

CLINICAL TRIALS DESIGN & CONDUCT (CTSC 5102S)

Spring 2024 (3 credits)

Course Syllabus

Course Director

Marc Sturgill, PharmD

Associate Professor and Chair, Department of Pharmacy Practice & Administration

Rutgers Ernest Mario School of Pharmacy (EMSOP)

Director of Education, Clinical Research Center

Robert Wood Johnson Medical School

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Course Times: Tuesdays and Thursdays, 10:30 AM-12:00 PM on Zoom

Course Faculty

Luigi Brunetti, PharmD, PhD, MPH, BCPS, BCGP, Professor, Department of Pharmacy Practice and Administration, EMSOP	Zeba Khan, PhD, Interim Director, Center for Health Outcomes, Policy, and Economics and HOPE Masters Program, and Adjunct Professor, Department of Pharmacy Practice and Administration, EMSOP
Chintan Dave, PharmD, PhD, Assistant Professor, Pharmacy Practice and Administration, Pharmacoepidemiology and Treatment Sciences, Institute for Health Sciences	Fred Kobylarz, M.D., Associate Professor of Family Medicine and Community Health and Co-Director, Geriatric Fellowship Program, RWJMS
Sunanda Gaur, MD, Professor of Pediatrics and Director, Clinical Research Center, RWJMS	L. Nandini Moorthy, M.D., Associate Professor of Pediatrics, RWJMS
Tobias Gerhard, BScPharm, PhD, FISPE, Associate Professor, Department of Pharmacy Practice and Administration, EMSOP, and Rutgers Institute for Health, Health Care Policy and Aging Research	Post-Doctoral Fellow, Rutgers (EMSOP) Pharmaceutical Industry Fellowship Program
Elizabeth George, RPh, BCOP, Research Pharmacy Services, Clinical Research Center, RWJMS	

Canvas

A Canvas website will be created for the course. Weekly PowerPoint lectures, the course syllabus, protocol/consent form/IRB application templates, and other relevant course materials will be posted.

Grading

Assignment	Points	Percentage	Final grade
Examinations	300	90-100	A
Class attendance and participation	50	86-89	B+
Total	350	80-85	B
		76-79	C+
		70-75	C
		<70	F

Class will be held each week on Zoom:

Time: Every week on Tue, Thu, at 10:30 AM until Apr 30, 2024

2024 CLASS SCHEDULE

JAN 16	TUE	The FDA and Clinical Trials	Dr. Sturgill
JAN 18	THUR	An Introduction to Trial Design	Dr. Sturgill
JAN 23	TUE	Biostatistical Considerations in Trial Design & Assessment I	Dr. Brunetti
JAN 25	THUR	Biostatistical Considerations in Trial Design & Assessment II	Dr. Brunetti
JAN 30	TUE	Early Phase I (Phase 0) and Phase I Cancer Trials	Dr. Sturgill
FEB 1	THUR	Phase I Pharmacokinetic Trials	Dr. Sturgill
FEB 6	TUE	Bioequivalence Studies	Dr. Sturgill
FEB 8	THUR	Phase II Trials and the Go-No Go Decision	Dr. Sturgill
FEB 13	TUE	Exam 1 (Jan 16 through Feb 6)	
FEB 15	THUR	Phase III Trials	Dr. Sturgill
FEB 20	TUE	Phase IV Trials	Dr. Sturgill
FEB 22	THUR	Informed Consent	Dr. Sturgill
FEB 27	TUE	Large Simple Trials	Dr. Gerhard
FEB 29	THUR	Study Power; Statistical and Clinical Significance	Dr. Sturgill
MAR 5	TUE	Pragmatic Trial Design	Dr. Dave
MAR 7	THUR	Diversity in Clinical Trial Populations	Dr. Gaur
MAR 9-17		SPRING BREAK	
MAR 19	TUE	Exam 2 (Feb 8 through Mar 7)	
MAR 21	THUR	Research in Populations with Additional Protections	Dr. Sturgill
MAR 26	TUE	Non-Inferiority Trials	Dr. Sturgill
MAR 28	THUR	Personalized Medicine and Trial Design	Dr. Sturgill
APR 2	TUE	Post-Marketing Surveillance	EMSOP Fellows
APR 4	THUR	The Research Pharmacy and Clinical Trials	Ms. George
APR 9	TUE	Clinical Trials in Geriatric Patients	Dr. Kobylarz
APR 11	THUR	Regulatory Considerations in Drug Development	EMSOP Fellows
APR 16	TUE	Use of Patient-Centered HRQOL Measures in Clinical Trials	Dr. Moorthy
APR 18	THUR	Interdisciplinary Collaboration in Clinical Trials	EMSOP Fellows
APR 23	TUE	Collaboration between Pharma and Physicians	EMSOP Fellows
APR 25	THUR	Pharmacoeconomic Trials	Dr. Khan
APR 30	TUE	Exam 3 (Mar 19 through Apr 25)	

Attendance policy

Attendance means: The student is present at the beginning of the class. Professional behavior is expected of all students in the classroom. When students leave class during the class it disrupts the learning process.

