BIOMEDICAL ENGINEERING -- CLASS ORGANIZATION INFORMATION

BME-59500	Preclinical and Clinical Study Design	Summer	2011
Course No.	**Course Name**	**Semester**	**Year**

Course Credit is: Lecture x Laboratory _____ Clinic _____ Other _____

Course Meets: TTH 840 – 1030 am Lab. _____

Clinic _____ Other _____

Instructor-of-Record for this Course: Dr. Lynetta Freeman

Formal Laboratories: No. of Instructors Present _____ No. of Students Present _____

Objectives:

To assist students in building a solid foundation for cutting-edge engineering research. The student will be able to:

1. Recognize the importance of an integrated marketing, regulatory, pre-clinical, and clinical strategy for bringing new medical devices to market
2. Recognize the phase or phases in the product development life cycle when pre-clinical and clinical testing is implemented
3. Appreciate the bioethics concerns in animal and human testing
4. Understand the difference between feasibility, pilot, and pivotal studies and when each is used in product development and marketing
5. Appreciate the role of Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) in evaluation of new medical devices
6. For a sample product, select an animal model or study population, determine appropriate end points for efficacy of treatment, and design an appropriately-powered study to detect differences, if they exist
7. Understand the practical issues of study logistics such as selecting a site or contract research organization, developing timelines and budgets, maintaining communication, documentation and monitoring, and issuing final reports
8. Integrate knowledge to provide input on pre-clinical and clinical study design to other types of products that are not covered specifically in this class.
9. Appreciate the integration of information from preclinical and clinical studies to support marketing claims, clinical outcome, publications, and reimbursement.

Grade in Course is Based on (% for each):

_____	Short Quiz	_____	Oral Reports	_____	Attendance
_____	Hour Exams	100%	Written Reports	_____	Attitude & Motivation
_____	Final Exams	_____	Lab. Perform.	_____	Other _____

Distribution Points for Letter Grades (if Pass-Not Pass Define "C" Level).

97.5 – 100% A+	77.5 - 79.9% C+
92.6 – 97.4% A	72.6 – 77.4% C
90.0 – 92.5% A–	70.0 – 72.5% C–
87.5 – 89.9% B+	69.0 – 69.9% D+
82.6 – 87.4% B	67.0 – 68.9% D
80.0 – 82.4% B–	65.0 – 66.9% D–
	less than 64.9 F

Policy on Academic Dishonesty. [*Academic dishonesty is defined as: Dishonesty in connection with any University activity. Cheating, plagiarism, or knowingly furnishing false information to the University are examples of dishonesty. The commitment of the acts of cheating, lying, stealing, and deceit in any of their diverse forms (such as the use of ghost-written papers, the use of substitutes for taking examinations, the use of illegal cribs, plagiarism, and copying during examinations) is dishonest and must not be tolerated. Moreover, knowingly to aid and abet, directly or indirectly, other parties in committing dishonest acts is in itself dishonest. (*after University Regulations, 1998-99, Part V, Section III-B-2-a, page 47)]

Students found guilty of cheating or academic dishonesty in any form will receive a grade of F for the course.

Also define expected student behavior on 1) writing assignments, 2) laboratory projects, and 3) take-home examinations if utilized in this course.

Completion of class assignments are expected to be the product of individual work unless otherwise specified by the instructor. All students are expected to attend class and to arrive on time. Notification of absence from class should be sent to the professor of record for the course.

Participation in class discussions and in giving feedback to peers is expected of each student.

Policy on Make-up Examinations:

Make-up examinations should be given within seven (7) school days of the student's return. Occasionally, an instructor may permit a student to take the examination prior to the regularly scheduled date.

Current Course Description:

Students will more thoroughly understand 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.

This course is expected to be a CRITICAL thinking class, with students attending, participating in group discussions and each student providing completed written assignments. Grading of the written reports will be from instructor review, based on a rubric which will be discussed during the first class.

Class Schedule:

TTH 8:40 -10:30 am

Recommended Reading:

Will be announced in class

Instructors:

Dr. Andrew Brightman
Dr. Lynetta Freeman
Jennifer Kerr

LECTURE/CLASS SCHEDULE SUMMER 2011

Date	Class	Main Topic	Instructors/Other Events	Assignments Due
June 2	**1**	**FDA's Advice for Pre-Clinical Research with Medical Devices**		
June 7	**2**	**Overview – Biomedical Device Development and Regulatory Pathways; Life Cycle Process**	**Lyn Freeman / Jennifer Kerr**	
June 9	**3**	**The Use of Animals in Biomedical Research Bioethics in Human Clinical Trials; Informed Consent**	**Alan Beck Rick Mattes**	
June 14	**4**	**Preclinical - Animal welfare and animal welfare laws; IACUC – (GLP)**	**Bill Ferner**	
June 16	**5**	**Overview of the US Regulatory Approval Process; Investigational Plan; decision making strategies (GCP)**	**Jennifer Kerr**	**Ethics assignment**
June 21	**6**	**Preclinical Strategies**	**Lyn Freeman**	
June 23	**7**	**Preclinical Device Evaluation**	**TBD**	
June 27	**8**	**Animal clinical trials - experimental design and animal number**	Dr. Moore	**Pre-Clinical Strategy**
June 28 – July 9		**SUMMER BREAK – NO CLASS**		
July 12	**9**	**Preclinical – evaluation strategies: benchtop testing, feasibility, proof of principle, model development; efficacy of therapy, endpoints for device studies**	**TBD**	
July 14	**10**	**Clinical Protocol Design – P1 Study "types" & design; patient populations / sample size/ statistical analysis plans**	**Scott Snyder, PhD**	
July 19	**11**	**Clinical Protocol Design – P2 Endpoints, Hypothesis Testing & Sample Size Calculations Implementation Issues CRFs & Data Management**	**Scott Snyder, PhD**	
July 21	**12**	**Imaging Management for Device Clinical Trials Clinical – Study site selection; IRB; Clinician support; and data collection**	**Anthony Yoder, R.T.(R), Manager of Imaging Management**	**Sample Size Calculations Homework**
July 26	**13**	**Integrating Clinical Study Data into Regulatory Submissions; Local & Global Considerations**	**Aaron Lottes, PhD, RAC Ted Heise, PhD, RAC**	
July	**14**	**Other Considerations:**	**Jennifer Kerr**	

28		**Contracting & budgeting** **Legal & ethical considerations** **Integration with marketing for claim support, promotions, publications, reimbursement**	**Patrick Sullivan, JD**	
Aug 2	**15**	**Bringing it all together:** **Clinical management perspective – protocol enforcement, monitoring, site compliance, protection of subjects** **Support of regulatory initiatives – data analysis & submission**	**Beth Hess, PhD**	
Aug 4	**16**	***No class***		**<u>Final assignment:</u>** **Clinical protocol** **Case Report Form** **Informed Consent Document**