

University of Florida
College of Public Health & Health Professions Syllabus
PHC 6063: Biostatistical Consulting (3 credit hours)
Wednesday 3:00 pm – 3:50pm; Friday 1:55pm – 3:50pm
Spring: 2022

Delivery Format: Online for the M.S. online program and On-Campus for all others.

Instructor Name: Ji-Hyun Lee and Shu Wang
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Office Hours: Friday, 11:30-12:30
Teaching Assistant: Runzhi Zhang, email: runzhi.zhang@ufl.edu
Preferred Course Communications: email

Prerequisites: PHC 6050c: Biostatistical Methods I; PHC 6051: Biostatistical Methods II; PHC 6937: Introduction to Biostatistical Theory; PHC 6937: Biostatistical Computing.

PURPOSE AND OUTCOME

Course Overview

This course covers fundamental analytical skills, communication techniques, professional roles/responsibilities, and ethical considerations for practicing biostatisticians in health science research. Over the course, we will explore the spectrum of biostatistical consulting via lectures, readings, discussions, written assignments, presentations, and participation in statistical consultations with U.F. investigators.

Relation to Program Outcomes

Successful completion of this course fulfills the consulting requirement of the M.S. and Ph.D. programs in Biostatistics.

Course Objectives and/or Goals

By the end of this course, the students should be able to:

- (1) Fully understand the minimum basic skills required for common collaborative projects.
- (2) Define an effective collaboration model with a researcher.
- (3) Understand the ethical guidelines of biostatistical practices.
- (4) Facilitate discussion and conduct an effective meeting, discerning the overall goal of the investigator, determining specific aims of the proposed project, translating clients' scientific questions of interest into statistical questions, choosing an appropriate statistical method, and defending that choice.
- (5) Understand a research grant and a clinical trial protocol, and the requirements of the analysis section.
- (6) Provide the required sample size, power evaluation, and randomization schedule for various observational and clinical trial designs.
- (7) Write a report of a consulting session and an analysis, prepare publication-quality tables and graphics, and make an oral presentation of results in a reproducible manner.
- (8) Discuss current issues in statistics and data sciences, including reproducibility and statistical significance.

Instructional Methods

Class sessions will combine presentation of major topics, class discussion of the presentations, homework, and additional readings. Students are expected to take an active role in initiating and leading discussions and debates. Participation in statistical consulting sessions with investigators at the University of Florida is also expected.

What is expected of you? You are expected to engage in the course throughout the semester actively. You must come to class prepared by completing all out-of-class assignments. This preparation gives you the knowledge or practice needed to engage in higher levels of learning during the live class sessions. If you are not prepared for the face-to-face sessions, you may struggle to keep pace with the activities occurring in the live sessions, and it is unlikely that you will reach the higher learning goals of the course. Similarly, you are expected to participate in the live class actively. Your participation fosters a rich course experience for you and your peers, facilitating overall mastery of the course objectives.

DESCRIPTION OF COURSE CONTENT

Topical Outline/Course Schedule:

- W- Wendsday (3:00 pm – 3:50pm) F-Friday (1:55pm – 3:50pm)
- The schedule may change depending on the number of enrolled students and group projects.

Week	Date	Topics Covered	
1	1/5 (W)	Review session Part Ia: Introduction to (Bio)statistics	
1	1/7 (F)	Review session Part Ib: Estimation & Hypothesis and Statistical tests I	
2	1/12 (W)	Review session Part IIa: Statistical tests II	
2	1/14 (F)	Review session Part IIb: Clinical trials and Survival analysis	HW1 Due
3	1/19 (W)	Review session Part IIIa: Study designs	
3	1/21 (F)	Review session Part IIIb: Study designs	
4	1/26 (W)	Study design considerations – Randomization	
4	1/28 (F)	Study design considerations – Sample size calculation	
5	2/2 (W)	Ethical guidelines of biostatistical practices and clinical trials. Part I	
5	2/4 (F)	Ethical guidelines of biostatistical practices and clinical trials. Part II	HW2 Due
6	2/9 (W)	Reproducible Issues and Biostatistician's roles	
6	2/11 (F)	Reproducible practice with statistical software	
7	2/16 (W)	Public data usage – SEER (Guest speakers)	
7	2/18 (F)	Public data usage – PATH, TCGA (Guest speaker)	
8	2/23 (W)	Clinical trial protocols/Grant proposals/Manuscripts. Part I	
8	2/25 (F)	Clinical trial protocols/Grant proposals/Manuscripts. Part II	HW3 Due
9	3/2 (W)	Preparation of presentations	
9	3/4 (F)	Midterm exam	
10	3/9 (W)	Spring break	
10	3/11 (F)	Spring break	
11	3/16 (W)	Scientific investigators (Guest speakers)	
11	3/18 (F)	Presentation: Phase I	
12	3/23 (W)	Presentation: Phase I (cont'd)	HW4 Due
12	3/25 (F)	Student presentations of research	
13	3/30 (W)	Student presentations of research	
13	4/1 (F)	Student presentations of research	
14	4/6 (W)	Student presentations of research	
14	4/8 (F)	Student presentations of research	HW5 Due
15	4/13 (W)	Student presentations of research	
15	4/15 (F)	Students' evaluation/discussion for other groups	

