CTSC 5600: Statistics in Clinical Research (2 Credits)
July 16 – September 21, 2010

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MCR: Verna Hoverman, (77)4-5595

Textbook: Moore, DS, McCabe, GP & Craig, BA, Introduction to the Practice of Statistics,
6th Edition. New York: WH Freeman, 2009. Paperback copies with CD are
available for purchase at Mayo Bookstore, Plummer 11. Cost is $116.56 after
10% discount (no tax). A hardcover copy with CD can also be obtained from the
Bookstore for $126.86 after 10% discount.   Scholars in Florida or Arizona may
call the bookstore at (77)**4-2279**.   Please allow at least 5 days for delivery.

Audience: No prior statistics knowledge will be assumed. Knowledge of basic algebra
concepts is required. This course is sufficient for Certificate students; Master's
scholars must also enroll in CTSC5601-Utilizing Statistics in Clinical Research to
fulfill the introductory statistics requirement.

Last Registration Date: Friday, July 23, 2010

Last Withdrawal Date: Monday, August 16, 2010

Course Description: This course introduces basic statistical methods used in a variety of clinical
study designs. Course materials use published or ongoing clinical research
studies and emphasize statistical reasoning and concepts. General concepts
covered are exploratory data analysis, descriptive statistics, estimation, and
inference. Statistical techniques covered are those for comparing
counts/proportions, for comparing means, and for comparing diagnostic tests.
Coverage of each statistical technique includes identifying what research

questions it can address, verifying that assumptions are adequately met, and identifying the limitations of the conclusions.

Objectives: To provide a broad overview of basic statistical concepts, reasoning, and methods. In particular, the primary goals for this course are to help you to develop:
- the ability to interpret the results of a variety of basic statistical techniques, including both exploratory and inferential methods;
- the ability to recognize, define, and differentiate fundamental concepts of statistics, such as variability, distribution, association, causation, sampling, experimentation, confidence, and significance;
- tools to determine appropriate statistical methods for different types of data and study designs; and
- a critical perspective with which to assess and defend statistical arguments such as those in scholarly publications.

Course Format: Before the Course:
The course website includes a folder of tasks to be completed before the course begins. These are a combination of pre-course assessments and tools to help you learn to navigate Blackboard. In addition, you will be asked for information to include in a course directory which will be available to all course participants.

Modules:
The course is organized into seven modules with new content, as well as a short review module prior to each course examination.

Website:
It is anticipated that a great deal of discussion regarding this course will take place online. Students should access the website once each week **at the absolute minimum**. Students are encouraged to ask questions online in the appropriate thread. Students are also encouraged to answer or discuss each other's questions. A TA or instructor will correct invalid answers.

Practice Quizzes
In each module, three practice quizzes will be available within Blackboard. These are not required; you may do as many or as few of them as you prefer.

Evaluation: Individual Homework:
There will be seven individual homework assignments (one for each module). You may not work with other students on homework assignments. Your homework grade will be based on your top 5 homework scores.
These individual homework assignments will be completed in Blackboard. You may resubmit your answers until the due date. **Homework is always due by 11:00 p.m. Central Time on the evening of the date indicated**. You must start the assessment by this time. In case of technical difficulties, we will accept submissions completed by 800 a.m. the morning after the assessment is due. Please use this syllabus as the guide for all due dates. Scores will not be available until after text-based questions have been reviewed and graded, so you should plan to read the answer key carefully. Comments specific to your

answers to the text-based questions will be provided when graded, and should be helpful to you.

Calibrated Peer Review:
There will be two Calibrated Peer Review (CPR) assignments, during Modules 4 and 6. These will be graded as pass/fail (completed or incomplete). These are worth 5 points each within Homework 4 and Homework 6. More information on CPR will be provided during M1T1 and at the time of each assignment.

Required Quiz:
The practice quizzes (above) are optional; in addition to these there will be one required quiz during Module 7. The required quiz will be graded as pass/fail (completed or incomplete). You will be provided feedback for this quiz.

