Term and Year: Spring 2022 **Course Number and Course Title:** GS01 1033 INTRODUCTION TO BIOSTATISTICS AND CLINICAL TRIALS **Credit Hours: 3** **Meeting Location: virtual** **Building/Room#: n/a** **WebEx/Zoom Link: Zoom Meeting ID: 286 800 7249, PWD: 912082**	**Program Required Course:** **X** Yes No **Approval Code:** Yes **X** No **(If yes,** the Course Director or the Course Designee will provide the approval code.) **Audit Permitted:** X Yes No **Classes Begin: January 11, 2002** **Classes End: April 26, 2022** **Final Exam Week: April 26, 2022**

Class Meeting Schedule

Day	Time
Tuesday & Thursday	**4:00 – 5:15 pm**

Course Director
Name and Degree: Suyu Liu, PhD
 	
Title: Assistant Professor
 	
Department: Biostatistics
 	
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Course Co-Director/s: (if any)
 	
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	    Name and Degree: Suyu Liu, PhD
	
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	    Email Address

	4.
	Name and Degree
Teaching Assistant: (if any)	Institution:
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Emily Wang emilywang@rice.edu	
Name and Email Address	5.
	Name and Degree
	Institution:
	Email Address

Course description:

This course provides an overview of statistical methodology useful in the practice of modern biostatistics. There are two major topics covered in the course at an introductory level: biostatistics for epidemiology and clinical trial design. More specific topics are listed in the attached daily syllabus.

Textbook/Supplemental Reading Materials (if any)

- **Statistics for Epidemiology**, by Nicholas Jewell. Publisher: Chapman & Hall/CRC

- **R package (can be downloaded from https://www.r-project.org/)**

Course Objective/s:
This course provides an overview of statistical methodology useful in the practice of modern biostatistics.

*Specific Learning Objectives***:**

1. Understand the basic concepts of experimental design

2. Know the common types of the observational studies and their characteristics

3. Master the basic skills to analyze the disease-exposure association study data

4. Understand the phase of clinical trials and the commonly used designs for each phase5.

Student responsibilities and expectations:

Homework: Each of the two major parts will include approximately 2-3 assignments, at least one of which will be data based. All students are required to complete the assignments. Homework will be submitted at the beginning of class on the due date. If circumstances beyond the student's control arise and an assignment cannot be submitted on the due date, an instructor should be contacted prior to the due date. With an instructor's permission, late homework may be accepted within one week of the due date. All decisions will be made on an individual student basis and the final decision rests with the instructor assigning the homework. **A penalty of 10 percentage points will be applied to late homework.**

Website: http://odin.mdacc.tmc.edu/~yyuan/ has more information about the Biostatistics part of the course and datasets for the homework.

Examinations: There will be three in-class quizzes and one final project in the course.

Course Grade: The material covered in the classroom serves two different course, STAT 453 (undergraduate) and 553 (graduate). Although the lectures will cover the same material for both courses, those enrolled in STAT 553 will be required to answer either additional questions or more challenging questions on the both the homework assignments and in-class quizzes. Although the requirements for the two courses are the same, different grading scales will be applied to the two courses according to their relative level. Both courses will be graded on the following component basis.

Component %
Homework 40
Quizzes and final project 60

Grading System: **X**   Letter Grade (A-F)   Pass/Fail

Student Assessment and Grading Criteria : *(May include the following:)*

Percentage	Description
Homework (40 %)	
Quiz & Final Presentation (60 %)	
Presentation (%)	N/A
Midterm Exams (%)	N/A
Final Exam (%)	N/A
Workshop or Breakout-Session (%)	
Participation and/or Attendance (%)	

CLASS SCHEDULE (see attached)

Disability Statement
Any student with a disability requiring accommodations in this course is encouraged to contact me after class or during office hours. Additionally, students will also need to contact Disability Support Services in the Ley Student Center.

<div align="center">**TENTATIVE DAILY SYLLABUS**</div>

Week	Date		Topic	Readings*	Instructor
1	1/11	Tue	Introduction	SE: 1, 2	Liu
	1/13	Thu	Study Design	SE: 3, 5	Liu
2	1/18	Tue	Disease-Exposure Association	SE: 4	Liu
	1/20	Thu	Contingency Tables: Association	SE: 6	Liu
3	1/25	Tue	Contingency Tables: Confounding	SE: 9	Liu
	1/27	Thu	Contingency Tables: Interaction	SE: 10	Liu
4	2/1	Tue	**Quiz 1**		
	2/3	Thu	Logistic Regression: introduction	SE: 12	Liu
5	2/8	Tue	Logistic Regression: estimation	SE: 13	Liu
	2/10	Thu	*No class*		
6	2/15	Tue	Logistic Regression: diagnosis	SE: 13	Liu
	2/17	Thu	Matched studies	SE: 16	Liu
7	2/22	Tue	Matched studies	SE: 16	Liu
	2/24	Thu	Logistic Regression: introduction	SE: 12	Liu
8	3/1	Tue	TBA		Liu
	3/3	Thu	**Quiz 2**		
9	3/8	Tue	Introduction to clinical trials and		Yua
	3/10	Thu	Bayesian statistics		Yua
10	3/15	Tue	*No class*		
	3/17	Thu	*No class*		
11	3/22	Tue	Introduction to clinical trials and		Yua
	3/24	Thu	Bayesian statistics		Yua
12	3/29	Tue	3+3 design		Yua
	3/31	Thu	CRM and BMA-CRM		Yua
13	4/5	Tue	Bayesian optimal interval design		Yua
	4/7	Thu	Handle Late-onset toxicity		Yua
14	4/12	Tue	Drug combination trials		Yua
	4/14	Thu	Phase I-II trial design		Yua
15	4/19	Tue	Phase II trial design		Yua
	4/21	Thu	**Final project presentation**		Yua
	4/26	Tue	**Final project presentation**		Yua

*SE: Statistics for Epidemiology textbook