

GSND 5235Q Principles of Clinical and Translational Research in Oncology
Fall 2022

COURSE DESCRIPTION:

Please provide description for your course

Understanding the principles governing the conduct of clinical research in Oncology

COURSE OBJECTIVES:

Please list the course objectives for the course

- Understand the principles of carcinogenesis and systemic therapy of Cancer
- Understand the regulations and processes governing human subject protection
- Understand the different phases of clinical trials
- Understand the statistics of conducting clinical trials
- Understand the drug development process
- Understand other types of clinical oncology research
- Understand the principles of inclusion of underserved populations in clinical trials
- Understand the principles of publishing clinical research

COURSE FORMAT:

Describe the course format (i.e. TBLs, lecture, labs, etc.)

Lectures and home study of human subjects protection.

FACULTY AND STAFF:

Please provide the contact information for the course

Sample Table:

FACULTY	DEPARTMENT	OFFICE	EXTENSION	E-MAIL ADDRESS
Robert Wieder	Medicine	MSB I-506	4871	wiederro@jms.rutgers.edu

COURSE TEXTBOOKS:

Please provide the course textbooks for your course

Optional reference on reserve in Smith Library: Clinical Trials in Oncology. Stephanie Green, Angela Smith, Jaqueline Benedetti, John Crowley. Chapman & Hall/CRC Third Edition 2012 Taylor and Francis Group, LLC, Boca Raton, FL. First Published in Paperback 2016.

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EVALUATION METHODS & COURSE GRADING

Assessment/Evaluation:

Three equally weighted multiple choice exams

Please provide details for course grading (i.e. midterm and final exam, quizzes, etc)

Estimation of Weighted Course Average

Please provide the weighted breakdown for the course

Exam/Quizzes	Weight (%)
Exam 1	33.33
Exam 2	33.33
Exam 3	33.33
Total	100%

Course Grading:

Please provide a grading scale for your course

A, B+, B, C+, C, F

EDUCATION PORTAL AND CANVAS COURSE ACCESS:

The CANVAS course website is an essential part of the Principles of Clinical and Translational Research in Oncology Course. CANVAS can be accessed using the Educational Portal website at <https://ep.njms.rutgers.edu> . The Education Portal provides single sign-on and “one stop shopping” site for various academic systems such as CANVAS, Education Management System, Digital Media Portal, Virtual Microscopy, SOCRATES, etc.

If the Education Portal is unavailable, direct links for CANVAS, NJMS Video, Virtual Microscopy etc., are provided below:

CANVAS: To access all course information log onto CANVAS at: <https://canvas.rutgers.edu/>

PODCAST ACCESS: Webex

WIRELESS ACCESS FOR ELECTRONIC EXAMS (ON CAMPUS EXAMS)

RU Health Sciences is the primary wireless network for SGS however you can use either RU Health Sciences or RU Wireless Secure for electronic exams. Please make sure you can connect to both prior to an exam. See <https://ruwireless.rutgers.edu/ruwireless-secure> for more information. **DO NOT USE RU Wireless.**

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EXAMSOFT SYSTEM REQUIREMENTS:

Note: These requirements will be updated by the SGS Office of Student Affairs and Admissions. The requirements below are from the 2019-2020 Academic year:

EXAMSOFT SYSTEM REQUIREMENTS:

The following laptop requirements are necessary for the School of Graduate Studies

REQUIREMENTS	
Windows	Mac OS
<ul style="list-style-type: none"> • Operating System: 32-bit and 64-bit Versions of Windows 10. Alternate versions of Windows 10 RT and 10 S are NOT supported at this time. • CPU Processor: 2.0 ghz Intel i3 processor or equivalent • RAM = 4 GB or higher • HD (needs at least 1 GB of free space) • 13' screen or larger (Laptops) • Minimum screen resolution of 1024x768 is required with a 32 bit color setting • Virtual machines & applications are not allowed • Surface Pro is allowed (non-pro Surface devices are not allowed) • Tablets are not allowed; nor Chromebooks, netbooks, etc. • For on-site support, a working USB port is required (newer devices may require an adaptor) 	<ul style="list-style-type: none"> • MacOS Catalina (version 10.15) is only compatible with Exemplify version 2.0.6 or higher (Released on 10/14/19 or later)Any server version of Mac OS is NOT supported • 1GHz Intel processor or higher • RAM = 4 GB or higher • HD (needs at least 1 GB of free space) • 13' screen or larger (Laptops) • Minimum screen resolution of 1024x768 is required with a 32 bit color setting • Virtual machines & applications are not allowed • iPads/tablets are not allowed • For on-site support, a working USB port is required (newer devices may require an adaptor)
<ul style="list-style-type: none"> • Microsoft Edge, Internet Explorer • Chrome • Firefox • Do not use beta versions. Other browsers are not supported. 	<ul style="list-style-type: none"> • Safari • Chrome • Firefox • Do not use beta versions. Other browsers are not supported.
Browser Settings - JavaScript Enabled - Cookies Enabled - CSS Enabled - Disable pop-up blockers	Browser Settings - JavaScript Enabled - Cookies Enabled - CSS Enabled - Disable pop-up blockers
Must have Administrator level account permissions.	
Disable Toolbars, Adware or Spyware programs. They may adversely affect the computer's performance and cause delays in loading testing questions.	
If you are using McAfee, you need to turn off Real-Time Scanning.	
Turn off Windows updates or virus scanner updates to avoid interruptions during testing.	
***The following requirements apply for exams with ExamID or ExamMonitor enabled	

