section 4.5<br><br>Assignment 1: Submit Biography and Pre-assessment of Baseline Knowledge by Tuesday noon (EST); Aug. 23 |
| Aug 24 | 2 | **Unmet Needs Analysis**<br><br>**Integrated Product Development Life Cycle** | Freeman | Quiz 1 |
| Aug 29 | 3 | **Opportunity and Outcomes:** Understanding the business need, financial constraints, the<br><br>value of first to market, the reimbursement environment | Chris Littel | Suggested Reading Assignment: *Biodesign,* sections 1.2, 2.1, 4.3, 4.4<br><br>Quiz 2<br><br>Assignment 2:<br><br>Write a 2-page paper from your experience in how you have worked to understand a medical device |

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|---|---|---|---|---|
| | | | | opportunity. Be specific. |
| Aug 31 | 4 | **Reimbursement** | Jacob Drapkin | Suggested Reading Assignment: *Biodesign,* sections 4.3, 5.6 |
| Sept 5 | | **Holiday** | | |
| Sept 7 | 5 | **Regulatory Strategy:** Thinking through the Regulatory Strategy – PC and Clinical Needs<br><br>Impact of claims on trial design:<br>• Intended use<br>• Indications for use<br>• Implied claims<br>• Comparative claims | **FDA**<br>Deborah Castillo, PhD<br><br>Misti Malone, PhD | Suggested Reading Assignment: *Biodesign,* sections 4.2, 5.4<br><br>Quiz 3 |
| Sept 12 | 6 | Ethical Decision-making in Engineering Design and Testing; Reflexive Principlism | Andrew Brightman, PhD | Online Ethics Case Material<br><br>Assignment 3: Ethics Case Report 1 |
| Sept 14 | 7 | Animal Welfare<br>PACUC Oversight of Preclinical Research | Brianne Gaskill, DVM, PhD | Reading Assignment: |
| Sept 19 | 8 | **Protection of Human Subjects:**<br>**Purdue/IU Arnett IRB** | Shannon Oates, MD | Assignment 4:<br><br>Writing assignment on animal welfare |

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|---|---|---|---|---|
| Sept 21 | 9 | **Bioethics of Risk in Human Clinical Studies; Informed Consent Policies & Procedures: IRB Oversight** | Peter Schwartz, MD, PhD | |
| Sept 26 | 10 | **Risk Management** | Becky Roeder, PhD<br><br>Ray Amos | Suggested Reading Assignment:<br><br>*Biodesign, 2nd ed, sections 4.6 and 5.2* |
| Sept 28 | 11 | **Risk Analysis**<br><br>How is risk identified and mitigated with engineering, nonclinical and clinical studies? | Becky Roeder, PhD<br>Ray Amos | Quiz 4 |
| Oct 3 | | **Preclinical Evaluation Strategy:**<br><br>Model Selection:<br><br>Cadaver studies, Acute PC studies<br><br>User needs, simulated use testing | Tony Ragheb, PhD (Engineering & Animal Testing Correlation)<br><br>Bill Van Alstine DVM | Suggested Reading Assignment:<br>Biodesign, 2nd edition<br>Sections 4.6 and 5.3<br><br>Quiz 5 |

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|---|---|---|---|---|
| Oct. 5 | | **Preclinical Evaluation Strategy:**<br><br>Dissecting FDA Guidance Documents | John Cummings, PhD (Ethicon Endo-Surgery) | Suggested Reading Assignment:<br>*Biodesign* sections 5.3<br><br>Writing Assignment 5: Review the |

| | | | | |
|---|---|---|---|---|
| | | Proof of principle, model development; determining efficacy of therapy,<br>Selecting endpoints for device studies | | design history file on the Improved MPIS Wire Guide and draw a flow chart to show how risks were identified and mitigated for this product. |
| Oct 10 | | **Fall Break** | | |
| Oct 12 | 14 | **Clinical Testing in Animals**<br><br>**OR**<br><br>**Premarket Regulatory Requirements:**<br>• Significant vs. non-significant risk<br>• Sponsor & investigator responsibilities<br>• Application contents<br>• Report of prior investigation<br>• Investigators Brochure | George Moore, DVM, PhD | |
| Oct 17 | | **Designing the Clinical Strategy**<br><br>Clinical studies - Experimental design<br><br>Developing a hypotheses<br><br>Endpoints, sample size, the data collection process | Scott Snyder, PhD<br><br><u>Class Discussion</u>: Application of statistics to study design | |
| Oct 19 | | **Designing the Clinical Strategy, continued** | Scott Snyder, PhD | <u>Writing Assignment 6:</u> Statistics Problem on sample size calculation |
| Oct 24 | | **Implementing the Clinical Study**<br>Site assessment | Dion Bates | |

