

Board of Trustees

Executive Committee

November 16, 2017

**RESOLUTION TO APPROVE THE MASTER OF SCIENCE  
IN REGENERATIVE MEDICINE AND  
ENTREPRENEURSHIP DEGREE PROGRAM**

WHEREAS, Article II, Section 1 of the Bylaws of the Board of Trustees (the “Bylaws”) for Case Western Reserve University (the “University”) states, in relevant part, that the Board of Trustees shall oversee the educational programs of the University; and

WHEREAS, Article V, Section A, Par. 2 of the Constitution of the University Faculty states in relevant part that the Faculty Senate shall make recommendations to the President for consideration and transmittal to the Board of Trustees with respect to policies governing standards for curricula and content of all degree programs; and

WHEREAS, at its meeting on October 2, 2017, the Faculty Senate approved the proposed Master of Science in Regenerative Medicine and Entrepreneurship.

NOW, THEREFORE, BE IT RESOLVED THAT:  
the Board of Trustees of the University authorizes the officers of the University to take and oversee all necessary actions in order to create the Master of Science in Regenerative Medicine and Entrepreneurship Degree Program.

APPROVED by the  
EXECUTIVE COMMITTEE  
Case Western Reserve University  
BOARD OF TRUSTEES  
*Elizabeth J. Keefer*  
SECRETARY OF THE CORPORATION



NATIONAL CENTER FOR  
REGENERATIVE MEDICINE

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**Program Development Proposal:**

Master of Science Degree in Regenerative Medicine and Entrepreneurship

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## I. Overview of Regenerative Medicine and Training Landscape

It has been more than 15 years since the term “regenerative medicine” entered the scientific lexicon.<sup>1</sup> According to the National Institutes of Health (NIH), “regenerative medicine is the systematic process of developing functional tissues to repair or replace tissue or organ function due to age, disease, damage, or congenital defects.” Further the impact of Regenerative Medicine has expanded to include applications towards therapeutic support enhancing clinical applications of stem cell derivatives. Critical challenges in this area of research includes understanding the interaction between cells and novel materials or regenerative cells; the effect of physical and chemical stimuli on cell function, including cell growth, migration and differentiation.<sup>2</sup> The need to identify important safety issues and the management of risks during preclinical and clinical development of stem cell therapeutics are paramount to researchers.<sup>3</sup> To date, the output of these studies have resulted in the development of scientific publications that not only are devoted to regenerative medicine research and discovery but are also widely integrative through-out medicine.

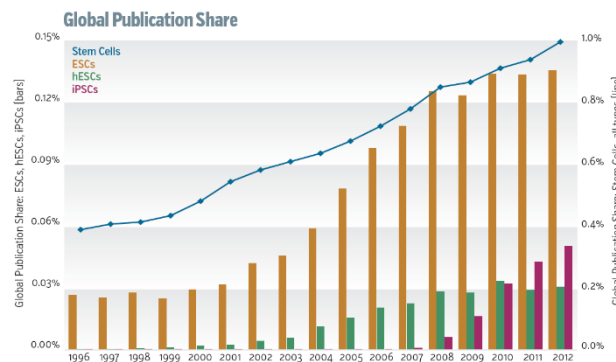


Figure 1.1 (Top): Global publication count. Figure 1.2 (Bottom): Global publication share. Graphs show data for all stem cells (Stem Cells), ES cells (all origins: ESCs), hES cells (hESCs), and IPS cells (iPSCs) from 1996-2012. See Appendix B for a breakdown of the key concepts contained within each data set. SOURCE: Scopus

2013 Stem Cell Report  
Trends and Perspectives on the Evolving International Landscape  
EuroStemCell & Elsevier

Despite the surge of preclinical studies and clinical trials, there’s still a limited number of formal regenerative medicine training programs that integrate all aspects of applications related to Regenerative Medicine. There are programs offerings for Master of Science degrees in Stem Cell Biology and Regenerative Medicine in the United States and Abroad. One of the newer programs was launched at the University of Southern California in the Fall 2014. This one-year

<sup>1</sup> <http://www.nature.com/nm/journal/v20/n8/full/nm.3658.html>

<sup>2</sup> <http://bioegrad.berkeley.edu/faculty/tissue#sthash.ZjVn8u4w.dpuf> Program Scope

<sup>3</sup> Burns LJ, Gajewski JL, Majhail NS, Navarro W, Perales MA, Shereck E, Selby GB, Snyder EL, Woolfrey AE, Litzow MR. Challenges and potential solutions for recruitment and retention of hematopoietic cell transplantation physicians: the National Marrow Donor Program’s System Capacity Initiative Physician Workforce Group report. *Biol Blood Marrow Transplant.* 2014 May;20(5):617-21.

program, with an optional second year research project, offers courses in developmental biology, human embryology, regenerative medicine, and translational and therapeutic aspects of stem cell technology.

