Engineering Faculty Document No. 44-19
October 9, 2019

TO: The Faculty of the College of Engineering

FROM: The Faculty of the School of Biomedical Engineering

RE: Change to Undergraduate-Level Course BME 48901 requisites

The faculty of the School of Biomedical Engineering has approved the change in requisites of the course listed below. This action is now submitted to the Engineering Faculty with a recommendation for approval.

FROM: **BME 48901 Senior Design Project**
Terms offered: Fall, Lab 8, Cr. 3
Restriction: Must be enrolled in the School of Biomedical Engineering
Concurrent Prerequisite: BME 49000

The biomedical engineering design process is completed starting from a preparatory design course, BME 39000, through a preliminary system design, build and test in Senior Design Project, BME 48901. Students will work with their teammates to implement (e.g. build, test, iterate and evaluate) a solution to address a biomedical engineering problem statement and meet the technical specifications set forth. The resulting project design is presented and evaluated through an oral presentation, laboratory demonstration, and a final written document.

TO: **BME 48901 Senior Design Project**
Terms offered: Fall, Lab 8, Cr. 3
Restriction: Must be enrolled in the School of Biomedical Engineering
Prerequisites: BME 20500 and BME 20600 and BME 30500 and BME 30600
Concurrent Prerequisite: BME 49000

The biomedical engineering design process is completed starting from a preparatory design course, BME 39000, through a preliminary system design, build and test in Senior Design Project, BME 48901. Students will work with their teammates to implement (e.g. build, test, iterate and evaluate) a solution to address a biomedical engineering problem statement and meet the technical specifications set forth. The resulting project design is presented and evaluated through an oral presentation, laboratory demonstration, and a final written document.

REASON: Skills and knowledge acquired in all BME labs (BME 20500, BME 20600, BME 30500, and BME 30600) are needed for success in the BME 48901 capstone lab.

George R. Wodicka

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

BME Senior Design Course Handbook

Version 8.1

(BME 489, 490)

Fall 2019

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Acknowledgements

The original work represents the collaborative efforts of:

- Andrew O. Brightman, Ph.D., Assistant Head in the Weldon School of Biomedical Engineering
- Jennifer Brown, Ph.D., Former Post-Doctorate in the Weldon School of Biomedical Engineering
- Jamie Brugnano, Ph.D., Former Graduate Student in the Weldon School of Biomedical Engineering
- Pedro Irazoqui, Ph.D., Professor in the Weldon School of Biomedical Engineering
- Marcia Pool, Ph.D., Former BME Instructional Laboratory Coordinator in the Weldon School of Biomedical Engineering
- Ann E. Rundell, Ph.D., Former Professor in the Weldon School of Biomedical Engineering
- Allison L. Sieving, Ph.D., Former Lab and Assessment Coordinator in the Weldon School of Biomedical Engineering
- Sherry L. Voytik-Harbin, Ph.D., Professor in the Weldon School of Biomedical Engineering and Basic Medical Sciences

with recent modifications and updates made by:

- Asem Aboelzahab, M.S., Instructional Lab Coordinator in the Weldon School of Biomedical Engineering
- Andrew O. Brightman, Ph.D., Assistant Head in the Weldon School of Biomedical Engineering
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- Hugh Lee, Ph.D., Assistant Professor in the Weldon School of Biomedical Engineering
- Ann E. Rundell, Ph.D., Former Professor in the Weldon School of Biomedical Engineering
- Lester Smith, Ph.D., Former Lab and Assessment Coordinator in the Weldon School of Biomedical Engineering

A special thanks to the following for their helpful comments, insights, and support throughout the development of the manual and course:

- The School of Electrical and Computer Engineering at Purdue University, for access to their model of senior design

Table of Contents

Course Syllabus

Faculty Instructors

Course	Time and location	Assigned Instructor	Instructor Email	Instructor Office
BME 490	M 9:30 – 11:20 AM MJIS 1097	Dr. Hugh Lee	hwlee@purdue.edu	MJIS 2082
		Dr. Andrew Brightman	aob@purdue.edu	MJIS 1021A
BME 489	TR 1:30 – 4:20 PM MJIS 1097	Dr. Hugh Lee	hwlee@purdue.edu	MJIS 2082
BME 489	TR 8:30 – 11:20 AM MJIS 1061	Dr. Nan Kong	nkong@purdue.edu	MJIS 3082
BME 489	WF 8:30 – 11:20 AM MJIS 1087	Dr. Paul Robinson	jpr@flowcyt.cyto.purdue.edu	LYNN G221

The BME senior design experience, composed of BME 488, 489, and 490, is a fully integrated experience. For documentation purposes the senior design faculty have been assigned to the specific components of the senior design experience. However, it is important to note their guidance and mentorship extends to all components of the senior design experience. Likewise the instructional support team consisting of two laboratory coordinators, a BME technician, and graduate teaching assistants (GTAs) will have a hand in the guidance and mentorship of all class participants.

Instructional Support Staff	Role	Email	Office Hours
Mr. Asem Aboelzahab	Lab Coordinator	aboelzahab@purdue.edu	By appointment
Mr. Norvin Bruns	BME Research Technician	bruns17@purdue.edu	
Ms. Jennifer Anderson	490 TA	ander934@purdue.edu	By appointment
Mr. Minku Kim	SD TA	kim2139@purdue.edu	By appointment: Teams may schedule times with a TA for use of the lab during non-class times. Requests for TA availability should be made with at least 2-day notice.
Mr. Jongcheon Lim	SD TA	lim263@purdue.edu	
Mr. Andres Gallardo	SD TA	allicoga@purdue.edu	

Prerequisites: Successful completion of BME 205 & 206, BME 305 & 306, BME 390 (pre-req to 490), and senior standing

Senior Design Experience Description and Objective: The capstone design (senior design courses) will provide each student with a significant original design experience in biomedical engineering. This will be an iterative decision-making process in which basic science, mathematics, and engineering are applied to solve a problem with clinical or biomedical research impact. Among the fundamental elements of the design process are the establishment of design objectives and criteria, synthesis, analysis, construction, testing, documentation, and evaluation. Through these courses, you will complete a series of design reviews, demonstrations, and reports that document and detail the design and development process associated with your project. These assignments have been developed to mimic a typical industrial design experience and to prepare you for success in the workforce as a biomedical design engineer.

The capstone design in biomedical engineering consists of three integrated components (courses), all of which are mandatory: a capstone design laboratory (BME 489) and a studio-style lecture with interactive work session (BME 490).

In addition to the integrated courses (BME 488, 489, and 490) for senior design, if a student is working on a project which is formally mentored by an expert in the field, the student may also register for BME 493, a pass/no pass course to formalize the mentoring relationship and provide a record of the expert's service.

BME 490 Professional Elements of Design (1 Credit Studio): Students will develop their professional and technical design skills. Students will learn a variety of skills consistent with a practicing biomedical engineer. These skills include: project management, experiment design, ethical considerations, regulatory affairs, entrepreneurship and commercialization, communication, documentation practices, and peer feedback. Before each class session, students are to complete assigned reading, watch assigned video segments, and complete any assigned peer assessments. In class, students work in their design team to complete in-class assignments learning topics primarily within the context of their senior design projects.

