

**BIostatistics 699**  
**DESIGN AND ANALYSIS OF BIostatistical INVESTIGATIONS**

Winter Term 2020  
Tu, Th 1:00pm - 3:00pm

**Instructors:**

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**Office hours**

Mike: 4:30-5:30pm, Tuesday; 2-3pm, Wednesday  
Jeremy: 5-6pm, Tuesday; 10-11am, Thursday  
Phil: 1-2pm, Monday; 10am-11am, Friday

**Location:** 3755 SPH I (plus 2750 SPH I & 1755 SPH I when there are student presentations).

**Course Objectives:**

The overall objective of this course is to help the student integrate and apply biostatistical methods presented in Master's level courses. The student will learn to identify the scientific objectives of a study and to develop a statistical strategy appropriate for those objectives. The student will learn to plan strategies for statistical design and analysis and to implement these strategies. The student will integrate methods learned in various courses during the analysis of multi-faceted projects. The student will learn to be aware of problems that arise in study design, power and sample size determination and data collection. The student will learn to communicate through presentation of oral and written reports, and through student and faculty critiques of these reports at both the intermediate and final stages of projects.

**Biostatistics Competencies:**

For MPH students:

- (1) Interpret the results of statistical analysis to public health audience.
- (2) Write scientific reports based on statistical analysis for effective collaboration with public health related scientists in epidemiology, health management and policy, environmental health sciences, nutrition, and health behavior and health education.

For MS students:

- (1) Interpret the results of statistical analysis in a variety of health-related areas (e.g. public health, medicine, genetics, biology, psychology, economics, management and policy, nursing, or pharmacy) for the broad scientific community.
- (2) Communicate statistical analysis through written scientific reporting for public health, medical, and basic scientists, and/or educated lay audiences.

For PhD students:

- (1) Communicate through written and oral presentation based on statistical analysis for audience from a variety of health-related areas (e.g. public health, medicine, genetics, biology, psychology, nursing, or pharmacy) and for the broad scientific community.

**Organization of Class:**

See the current draft schedule on Canvas.

The 4 hours per week will be divided among:

- 1) Presentation and initial discussion of projects (led by faculty or visiting presenters).
- 2) Presentation of intermediate and final results of projects (led by students).
- 3) Discussion of problems that arise in the design and analysis of biostatistical investigations (led by faculty).
- 4) Presentation and discussion of journal articles with statistical applications (led by students).
- 5) Discussion of topics in statistical methodology (led by faculty).

Students will be expected to:

- 1) Present intermediate and final written and oral reports of analyses.
- 2) Read, critique, and discuss journal articles selected by faculty.
- 3) Actively participate in classroom discussions of projects and articles.

### **Journal Article Presentation and Discussion:**

Three times during the semester (2/18, 3/26, and 4/14), we will use half of our class time (~55 minutes) on journal article presentations and discussions. After spending the first half of class together as usual in SPH I 3755, we will split up into thirds as on presentation days. Each room will discuss the same two pre-assigned journal articles using a presentation-discussion format. Every student will take on the role of presenter, discussant, or audience member.

*Responsibilities of presenters:* Instructor-assigned groups of 3-4 students will collectively prepare a powerpoint-style presentation of the journal article, very briefly presenting the background, describing the study design and analysis, and giving the main results and conclusions. Presenters should work together as a group to prepare a single presentation requiring 10-15 minutes.

*Responsibilities of discussants:* The discussants will carefully and thoroughly read the article so as to be sufficiently equipped to engage with the presenters on the journal article. As appropriate, discussants should critique the appropriateness of the statistical analysis for the primary hypotheses of interest in the paper and the statistical soundness or limitations of the findings in the article. Discussants may work together in preparation, but each should be independently prepared to contribute to the discussion, which will be 10-15 minutes.

*Responsibilities of audience member:* Those students who are not assigned to either of the above roles are considered 'audience members' and should read the article in advance so as to be able to meaningfully follow and, as appropriate, contribute to the discussion.

Throughout the semester every student will be a *presenter* exactly once and a *discussant* exactly once, otherwise being an *audience member*.

### **Projects:**

There will be five projects throughout the semester. Note that due to time constraints, successive projects will overlap slightly with each other. Each project will span 7-8 class periods and will have the following timeline:

- (a) A scientific investigator with little or no formal statistical training will attend class and introduce the scientific objectives for the project. During this presentation and later class periods, students are expected to ask questions in order to develop a relevant statistical approach for the project and to collaborate with the scientist in the definition and formalization of the statistical objectives of the project. The scientific investigator will be available for questions

at the initial presentation; the instructors will act as the scientific investigator in subsequent class periods.

(b) About 3-4 class periods later, half of the students will give a 7-8 minute **interim** presentation covering the preliminary stages of their investigation with slides formally created with Microsoft PowerPoint, LaTeX, or other software. This interim report will include a description of the problem, objectives, hypotheses, models (equations), proposed tables and diagnostics, an interim report of analyses already performed, and any identification of questions that may have been raised by the analysis. Each student giving an interim presentation must turn in a copy of their oral report to the instructors. All students are expected to thoroughly discuss the issues raised in each presentation.

