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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 serving as consultants and collaborators in health science research. Over the course, we will explore the spectrum of biostatistical consulting via lectures, readings, discussions, written assignments, and presentations as well as participation in statistical consultations with University of Florida Health Science investigators.

Relation to Program Outcomes
Successful completion of this course fulfills the consulting requirement of the MS and Ph.D. programs in Biostatistics.

Course Objectives and/or Goals
By the end of this course, the student should be able to:

1. Problem definition: Describe approaches of establishing an effective collaboration with a researcher or co-investigator.
2. Understanding the ethical guidelines of biostatistical practices.
3. Discovery phase: Facilitate discussion and conduct an effective meeting, discerning the overall goal of the investigator and determining specific aims of the proposed project.
4. Implementation: Translate a client’s scientific questions of interest into statistical questions, chose an appropriate statistical method to address the scientific objectives, and defend that choice by articulating pros and cons of it and alternatives.
5. Explain the outline of a research grant and the requirements of the analysis section.
6. Critique a clinical trial protocol.
7. Provide sample size, power, and randomization schedule for a variety of observational and clinical trial designs.
8. Understand issues with safety and efficacy analyses, interim analyses, multiple endpoints, missing data, and model subset selection.
9. Write a report of a consulting session and an analysis, prepare publication-quality tables and graphics, and make an oral presentation of results.
10. Current issues in statistics and data sciences including reproducibility and statistical significance.
Instructional Methods
Class sessions will be a combination of 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 actively engage in the course throughout the semester. 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 actively participate in the live class. Your participation fosters a rich course experience for you and your peers that facilitates overall mastery of the course objectives.

DESCRIPTION OF COURSE CONTENT

Topical Outline/Course Schedule

<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topics Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1/15</td>
<td>Review session I for consulting</td>
</tr>
<tr>
<td>2</td>
<td>1/22</td>
<td>Review session II for consulting</td>
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<tr>
<td>3</td>
<td>1/29</td>
<td>Review session for study designs</td>
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<tr>
<td>4</td>
<td>2/5</td>
<td>Sample Size Calculations and Randomization</td>
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<tr>
<td>5</td>
<td>2/12</td>
<td>Ethical guidelines of biostatistical practices and clinical trials; Statistics as Profession</td>
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<tr>
<td>6</td>
<td>2/19</td>
<td>Public data usage (SEER, PATH, TCGA) – Guest speakers</td>
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<tr>
<td>7</td>
<td>2/26</td>
<td>Reproducible Issues and Biostatistician’s roles</td>
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<tr>
<td>8</td>
<td>3/5</td>
<td>Clinical trial protocols/Grant proposals-Manuscripts</td>
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<tr>
<td>9</td>
<td>3/12</td>
<td>Midterm exam</td>
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<tr>
<td>10</td>
<td>3/19</td>
<td>Presentation: Phase I (all groups)</td>
</tr>
<tr>
<td>11</td>
<td>3/26</td>
<td>Guest speakers (scientific investigators)</td>
</tr>
<tr>
<td>12</td>
<td>4/2</td>
<td>Student presentations of research (Groups 1 &amp; 2)</td>
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<tr>
<td>13</td>
<td>4/9</td>
<td>Student presentations of research (Groups 3 &amp; 4)</td>
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<tr>
<td>14</td>
<td>4/16</td>
<td>Student presentations of research (Groups 5 &amp; 6)</td>
</tr>
<tr>
<td>15</td>
<td>4/23</td>
<td>Final exam</td>
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</table>

Grading

<table>
<thead>
<tr>
<th>Component</th>
<th>%</th>
<th>Note</th>
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</thead>
<tbody>
<tr>
<td>Midterm</td>
<td>20%</td>
<td>Close book</td>
</tr>
<tr>
<td>Final Exam</td>
<td>20%</td>
<td>Close book</td>
</tr>
<tr>
<td>Presentation 1</td>
<td>10%</td>
<td>Proposal for a research topic</td>
</tr>
<tr>
<td>Presentation 2</td>
<td>10%</td>
<td>Final report of the research</td>
</tr>
<tr>
<td>HW</td>
<td>20%</td>
<td>5 times x 4% each</td>
</tr>
<tr>
<td>Course Participation</td>
<td>10%</td>
<td>Attendance as well as discussion</td>
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</tbody>
</table>
**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 UF Help Desk at:
- Learning-support@ufl.edu
- (352) 392-HELP - select option 2
- https://lss.at.ufl.edu/help.shtml

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**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**

Grades will be based on projects (40%); attendance and leading and participation in discussions (30%); and two homework assignments (30%). All deadlines must be met. Any assignment turned in after the deadline will be penalized, including non-acceptance of the assignment, at the discretion of the instructors. No midterm or final exam will be required in this course.

**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 ticket number received from LSS when the problem was reported to them. The ticket number will document the time and date of the problem. You MUST e-mail 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 UF policy for excused absences. For information regarding the UF Attendance Policy see the Registrar website for additional details:

https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx

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**STUDENT EXPECTATIONS, ROLES, AND OPPORTUNITIES FOR INPUT**

**Expectations Regarding Course Behavior**

Class attendance is mandatory. Excused absences follow the criteria of the UF 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 UF 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.

**Online Faculty Course Evaluation Process**

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at https://evaluations.ufl.edu. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at https://evaluations.ufl.edu/results/.

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**SUPPORT SERVICES**

**Accommodations for Students with Disabilities**

If you require classroom accommodation because of a disability, you must register with the Dean of Students Office http://www.dso.ufl.edu within the first week of class. The Dean of Students Office will provide documentation of accommodations to you, which you then give to me as the instructor of the course to receive accommodations. Please make sure you provide this letter to me by the end of the second week of the course. 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.
- You 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

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.