BME 489 Senior Design Project Laboratory (3 Credit Laboratory): In this course, students focus on the preliminary stages of engineering design, planning, and problem solving techniques followed by prototype iteration and testing to develop a novel engineering solution to a real-world biomedical problem. The ability to engineer independent and original solutions to complex problems remains the primary objective and basis for grading throughout this portion of the course. Information developed in BME 490, such as project management, documentation, safety, appropriate animal and human subject usage, and quality assurance are expected to be employed in order to master the objectives of this course. Students will have the opportunity to hone their technical communication skills in both oral communications and device demonstrations as the course progresses. Student teams will complete a thorough literature review relevant to assigned project and develop necessary design specifications to address customer needs and realistic constraints. Student teams will derive and justified a preliminary design and outlined a plan to successfully complete their project. They will then execute this plan by iteratively prototyping, testing, and refining their designs. The design process will be documented through a Design History File. An end-of-semester public presentation and device demonstration will give the broader engineering community an opportunity to appreciate the students' achievements and provide constructive feedback.

BME 493 (for mentored projects): is a 1-credit mentored engineering design course. This course is to formalize the mentoring relationship between students and the associated Purdue faculty mentor whose expertise are used for the project. Design teams will provide regular feedback to project mentors on a weekly to bi-weekly basis through in-person meetings, telephone communications, and/or electronic communications. The form and timeline of communication is to be determined among the team and the project mentor. Mentors are to provide heightened awareness of important issues.

Mentors are not to provide intellectual contribution to the design. Senior design mentors will provide feedback to the senior design instructors on team progress. Additionally, mentors will provide constructive feedback for the preliminary and design review, team demonstrations, and final paper submission. This is a pass/no pass course. A "no pass" on this course will not have an impact on your grade in BME 489 or 490. Assessment will be based on attendance, participation, and satisfactory performance on the ability to communicate in a respective and open manner.

"Sponsored Student Class Project Notice: This course permits you, the student to participate in a class project that has been sponsored by a third party other than the University. The University encourages and supports your participation in this practical learning experience. Although your course requirements may include a practical learning project, you are not required to participate in a project that is sponsored by an outside third party. Prior to your participation in a project sponsored by an outside third party, we would like you to carefully consider that your participation (i) may require you to assign your intellectual property rights to any intellectual property for which a student would retain ownership under the University's Policy I.A.1 on Intellectual Property and/or (ii) may require you sign a non-disclosure (confidentiality) agreement with the sponsor. If you sign an agreement regarding intellectual property rights or a non-disclosure agreement, you may incur personal liability (with respect to breach of a non-disclosure agreement) or you may lose economic benefits associated with your ownership of intellectual property (with respect to a license or assignment of intellectual property). You are encouraged to retain independent legal counsel for advice on these types of agreements. In addition, if you choose not to sign a non-disclosure or intellectual property rights agreement, your professor will provide you with an alternate project at no penalty to you." You are responsible for making any Purdue Faculty and Staff mentors aware of the sponsored nature of the project.

Laboratory Access: Lab is available for use Monday – Thursday until 9 pm and on Fridays until 5 pm. Saturday and Sunday office hours are 2 – 5 pm by appointment only. If you will need to come in during the weekend you will need to make an appointment; see Blackboard for the scheduling link. There will be no access to the laboratory during the following University Holidays: Labor Day, October Break, and Thanksgiving break.

Academic Conduct: Academic integrity is one of the highest values that Purdue University holds. To maintain the integrity of a Purdue degree, it is vital that each student adhere to the highest standards of fairness and honesty. You are expected to conduct yourself in a professional and ethical manner in all aspects of BME Senior Design. Plagiarism, cheating, or other acts of academic dishonesty will not be tolerated. While collaboration is encouraged in many aspects, individual assignments must be completed by the individual student and each student is expected to be able to demonstrate their individual contributions to team projects. Should there be any doubt, clarify with your instructor how much collaboration, if any, is permitted or expected when working on projects or assignments with other students. Incidents of academic misconduct in this course will be addressed by the course instructor and referred to the Office of Student Rights and Responsibilities (OSRR) for review at the university level and to be recorded on your permanent academic record. Any violation of course policies as it relates to academic integrity will result minimally in a failing or zero grade for that particular assignment, and at the instructor's discretion may result in a failing grade for the course. If an individual behaves in any other manner that is unprofessional or unethical during the semester, the course instructor(s) reserves the right to fail the student for that as well. For more information, see the Office of the Dean of Students' "Academic Integrity: A Guide for Students" page at: https://www.purdue.edu/odos/osrr/academic-integrity/index.html .

Required Supplies:

- Senior Design Laboratory Manual (available on Blackboard); https://mycourses.purdue.edu/
- Yock, P. G., Zenios, S., Makower, J., and Brionton T. J. Biodesign: the process of innovating medical technologies, 2nd ed. Cambridge, UK; New York: Cambridge University Press. 2015.

Laboratory Attire: Safety regulations require that you wear long pants (or equivalent) and closed-toe shoes while working in the laboratory. Laboratory coats and safety goggles are available upon request.

Campus Emergency Response Procedures:

- Fire Alarm – Evacuate the building using the exits on the south side (end closer to Harrison Street) of MJIS. Only gather personal items if it does not jeopardize your safety. Assist those who need help, if possible. Proceed to the west side of Lily Hall. Report to a course instructor and give them your name before leaving the emergency assembly area.

- All hazards warning (examples of hazards: tornado (severe weather)/hazardous materials release/civil unrest/directed by police personnel) – When you hear the all hazards alarm immediately seek shelter/shelter-in-place. For a tornado, move to the MJIS basement via the southeast (stairwell closer to senior design laboratory) or northwest (stairwell closer to S. Martin Jischke Dr.) stairwell.

Campus Emergency Policy: In the event of a campus wide emergency, the course outline and requirements may be subject to change. The course instructor will provide information in regards to changes in the course requirements or course schedule as a result of a campus wide emergency. Check Blackboard and your Purdue email accounts for information.

Design Teams: Students will be assigned to a design team. Teams will consist of 3 – 6 students.

Removal from a Team: If an individual is consistently unproductive or lacks adequate participation, the team may elect to remove the individual from that team. To do so, the team, as a group, must submit a formal written complaint to the course instructor. The course instructor will hold a meeting with the aggrieved parties to establish fair and specific goals for the unproductive team member to meet in a timely manner. If the team member fails to meet these requirements, the course instructor has the right to remove a member from a team. In the event a student is removed from a team, a failing grade may be awarded for the course.

Faculty and Staff Responsibilities: Professors, teaching assistants, and professional staff members will serve as consultants to your design team. Their role is to advise you in achieving your design goals. This is to help you implement your own original solutions. Please note that when you contact a faculty or staff member via email, you must include "BME SENIOR DESIGN" in the subject line of your message. If you do not do so, your email may not be read.

Project Storage: Student work space must be cleaned at the end of each laboratory session. Teams are assigned plastic bins in the metal storage lockers to store supplies in-between work sessions. Please consult with a lab coordinator to identify appropriate areas to claim as work space.