Exams:
There will be one midterm exam and one final exam. The final exam is cumulative, although more questions will pertain to the latter half of the course. Exams are given in person and are open book and open notes. There will be an optional question and answer (Q&A) session prior to each exam; see the next section for details. If you need any necessary special arrangements for an exam, you must notify Verna Hoverman **at least two weeks prior to the exam**.

In person course components:

	Date	Time	Location
Introductory Lecture (M1T1)	**(This lecture will be webcasted and available online approximately the following day)**		
Arizona	Fri.July 16	8:30-9:30 Pacific	MC LC58A
Florida	Fri. July 16	11:30-12:30 Eastern	DV_187W
Rochester	Fri. July 16	10:30-11:30 Central	Mathy Lecture Hall, Gonda 2-101
Face-to-Face Q+A Session for Midterm Exam*			
Arizona	Th. August 12	12:00-2:00 Pacific	Johnson 3-303
Florida	Th. August 12	3:00-5:00 Eastern	BI 127A
Rochester	Th. August12	2:00-4:00 Central	Plummer 3-25B
Midterm Exam			
Arizona	Fri. August 13	8:30-11:30 Pacific	C00E-23
Florida	Fri. August 13	TBD Eastern	TBD
Rochester	Fri. August 13	10:30-1:30 (A-L) or 2:00-5:00 (M-Z) Central	Generose M-101A&B, St. Mary's

*Face-to-Face Q+A Session for Final Exam**			
Arizona	Mon, Sept 20	12:00-2:00 Pacific	MC LC58A
Florida	Mon, Sept 20	3:00-5:00 Eastern	DV_187W
Rochester	Mon, Sept 20	2:00-4:00 Central	Plummer 3-25B
Final Exam			
Arizona	Tues, Sept 21	8:30-11:30 Pacific	C00E-23
Florida	Tues, Sept 21	TBD Eastern	TBD
Rochester	Tues, Sept 21	10:30-1:30 (A-L) or 2:00-5:00 (M-Z) Central	Generose M-101A&B, St. Mary's

* Sessions in italics are optional.

Course Grade:
The final score will be a weighted average of each component of the course work.   Grades will be based on the instructor's sense of the level of understanding represented by the total score.
The weights are as follows:
   6% Participation
   4% Module 7 required quiz (pass/fail only)
   25% Individual homework assignments (top 5 only) – includes grades for the
        2 CPR assignments
   30% Midterm exam
   35% Final exam

Calendar (tentative – subject to change)						
Module	**Module Dates**	**Module Content**	**Topic**	**Topics**	**Reading Text Sections**	**Assignments**
1	Fri, July 16 - Th, July 22	**Summary Statistics and Graphing**	1	Introduction to Course		
			2	Types of Data	Chapter 1, Introduction. pp. 1-5 Design of Experiments, pp. 178-188 Sampling Design, pp. 197-207 Toward Statistical Inference, pp. 212-220	
			3	Graphical/Numerical Summaries	Displaying Distributions with Graphs, pp. 6-17 Describing Distributions with Numbers, pp. 30-47	
			4	Normal Distribution	Density Curves & Normal Distributions, pp. 53-70 Random Variables, pp. 258-266 Inference for the Mean of a Population, pp. 418-420	**HW1 Due Fri, July 23 11:00 p.m. Central Time**
2	Fri, July 23 - Mon, Aug 2	**Confidence Intervals for Continuous Outcomes**	1	Central Limit Theorem; Standard Error of the Mean	Sampling Distributions, pp. 214-220 Sampling Distribution of a Sample Mean, pp. 335-344 Mean of a Random Variable, pp. 270-276	
			2	Confidence Interval of a Mean	Estimating with Confidence, pp. 356-364 The One-Sample t Confidence Interval, pp. 420-422	
			3	Confidence Interval for a Difference of Two Means: Independent Groups	The Two-Sample t Confidence Interval, pp. 454-466	
			4	Confidence Interval for a Difference of Two Means: Paired Groups	Matched Pairs Design, pp. 189-191 Matched Pairs t Procedure, pp. 428-433	**HW2 Due Tues, Aug 3 11:00 p.m. Central Time**

