



REGS 5210: Advanced Regenerative Medicine and Surgery Spring 2022 Syllabus and Schedule

REGS 5210: Advanced Regenerative Medicine and Surgery

Course Date and Time: June 6-10

Course Location: Virtual/In Person

Course Format: Blackboard/In Person

Blackboard link: <http://eduonline.mayo.edu>

**Use Google Chrome*

Credits: 2

Last Day to Register: May 23rd

Last Day to Withdraw: Wednesday, June 8th

Role	Name	Office	Phone	Email
Course Directors	Saranya Wyles, M.D., Ph.D.	Gonda 16-372	(77) 4-2555	Wyles.Saranya@mayo.edu
	Andre Terzic, M.D., Ph.D.	Stabile 5-60	(77) 4-5514	Terzic.Andre@mayo.edu
	Richard Hayden, M.D.	SP 1-ENT	(79) 2-2890	Hayden.Richard@mayo.edu
Course Contact	Courtney Paradise	Stabile 5-03	(77) 2-5736	Paradise.Courtney@mayo.edu
TA's	Armin Garmany	Stabile 5-48		Garmany.Armin@mayo.edu
	Dileep Monie	Gonda 19-400		Monie.Dileep@mayo.edu
	Eric Grewal	MI 1-25.2		Grewal.Eric@mayo.edu
	Hiba Saifuddin			Saifuddin.Hiba@mayo.edu

**Office hours by appointment.*

PREREQUISITES

REGS 5200: Fundamentals of Regenerative Sciences

COURSE DESCRIPTION

This course strategically encompasses the Principles and Practice of Regenerative Medicine, Regenerative Procedures, the Patient Portal to Clinical-Grade Manufacturing, Bench-to-Bedside Translation, and What Regenerative Medicine Means to You. This course will follow a discovery-translation-application curriculum that encourages students to integrate new knowledge into clinical practice. Interactive online lectures, virtual laboratory demonstrations, clinical highlights, and simulated patient interactions will enrich the content of this course and provide students with a unique experience of regenerative care at Mayo Clinic. This advanced course dives deeper into the regenerative clinical spectrum across various medical and surgical specialties. It focuses on validated clinical solutions and ongoing clinical trials to help adopt and deliver regenerative patient care.

LEARNING OBJECTIVES

At the end of this course, learners will be able to:

Educational Objectives

Successful completion of the two-part graduate school course and medical school selective will enable the students to achieve the following educational goals:

Regenerative Medicine: Principles to Practice

- Recognize patient unmet needs and how regenerative medicine offers a curative paradigm
- Understand the fundamental principles, tools, and platforms of regenerative medicine
- Describe the diagnostic and therapeutic applications of regenerative medicine and surgery
- Engage with the patient population seeking regenerative solutions

Regenerative Procedures

- Understand the challenges to effective delivery of regenerative therapeutics

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- Understand how current techniques are being used to provide regenerative solutions
- Engage in regenerative surgical techniques utilized in clinical trials

Patient Portal to Clinical-Grade Manufacturing

- Understand and demonstrate proficiency in the current practice
- Understand how cells are generated for clinical utilization (cGMP)
- Recognize the process leading to clinical utilization of regenerative therapeutics
- Recognize the current role of regenerative medicine and surgery in patient care

Bench-to-Bedside Translation

- Understand how current ethical issues have influenced the progress of stem cell research
- Recognize the importance of preclinical models for testing feasibility, safety and efficacy of regenerative therapeutics
- Understand the techniques used to deliver cell-based biologics in models of disease

Regenerative Medicine: What does this mean to me?

- Demonstrate an understanding for regenerative medicine and its contribution to meet patient and societal needs
- Learn about how to incorporate regenerative strategies into your clinical training
- Understand the steps to bring discovery into the community through commercialization and outreach

COURSE FORMAT

This course is a one-week selective that will take place in person and virtually through Blackboard. Students can expect to have activities from 9am-3:30pm CST each day. Students will be expected to complete reading and assignments independently.

REQUIRED READING

Students will be expected to read the articles/publications posted in the pre-class assignment section of Blackboard before class each day.