16	4/20 (W)	Written report submission	
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Course Materials and Technology

Course information, readings, and grades are available on the Canvas system at <http://lss.at.ufl.edu/>. You must have a Gatorlink account to log on.

Recommended texts are: 1) *Statistical Consulting* by Javier Cabrera and Andrew McDougall; and 2) *Statistical Consulting: A Guide to Effective Communication* by Janice Derr.

For technical support for this class, please contact the U.F. Help Desk at:

- helpdesk@ufl.edu
- (352) 392-HELP - select option 2
- <https://helpdesk.ufl.edu/>

Additional Academic Resources

[Career Connections Center](#): Reitz Union Suite 1300, 352-392-1601. Career assistance and counseling services.

[Library Support](#): Various ways to receive assistance with respect to using the libraries or finding resources.

[Teaching Center](#): Broward Hall, 352-392-2010 or to make an appointment 352- 392-6420. General study skills and tutoring.

[Writing Studio](#): 2215 Turlington Hall, 352-846-1138. Help brainstorming, formatting, and writing papers.

Student Complaints On-Campus: [Visit the Student Honor Code and Student Conduct Code webpage for more information.](#)

Online Students Complaints: [View the Distance Learning Student Complaint Process.](#)

ACADEMIC REQUIREMENTS AND GRADING

Assignments

Projects will be assigned. Attendance and active participation in all class discussions is required, and will be evaluated as part of the student's grade for the course. Students must read the required readings prior to each class session.

Grading

Component	%	Note
Midterm	20%	Close book
Presentation 1	10%	Proposal for a research topic
Presentation 2	10%	Presentation of the research
Final written report	20%	A 5-page report
HW	30%	5 times x 6% each
Course Participation	10%	Attendance as well as discussion

U.F. Canvas Grading Scheme (account: University of Florida)

A	100% to 94%
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A-	< 94% to 90%
B+	< 90% to 87%
B	< 87% to 84%
B-	< 84% to 80%
C+	< 80% to 77%
C	< 77% to 74%
C-	< 74% to 70%
D+	< 70% to 67%
D	< 67% to 64%
D-	< 64% to 61%
E	< 61% to 0%

More information on U.F. grading policy may be found at:

<http://gradcatalog.ufl.edu/content.php?catoid=10&navoid=2020#grades>

Policy Related to Make up Exams or Other Work

Please note: Any requests for make-ups due to technical issues MUST be accompanied by the U.F. Computing help desk (<http://helpdesk.ufl.edu/>) correspondence. You MUST email me within 24 hours of the technical difficulty if you wish to request a make-up.

Policy Related to Required Class Attendance

All faculty are bound by the U.F. policy for excused absences.

Excused absences must be consistent with university policies in the Graduate Catalog (<https://catalog.ufl.edu/graduate/regulations/#text>). Additional information can be found here: <https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>

STUDENT EXPECTATIONS, ROLES, AND OPPORTUNITIES FOR INPUT

Expectations Regarding Course Behavior

Class attendance is mandatory. Excused absences follow the criteria of the U.F. Graduate Catalogue (e.g., illness, serious family emergency, military obligations, religious holidays), and should be communicated to the instructor prior to the missed class day when possible. Missing three or more unexcused scheduled sessions will result in a failure. Regardless of attendance, students are responsible for all material presented in class and meeting the scheduled due dates for class assignments. Finally, students should read the assigned readings prior to the class meetings, and be prepared to discuss the material for each session.

Academic Integrity

Students are expected to act in accordance with the University of Florida policy on academic integrity. As a student at the University of Florida, you have committed yourself to uphold the Honor Code, which includes the following pledge:

“We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honesty and integrity.”

You are expected to exhibit behavior consistent with this commitment to the U.F. academic community, and on all work submitted for credit at the University of Florida, the following pledge is either required or implied:

“On my honor, I have neither given nor received unauthorized aid in doing this assignment.”