Students are expected to attend and participate in all class meetings. Absences will affect the final grade as follows. Exceptions will be considered only for students who notify the professor of their need to be absent and the reason for the absence prior to the class for which they will be absent. All work is required whether the student attends class or not.

- One absence: make up the work (Work assigned in class on that day will need to be made up within 2 weeks).

- **Two absences:** 5% will be deducted from the final grade (After the second absence you should make an appointment with the professor to discuss your progress in the course and any difficulties you may be having.)
- **Three absences:** 10% will be deducted from the final grade (The student should consider withdrawing from the class.)
- **Four absences:** The student will receive an F for the course.
- **Excessive lateness** (more than 15 minutes late). Please be on time. Students who arrive late unintentionally disrupt the learning process. Excessive lateness will have an impact on the attendance and participation portion of the grade.
- **Class participation:** Individual participation is a vital part of this class. Successful learning depends on the preparation and participation of each class member. Students are expected to have completed assigned readings prior to class. Students are expected to bring issues from the readings and questions to class for discussion. The class participation portion of the grade will be impacted for students who do not participate weekly in class discussions.
- **Individual consultation:** The professor is available to meet with students for individual consultation throughout the course of the semester. Students who are having difficulty with the course material or assignments should schedule an appointment to see the professor as soon as possible so that additional assistance can be offered as appropriate.

Rutgers Academic Integrity Policy. This course adheres to the Rutgers Academic Integrity Policy (<http://academicintegrity.rutgers.edu>).

Please consult the policy and note that all plagiarism is forbidden. Every Rutgers University student must:

- properly acknowledge and cite all use of the ideas, results, or words of others
- properly acknowledge all contributors to a given piece of work
- make sure that all work submitted as his or her own in a course or other academic activity is produced without the aid of unsanctioned materials or unsanctioned collaboration
- treat all other students in an ethical manner, respecting their integrity and right to pursue their educational goals without interference. This requires that a student neither facilitate academic dishonesty by others nor obstruct their academic progress (taken from: <http://academicintegrity.rutgers.edu/academic-integrity-at-rutgers/>).

Students are expected to follow the guidelines of the American Medical Association or another citation style of your choice (just be consistent). Any material other than one's own that is used in a paper must be properly cited in order to avoid the plagiarism of another's work. **Plagiarism** is grounds for a grade of **F** on the assignment and will be referred to the Dean for further disciplinary action.

Students caught cheating will receive an automatic F for the exam or paper. The student will be referred to the Dean for further disciplinary action.

Class cancellation policy

In the event of a class cancellation, students should check their email for instructions. Students are also required to check for email that may contain detailed class information and instructions.

Email policy

Students are expected to open a Rutgers University email account and provide that account to the

professor. E-mail accounts from other servers will not be accepted.

Cell phone policy

Please place cell phones on silent before the beginning of class. Leaving class to answer a call disrupts the class and detracts from your classroom participation. Emergencies may occur and students may leave class to handle the emergency and to return as soon as possible. If a student must leave the class for the rest of the session because of an emergency, please discuss this with your professor as soon as possible.

Expectations for remote learning via video

- Your VIDEO MUST BE ON ALL CLASS, excepting any scheduled breaks during class sessions. You may use a background and earphones for privacy.
- Sessions may be recorded for attendance and quality assurance purposes. Your attendance in the class is implied as your permission to have the instructor record the class session.
- Recordings of classes will be available in the chat for those who participated in the meeting. These are not to be shared without the permission of the instructor. If you would like access to the link to the video recording, contact the instructor. Access to recordings are not guaranteed and can only be accessed via permission with the instructor. Watching recordings does not take the place of attending class sessions.
- Please MUTE yourself when you are not talking and raise/lower your HAND to speak.
- Feel free to use the chat to ask questions or pose ideas, if you are uncomfortable saying them aloud or want something I have said spelled out in writing. Faculty will not be able to monitor the chat during lectures so questions should be asked verbally. All chat discussion will be recorded and should be appropriate to course content and respectful. Private conversations between students are not appropriate.
- Attendance is required and will count the same as attendance in a live class. Missed participation will be marked as absence.
- Communication with the instructor should be through Rutgers e-mail not online chat, unless it is during class time.
- When you join the meeting, turn your video camera ON and audio off unless your instructor has instructed you otherwise. To do this, click the microphone and video camera sliders so they are both set to off. You must turn the camera and audio on once the class begins.
- Blurring your background is permissible. To blur your background, click the middle slider when you join your meeting. This will open a panel on the right side of the screen with several background options. Pick Blur to obscure details of everything behind you.
- Students should be dressed and prepared for class in the same manner as face-to-face attendance. Students should be at a table (if possible) and dressed appropriately. Students should be facing their cameras. Others should NOT appear in the video screen.
- During remote learning, students should not be doing other work, texting, playing games on their device etc.
- The same confidentiality that applies in the classroom applies online. Maintaining confidentiality regarding issues raised by other students, including personal and professional disclosures, is of utmost importance.