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|---|---|---|---|---|
| | | IRB Approval Process | | |
| Oct 26 | | **Implementing the Clinical Study**<br>Financial & Legal Considerations<br>Clinical Study Training | Dion Bates | Quiz 6 |
| Oct 31 | | **Implementing the Clinical Study**<br>Screening & Consenting Patients/ Patient Recruitment<br>Monitoring<br>Data Reporting | Dion Bates | |

| | | | | |
|---|---|---|---|---|
| Nov 2 | 20 | **Integrating Study Data into Regulatory Submissions** | Jennifer Brown, PhD<br>Aaron Lottes, PhD, MBA, RAC | Writing Assignment 7: Dealing with data that is not favorable |
| Nov 7 | 21 | **Integrating Study Data into Regulatory Submissions** | Jennifer Brown, PhD<br>Aaron Lottes, PhD, MBA, RAC | Quiz 7 |
| Nov 9 | 22 | **Review and analyzing imaging for a clinical study**<br>**Imaging modalities**<br>**How to incorporate findings back into engineering** | Katharine Krol, MD | Quiz 8 |
| Nov. 14 | 23 | **Post-market safety monitoring** | TBD | |

| | | | | |
|---|---|---|---|---|
| | | Now that you have regulatory approval ... What's next? | | |
| Nov 16 | | **SAGES Guidelines for Introduction of a new technology - TBD** | Freeman | Quiz 9 |
| Nov 21 | 25 | **Guest Speaker – Stem Cell Based Therapies** | Mercedes Serabin | |
| Nov 23 | | **No Class - Thanksgiving** | | |
| Nov 28 | 26 | **Considerations when outsourcing a medical device clinical study - TBD** | TBD | |
| Nov 30 | 27 | **Global Considerations for Clinical Study Design - TBD** | | Quiz 10 |
| Dec 5 | 28 | **Combination Devices - TBD** | | |
| Dec 7 | | **Final Thoughts** | Freeman/Kerr | Assignment 8: IRB presentation assignment (approx. 3-minute video response to assignment) |
| Dec 12 | | | | Final Exam |

***Assignments are always due by 3:00 p.m. (EST), Monday or Wednesday before the lecture, unless otherwise noted above.***

**Grade Composition: Total 150 Points**

| Assignment | Points |
|---|---|
| Biography and Pre-assessment of Baseline Knowledge submitted (links to Qualtrics surveys will be provided for both assignments) | 5 |
| How to identify medical device opportunity (2-page paper) | 5 |
| Ethics case report #1 | 10 |
| Writing assignment on animal welfare | 5 |
| Flow chart – risk mitigation | 15 |
| Statistics/ study design problem | 5 |
| Ethics case report #2 – unfavorable data | 10 |
| IRB presentation assignment | 15 |
| Online quizzes (10 x 5 pts) | 50 |
| Final Exam | 30 |
| | |
| **Total** | **150** |

**Grading Scale:**

**A+ = (≥96%)**

**A = (≥92%)**

**A- = (≥89%)**

**B+ = (≥86%)**

**B = (≥82%)**

**B - = (≥79%)**

**C+ = (≥76%)**

**C = (≥72%)**

**C- = (≥69%)**

**D = (≥60%)**

**F = (below 59%)**

***Policy on academic honesty:***

The commitment of the acts of cheating, lying, stealing, and deceit in any of their diverse forms (such as the use of ghostwritten papers, the use of substitutes for taking examinations, the use of illegal cribs, plagiarism, and copying during examinations) is dishonest and not tolerated. Moreover, knowingly to aid and abet, directly or indirectly, other parties in committing dishonest acts is in itself dishonest.

***Emergency statement:***

In the event of a major campus emergency, course requirements, deadlines and grading percentages are subject to changes that may be necessitated by a revised semester calendar or other circumstances.

***Adaptive programs statement:***

Students with disabilities must be registered with Adaptive Programs in the Office of the Dean of Students before classroom accommodations can be provided. If you are eligible for academic accommodations because you have a documented disability that will impact your work in this class, please schedule an appointment with the instructor as soon as possible to discuss your needs.