It is your individual responsibility to know and comply with all university policies and procedures regarding academic integrity and the Student Honor Code. Violations of the Honor Code at the University of Florida will not be tolerated. Violations will be reported to the Dean of Students Office for consideration of disciplinary action.

For additional information regarding Academic Integrity, please see Student Conduct and Honor Code or the Graduate Student Website for additional details:

<https://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/>

<http://gradschool.ufl.edu/students/introduction.html>

Please remember cheating, lying, misrepresentation, or plagiarism in any form is unacceptable and inexcusable behavior.

Professionalism and COVID

As students pursuing a path in the health professions or public health, it is crucial to demonstrate professional behaviors that reflect integrity and commitment to the health of patients, fellow health professionals, and to populations we serve. To accomplish this, a strong responsibility for the well-being of others must be evident in our decisions, along with accountability for our actions. Professionalism in the health disciplines requires adherence to high standards of conduct that begin long before graduation. This is particularly true during times of health emergencies such as the COVID pandemic, given our professional habits can have a direct impact upon the health of persons entrusted to us.

If you are not vaccinated, get vaccinated. Vaccines are readily available at no cost and have been demonstrated to be safe and effective against the COVID-19 virus. Visit this link for details on where to get your shot, including options that do not require an appointment: <https://coronavirus.uflhealth.org/vaccinations/vaccine-availability/>. Students who receive the first dose of the vaccine somewhere off-campus and/or outside of Gainesville can still receive their second dose on campus.

In response to COVID-19, the following professional practices are in place to maintain your learning environment, to enhance the safety of our in-classroom interactions, and to protect the health and safety of ourselves, our patients, our neighbors, and our loved ones.

- You are required to wear approved face coverings at all times while in Health Science Center classrooms and within Health Science Center buildings even if you are vaccinated.
- If you are sick, stay home and self-quarantine. Please visit the U.F. Health Screen, Test & Protect website about next steps, retake the questionnaire and schedule your test for no sooner than 24 hours after your symptoms began. Please call your primary care provider if you are ill and need immediate care or the U.F. Student Health Care Center at 352-392-1161 (or email covid@shcc.ufl.edu) to be evaluated for testing and to receive further instructions about returning to campus. U.F. Health Screen, Test & Protect offers guidance when you are sick, have been exposed to someone who has tested positive or have tested positive yourself. Visit the U.F. Health Screen, Test & Protect website for more information.
- Continue to follow healthy habits, including best practices like frequent hand washing.
- Avoid crowded places (including gatherings/parties with more than 10 people)

Sanitizing supplies are available in the classroom if you wish to wipe down your desks prior to sitting down and at the end of the class. Hand sanitizing stations will be located in every classroom.

Course materials will be provided to you with an excused absence, and you will be given a reasonable amount of time to make up work. If you are withheld from campus by the Department of Health through Screen, Test & Protect you are not permitted to use any on campus facilities. Students attempting to attend campus activities when withheld from campus will be referred to the Dean of Students Office.

Continue to regularly visit coronavirus.UFHealth.org and coronavirus.ufl.edu for up-to-date information about COVID-19 and vaccination.

COVID-19 Symptoms

See <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html> for information about COVID-19 symptoms, which may include fever, cough, shortness of breath or difficulty breathing, fatigue, chills, muscle or body aches, headache, sore throat, congestion or runny nose, nausea or vomiting, diarrhea, and loss of taste or

smell.

Recording Within the Course:

Students are allowed to record video or audio of class lectures. However, the purposes for which these recordings may be used are strictly controlled. The only allowable purposes are (1) for personal educational use, (2) in connection with a complaint to the university, or (3) as evidence in, or in preparation for, a criminal or civil proceeding. All other purposes are prohibited. Specifically, students may not publish recorded lectures without the written consent of the instructor.

A “class lecture” is an educational presentation intended to inform or teach enrolled students about a particular subject, including any instructor-led discussions that form part of the presentation, and delivered by any instructor hired or appointed by the University, or by a guest instructor, as part of a University of Florida course. A class lecture does not include lab sessions, student presentations, clinical presentations such as patient history, academic exercises involving solely student participation, assessments (quizzes, tests, exams), field trips, private conversations between students in the class or between a student and the faculty or lecturer during a class session.

Publication without permission of the instructor is prohibited. To “publish” means to share, transmit, circulate, distribute, or provide access to a recording, regardless of format or medium, to another person (or persons), including but not limited to another student within the same class section. Additionally, a recording, or transcript of a recording, is considered published if it is posted on or uploaded to, in whole or in part, any media platform, including but not limited to social media, book, magazine, newspaper, leaflet, or third party note/tutoring services. A student who publishes a recording without written consent may be subject to a civil cause of action instituted by a person injured by the publication and/or discipline under U.F. Regulation 4.040 Student Honor Code and Student Conduct Code.