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- Exemplify version 2.3.2 or greater
- Hard Drive: 2GB or higher available space
- RAM: 8GB or higher recommended; 4GB required
- Webcam
- Microphone (no headphones!)
- Internet: 2Mbps upload speed

EXAMSOFT EXAMPLIFY LINKS:

Mac : <https://examsoft.force.com/emcommunity/s/article/Exemplify-Minimum-System-Requirements-for-Mac-OS-X>

Windows: <https://examsoft.force.com/emcommunity/s/article/Exemplify-Minimum-System-Requirements-for-Windows>

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ABSENCE FROM COURSE QUIZZES AND EXAMS:

SGS has issued a **MISSED EXAM POLICY** for students enrolled in their programs. Below are the valid excuses for missing a quiz or exam in this course (verbatim from the SGS Exam Policy):

- 1) Significant illness, with official note by doctor, which must include a valid reason for missing the exam. The doctor's note cannot result from a remote (online) diagnosis.
NOTE: Illness prior to the exam ("didn't have time to study") does not constitute a valid excuse, although exceptions can be given by the SGS Associate Dean of Student Affairs if the prior illness has been severe or lengthy.
- 2) Death in the immediate family (parents, siblings, children, grandparents, aunts/uncles, niece or nephew, sister-in-law or brother-in-law, parents-in-law, first-cousins).
Verification, with dates, is required, but this can be a newspaper announcement, event (e.g. wake) announcement, etc.
- 3) Medical/dental school interview, in which the interview or unavoidable travel overlaps with the exam. Copy of the invitation letter.
- 4) Presentation at a meeting. Proof of attendance required.
- 5) More than two final exams on the same day. (NOTE: An exam should not be rescheduled for an individual with two exams on the same day). If a student has more than two exams on the same day, they will need to contact the SGS Associate Dean of Student Affairs, who will contact the course directors about allowing the student to take one of the exams on a different day. The vast majority of schools across the country, including Rutgers New Brunswick, allow up to two final exam in the same day.
- 6) Permission of SGS Associate Dean of Students Affairs, with consultation of course-director. This will be rare, but is meant to account for valid, but unforeseen circumstances.

Each of these reasons will require some form of documentation to be submitted to verify the absence. For the full policy, please follow this link:

http://njms.rutgers.edu/sgs/current_students/docs/new/ExamPolicy.pdf

CODE OF PROFESSIONAL CONDUCT (COURSE EXAMINATIONS):

All students have a fundamental responsibility for maintaining academic integrity and intellectual honesty in their academic and professional endeavors. They are expected to observe generally accepted principles of scholarly work, to submit their own rather than another's work, to refrain from falsifying data, to acknowledge the published work of others in an appropriate manner, and to refrain from receiving or giving aid during examinations or other work requiring independent effort. When submitting written material, students take full responsibility for the originality of all work not otherwise identified by appropriate

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acknowledgments and imply that both the ideas and words used are their own. All students are expected to respect the property of faculty and other students, and not use research equipment or laboratory supplies of others without permission.

Specific examples of appropriate behavior in examinations exams are given below:

Examinations: The purpose of an examination is to assess a student's knowledge of a topic defined within a course or courses. **Unless given explicit written instructions to the contrary, a student must work without assistance on an examination.**

- **Classroom examination:** Each student will provide answers to questions as directed. Unless otherwise stated, no material (books, calculators, computers, communication devices) of any kind can be used during an examination.
- **Take-home examination:** Each student will provide answers as directed. Unless otherwise stated, research and writing must be done individually without assistance or exchange of information with others. The ability to use source material in the research of answers will be defined for each examination. But, unless stated otherwise, all source material should be cited appropriately as outlined below.