(c) About 3-4 additional class periods later, the remaining half of the students will give a 7-8 minute **final** presentation with slides formally created with Microsoft PowerPoint, LaTeX, or other software and will provide a copy of this presentation to the instructors.

(d) All students, regardless of type of report (interim or final), will hand in a final written report for each project. *Late reports will not be allowed except in special circumstances and with prior approval of the instructors.*

(e) Students will work individually on Projects 1-4, and students will work in pairs assigned by the instructors for Project 5. Oral presentations and written reports are required for Projects 1-4, while Project 5 will require each pair of students to produce a single **poster** that updates and combines their results from one of the earlier projects. The posters will be presented on the final day of class.

(f) Written reports are to be printed double-spaced and are limited to a maximum of six pages of text (excluding tables and supporting output). Reports and computer output must be produced on a laser or Xerox printer using a clean dark font. The written report should use language appropriate for a medical journal (e.g. NEJM) and should include the following:

- 1) **Title**, date, and student identifier (last 4 digits of student id). Student names **must not** be used.
- 2) **Abstract** or executive summary (half page): A summary of the main findings. Abstracts should stand alone, meaning that a reader should be able to understand, at a very high level, the problem, the approach, and the main findings that are subsequently described in the manuscript.
- 3) **Introduction**: A short description of the problem. Students are discouraged from providing extensive literature reviews and can generally depend upon the scientific background provided by the investigator (1-2 paragraphs)
- 4) **Statistical Methods**: This description can include technical language and equations, but they should be provided in the context of the problem and with appropriate interpretation for non-technical readers. It may be appropriate to intersperse the methods with the results section if there are several distinct parts to the analysis. You do not need to include print outs of your code.
- 5) **Results**: May include any of the following: summary statistics of the data, description and interpretation of the fitted models and parameters estimated, the values of estimates, hypotheses tested, relevant inferences (e.g. probabilistic inferences such as confidence intervals,  $p$ -values), and tabular and graphical representation of the results. Appendices should include analysis results documenting the details of your analyses, such as evaluating the validity of the

assumptions or models used in the analysis, even if these details are not included in the written report. Tables and figures that are of major relevance to the main aims of the project should be placed in the main text. Tables and figures that are not directly linked to the main goals of the project should be placed in the Appendix. References in the main report to tables, graphs, and computer output in the Appendix should identify the relevant pages. Tables and graphs should be clearly labeled and numbered but need not be of presentation quality.

- 6) **Conclusions** (1 to 3 paragraphs): Descriptions of the scientific conclusions that can be drawn from the analysis results; unanswered questions needing additional study may be included. This section should directly relate the performed analyses to the scientific question addressed. Try to make this more than just a listing of alternative methods you could have done but didn't have the time to finish

Some examples of do's and don'ts: *Don't describe the four correlation structures for your correlated errors that you decided not to use. Reporting a log-odds ratio of 0.53 without any additional interpretation is unhelpful and not good practice. Plots that show your fitted model are good to put in the main text; residual plots belong in the appendix. Copying and pasting R output directly to table is not helpful to readers. Giving 6 significant digits in tables is rarely necessary and always distracting. Make your column labels informative*

#### Grading rubric for written reports:

Criterion name	Criterion expectations	Points Possible
<b>Abstract / Introduction</b>	<ul style="list-style-type: none"> <li>Does the abstract <u>concisely</u> describe the study question, design, and findings?</li> <li>Does the introduction provide a clear explanation and understanding of the problem and scientific hypotheses?</li> </ul>	5
<b>Statistical methods (application and interpretation)</b>	<ul style="list-style-type: none"> <li>Are the statistical methods and models clearly explained and appropriately applied?</li> <li>Are the statistical analyses focused?</li> <li>Are the results interpreted correctly, clearly explained, and presented in context of the research setting?</li> </ul>	25
<b>Presentation of results</b>	<ul style="list-style-type: none"> <li>Is there an appropriate number of figures and tables in the main text, and are they the "right" ones?</li> <li>Are the figures and tables easy to read and understand?</li> </ul>	5
<b>Conclusion</b>	<ul style="list-style-type: none"> <li>Is there a discussion of the realistic limitations of study design and analysis?</li> <li>Is there discussion of how the findings fit in to the scientific context?</li> </ul>	5
<b>Organization</b>	<ul style="list-style-type: none"> <li>Is the report structured in a logical fashion? Is each paragraph a logical sequence of sentences, and each section should be a logical sequence of paragraphs?</li> <li>Are the tables and figures placed closed to their first reference in the manuscript?</li> </ul>	5
<b>Style and Clarity</b>	<ul style="list-style-type: none"> <li>Is the writing style appropriate to the audience?</li> <li>Are the spelling and grammar correct?</li> </ul>	5
<b>Total</b>		<b>50</b>

**Training in human subject research:**

All students are required to take the UM PEERRS online training available at <http://my.research.umich.edu/peerrs/#requirements>

All students should obtain certification in the following four modules:

**Conflict of Interest**

**Foundations for Research Practice**

**Human Subjects Research Protections**

**Authorship**

All students are required to submit a PDF copy of their certificate of completion on Canvas by **February 3, 2020**. Students not submitting a certificate will not receive a final grade in the course until the certificate is submitted. Failure to comply with the due date may also impact the final grade received.