Policy Related to Guests Attending Class:

Only registered students are permitted to attend class. However, we recognize that students who are caretakers may face occasional unexpected challenges creating attendance barriers. Therefore, by exception, a department chair or his or her designee (e.g., instructors) may grant a student permission to bring a guest(s) for a total of two class sessions per semester. This is two sessions total across all courses. No further extensions will be granted. Please note that guests are **not** permitted to attend either cadaver or wet labs. Students are responsible for course material regardless of attendance. For additional information, please review the Classroom Guests of Students policy in its entirety. Link to full policy:

<http://facstaff.php.ufl.edu/services/resourceguide/getstarted.htm>

Online Faculty Course Evaluation Process

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at <https://gatorevals.aa.ufl.edu/students/>. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via <https://ufl.bluera.com/ufl/>. Summaries of course evaluation results are available to students at <https://gatorevals.aa.ufl.edu/public-results/>

SUPPORT SERVICES

Accommodations for Students with Disabilities

If you require classroom accommodation because of a disability, it is strongly recommended you register with the Dean of Students Office <http://www.dso.ufl.edu> within the first week of class or as soon as you believe you might be eligible for accommodations. The Dean of Students Office will provide documentation of accommodations to you, which you must then give to me as the instructor of the course to receive accommodations. Please do this as soon as possible after you receive the letter. Students with disabilities should follow this procedure as early as

possible in the semester. The College is committed to providing reasonable accommodations to assist students in their coursework.

Counseling and Student Health

Students sometimes experience stress from academic expectations and/or personal and interpersonal issues that may interfere with their academic performance. If you find yourself facing issues that have the potential to or are already negatively affecting your coursework, you are encouraged to talk with an instructor and/or seek help through University resources available to you.

- The **Counseling and Wellness Center** 352-392-1575 offers a variety of support services such as psychological assessment and intervention and assistance for math and test anxiety. Visit their web site for more information: <http://www.counseling.ufl.edu>. On line and in person assistance is available.
- **U Matter We Care** website: <http://www.umatter.ufl.edu/>. If you are feeling overwhelmed or stressed, you can reach out for help through the You Matter We Care website, which is staffed by Dean of Students and Counseling Center personnel.
- The **Student Health Care Center** at Shands is a satellite clinic of the main Student Health Care Center located on Fletcher Drive on campus. Student Health at Shands offers a variety of clinical services. The clinic is located on the second floor of the Dental Tower in the Health Science Center. For more information, contact the clinic at 392-0627 or check out the web site at: <https://shcc.ufl.edu/>
- Crisis intervention is always available 24/7 from: Alachua County Crisis Center: (352) 264-6789 <http://www.alachuacounty.us/DEPTS/CSS/CRISISCENTER/Pages/CrisisCenter.aspx>
- **University Police Department:** [Visit U.F. Police Department website](#) or call 352-392-1111 (or 9-1-1 for emergencies).
- **U.F. Health Shands Emergency Room / Trauma Center:** For immediate medical care call 352-733-0111 or go to the emergency room at 1515 SW Archer Road, Gainesville, FL 32608; [Visit the U.F. Health Emergency Room and Trauma Center website.](#)

Do not wait until you reach a crisis to come in and talk with us. We have helped many students through stressful situations impacting their academic performance. You are not alone so do not be afraid to ask for assistance.

Inclusive Learning Environment

Public health and health professions are based on the belief in human dignity and on respect for the individual. As we share our personal beliefs inside or outside of the classroom, it is always with the understanding that we value and respect diversity of background, experience, and opinion, where every individual feels valued. We believe in, and promote, openness and tolerance of differences in ethnicity and culture, and we respect differing personal, spiritual, religious and political values. We further believe that celebrating such diversity enriches the quality of the educational experiences we provide our students and enhances our own personal and professional relationships. We embrace The University of Florida's Non-Discrimination Policy, which reads, "The University shall actively promote equal opportunity policies and practices conforming to laws against discrimination. The University is committed to non-discrimination with respect to race, creed, color, religion, age, disability, sex, sexual orientation, gender identity and expression, marital status, national origin, political opinions or affiliations, genetic information and veteran status as protected under the Vietnam Era Veterans' Readjustment Assistance Act." If you have questions or concerns about your rights and responsibilities for inclusive learning environment, please see your instructor or refer to the Office of Multicultural & Diversity Affairs website: www.multicultural.ufl.edu