Format for Written Assignments: For all written assignment submissions, ***figures and tables*** should be used to convey information in a clear and concise manner. All figures and tables should be appropriately labeled and cited in text. IEEE is the only accepted reference style in all documents for all items except webpages: *http://www.ieee.org/documents/ieeecitationref.pdf* Webpages must be cited using the standard from NCBI: http://www.ncbi.nlm.nih.gov/books/NBK7274/ in chapter 25 on websites.

Blackboard Learn: Course announcements and supplemental information and documents will be posted to Blackboard Learn. All assignments must be submitted through Blackboard except for notebooks.

Additional Suggested References:

1. L. A. Geddes, L. E. Baker, *Principles of Applied Biomedical Instrumentation 3rd ed.*, New York: Wiley, 1989.
2. D. Purves, *et al*, *Neuroscience 3rd ed.*, Massachusetts: Sinauer Assoc., 2004.
3. K. Otto, K. Wood, Product *Design: Techniques in Reverse Engineering and New Product Development*, Upper Saddle River, NJ: Prentice Hall, 2001.
4. P. King, R. Fries, *Design of Biomedical Devices and Systems*, New York: Dekker, 2002.
5. J. G. Paradis, M. Zimmerman, *The MIT Guide to Science and Engineering Communication 2nd ed.*, MIT Press.
6. National Academy of Engineering, *The Engineer of 2020: Visions of Engineering in the New Century*, National Academy Press, 2004.

Program and Course Outcomes:

Senior design provides many opportunities for you to demonstrate accomplishment of essential BME skills. Ultimately, students who successfully fulfill the course requirements will have demonstrated the ability to:

BME 489 (Laboratory Components of Senior Design)

	Student Outcomes for this Course	**Relationship to Student Outcomes of BME program**
I	Integrate and apply knowledge and skills obtained in earlier course work with new concepts and practices essential to the design and testing of a system or device to meet desired needs.	A, B, K, L, M
II	Implement the engineering design process and project management within the context of relevant design constraints.	C, E, G
III	Effectively communicate skills in oral and written form, both individually and as part of a team.	D, G, I
IV	Explain/discuss realistic design constraints, including regulatory issues, societal influences, and ethical and professional responsibilities of biomedical engineers, as related to the engineering design process.	C, E, F, J

BME 490 (Professional Development Component of Senior Design)

	Student Outcomes for this Course	**Relationship to Student Outcomes of BME program**
I	Effectively communicate skills in oral and written form, both individually and as part of a team.	D, G
II	Explain/discuss realistic design constraints, including regulatory issues, societal influences, and ethical and professional	C, E, F, J

	responsibilities of biomedical engineers, as related to the engineering design process	
III	Generate and justify solutions to a medical and/or biological problems that address customer needs and realistic constraints	C, H, I, L, M

Student Outcomes and Performance Indicators

As biomedical engineering faculty, and in consultation with industry and academic partners, we have designed our undergraduate biomedical engineering program to enable students to master the engineering program outcomes defined by ABET for a Biomedical engineering programming. Achievement of each outcome is assessed through the performance indicators listed next to each outcome description. The performance indicators are our means of assessing our success in imparting these important skill sets to you (our students). To facilitate the assessment process, all assignments in this course are mapped to the list of performance indicators.

Student Outcomes and Performance Indicators

BME A	*an ability to apply knowledge of mathematics, science, and engineering*
A1. Apply advanced mathematics (including differential equations), engineering principles, and a knowledge of biological sciences and physiology to model, solve, or analyze biomedical engineering problems.	
BME B	*an ability to design and conduct experiments, as well as to analyze and interpret data*
B1. Outline a directed approach to explore concepts or hypotheses related to biological or medical systems using safe and appropriate experimental methodology and validation. B2. Conduct investigational protocols and procedures to measure and record signals and data from living systems. B3. Statistically support or refute a hypothesis based on experimental data. B4. Interpret and comprehend scientific information and/or data represented in graphical or tabular format. B5. Use quantitative metrics to describe and interpret observations and data from a living system.	
BME C	*an ability to design a system, component, or process to meet desired needs within realistic constraints (RC) such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability*
C1. Formulate appropriate and quantitative design specifications, with respect to realistic constraints derived from customer, regulatory and societal needs. C2. Evaluate potential design solutions in terms of realistic constraints. C3. Implement, test, and demonstrate that an engineered result meets design specifications. C4. Identify and apply regulatory guidelines to a biomedical engineering design solution.	
BME D	*an ability to function on multi-disciplinary teams*
D1. Identify key technical capabilities needed of team members in order to create a multidisciplinary team to solve a biomedical engineering design problem. D2. Educate, respect, and compromise with individuals from different perspectives to solve a biomedical problem.	
BME E	*an ability to identify, formulate, and solve engineering problems*
E1. Identify an engineering problem relating to healthcare, medical, or biological applications. E2. Identify stakeholders and their needs relating to a healthcare, medical, or biological problem. E3. Formulate and write a problem description for a healthcare, medical or biological application that contains appropriate design specifications, with respect to the customer, regulatory, and societal needs. E4. Given a biomedical engineering problem description, generate a solution.	
BME F	*an understanding of professional and ethical responsibility*
F1. Recognize and describe professional and ethical codes of conduct, and ethical dilemmas which pertain to a practicing biomedical engineer. F2. Explain ethical considerations relevant to experimentation with animal and human subjects.	
BME G	*an ability to communicate effectively*
G1. Construct a logical and articulate argument in written format from independent collection of information that is appropriate for the intended audience. G2. Construct and deliver a logical and articulate oral presentation based on independent collection of information that is appropriate for the intended audience. G3. Evaluate oral and/or written presentations for clarity and content. G4. Create a scheduled plan to implement a design solution for a medical or biological application with subtasks for implementation. G5. Organize and represent data collected in a form such that it clarifies and enhances the ability to interpret it. G6. Record procedures, observations, and results of an experiment in a manner which allows for independent replication.	
BME H	*the broad education necessary to understand the impact of engineering solutions in a global, economic, environmental, and societal context*
H1. Recognize regulatory agencies and how they impact research or product development for medical devices. H2. Justify selection of a biomedical engineering process in research or product development based on an economic analysis. H3. Identify and/or describe how biomedical engineering solutions affect society.	
BME I	*a recognition of the need for, and an ability to engage in life-long learning*
I1. Collect relevant technical information, data, and ideas from multiple sources. I2. Identify multiple career pathways that are available to a biomedical engineer. I3. Recognize opportunities that enhance professional career development.	
BME J	*a knowledge of contemporary issues*
J1. Recognize contemporary issues impacting biomedical engineering.	
BME K	*an ability to use the techniques, skills, and modern engineering tools necessary for engineering practice*
K1. Apply engineering and science techniques, skills, and tools at the biomolecular, cellular, tissue, or system level. K2. Select the appropriate engineering and science tools and techniques to solve a biomedically relevant problem.	

