

**Course Title: Biostatistical Methods for Clinical Research III**  
**Course Number: Biostatistics 209**  
**Spring 2019**

**A. Objectives**

This is the third course in a statistics sequence, covering multi-predictor regression methods in survival and repeated measures outcome data. Emphasis is on the practical and proper use of statistical methodology and its interpretation. The statistics package **STATA** will be used throughout the course.

At the end of the course, students will be able to:

- Conduct a Cox proportional hazards analysis for survival data
- Undertake a data analysis with repeated measures outcome data
- Perform and write up the results of a data analysis for class discussion

**B. Prerequisites**

Designing Clinical Research (Epi 202), Biostatistical Methods II (Biostat 208), and possession of a M.D., Ph.D., D.D.S. or Pharm.D. or equivalent doctoral degree. Exceptions to these prerequisites may be made with the consent of Dr. Huang, space permitting.

**C. Faculty**

|                  |                                                                                                             |
|------------------|-------------------------------------------------------------------------------------------------------------|
| <b>Course</b>    | Chiung-Yu Huang, Ph.D.                                                                                      |
| <b>Director:</b> | Email: <a href="mailto:ChiungYu.Huang@ucsf.edu">ChiungYu.Huang@ucsf.edu</a>                                 |
| <b>Lecturer:</b> | Chuck McCulloch, Ph.D.<br>Email: <a href="mailto:Charles.McCulloch@ucsf.edu">Charles.McCulloch@ucsf.edu</a> |
| <b>TA:</b>       | Kristina Van Dang, MPH<br>Email: <a href="mailto:kristina.dang@ucsf.edu">kristina.dang@ucsf.edu</a>         |
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## D. Format

|                                 |                                  |                         |
|---------------------------------|----------------------------------|-------------------------|
| 1. Lectures:                    | Tuesdays (Through 5/14/19) & 5/2 | 10:30 to 12:00, MH 1400 |
| 2. Labs:                        | Thursdays (Through 5/16/19)      | 10:30 to 12:30, MH 1400 |
| 3. Homework Reviews:            | <u>4/16/19 &amp; 5/2/19</u>      | 12:00 to 1:00, MH 1400  |
| 4. Projects Due:                | <b>5/23/19 by 5pm</b>            |                         |
| 5. Data Analysis Presentations: | May 28 and June 4, 2019          | 10:00 to 1:00           |
|                                 | May 30 and June 6, 2019          | 10:30 to 1:00           |

## E. Textbook

Regression Methods in Biostatistics by Vittinghoff, Glidden, Shiboski and McCulloch. **2<sup>nd</sup> Edition.**

## F. Grading

Grades will be based on **5** homework assignments (70%) and a data analysis project (30%, **due on 5/23/19**).

**Late work is not accepted.**

**G. Syllabus** (for updates, please see <https://courses.ucsf.edu/course/view.php?id=5577>)

| Date/Time | Faculty | Title/Content                                                                                                                                                     | Reading & Assignment                                                                |
|-----------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
|           |         |                                                                                                                                                                   | Useful to review<br>Chapter 3.5 in advance                                          |
| 4/2/19    | Huang   | <b>Survival Data</b><br><i>Survival data, hazards functions, hazard ratios, basics of the Cox model</i>                                                           | Chapters 6.1-6.2.4, VGSM<br>Assignment: Homework #S1<br>Due: 04/16/19 by 10.30 am   |
| 4/9/19    | Huang   | <b>Survival Data</b><br><i>Cox model with binary, categorical and continuous predictors; confounding, mediation and interaction; adjusted survival curves</i>     | Chapters 6.2.5-6.2.13 VGSM<br>Assignment: Homework #S2<br>Due: 04/23/19 by 10.30 am |
| 4/16/19   | Huang   | <b>Survival Data</b><br>Extensions and Diagnostics for the Cox Model:<br><i>time dependent covariates; stratified Cox model; model checking for the Cox model</i> | Chapters 6.3-6.5, VGSM                                                              |

|          |           |                                                                                                                                                      |                                                                                                                 |
|----------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| 4/23/19  | McCulloch | <b>Repeated Measures Data</b><br><i>Introduction to repeated measures data; correlation structures</i>                                               | Chapter 7.1-7.3, VGSM<br>Assignment: Homework #R1<br>Due: 05/14/19 by 10.30 am                                  |
| 4/30/19  | Huang     | <b>Common Biostatistical Problems</b><br><i>Misinterpretation of p-values; estimates and confidence intervals.</i>                                   | 1 or 2 journal articles, TBA<br>Assignment: Homework #C1<br><b>Due by and will be discussed 10.30 am 5/2/19</b> |
| 5/2/19   | Huang     | <b>Common Biostatistical Problems and Competing Risks Survival Analysis</b><br><i>Discussion of readings. Competing risks and Fine-Gray modeling</i> |                                                                                                                 |
| 5/7/19   | McCulloch | <b>Repeated Measures Data</b><br><i>Fixed and random factors; prediction; Stata's XTMIXED and XTGEE, model checking</i>                              | Chapter 7.4-7.6, VGSM<br>Assignment: Homework #R2<br>Due: 05/21/19 by 10.30 am                                  |
| 5/14/19  | McCulloch | <b>Repeated Measures Data</b><br><i>Generalized linear models; non-normal outcomes; robust standard errors; use of nonlinear link functions</i>      | Chapter 7.7-7.9, VGSM                                                                                           |
| 5/28-6/6 | Various   | <b>Project Presentations</b><br>5/28 and 6/4 (Tuesdays 10:00 AM to 1:00 PM)<br>5/30 and 6/6 (Thursdays, 10:30 AM to 1:00 PM)                         |                                                                                                                 |