USC's program and others alike are noteworthy, however, the overall scope of these programs are designed to train individuals to work in conventional academic environments. Our new and innovative Master's program **WILL** integrate academic research, commercial entrepreneurialism, biotechnology support, regulatory aspects of stem cell and regenerative medicine, as well as business and compliance training. NCRM's Regenerative Medicine and Entrepreneurship (RGME) program will train individuals to work in academic, commercial and clinical settings to support biotechnology innovation, business development, compliance and cellular manufacturing activities

To support CWRU's mission to advance thriving disciplines as well as new areas of interdisciplinary excellence, while strengthening its relationships with world-class institutions across greater Northeast Ohio, NCRM is requesting the approval of our initiative to develop a two-year Master of Science degree program in Regenerative Medicine and Entrepreneurship bridging together four corners of foundational programs at CWRU: School of Arts and Sciences, School of Engineering, School of Medicine and the School of Business.

This program will target individuals seeking advanced skills and training in regenerative medicine to support business development and operations related to the emerging field of Regenerative Medicine. Program recruitment and marketing strategies will be developed for the following target audiences.

- Biotechnology/Regenerative Medicine workforce
- Clinician-investigators
- New graduates (Life Sciences & Biomedical Engineering programs)
- Medical Studies
- Pharmacy Students

NCRM will leverage marketing resources available through the School of Medicine along with insight from NCRM's executive advisory board, corporate partners, and general members.

## **II. Needs Assessment**

Regenerative medicine research yielded translational discoveries resulting in innovative biotechnologies, novel cellular therapeutics and cutting-edge patient care models. Over the past decade, the field of stem cells and regenerative medicine have expanded rapidly and is bringing new opportunities and challenges to commercial and clinical entities. As a result, there is a critical need to address content knowledge gaps. There is a rising demand to train a

specialized workforce to meet employment and skill gaps in commercial, clinical, and academic settings supporting industry activities.

The need for individuals to be trained in this area is evident upon reviewing the number of peer-reviewed articles addressing regenerative medicine training gaps, available funding opportunities for training programs, and conference sessions addressing knowledge gaps in the field.

A recent workforce analysis, conducted by NCRM, revealed that experts in the field believed there is a growing demand for regenerative medicine training programs for entry level and mid-level career professionals. Interviewees felt more programs formally merging the supporting disciplines of regenerative medicine will be implemented throughout the country.

- 95% of academic faculty and industry executives felt there is a demand for training individuals in regenerative medicine and entrepreneurship
- 90% of industry executives felt master's level trained individuals would adequately support current and future operations related to regenerative medicine projects
- 95% of industry executives felt hiring master's level trained individuals would have a positive impact on company financial resources allowing to reinvest in research and development
- 100% of industry executives and academic faculty felt cross-training students in business development and communication skills would make students more competitive in the emerging job market
- 85% of industry executives felt having a general knowledge of compliance and regulatory issues provided an applicant with a competitive advantage over other applicants not possessing this knowledge
- 80% of industry executives felt having a general knowledge of ethics and public policy was useful

Due to decreased enrollment into traditional doctoral science programs, a master's degree program could serve as a viable alternative for students reluctant to enrolling into a PhD program. Preliminary market research indicates universities are integrating specialized tracks into their existing stem cell biology and developmental biology programs to meet the demand of students interested in regenerative medicine. A recent search for job opportunities on professional networking, academic, healthcare, and corporate websites validated the integration of specialized tracks within these existing programs.

Universities implementing specialized tracks include:

- University of Southern California (Regenerative Medicine)
- Stanford University (Stem Cell Biology and Regenerative Medicine)
- University of California, Berkley (Tissue Engineering and Regenerative Medicine)

- University of Wisconsin (Cell and Regenerative Biology)
- University of Minnesota (Stem Cell Biology)

Further, there is a growing trend among life sciences programs to incorporate coursework related to business development & entrepreneurship into graduate level training program curriculums. Traditional life sciences programs have limited exposure to formal project management strategies, roadmaps for commercializing biotechnologies and/or initiating a start-up venture which in today's market are required to connect the basic science to the world of clinical translation. In recent years, there is an increasing demand to train researchers with business development skills to improve their marketability and competitiveness within the industry's commercial sector.

Similar to our initiative, the following universities have developed programs to address business development and regulatory knowledge gaps.