NOTE: THESE POLICIES ALSO HOLD TRUE FOR ALL EXAMS ADMINISTERED REMOTELY.

To view the full policy for the Code of Professional Conduct in the School of Graduate studies regarding examinations, research and oral presentations follow this link:

http://njms.rutgers.edu/sgs/current_students/ac_integ.php

ACADEMIC WARNING POLICY:

http://njms.rutgers.edu/sgs/documents/policys/SGS_Academic_Warning_Policy.pdf

Each program shall clearly inform students of the criteria for satisfactory academic performance. Academic standing will be reviewed each semester by the Program's Academic Standing Committee. Students who receive less than an average grade of "B" in the designated Core course(s) or have a GPA less than 3.0 will receive an academic warning notice. Students performing below satisfactory levels of proficiency as outlined by the program may also receive a written warning notice. The written warning states the problem(s), outlines those measures needed for improvement and sets a deadline for compliance. Letters informing students of an academic warning will be sent within 30 calendar days of the end of the semester. A request will be made to students receiving academic warning letters to meet with the Program Director and/or the Academic Standing Committee.

COURSE ADD/DROP POLICY:

Policy for the Addition of a Course:

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Students may add courses with the approval of the instructor (when required) and the program director. A student wishing to add a course after the general registration period has closed, must complete the “Add/Drop/Withdraw” form and have appropriate approval of the course instructor (when required) and program director prior to the start of the course. Registration will not be permitted beyond the first week of a course. Credit will not be given for courses in which the student was not registered.

Add Course Form Link:

<https://na2.docusign.net/Member/PowerFormSigning.aspx?PowerFormId=96fcae95-bc67-45fb-8da3-11300ded2e99>

Policy for Dropping a Course:

Students may drop courses with approval of the instructor (when required) and the program director. Students submitting a completed “Add/Drop/withdraw” form to the SGS Registrar’s office within 10 academic days of the start of the course will receive a full tuition refund and the course will not appear on their official transcript. The drop period of 1-10 *academic days, is distinguishable from the withdrawal period in that the drop period is without penalty. A completed and approved Add/Drop/Withdraw” form(s) must be received by the Registrar’s office within the time periods set forth above in order for a course(s) to be “dropped”.

Drop Course Form Link:

<https://na2.docusign.net/Member/PowerFormSigning.aspx?PowerFormId=c45635ca-6a1e-4936-b436-337b211b8433>

***An academic day is defined as a day that the SGS campus at which the student is enrolled is open for business.**

REASONABLE ACCOMMODATIONS AT RUTGERS SCHOOL OF GRADUATE STUDIES:

Rutgers School of Graduate Studies is committed to providing equitable access to learning opportunities to students with documented disabilities (e.g. mental health, attentional, learning, chronic health, sensory, or physical). To ensure access to this please contact Student Affairs, to engage in a confidential conversation about the process for requesting reasonable accommodations in the classroom setting. Students are encouraged to register with the Office of Student Affairs as soon as they begin their program. Accommodations are not provided retroactively. Rutgers School of Graduate Studies encourages students to access all resources available through the School for consistent support and access to their program.

More information can be found online at

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http://njms.rutgers.edu/education/student_affairs/student_support/disability_services.cfm.

Rutgers University welcomes students with disabilities into all of the University's educational programs. In order to receive consideration for reasonable accommodations, a student with a disability must complete the ODS registration form: <https://webapps.rutgers.edu/student-ods/forms/registration> and contact the RBHS Office of Disability Services at 973-972-5396 or cindy.poorepariseau@rutgers.edu to make an appointment for an intake interview. You will also be asked to provide documentation of your disability:

<https://ods.rutgers.edu/students/documentation-guidelines>.

If the documentation supports your request for reasonable accommodations, the Office of Disability Services will provide you with a Letter of Accommodations. This Letter will be used to notify appropriate school personnel about the accommodations you are qualified to receive. To begin this process, please complete the Registration form on the ODS web site at: <https://webapps.rutgers.edu/student-ods/forms/registration>.

TEACHER-LEARNER POLICY RUTGERS SCHOOL OF GRADUATE STUDIES:

The Rutgers SGS Newark Health Science Campus strongly believes that teaching and learning should take place in a climate of mutual respect where students and faculty are equally responsible for maintaining a professional and collegial environment. An environment where students are evaluated based upon accomplishment, professionalism and academic performance. We are committed to maintaining a positive learning environment and the highest standards of behavior in the teacher-student relationship.

To view the full Teacher-Learner policy for the School of Graduate studies, please follow this link: https://njms.rutgers.edu/sgs/current_students/docs/Teacher%20Learner%20Policy.pdf