Student Outcomes and Performance Indicators, Continued

BME L	*An understanding of biology and physiology*
L1. Recognize and describe biological and physiological processes/systems.	
L2. Examine a molecule, material, integrated medical device, or schematic representation thereof and explain the relationship between its structure and function and how this relationship is useful in biomedical engineering applications.	
BME M	*The ability to address problems associated with the interaction between living and non-living materials and systems.*
M1. Recognize, identify, and describe the need for an engineering solution to address current challenges in life sciences and medicine.	
M2. Describe the challenges associated with interactions between living tissues or cells and engineered devices or materials and propose strategies to overcome these challenges.	

BME 489/490: Course Grading and Syllabus

BME 489, 490 Grading Policy: The following grading scale is a guaranteed minimum; however, based upon individual student performance* (as determined by reviews and by achievement of Student Outcomes and Performance Indicators) and/or the functionality of the final demonstration, final grades may be curved by the instructor.

GPA	Grade	Percent Range
4	A	≥93
3.7	A-	92 – 90
3.3	B+	89 – 87
3.0	B	86 – 83
2.7	B-	82 – 80
2.3	C+	79 – 77
2.0	C	76 – 73
1.7	C-	72 – 70
1.3	D+	69 – 67
1	D	66 – 60
0	F	≤59%

** Note: Instructor reviews and peer reviews of an individual's performance may be used to modify final grades by as much as +/- two letter grades.*

Re-grade Policy: Students have the right to contest grades throughout the semester. In the event that a student feels an assignment has been inappropriately graded, the student must submit a one page typed document indicating the nature of the problem and an explanation for the re-grade submission. Along with this document, the original assignment must be returned to the instructor. Students have one week after the return of a graded assignment to protest a grade; after this time, grade disputes will not be accepted. Papers submitted for a re-grade will be completely reevaluated (i.e., the entire paper will be re-graded, not only the portion under protest), which means that students may lose additional points for mistakes missed during the first grading process.

BME 489 Grading Scheme and Schedule

Assessment	***Value (individual)***	***Due Date***
Preliminary design presentation	5%	9/3 – 9/6
Individual demo (physical demonstration/early prototype)	5%	9/24 – 9/27
Design review presentation	10%	10/22 – 10/25
Team demonstration – integrated system at bench	5%	11/19 – 11/22
Notebook spot check and final notebook evaluation	5%	9/10 – 9/13 12/3 – 12/6
Final team demonstration	15%	12/6 – 12/7
Final DHF (contains all sections)	20% total (10% for individual subcomponent sections of 5, 7, and 9)	12/9
Final presentation	10%	Presentation TBD
Team Participation, instructor interaction, CATME Peer reviews, lab clean up, and attendance+	10%	9/6 CATME 10/18 CATME 12/9 CATME
Evidence of design iteration	10%	Evaluated continuously and awarded at completion of semester
Innovation and scientific/engineering rigor	5%	Evaluated continuously and awarded at completion of semester
Total	***100%***	

+In order to receive participation grades, each student must demonstrate that he/she has completed the end of course evaluations prior to the final design documentation.

490 Schedule

Date	Course Topics	Pre-class Assigned Reading and Videos	Recommended In-class Activities	Related Assignments, Quizzes, and Peer Review Items Due
8/19	• Course Intro • Intellectual property • Entrepreneurship • Ethics of Engineering Practice • SWOT analysis	• Biodesign 5.1: Intellectual Property Strategy	• Read MOU and identify mentors • Review the NSPE & BME Ethics Codes • SWOT analysis of Design Project (Team) • Write Problem Statement and create Design Specifications (DHF Section 2 and 4)	• Signed MOU (8/26)
8/26	• Regulatory affairs • Design and development planning • Prototyping I	• Biodesign 4.2: Regulatory Basics • Biodesign 4.5: Prototyping • FDA Design Control Guidance for Manufacturers: Section B	• Background and ideation • Prototype development and staging (planning with sticky notes) • Regulatory assignment: Part 1 • DHF section 9: Schedule (Gantt chart) Budget spreadsheet	• Draft DHF sections 2, 3, 5.1, 9, 10 (8/30) • Regulatory assignment: Par 1 (9/9)
9/2	Labor Day – No class			
9/9	• Prototyping II • Design input • Specification development • Ethics of engineering testing	• Ted Talk: Joi Ito: Want to innovate? Become a "now-ist". (13:20 min) • FDA Design Control Guidance for Manufacturers: Section C • Watch: A Brief History of Human Subject Research (14 min.) • History of Animal Research (12:30 min.) • Read: excerpt of Belmont report and article on Ethics and Animal Welfare	• Design input • DHF section 4 & 5 • Discuss ethics of animal and human subject testing • Draft your strategy for testing prototype / components (**determine if PACUC or IRB approval needed for protocol**)	• Quiz 1 (9/16) • (Updated) DHF sections 2 - 5, 9, 10 (9/16)
9/16	• Risk management • Design output	• Introduction to FMEA (8:20 min) • Risk Management for Medical Devices (5:32 min) • Biodesign 5.5: Quality and	• Navigate FDA website for similar but recalled products: update regulatory affairs assignment • DHF Section 6: FMEA	• DHF section 6, and updated sections 2-5, 9, 10 (9/23) • CATME #1

		Process Management • FDA Design Control Guidance for Manufacturers: Section D		
9/23	• TBD	• Medical device standards: part 1 (11:32 min) • Verification and validation (2:06 min) • FDA Design Control Guidance for Manufacturers: Section F	• Identify standardized testing protocols from regulatory and standardization agencies • DHF Section 7.1: Plan verification experiment for sub components	• Quiz 2 (9/30) • (Updated) DHF section 2 - 7.2, 9, 10 (9/30)
9/30	• Design review • Design verification • Testing I	• Statistical analysis (9:32 min) • Supplemental statistical analysis methods paper	• Use standardized protocols and review literature for similar tests and precedence • Ensure testing addresses **safety and effectiveness** and evaluates all design specifications • DHF sections 7.1 and 7.2 (show plan of analysis and presentation)	
10/7	Fall Break – No Class			
10/14	• TBD		• Update all sections • Pivot?	• Quiz 3 (10/21)
10/21	• Testing II • Design review II		• Design review • Regulatory assignment: Part II • Update DHF sections • DHF sections 1, 7.3, and 7.4 (show analysis and presentation)	• Regulatory assignment: Part II (10/28) • (Updated) DHF sections 1 - 10 (11/4)
10/28	• Design validation	• FDA Design Control Guidance for Manufacturers: Section G	• DHF sections 7.5 and 7.6	• Quiz 4 (10/28)
11/4	• Clinical trial • FDA databases	• Biodesign 5.3: Clinical Strategy	• Update Regulatory Assignment on pathway to translation to incorporate validation experts as appropriate	• (Updated) Regulatory Assignment (11/18)
11/11	• Entrepreneurship • Tech transfer	• Biodesign 5.9: Competitive Advantage and Business Strategy	• Recognize innovation activity • Intellectual property assignment • Outline content for Project pitch video • Watch and review Project pitch videos during class	• Peer review of DHF (11/18) • IP assignment (11/25) • Project pitch video (12/9)