3	Tues Aug 3 - Mon, Aug 9	**Confidence Intervals for Binary Outcomes**	1	Confidence Interval of a Proportion	Sampling Distributions for Counts & Proportions, pp. 311-331 Inference for a Single Proportion, pp. 488-491 Confidence Intervals Provide Additional Information, p. 496-497	
			2	Notation for Proportions		
			3	Comparing Two Proportions (Cohort and Cross-Sectional Studies)	Comparing Two Proportions, pp. 505-509 Relative Risk, pp. 515-516	
			4	Comparing Two Proportions (Case-Control Study)		**HW3 Due Tues, Aug 10 11:00 p.m. Central Time**
Review 1	Tues, Aug 10 - Fri., Aug 13			Review		
	Th, Aug 12			*Optional Live Q & A Session*		
	Fri, Aug 13			**Midterm Exam**		
4	Sat, Aug 14 - Fri., Aug 20	**Introduction to Hypothesis Testing**	1	Hypothesis Testing 1	Test of Significance, pp. 372-389 Inference as a Decision, pp. 406-410	
			2	Hypothesis Testing II	Use & Abuse of Tests, pp. 394-398	**CPR Due Fri, Aug 20 11:00 p.m. Central Time**
			3	Sample Size and Power	Choosing the Sample Size, pp. 364-367 Power & Inference as a Decision, pp. 401-405 The Power of the t-Test, pp. 433-435	

			4	Single Sample t-Test	The t Distributions, pp. 418-420 The One-Sample t Test, pp. 422-428 Robustness of the t Procedures, pp. 432-433 The Two-Sample t Significance Test, pp. 451-454	**HW4 Due Sun, Aug 22 11:00 p.m. Central Time**
5	Sat, Aug 21 - Tues, Aug 31	**Hypothesis Testing for Continuous Outcomes**	1	Paired t-Test Wilcoxon Sign-Rank Test	Matched Pairs t-Procedures, pp. 428-431 Online15.2, 15-17, 15-20, 15-21	
			2	Unpaired t-Test Wilcoxon Rank Sum Test	The Two-Sample t Procedures, pp. 450-451 The Two-Sample t Significance Test, pp. 451-454 Robustness of Two-Sample t Procedures, p. 456 Inference for Small Samples, p. 457 Software Approx. for Degrees of Freedom p, pp. 460-461 The Pooled Two-Sample t Procedures, pp. 461-466	
			3	Analysis of Variance; Multiple Comparisons	Inference for One-Way ANOVA, pp. 638-654 Comparing the Means, pp. 655-665	
			4	Kruskal-Wallis Test	Online 15.3, 5-26 to 15-28	**HW5 Due Wed, Sept 1 11:00 p.m. Central Time**
6	Wed, Sept 1 - Fri, Sept 10	**Hypothesis Testing for Categorical Outcomes**	1	Assessing a Single Proportion	Significance Test for a Single Proportion, pp. 493-496	
			2	Chi-Square Test of Independence	Inferences for Two-Way Tables, pp. 525-534 Formulas & Models for Two-Way Tables, pp. 536-545	
			3	Fisher's Exact Test		

			4	McNemar's Test		**CPR Due Fri, Sept 10 11:00 p.m. Central Time**
			5	Chi-Square Test of Goodness of Fit	Goodness of Fit, pp. 545-548	**HW6 Due Sun, Sept 12 11:00 p.m. Central Time**
7	Sat, Sept 11 - Fri, Sept 17	**Time-to-Event Data and Agreement**	1	Time-Dependent Data: Survival Curves Comparison of Survival Curves Kappa Test; Bland-Altman Plot		**HW7 Due Fri, Sept 17 11:00 p.m. Central Time**
Review 2	Sat, Sept 18 - Tues, Sept 21			Review		
	Mon, Sept 20			*Optional Live Q & A Session*		
	Tues, Sept 21			**Final Exam**		