OAKLAND UNIVERSITY
DEPARTMENT OF MATHEMATICS & STATISTICS
STUDENT INFORMATION SHEET AND SYLLABUS

COURSE: BST 5551: Clinical Trials and Ethics in Biomedical Sciences (CRN: 14147)

SEMESTER: Winter 2018

Faculty	Office	Class Time	Room	Phone
Subbaiah Perla	544 MSC	MW 5:30-7:17 p.m.	364 MSC	370-3429

OFFICE HOURS: M W 3.00 - 4.00 p.m. or by appointment.

PREQUISITE: STA 5002, or permission of the instructor.

TEXT: *Clinical Trials: A Methodologic Perspective* by Steven Piantadosi (2017), 3rd edition, published by John Wiley & Sons, Inc.

HOMEWORK: Homework will be assigned regularly. The assignments will be worth 100 points. A final project worth 50 points will be included. Each student will have a different project.

TESTS: There will be a midterm exam (worth 100 points) scheduled for **February 7.** The final exam (worth 150 points) will be on **April 25 (Wednesday) 7.00 - 10.00p.m.**

EMERGENCY CLOSING: If the University is closed at the time of a scheduled test, or examination (for example, because of snow), it will be given during the next class period when the University reopens.

GRADING POLICY: The midterm exam is worth 100 points, the homework assignments worth 100 points, the final project 50 points, and the final exam 150 points. Your course grade will be based upon the percentage of total points you have earned out of all the points available to you. There is no fixed grading scale for this course; a conversion formula from your percentage score to Oakland University grades will be determined at the end of the course. However, the following list shows the lowest possible grade that a given percentage score will earn (the grade may be higher than this): 95%-->4.0, 80%-->3.0, 65% -->2.0, 50%-->1.0. After each test, an indication of class performance on that test and an approximate grade conversion for that test will be announced.

MAKE-UP POLICY: There will be no make-up tests. If you miss a test and present evidence of a valid excuse, your course grade will be determined by giving more weight to the final examination.
ACADEMIC HONESTY: Cheating is a serious academic crime. Oakland University policy requires that all suspected instances of cheating be reported to the Academic

Conduct Committee for adjudication. Anyone found guilty of cheating in this course will receive a course grade of 0.0, in addition to any penalty assigned by the Academic Conduct Committee. Working with others on a homework assignment does not constitute cheating; handing in an assignment that has essentially been copied from someone else does. Receiving help from someone else or from unauthorized written material during a test, or final exam is cheating, as is using a calculator as an electronic "crib sheet."

Important Dates

January 3:	Classes begin 7.30am
January 15:	Martin Luther King Day (no classes)
January 17:	Last day "no-grade" drops
February 17-25:	Winter recess
March 14:	Last day for official withdrawal (W grade)
April 17:	Winter classes end 10:00 PM
April 25:	**Final exam, 7:00 -- 10:00 pm**

TENTATIVE SYLLABUS: (Winter, 2018)

	Date	Chapter	Topics
Jan.	3	1, 2	Preliminaries, Clinical Trials as Research
	8	3	Why Clinical Trials are Ethical
	10	4	Contexts for Clinical Trials
	15		**MLK day (no class)**
	17	5	Measurement
	22	6, 7	Random Error and Bias, Statistical Perspectives
	24	8	Experiment Design in Clinical Trials
	29	9, 10	The Trial Cohort, Development Paradigms
	31	11, 12	Translational Clinical Trials, Early Development and Dose-Finding
Feb.	5	12	Early development and Dose-Finding
	7		**Midterm Exam**
	12	13	Middle Development
	14	14	Comparative Trials
	19		**Winter Recess**
	21		**Winter Recess**
	26	15	Adaptive Design Features
	28	16	Sample Size and Power
March	5	16	Sample Size and Power
	7	17	Treatment Allocation
	12	18	Treatment Effects Monitoring
	14	19, 20	Counting Subjects and Events, Estimating Clinical Effects
	19	20	Estimating Clinical Effects
	21	21	Prognostic Factor Analyses
	26	22, 23	Factorial Designs, Crossover Designs
	28	24	Meta-Anlyses
April	2	25	Reporting and Authorship
	4	26	Misconduct and Fraud in Clinical Research
	9		**Project Presentations**
	11		**Project Presentations**
	16	Review	
	18	---	
	23	---	
	25		**Final Exam (7.00pm)**

Final Exam: April 25, Wednesday, 7.00-10.00 p.m.

Additional References:

1. L. M. Friedman, C. Furberg, and D. L. DeMets (2015) Fundamentals of Clinical Trials, 5th edition, Springer, New York.
2. Shein-Chung Chow, and Jen-Pei Liu (2004) Design and Analysis of Clinical Trials, 2nd edition, Wiley & Sons.

BST 5551
Winter '18

Student Name :   _____

Program: _____

Stat. courses taken: _____

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Math. Courses taken: _____

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Company: _____

Tel. No: _____

email address: _____