			• Revise Project Pitch video plans/script • Finalize IP assignment	
11/18	• Ethics of Engineering design practice	• Read: Extract from article on pediatric valve case study and • Read article on New Surgical Devices and Ethical Principles	• Discuss ethics case study • Discuss paper on new surgical devices and ethical principles	• CATME #2
11/25	• Ethics and Global Engineering Values	• Biodesign 6.3 pgs 676-686: Funding Sources	• Discuss global perspectives on human and animal testing	• Final DHF (12/9)
12/2	• Ethics of Engineering Medicine	• Watch: Money and Medicine (60 min)	• Discuss ethical issues in medicine • Finalize Project Pitch Video • Finalize DHF	• Quiz 5
12/9	FINALS WEEK			

BBVideos are links to videos posted on Blackboard and will be made available at least one week before; † Supplemental materials are available on the BME 490 Blackboard site

BME 490 Grading Scheme

Assessment	***Value (individual)***	***Due Dates***
Quizzes	20 (4)	• 9/16 Quiz #1 • 9/30 Quiz #2 • 10/22 Quiz #3 • 10/29 Quiz #4 • 12/2 Quiz #5
Attendance/participation	10	• Attendance: continuous/random check • 8/26 Signed MOU
CATME	10 (5)	• 9/16 CATME #1 • 11/18 CATME #1
IP assignment	10	• 11/25 IP assignment
Regulatory assignments	10	• 9/9 Regulatory assignment: Part 1 • 10/29 Regulatory assignment: Part 2 • 11/18 Updated regulatory assignment
Project pitch video	10	• 12/9 Final project pitch video
DHF peer review	5	• 11/18 Peer review of DHF
Final DHF	25	• 8/30 DHF sections 2, 3, 5.1, 8, 9 • 9/16 Updated DHF sections 2, 3, 4, 5, 8, 9 • 9/23 DHF section 6 • 9/30 Updated DHF sections 2, 3, 4, 5, 6, 7.1, 7.2, 8, 9 • 11/4 Updated DHF sections 1, 2, 3, 4, 5, 6, 7, 8, 9 • 12/9 Final DHF
Total	***100%***	

+In order to receive participation grades, each student must demonstrate that he/she has completed the end of course evaluations prior to the final design documentation.

BME 489 Assignment Descriptions

Questions about assignments should be directed to the lab coordinators or course instructors. Due to the nature of this course, email communications and Blackboard will be used as communication vehicles for changes to the course and reminders of important due dates. Meetings with course instructors can be made via email. Be sure to include in the subject headline "BME SENIOR DESIGN".

Design History File (DHF): the master document

For the purposes of senior design, your DHF will serve as your technical report for BME 489. BME 490 will help develop some aspects of the report. A design history file is a continually updated document which identifies and documents design controls in the development process of a medical product to ensure safety and adherence to design requirements. A DHF is required by the U. S. Food and Drug Administration (FDA) and the Code of Federal Regulations—Title 21 (21 CFR 820), and components of the DHF are cross-referenced with quality standards ISO 9001 and ISO 13485. Components of a DHF typically include: design specifications, failure modes and effects analysis, design documents (schematics/drawings/CAD images, etc.), verification/validation plans, verification/validation results, and a manufacturing plan.

Section 1: Executive Summary
Section 2: Problem Statement and Clinical Need Statement
Section 3: Problem Description
Section 4: Design Specifications
Section 5: Solution Statement and Drawing
Section 6: Failure Modes and Effects Analysis (FMEA)
Section 7: Verification and Validation of Design
Section 8: Final Project Outcomes
Section 9: Project Planning
Section 10: References

A DHF template is provided on Blackboard. Suggestions are given for the length of the sections of the DHF in the template. The DHF must have 1" margins, font size of 11pt or larger, allowable fonts are Times New Roman, Arial, or Calibri. The document should be single spaced. All submitted files associated with the DHF or its development should be pdf. The naming convention of the submitted files is given by the report title of that upload followed by your team number, for example: prelim_DHF_team#.pdf, final_DHF_team#.pdf, etc.

Final DHF

This is your final report for your senior design project. It contains revised text from BME 490 and new material addressing integrated system verification and validation testing plans and results. References are necessary to support the information in the report. It comprises all sections of the DHF template. More details on the anticipated content is provided in the template.

Senior Design Notebook (evaluated at least 2 times)

Information maintained in a senior design notebook is useful for many purposes:

1. For you to refer back to when writing a project summary/report.
2. For a colleague to refer to when continuing your project.

3. By a legal department when filing a patent application.

Each team member must maintain a senior design notebook to document their individual contributions to the design project. The purpose of your senior design notebook is to provide a complete and chronological record of your work on the Design Project; this will include individual literature searches, personal planning sessions, team planning sessions, laboratory sessions, etc. Ultimately, each step you take towards achieving a design solution must be documented in your notebook. Notebooks will be spot checked throughout BME 489, with a final grade being determine from the rubric supplied on Blackboard Learn. Grading of your notebook will be primarily determined by whether a person versed in the field but unfamiliar with your work, could duplicate your efforts with only your notebook to go by.

Design Notebook Entries

Entries to your senior design notebook are to be made during, or immediately after, each working session. Each entry **must** include: date, time, location, your objective for the session, and a record of what you did or accomplished in the session. Different events will result in different entries. This notebook can be electronic, paper, or a hybrid which has entries in both electronic and written format: a table of contents should describe where the documents are located if it is electronic.

Overall Organization: This document should be structured in a manner that allows for a reader versed in the field to readily understand the document. A table of contents is to be included for the major sections of the notebook: literature background, team planning, component cost analysis, and design, build, and testing sections.
When using equations, formulas, derivations, graphs, figures, etc. to help explain design choices or system outputs use the following guidelines for design notebook entry:

a) Equations/Formulas/Methods. Equations used as part of your design solution must be documented in your notebook so that they are easy to refer back to at a later date. If you derive an equation or formula, include enough of the derivation so that the derivation process is transparent.
b) Figures/Graphs/Schematics. Items included in this category are: concept sketches block diagrams, flow charts, drawings of the system, circuit diagrams, graphs of system outputs, images which show cellular viability, etc. (computer codes should not be printed. Include in the notebook the file name and location of the code to document activity on coding). For Figures: Captions should be placed near each image. A caption under a schematic of the first floor of the MJIS building may read: "MJIS – First Floor Layout". For Tables: Captions must be near each table. A caption above a table of the number of students enrolled in BME senior design may read: "Table 1. Student enrollment in BME Senior Design. Data in this table is representative of students attending senior design between fall 2007 – spring 2011."

Notebook Content

1. *Background:* Should provide the background on the solution to problem and tests.
   a. Supporting Observations: Document all supporting observations that lend to better understanding of the problem or development of the solution to the problem. This may include observing the problem, interviewing people associated with the problem, finding literature describing the problem, etc. For referenced literature, be sure to document the following details in the senior design notebook:
      (1) Search process documentation: Describe the method used to find sources. Include: search engine, search terms, and recovered references

(2) Reference summary: include a descriptive header to allow the reader to match the summary statement to a specific reference. Summary should include a brief description of the useful content of the reference towards the project solution.

(3) Reference list: For the DHF you will need to follow IEEE format or NCBI website style. For the notebook, enough information should be provided to be able to relocate the original source.