**Final grade:**

The final grade will be determined by the quality of the oral and written reports and by the participation and leadership of the student in classroom discussions. Both technical content and the presentation of that content are important (e.g. organization and clarity of language). The first project will be down-weighted as it is considered as an initial learning exercise. Active participation in class discussions is important for success in the class.

The following will be considered in the final evaluation:

1. Quality of the technical and statistical aspects of project analyses (approximately 40%).
2. Quality of the written presentations of projects (organization, completeness, clarity, and conciseness) (approximately 40%).
3. Quality of the oral presentation of projects, scientific papers, and discussions, specifically related to identifying and summarizing the major issues (approximately 10%).
4. Class participation (approximately 10%).

**SPH Policy Statement on Academic Integrity:**

The faculty of the School of Public Health believes that the conduct of a student registered or taking courses in the School should be consistent with that of a professional person. Students should show courtesy, honesty, and respect toward faculty members, guest lecturers, administrative support staff, and fellow students. Similarly, students should expect faculty to treat them fairly, showing respect for their ideas and opinions and striving to help them achieve maximum benefits from their experience in the School. Student academic misconduct refers to behavior that may include plagiarism, cheating, fabrication, falsification of records or official documents, intentional misuse of equipment or materials (including library materials), and aiding and abetting the perpetration of such acts. The preparation of reports, papers, and examinations, assigned on an individual basis, must represent each student's own effort. Reference sources should be indicated clearly. The use of assistance from other students or aids of any kind during a written examination, except when the use of aids such as electronic devices, books or notes has been approved by an instructor, is a violation of the standard of academic conduct.

**Student Well-Being:**

SPH faculty and staff believe it is important to support the physical and emotional well-being of our students. If you have a physical or mental health issue that is affecting your performance or

participation in any course, and/or if you need help connecting with University services, please contact the instructor or the Office of Academic Affairs.

Please visit <http://sph.umich.edu/student-life/wellness.html> for information on wellness resources available to you.

### **Student Accommodations:**

Students should speak with their instructors before or during the first week of classes regarding any special needs. Students can also visit the Office of Academic Affairs for assistance in coordinating communications around accommodations.

Students seeking academic accommodations should register with Services for Students with Disabilities (SSD). SSD arranges reasonable and appropriate academic accommodations for students with disabilities. Please visit <https://ssd.umich.edu/topic/our-services> for more information on student accommodations.

Students who expect to miss classes, examinations, or other assignments as a consequence of their religious observance shall be provided with a reasonable alternative opportunity to complete such academic responsibilities. It is the obligation of students to provide faculty with reasonable notice of the dates of religious holidays on which they will be absent. Please visit [http://www.provost.umich.edu/calendar/religious\\_holiday\\_guidance.html](http://www.provost.umich.edu/calendar/religious_holiday_guidance.html) for the complete University policy.

### **Diversity, Equity, and Inclusion (DEI):**

At SPH, our mission to promote population health worldwide is inseparable from our aim to develop more effective and socially just systems for creating and disseminating knowledge. As part of this, we recognize the historical and contemporary expressions of social discrimination globally, and seek to promote and extend opportunities for members of all groups experience such marginalization. We commit to developing the institutional mechanisms and norms necessary to promote the values of diversity, equity, and inclusion, both inside and outside our classrooms. To this end, SPH upholds the expectations that all courses will (1) **be inclusive**, (2) **promote honest & respectful discussions**, (3) **follow multicultural ground rules** and (4) **abide by UM policies and procedures**.

- 1) **Inclusive courses**, are those in which teachers and learners co-create and co-sustain environments that support and encourage all members to participate equitably. See <http://crlt.umich.edu/multicultural-teaching/inclusive-teaching-strategies> for more resources.
- 2) **Honest & respectful** (rather than safe) discussions promote diversity and social justice learning by acknowledging dynamics of oppression and privilege both inside and outside the classroom.
- 3) **Multicultural ground rules** acknowledge diverse experiences in the classroom and offer strategies for holding one another appropriately accountable. See examples from the UM Program on Intergroup Relations and others at <http://ncdd.org/rc/item/1505>.
- 4) **UM policies and procedures** can be found at <http://diversity.umich.edu> with additional resources and instructions for reporting discrimination at <https://sph.umich.edu/diversity-equity-inclusion/resources.html>.