SUGGESTED RESOURCES/REFERENCE MATERIALS

See blackboard for resource/reference materials.

ATTENDANCE & PARTICIPATION

- Students will be expected to take part in the daily small group discussions
- Students will need to participate in the final presentations
- Students will be expected to attend a minimum of three days to receive credit for the course
- Students will be expected to complete a critical clinical trial review

COURSE OUTLINE – SCHEDULE SUBJECT TO CHANGE

- **Monday, June 6th**
 - Atta Behfar, M.D., Ph.D. – Regenerative Medicine Model of Care & Regenerative Cardiology
 - Mohamad Bydon, M.D. – Spinal Cord Regeneration
 - Ian Parney, M.D., Ph.D. – Regenerative Neurosurgical Oncology
 - Samir Mardini, M.D. – Face Transplant: The Ultimate Regenerative Frontier
- **Tuesday, June 7th**
 - Eric Dozois, M.D. – Regenerative Colorectal Surgery
 - Jorge Mallea, M.D. – Regenerative Pulmonology

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- Vijay Shah, M.D. – Regenerative Gastroenterology
- Scott Nyberg, M.D., Ph.D. – Regenerative Hepatology
- LaTonya Hickson, M.D. – Regenerative Nephrology

- **Wednesday, June 8th**
 - David Lott, M.D. – Regenerative Otolaryngology
 - Jeffrey Janus, M.D. – Regenerative Maxillofacial Surgery
 - Daniel Saris, M.D., Ph.D. – Regenerative Orthopedics: Cartilage Repair
 - Rafael Sierra, M.D. – Regenerative Orthopedics: Bone Repair
 - Shane Shapiro, M.D. – Outpatient Musculoskeletal Practice

- **Thursday, June 9th**
 - Alison Bruce, M.B., Ch.B. – Regenerative Dermatology
 - Saranya Wyles, M.D., Ph.D. – Regenerative Wound Healing
 - Steven Moran, M.D. – Regenerative Plastic Surgery
 - Antonio Forte, M.D., Ph.D. – Regenerative Lymphedema Care
 - Leo Maguire, M.D. – Corneal/Ocular Transplantation

- **Friday, June 10th**
 - Saad Kenderian, M.B., Ch.B. – Regenerative Immunotherapy
 - Mauro Schenone, M.D. – Regenerative Fetal Medicine
 - Cassandra Kisby, M.D. – Regenerative Women’s Health

ASSESSMENT OF STUDENT

- There will be a required critical clinical trial review and a final presentation required of each student.

<i>Element</i>	<i>Percentage</i>
Daily Participation	20%
Final Presentation	40%
Critical Review of Regenerative Clinical Trial	40%

GRADING SYSTEM

S = standard letter (see scale below)

A = 96-100	B+ = 87-89	B- = 80-83	C+ = 75-79	F = Below 70
A- = 90-95	B = 84-86		C = 70-74	

GRADING RUBRICS

Writing Assignments Rubric – As part of your participation, we would like to further develop your critical analytical skills in reviewing clinical trials that utilize regenerative therapeutics. Two articles will be given as options for review and you will need to complete the critical appraisal form for regenerative therapy as part of the review. Briefly summarize the clinical trial including strengths/weaknesses, then complete the outline provided for in-depth analysis.

Presentations Rubric – As part of your participation, we ask that you create a short (5-minute maximum) presentation about translational validation of a potential regenerative medicine therapy or surgical procedure. This brief exercise aims to inspire you to think through the steps of translating a therapy from basic science into active clinical use or practice, as the course will illustrate through the week. An idea for a therapy can be

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something from your own work or lab, or can come from an idea you've seen in papers (no need to do an extensive literature review).

The key sections to be included in your PowerPoint or PDF slide would include:

- Introduction – briefly explain what the technology is and what disease or condition it would aim to treat
- Biomanufacturing considerations – how would this cell product, device, or tools for a procedure be generated in a cGMP-compliant manner?
- Preclinical validation – what data (existing or theoretical) would show its efficacy in vitro or in animal studies for the purposes of FDA sanction?
- First-in-human study – broadly, what would a human clinical trial for this therapy encompass? What would the two treatment arms be, and what endpoints would be most relevant?
- Post-approval and clinical practice – if approved, how would this product or procedure be delivered to patients, and are there any limitations or caveats?