2. *Team Planning Session Entries:* Documents team decisions on how to solve the problem and assignments of team members to specific tasks.
3. *Component cost analysis*

   A section of the lab notebook is to be dedicated to a detailed list of parts used to develop subcomponent and whole system integration. A complete parts list should include manufacturer, catalog number, cost/item, and description and rationale of how the component is used in the development of the final product. It is acceptable to reference the reader to specific pages within the notebook for component use description. However, an all-inclusive parts list must be included in the lab notebook as its own section. Parts list should include any test equipment/devices that the university has supplied for use during senior design (oscilloscopes, biosafety cabinet, incubator, etc.). If you are unsure of what information should be detailed in the parts list, please consult with a course instructor.
4. ***Design, Build, and Test Entries***
   a. Design/Build: The process of developing a solution to the project needs to be documented. This includes brainstorming activities, sketches, and flow charts. A reader should be able to understand the solution that is being proposed.
   b. Testing: Complete testing plans need to be documented. Testing should include the following:
      a. Test Objective (note if it is to show the ability to meet a technical specification)
      b. Materials and Methods
      i. If a test is repeated multiple times it is acceptable to refer the evaluator to the appropriate page in which the materials and methods have been previously documented.
      c. Sketches of testing set-up (if appropriate)
      d. Documentation of raw data
      e. Documentation of analyzed data (with accompanying graphs or tables)
      f. Discussion of test results (data interpretation/analysis)
   g. Evidence of Design Iteration: this text should explicitly call out and highlight design changes you have made as a result of an experiment, prototype, or model evaluation. Rationale should be provided to justify the design changes; these could be as simple as "to improve the accessibility by the user" or "to improve the accuracy of the spectrophotometer testing results."

Team Participation, Instructor Interaction, and Attendance

Your continued participation in the senior design experience is essential for project success. A portion of your grade will be dependent upon your continued team participation and attendance. Students are expected to attend all laboratory sessions. In case of extenuating circumstances (i.e., death in family, illness) the course instructor is to be notified, preferably prior to the laboratory. Questions or concerns about the attendance policy for the laboratory portion of the course should be addressed to a course instructor.

For the peer assessment, you will evaluate your own participation in your team endeavors as well as the contributions of each of your teammates using CATME. Feedback from these surveys will be used to help guide instructor/student interactions. You may be given a summary feedback from the peer reviews; however, all evaluations will remain anonymous. Please note that these results are factored in as part of your overall course grade. Peer reviews will be evaluated both by your ability to provide constructive comments to your peers as wells as your peers' impressions of your team performance.

In addition to the peer assessment course instructors will be monitoring your contributions to the project. A noted lack in team participation or responsiveness and engagement in interaction with the instructors and TAs will result in a grade reduction.

Preliminary Design and Design Review Oral Presentations

Team presentations are 15-minute power point presentations, which summarizes your team's design. The presentation will be given to BME faculty, lab coordinators, GTAs, and your peers. Following the presentation there will be a question and answer session. The entire session for each team will last no more than 20 minutes. Your team should be prepared to address detailed technical and financial questions about your integrated system and subsystems.

Your team's Power Point file must be submitted (via email) to the laboratory instructor one hour prior to the start of class on the due date.

Design reviews are intentionally challenging. This mimics real world design reviews where the customer must decide after the review if they want to provide you with substantial funding to generate a complete prototype or working system. Thus they will ask questions, interact, and negotiate on system specifications to ensure that they have a reasonable level of comfort to proceed to the final design stages. In extreme cases, the customer may fire a team or force them to start over should the design be totally insufficient.

Please find below some general recommendations for presentation content.

1) **Title Slide, Team Name, and Team Members**
   This slide should be designed to be creative and attention-grabbing. Also include on this slide the key objective statement which describes the basic idea or value proposition that your product will provide.

2) **Problem / Opportunity and Definition of customer and size and scope of your market**
   Include a concise description and overview of the problem (current or emerging) that your team is going to solve. Briefly explain why the problem exists and describe any current therapeutic strategies that are commercially available and their associated limitations. Make sure to define your customer and describe the size and scope of your market (include relevant charts, tables, and references). Include rationale and justification as to how your product is innovative and how it is designed to uniquely solve the problem.

3) **Design overview, subsystems and system integration**
   Describe your overall design solution by providing sound technical reasoning (i.e., correlation to mathematic relationships, engineering principles, and biological phenomena) for design choices. Provide images of the final solution, flow and/or block diagrams to help the audience understand

the design. Include technical and operating specifications for your design. Justify technical specifications based upon design specifications.

4) **Design Status**

We are looking for current progress on each subcomponent of your design and whole system.

Preliminary Review – Provide a technical description of the subcomponents of the design solution and how they integrate with one another to achieve a working system. Describe the current build status of each subcomponent.

Design Review – Update on the design and testing status of each subcomponent. The status of each subsystem can be expressed through prototypes (or images) that have been constructed (CAD or actual), sample code, circuit diagrams, cell imaging, etc. Updates must include analyzed test results (presented as figures or tables) with appropriate statistical analyses for the subcomponents. When possible, cite and include published data that supports your design and testing strategy. Analyzed data demonstrating proof-of-concept with the current direction of the project is to be presented at the whole system and subcomponent levels.

If you are unsure of what is expected to be presented please consult a course instructor.

Individual Demonstration

This is not a presentation. It will be an interactive session at the laboratory bench with the course instructors where each team member shows the instructors their subcomponent and demonstrates its functionality. For this demonstration, each member of the team is expected to briefly tell the instructors what their subcomponent is supposed to do and how it contributes to the overall system design. Each member will demonstrate the subcomponent working and achieving any relevant design specifications. The team member should be prepared to address technical questions about the subcomponent design, planned integration with the system as a whole, calibration procedures, data collection, data and statistical analysis, and next steps in the progress of the design. The instructors may ask the team member to demonstrate how the subsystem will respond if a setting or component is changed. **The bulk of the demonstration grade will depend upon the ability of the individual to demonstrate the complete functionality of their subsystem**.

Team Demonstration – Integrated System

This is not a presentation. It will be an interactive session at the laboratory bench with the course instructors where the team shows the instructors the performance of the integrated system and demonstrates its current functionality. For this demonstration, the team will demonstrate to the instructional staff the current status of operation of the whole system. It is expected that the system is fully integrated and the team is working on interactions to continue the improvement of the system to achieve the design specifications. In the event that the system is not fully integrated, demonstrate the components of your system that are integrated and indicate which aspects need further refinement. The instructors may ask the team to demonstrate how the system will respond if a setting or component is changed. **The bulk of the demonstration grade will depend upon the extent of the integration and the ability of the integrated system to meet some (or all) of the design specifications**.

Final Team Demonstration

This is not a presentation. It will be an interactive session at the laboratory bench with the course instructors where you and your team will demonstrate that your integrated design solution meets all of the design specifications. In the event that the system is not fully functional, demonstrate the components of your system that work and indicate which aspects do not. The instructors may ask the team to demonstrate how the system will respond if a setting or component is changed. **The bulk of the demonstration grade will depend upon the ability of the integrated system to meet all of the design specifications**.

