

## Biostat 699: Biostatistical Investigations, Winter 2023

Tuesday/Thursday 1-3pm

### Instructor Information:

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<b>Office Hours</b>	TBD	TBD	TBD	TBD

### Course Objectives:

The overall objective of this course is to help the student integrate and apply biostatistical concepts and techniques 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 biostatistical approaches 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.

### Organization of Class:

See the Canvas for the current course schedule.

The 4 in-class 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. 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. Actively participate in classroom discussions of projects and articles,

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### Projects:

There will be four projects throughout the semester. Projects 1,2, and 4 will involve analysis of data collected as part of studies or experiments, while project 3 is focused on study design. Note that due to time constraints, successive projects will overlap with each other. There will be some variation in the structure and timeline for each project, but most of the projects will span 6-9 class periods.

Projects will have the following structures:

#### **Projects 1, 2 and 4:**

(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) **(Projects 2 and 4 only)** About 3-4 class periods later, half of the students will give an 13 minute **interim** presentation covering the preliminary stages of their investigation with slides formally created using any software. Interim presentations will be given over two days. However, slides should be uploaded to canvas before the first presentation class session begins. This interim presentation 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. All students are expected to be attentive during presentations and participate by asking questions or engaging in discussion. Note: Each student will give an interim presentation for project 2 OR project 4 (not both).

(c) **(Projects 2 and 4 only)** On the last day of the project, students who did not give an interim presentation will give a 7 minute **final** presentation with slides created using any software. Slides should be uploaded to canvas before the presentation class session begins. The final presentation should include a summary of objectives, hypotheses, models, and results. Due to time constraints, final presentations can omit the background of the project.

(d) All students, regardless of type of oral presentation (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) Presentations and reports should all be created individually.

#### **Project 3 (study design):**

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(a) At the beginning of the project, an instructor will present the objective of the project. The instructor may "play the role" of an investigator.

(b) Project 3 will be completed in pairs.

(c) There is no written report for project 3. Students will answer structured questions with supporting figures/tables to be handed in on the first day of final presentations.

(d) During the last two class periods of project 3, all pairs of students will give a 13 minute final presentation. This presentation should cover the objective of the project, the approach taken, and results. Final presentations will be given over two course periods. Slides should be uploaded to canvas before the first presentation class session begins.

### Report Structure

Written reports are limited to a maximum of six pages of text double spaced in 11 point font (excluding tables, figures, and supporting output). The written report should use language appropriate for a medical journal (e.g. NEJM) and should include the following:

- **Title**, date, and student identifier (**The name of the professor whose classroom you were in** and the last 4 digits of student id). **Do not put your name on the title page or use your name in the filename.**
- **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.
- **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)
- **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.
- **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

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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 self-contained and should be clearly labeled and numbered but need not be of presentation quality.

- **Conclusions and Discussion** (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.

For project 1, students will complete a guided report in the form of typed answers to a series of short answer questions corresponding to each element of the report. For projects 2 and 4, students will hand in a more traditional report (but can and are encouraged to look back at the guided questions for direction).

**Grading rubric for written reports:** Each report will be graded by two instructors who each assign a score out of 50 according to the rubric below. The final score is the sum of the two instructor scores and is out of 100.

Criterion Name	Criterion Expectations	Possible Points
<b>Abstract / Introduction</b>	Does the abstract <u>concisely</u> describe the study question, design, and findings?  Does the introduction provide a clear explanation and understanding of the problem and scientific hypotheses?	5
<b>Statistical methods (application and interpretation)</b>	Are the statistical methods and models clearly explained and appropriately applied?  Are the statistical analyses focused?  Are the results interpreted correctly, clearly explained, and presented in context of the research setting?	25
<b>Presentation of results</b>	Is there an appropriate number of figures and tables in the main text, and are they the "right" ones?	5

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	Are the figures and tables easy to read and understand?	
<b>Conclusion</b>	Is there a discussion of the realistic limitations of study design and analysis?  Is there discussion of how the findings fit in to the scientific context?	5
<b>Organization</b>	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?  Are the tables and figures placed closed to their first reference in the manuscript?	5
<b>Style and Clarity</b>	Is the writing style appropriate to the audience?  Are the spelling and grammar correct?	5
<b>Total</b>		50

### 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 two modules:

- Responsible Conduct of Research & Scholarship Training (RCRS)
- Human Subjects Research Protections

All students are required to complete these modules by **January 17, 2023**.

Students will not receive a final grade in the course until the modules are completed. Failure to comply with the due date may also impact the final grade

### Final grade:

The final grade will be determined by the quality of the oral and written reports. Both technical content and the presentation of that content are important (e.g. organization and clarity of language).

The following will be considered in the final evaluation:

1. Project 1 final (guided) report: 15%
2. Project 2 final report: 23%
3. Project 3 final presentation 8%

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- 4. Project 3 question answers: 15%
- 5. Project 4 final report: 23%
- 6. Interim presentation (project 2 or 4): 8%
- 7. Final presentation (project 2 or 4): 8%

### **Participation:**

There are no formal points attached to class participation. However, students are strongly encouraged to take an active role in class discussions. The following are possible avenues for participation:

- a) Asking or answering questions about projects or lecture topics during in-class discussion
- b) E-mailing a question to a professor to be answered publicly in class (questions can be read anonymously if desired).
- c) Posting questions or answers on class discussion boards.

### **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.

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### **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 <https://sph.umich.edu/community/student-experience/health-well-being.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/students> 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

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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**.

- **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.
- **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.
- **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://www.ncdd.org/>.
- **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>.