If you are having trouble coming up with ideas, you might be inspired by some of the disease and themes we will discuss throughout the week:

- Cardiovascular & Nervous Systems: ischemic heart disease, exosome-based therapies, spinal cord injury, mesenchymal stem cells, brain tumors
- Digestive, Endocrine, & Urinary Systems: inflammatory bowel disease, lung transplant, chronic kidney disease
- Skeletal, Muscular System, & ENT: laryngeal cancer, joint replacement, bone grafts, platelet rich plasma, wound healing
- Eyes, Blood, & Tissue: peripheral vascular disease, macular degeneration, CAR T-cells, synthetic organs, and tissue transplantation

WITHDRAWAL PROCESS

If you are considering withdrawing from the course, you are encouraged to discuss your options with the course director/instructor. However, if you decide to withdraw, please follow the following process to ensure your withdrawal is received and accepted by the Mayo Clinic Graduate School of Biomedical Sciences.

- Submit the [Late Registration/Course Withdrawal Form](#) **before or on** the date noted above.
- Withdrawal forms **MUST** be received by the indicated date above and on the course schedule below. An attempt to withdraw after that date will not ensure removal of a grade or Incomplete on your transcript.
- Verbal and/or email withdrawal requests will not be accepted.

VIRTUAL LEARNING RESOURCES

- At minimum, a Blackboard shell of the course must exist with syllabus but delivery of content can be done using other options, such as Zoom.
- See resources on the [MCGSBS Virtual Learning page](#).
- Blackboard is best optimized with Google Chrome. DO NOT USE INTERNET EXPLORER.

Technical Assistance

If you need technical assistance at any time during the course or to report a problem with Blackboard, visit the ETC Blackboard [Webpage](#).

POLICIES

You are responsible for knowing and complying with all [MCGSBS-applicable Policies and Procedures](#), including but not limited to, the most relevant listed below.

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- **Course and Syllabus Management Policy:**
<http://mayocontent.mayo.edu/collegeofmedicine/DOCMAN-0000204351>
- **Course Registration & Withdrawal Policy:**
<http://mayocontent.mayo.edu/collegeofmedicine/DOCMAN-0000149781>
- **Non-Academic Deficiency Policy:**
<http://mayocontent.mayo.edu/collegeofmedicine/DOCMAN-0000140215>

Plagiarism Guidelines

- All work submitted must consist of the student's original ideas. If other sources are included in your work, they must be properly identified and cited. You may not use work you submitted for another course unless approved by the course director.
- Plagiarism is a form of academic dishonesty. Penalties for plagiarism range from failing the course to suspension from Mayo Clinic Graduate School of Biomedical Sciences.
- Faculty will utilize plagiarism tools to monitor for academic honesty for work submitted.

Plagiarism Resources

To ensure you are not inadvertently plagiarizing please utilize the [text matching](#) services offered through Scientific Publications.

Research Misconduct Policy: http://mayocontent.mayo.edu/research-policy/MSS_661918

Mayo Clinic Social Media Code of Ethics

- **Brand Resource Center:**
<http://intranet.mayo.edu/charlie/brand-standards/media-specific-standards/social-media/social-media-code-of-ethics/>
- **Social Media Policy (College):**
<http://mayocontent.mayo.edu/collegeofmedicine/DOCMAN12-0000414980?qt=Social%20Media>

COURSE ACCESSIBILITY STATEMENT

The Mayo Clinic College of Medicine and Science (MCCMS) strives for an inclusive learning environment. If you anticipate or experience any barriers related to the format or requirements of this course, please contact the instructor to discuss ways to ensure full access. If you determine that additional disability related accommodations are necessary, please contact the Office of Wellness and Academic Success-Disability Services office at MCCMC.DS@mayo.edu to schedule an appointment.