Evidence of Design Iteration (continuous)

Accomplished design engineers iterate on designs continuously. To achieve the best design result, practicing engineers engage in a continuous cycle of: design, build, test and evaluate, redesign, etc. Over the course of the semester, you must demonstrate to the TAs and instructors iterations on the design of your subcomponents and final system. Successful designs will undergo multiple design iterations. To be able to complete design iterations in one semester you must get started early. Documentation of the design iteration should be present in your notebook and in a summarized form in the DHF. Assessment of your ability to perform design iteration will be done considering all resources including instructor interaction, notebook and DHF documentation, demonstrations, and oral presentations.

Innovation and scientific/engineering rigor (continuous)

The senior design experience is the capstone experience of your undergraduate engineering education. You are expected to draw upon what you have learned to date. In addition to applying previously learned principles, successful design engineers often learn a new skill and teach themselves a new subject to effectively solve the problem. An assessment will be made of your ability to generate a solution to your design problem through innovation and application of scientific and engineering skills and knowledge. Documentation of the scientific/engineering rigor should be present in your notebook and in a summarized form in the DHF. Assessment of your engineering rigor will be done considering all resources including instructor interaction, documentation, notebook and DHF demonstrations, and oral presentations.

Final Presentation (scheduled during Finals week)

The final presentation is your opportunity to relay your team's design strategy and findings to BME faculty, company representatives, BME staff, and BME students. Your team will briefly present your design and results to an audience.

Lab Clean Up (due Monday after finals week)

A portion of your grade in this course is based upon work space cleanliness. Each person has until the Monday after finals week to clean up all lab space work areas. Students that have not cleaned up their workspace by the deadline will have a grade reduction in the team participation, peer reviews, and attendance assessment.

BME 490 Assignment Descriptions

Questions about assignments should be directed to the course instructors, TAs, or lab coordinators. Due to the nature of this course, email communications and Blackboard will be used as communication vehicles for changes to the course and reminders of important due dates. Meetings with course instructors can be made via email. Be sure to include in the subject headline "BME490". All document exchange will occur through the BME 490 Blackboard Learn Site.

Design History File (DHF) Related Assignments

BME 490 assists with the completion of a few new sections of the DHF. BME490 focuses on elements of the DHF that have not been extensively covered previously. Rubrics will be provided to indicate the anticipated final content of these documents. Submitted DHF sections will undergo peer and instructor review for constructive feedback prior to grading in BME 489. Documents should be revised from the feedback for incorporation into their finalized DHF document.

Memorandum of Understanding (MOU)

This document covers the confidentiality, material transfer, and intellectual property related to the senior design projects courses: BME 48900/49000. It should be signed initially by all members of the team and by any mentors (faculty, industry, or clinical) and **updated whenever any changes arise in IP or mentoring.**

Project Pitch Video

Each senior design team will develop and submit a 3 minute Project Pitch Video. This video presents your project as if you are pitching it to investors and seeking funding to continue to develop the project beyond the senior design experience. The Project Pitch Video must be compelling and clearly describe the problem and clinical need you have solved, demonstrate your design accomplishments, and indicate the potential market for your solution. It should contain images or views of your design solution to show the status of your project and indicate the next major translational steps. The Project Pitch Video will be presented to class for peer and instructor feedback during development. The finalized Project Pitch Video will be submitted for grade at the end of the course. However, you might want to complete a final version earlier to use if plan to continue the project in the spring semester or to submit to design competitions with earlier due dates. The final videos from the course may be disseminated on the web, provided to NIH, or used by the Weldon School of Biomedical Engineering at recruitment, awards, publicity, and evaluation events.

Design Project Abstract

This abstract is limited to 300 words. It is used to promote your design project accomplishments to the greater BME community. The abstract succinctly summarizes the problem, its societal importance and associated need, your design solution and the results you achieved. It should also highlight why your solution is unique and innovative. In addition to the typical round of BME 490 peer and instructor feedback, the BME 290 class will provide peer review feedback on a draft to ensure it is broadly accessible by a general technical audience.

Peer Reviews

The final DHF will be subjected to peer review. As a peer reviewer you are expected to critically analyze student work and provide constructive feedback that will enhance the final product. For this peer reviewed assignment, you will be reviewing another team's submission. Your completion and ability to constructively contribute to peer reviews for the assigned material is used to determine your peer review grade. These peer reviews will be completed using online rubrics.

Online Quizzes

At least 5 quizzes will be administered (if we suspect the pre-class assignments have not been completed, additional quizzes may be administered). These quizzes will cover the material indicated and are intended to assess your knowledge of the pre-class assigned material. For the most part, they will be multiple choice. Students may use published materials to complete the quizzes (lecture notes, course textbook, etc.).

Safety in the Laboratory

Safety is an important aspect of any laboratory as it ensures a non-hazardous working environment for the laboratory users. The likelihood of a laboratory accident in a collegiate setting is 100 times that of an occurrence in a professional lab (www.labsafety.org); therefore, it is important that you adhere to the safety guidelines set forth in this document. The safety guidelines relevant to this lab are broken down into three sections: general, electrical, and animal safety.

General Lab Safety

The general safety procedures that apply to any laboratory environment are also applicable in this course. These procedures include, but are not limited to the following guidelines:

- No eating or drinking in the laboratory.
- Open-toed sandals or shoes are not allowed in the laboratory.
- Immediately inform the instructor of any sparks, fires or spills in the laboratory.
- Absolutely no horseplay! Do not throw instruments or components around the laboratory. Handle all lab devices with care.
- Turn off all electrical equipment prior to leaving the laboratory.
- Know the location of lab fire extinguishers and telephones for use in emergency situations.
- There should be at least two people working in the lab at the same time.

All accidents must be reported to the instructors. If necessary they will assist you to the Purdue University Health Center or an alternative health care provider. Should you experience symptoms of an illness after class, you should report to the Purdue University Health Center.

If you are pregnant or immune compromised you should avoid exposure to chemical agents known to be teratogenic (impair embryonic development). All infectious agents pose as a significant risk. Please inform the laboratory instructors of any health conditions or concerns about your personal risk.

You are encouraged to address concerns or questions with your laboratory instructors. Questions and suggestions to safety guidelines will only enhance the laboratory experience.

Electrical Safety

Electrical hazards. **Fire** and **electrical shock** are the primary hazards associated with electricity and electrical shock. Living organisms experience electrical shock when electrical currents travel through the body. Exposure to electrical currents can occur when an individual comes in contact with both wires of an electrical circuit, one wire of an energized circuit and the ground, or a metallic part that has become charged due to contact with an electrical conductor. The severity of and consequences associated with an electrical shock are dependent on a number of factors, including: the current pathway through the body, duration of exposure, and whether the exposed area is wet or dry. In general, the consequences of electrical shock can range from mild sensation to cardiac arrest and death. In this course, you will work with electrolytic solutions, which are excellent conductors; therefore, you must practice extra caution when working with these solutions.

Electrical and electronic safety. Follow these guidelines to minimize the risk of electrical accidents.

