NJIT New Jersey's Science & Technology University

THE COLLEGE OF SCIENCE AND LIBERAL ARTS

THE DEPARTMENT OF MATHEMATICAL SCIENCES

MATH 654-102: Design and Analysis of Clinical Trials
Spring 2020 Graduate Course Syllabus

NJIT Academic Integrity Code: All Students should be aware that the Department of Mathematical Sciences takes the University Code on Academic Integrity at NJIT very seriously and enforces it strictly. This means that there must not be any forms of plagiarism, i.e., copying of homework, class projects, or lab assignments, or any form of cheating in quizzes and exams. Under the University Code on Academic Integrity, students are obligated to report any such activities to the Instructor.

COURSE INFORMATION

Course Description: Statistical methods and issues in the design of clinical trials and analysis of their data. Topic include clinical trial designs for phases 1-4, randomization principle and procedures, analysis of pharmacokinetic data for bioequivalence, multi-center trials, categorical data analysis, survival analysis, longitudinal data analysis, interim analysis, estimation of sample size and power, adjustment for multiplicity, evaluation of adverse events, and regulatory overview. Effective From: Fall 2007.

Number of Credits: 3

Prerequisites: Math 665 or equivalent with Departmental approval.

Course-Section and Instructors

Course-Section	Instructor
Math 654-102	Professor W. Guo

Office Hours for All Math Instructors: Spring 2020 Office Hours and Emails

Required Textbooks:

Title	*Clinical Trial Design: Bayesian and Frequentist Adaptive Methods*
Author	Guosheng Yin
Edition	1st
Publisher	Wiley
ISBN #	978-0470581711

ExtraInfo

University-wide Withdrawal Date:The last day to withdraw with a **W** is **Monday, April 6, 2020**. It will be strictly enforced.

POLICIES

DMS Course Policies: All DMS students must familiarize themselves with, and adhere to, the Department of Mathematical Sciences Course Policies, in addition to official university-wide policies. DMS takes these policies very seriously and enforces them strictly.

Grading Policy: The final grade in this course will be determined as follows:

Homework	25%
Project	15%
Midterm Exam	25%
Final Exam	35%

Your final letter grade will be based on the following tentative curve.

A	90 - 100	**C+**	75 - 79
B+	85 - 89	**C**	70 - 744
B	80 - 84	**F**	0 - 69

Attendance Policy: Attendance at all classes will be recorded and is **mandatory**. Please make sure you read and fully understand the Math Department's Attendance Policy. This policy will be strictly enforced.

Exams: There will be one midterm exam held in class during the semester and one comprehensive final exam. Exams are held on the following days:

Midterm Exam	March 23, 2020
Final Exam Period	May 8 - 14, 2020

The final exam will test your knowledge of all the course material taught in the entire course. Make sure you read and fully understand the Math Department's Examination Policy. This policy will be strictly enforced.

Makeup Exam Policy: To properly report your absence from a midterm or final exam, please review and follow the required steps under the DMS Examination Policy found here:

- http://math.njit.edu/students/policies_exam.php

Cellular Phones: All cellular phones and other electronic devices must be switched off during all class times.

ADDITIONAL RESOURCES

Accommodation of Disabilities: Disability Support Services (DSS) offers long term and temporary accommodations for undergraduate, graduate and visiting students at NJIT.

If you are in need of accommodations due to a disability please contact Chantonette Lyles, Associate Director of Disability Support Services at 973-596-5417 or via email at lyles@njit.edu. The office is located in Kupfrian Hall, Room 201. A Letter of Accommodation Eligibility from the Disability Support Services office authorizing your accommodations will be required.

For further information regarding self identification, the submission of medical documentation and additional support services provided please visit the Disability Support Services (DSS) website at:

- https://www.njit.edu/studentsuccess/accessibility/

Important Dates (See: Spring 2020 Academic Calendar, Registrar)

Date	Day	Event
January 21, 2020	T	First Day of Classes
January 31, 2020	F	Last Day to Add/Drop Classes
March 15 - 22, 2020	Su-Su	Spring Recess: No Classes/ University Open
April 6, 2020	M	Last Day to Withdraw
April 10, 2020	F	Good Friday - University Closed
May 5, 2020	T	Friday Classes Meet - Last Day of Classes
May 6 & 7, 2020	W & R	Reading Days
May 8 - 14, 2020	F - R	Final Exam Period

Course Outline

Date	Lecture	Sections	Topic	Assignment
WEEK 1 1/27	1	Lecture Notes	Introduction to Epidemiology	Homework 1
WEEK 2 2/3	2	Chapter 1 and Lecture Notes	Introduction to Clinical Trials	
WEEK 3 2/10	3	Chapter 4 and Lecture Notes	Phase I Clinical Trials	Homework 2
WEEK 4 2/17	4	Chapter 5 and Lecture Notes	Phase II Clinical Trials	
WEEK 5 2/24	5	Chapter 2 and Lecture Notes	Phase III Clinical Trials	Homework 3
WEEK 6 3/2	6	Chapter 7 and Lecture Notes	Randomization	
WEEK 7 3/9	7	Sections 6.1-6.3 Lecture Notes	Sample Size Calculations	Homework 4
WEEK 8 3/16	**SPRING RECESS- NO CLASSES SCHEDULED**			
WEEK 9 3/23	**MIDTERM EXAM: MONDAY ~ MARCH 23, 2020**			
WEEK 10 3/30	8	Section 6.6 and Lecture Notes	Group Sequential Methods (I)	Clinical Trials Project
WEEK 11 4/6	9	Lecture Notes	Group Sequential Methods (II)	Homework 5
WEEK 12 4/13	10	Lecture Notes	Multiple Comparisons Procedures (I)	
WEEK 13 4/20	11	Lecture Notes	Multiple Comparisons Procedures (II)	Homework 6
WEEK 14 4/27	12	Section 6.7 and	Introduction to Adaptive Design	
WEEK 15 5/4	**STUDENTS' PROJECT PRESENTATION**			

WEEK 16 5/11	**FINAL EXAM: MONDAY ~ MAY 11, 2020**