1. Know the location of electrical shut-off switches and circuit breakers in/near the room so that the power can be quickly terminated in the event of a fire or accident.
2. Turn off the power before touching electric circuits.
3. Complete your wiring and check it before activating the power supply.
4. Turn off the power supply before reconfiguring, rewiring, disassembling the circuit, and checking or replacing a fuse.
5. You will perform electrical experiments with liquids in a controlled setting, but you must exercise extreme caution when working with conductive liquids. Clean any spills immediately, as they may provide a harmful current pathway.
6. Do not use cords that have frayed wiring, loose connections, or cracked insulation. Report damaged cords to a lab instructor.
7. Check the electrical ratings of lab equipment you work with, and verify that the equipment is used within its ratings.
8. Do not leave electrical systems unattended.
9. Only equipment with three-prong plugs should be used in the laboratory. The third prong provides a path to ground that helps prevent the buildup of voltages that may lead to an electrical shock or spark. Never remove or compromise the ground connection on a plug.
10. Make sure equipment casings or cabinets are grounded.
11. When working on a live/active circuit, use only one hand.

Electrical emergency response.

- *Electric Shock.* A person that suffers a serious electrical shock may be knocked unconscious. If the victim is still in contact with the circuit, he or she may still be conducting current. DO NOT TOUCH A VICTIM IN CONTACT WITH A POWER SOURCE! Immediately turn off the power source or try to separate the victim from the source using a non-conducting object, i.e. a wooden broom stick or a block of rubber.

- *Electrical Fire.* Sparks from electrical equipment can ignite flammable materials in the lab. In the event of an electrical fire, try to disconnect the power supply ***only*** if you can do so without injuring yourself. Use the fire extinguisher to put out or control small fires. DO NOT use water to put out an electrical fire because it may create a current pathway, which can cause further damage.

- *Emergency Action Team.* In the event of an electrical accident, four students will help respond to the accident.
  - One will call 911 and inform the operator of the nature of the emergency and the location where it occurred (MJIS 1087).
  - One will turn off the power at its electrical shutoff. This person will then 1) check to that the shock victim is disconnected from the power source, 2) check the victim's vital signs, and 3) administer first aid until paramedics arrive.
  - Two will go to the major ambulance entrances, the dock entrance of MJIS (North side of the building.) and the east entrance (between RM 1061 and RM 1087) of the building, and wait for the paramedics/fire department. Upon paramedics' arrival, these students will lead them to the laboratory.

Everyone in the class must be prepared and willing to perform the duties of the Emergency Action Team. During the first laboratory period, the instructors will show you the location of the telephone and the outside locations where students should wait for paramedic/fire teams, should the need should arise.

Animal Safety.

Possible health risks associated with using a mammalian animal include allergic reactions and development of zoonotic diseases. Allergens are antigens that your immune system interprets as an infection; primary sources include: fur, saliva, hair dander, and urine. Symptoms typically associated with an allergic response include a runny nose, sneezing, asthma, dermatitis, and watery eyes. The onset of these symptoms may occur immediately after exposure or develop with time after an exposure. The best way to minimize your exposure to allergens is to wear proper personal protection equipment (PPEs; including gloves, a lab coat, and a face mask) and to wash your hands immediately following work with animals.

In addition to inducing allergic reactions, animals also have the potential to pass diseases to humans. The spread of disease from animal to human is very uncommon. The few infections that can be carried by both humans and animals are referred to as *zoonoses*. Animals that carry *zoonotic* diseases may appear perfectly healthy because these animals have developed an immunological resistance to the microorganisms. Zoonotic diseases are commonly transmitted through bites, scratches, or ingestion (orally or inhalation). Zoonotic diseases include: rabies, toxoplasmosis, leptosprirosis, ascariasis, psittacosis, and Q fever. More details on these diseases can be found at: https://www.purdue.edu/ehps/rem/eh/animalbite.htm. Due to this risk, you should always be informed on the type of laboratory animal you will be working with so that you may take the proper precautions to avoid disease exposure. If after working with an animal you become ill (fever or other sign of infection) you should inform your physician about your animal exposure. Be sure that you have information regarding the species, the company from which the animals were obtained from, the date they were acquired, how you were exposed to the animal, and your exposure time to the animal. This information will accelerate the diagnosis time of the diseased condition and application of treatment if necessary.

A person can minimize the potential health hazards identified above by being knowledgeable and behaving responsibly. In general, maintaining cleanliness in routine tasks and washing your hands after all procedures will decrease your risk of infection. The following steps outline proper techniques which will minimize your risk of an infection following exposure to an animal:

1. Wear the proper PPEs; at minimum, gloves, eye protection, and a lab coat.
2. After working with animal tissue, clean all supplies and your work area with either a 70% ethanol solution or a 10% bleach solution.
3. Dispose of all tissues in specially designated containers.
4. Wash your hands!

Inhalation Anesthetics Hazards.
Following PACUC guidelines, some animals may be maintained under general anesthesia with isoflurane. Isoflurane is a halogenated anesthetic gas. If this gas is not properly controlled in a well-ventilated room it can pose as a potential hazard to anyone within the vicinity of the anesthetic. Symptoms of exposure to isoflurane include dizziness, nausea, and fatigue. Exposure to isoflurane can lead to sterility, miscarriages, birth defects, cancer, and liver and kidney disease. The BME animal technical staff take great care in maintaining the machines that deliver anesthesia to the animal to prevent accidental exposure to isoflurane. However, due to the extreme nature of this anesthetic all individuals that are pregnant or suspect that they are pregnant will not be allowed into the surgical suite during the demonstrations. If you are pregnant or suspect to be pregnant please contact the faculty mentor in charge of the course for direction.

Physical hazards.
In this class you will be using sharps such as scalpel blades and needles. To control the risk with using a sharp, care must be given during handling. Prior to using a sharp you will be instructed by an instructor as to the safety practices employed in the proper handling of a sharp. In general, sharps are a hazard at all times. Always be aware of your environment to avoid incident with unattended sharps. Accidents can occur during the installation or removal of a scalpel blade. Needles should never be recapped. After use they should immediately be disposed of in a sharps container. Sharps containers are commonly a red plastic bin that displays stickers that say "BIOHAZARD SHARPS CONTAINER". Containers that do not have this type of labeling may not be used for the disposal of a sharp. Improper disposal of a sharp readily leads to a hazardous work environment. If you are unsure as to the proper disposal container for a sharp consult an instructor.

Additional Information:

Animal Exposure Program:
http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/occhealthprogram.php
Care and Use of Animals:

http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/docs/Handbook.pdf
Environmental Health:
www.purdue.edu/rem/eh/eh.htm

Working with hazardous agents: Environmental management (REM) at 494-6371
Biohazard Cleanup (physical facilities) at 494-9999; after 4 pm call police dispatcher at 494-8221

Special Note: The information provided in this handout and throughout the course is designed to keep you safe. Therefore, you will be expected to strictly adhere to the suggested guidelines. Professional and appropriate behavior is required at all times while in the laboratory. Failure to comply with any safety procedures will result in immediate dismissal from the lab for the day and perhaps the revocation of training certification. To ensure understanding of the safety regulations you are required pass the safety quiz with a 100% prior to the commencement of the first lab.

Safety References

1. http://www.labsafety.org
2. http://www.egr.msu.edu/classes/ece480/goodman/docs/safety.pdf