- Harvard (Biotechnology and Management)
- Johns Hopkins (Biotechnology Enterprise and Entrepreneurship)
- Johns Hopkins University (Regulatory Science)
- The George Washington University (Regulatory Affairs)
- University of Maryland (Biotechnology Regulatory Affairs)

### **III. Academic Quality**

To implement this program, NCRM will leverage the expertise of faculty from across CWRU and affiliate institutions including CWRU, University Hospitals, Cleveland Clinic, MetroHealth and the Veterans Association. Further, the development of the program goes across disciplines and schools with a focus on the medicine, biology and mechanisms, engineering and business management. NCRM will solicit participation from faculty within the following CWRU academic departments and clinical institutions.

- School of Medicine
- Biology
- Biomedical Engineering
- Weatherhead School of Management
- University Hospitals
- Cleveland Clinic

Faculty within these academic departments have expertise and notable accomplishments in research and business development efforts. In 1969, CWRU established one of the first inter-school departments (Biomedical Engineering, School of Medicine and School of Engineering). With over 45 years of experience in supporting interdisciplinary programs, our institution at CWRU and its affiliate and commercial partners possesses the infrastructure to support this

innovative graduate program. As emphasized by the multidiscipline and character of the School of Medicine's new and innovative multi-affiliate programs.

## **V. Competitive Advantage**

CWRU has a proven track record of offering innovative education and training programs. The biomedical research center currently ranks 12<sup>th</sup> among the nation's 122 medical schools in NIH research funding crossing discipline through-out the institution. In addition, CWRU is well-known for having a culture of collaborative research and a strong commitment from institutional leadership to develop interdisciplinary programs.

With limited programs in the mid-west and throughout the country addressing regenerative medicine, entrepreneurial legal issues and regulatory affairs under one programmatic platform, CWRU will establish a competitive advantage by creating an integrated niche graduate program. Since University Hospitals and the Cleveland Clinic are founding institutions of the NCRM, students enrolled in the RGME program will have access to cutting-edge clinical and research facilities along with small biotechnology companies within NCRM's network.

## **VI. Statewide Program Alternatives**

The RGME program is distinctly different from other graduate programs offered at CWRU and across the state of Ohio. There are no existing programs within the state offering a master of science degree in regenerative medicine and entrepreneurship. Even within the CWRU's Biology department there is a two-year professional master degree program in Biology with an Entrepreneurial Biotechnology track, which on average, receives 25 admission applications per enrollment year. This program has limited integration of the school of Engineering or infrastructure to engage the School of Medicine. Fifteen applicants are accepted each year. However, the core curriculum vastly differs from the proposed coursework needed to fulfill core requirements in the RGME program. Offering a track within this existing program would not adequately meet the overall scope of this proposed program.

## **V. Program Summary**

The Center for Regenerative Medicine in the School of Medicine will serve as the home for this academic program. This program is intended to provide students with an interdisciplinary program platform. This program will combine experimental, theoretical and practical approaches to regenerative medicine research and entrepreneurship.

### **Core Competencies/Topics**

- Stem Cell Biology and Therapeutics
- Tissue Regeneration/Engineering

- Business Development and Entrepreneurship
- Compliance and Regulatory Affairs

Each student will be guided in a course of study by a program mentor to ensure the successful completion of the program and to support individual career development goals. The minimum graduation requirements will entail the completion of 30 credit hours (18 core credits/12 elective credits) of 400 level or higher coursework and the completion of an independent study consisting of either a research project or internship. Of the four required program electives, students must complete 2 science-based electives. NCRM will create four new courses for this program.

- **RGME 545** Stem Cell Biology & Therapeutics
- **RGME 550** Translational Regenerative Medicine & Regulatory Affairs
- **RGME 560** Independent Study
- **RGME 565** Internship

Required Core Curriculum (18 Credit Hours required)		
Course Number	Course Name	Credits
RGME 525	Foundations in Regenerative Medicine	3
RGME 545	*Stem Cell Biology and Therapeutics	3
EBME 425	Tissue Engineering and Regenerative Medicine	3
ENTP 445	Business Development in the Bioscience Sector	3
ENTP 427	Entrepreneurial Behavior	3
RGME 560	*Independent Study <i>or</i>	3
RGME 565	*Internship	3

*\* New course proposal will be submitted for approval.*

Appendix 1.1: Core curriculum & Program electives

Appendix 1.2: RGME Course Schedule-SAMPLE

## Master of Science Degree/Plan B (Non-Thesis)

This program will be designated under the Plan B course of study and will not require a formal thesis. All curriculum plans will be approved by program mentors with a specific timing algorithm for development of each student's program which will require the Core Curriculum as well as a specific focus indicated by selected course electives. There are two specific directions of study.

**Program I-Independent Study:** These students will opt for completing a research project; they will be required to enroll in an independent study course (RGME 550). The final project must be relevant to the field of regenerative medicine and demonstrate a significant time of investment



and research as defined by a submitted paper, review of presentation at a Regenerative Medicine focused meeting. Students working and pursuing this degree route will be required to demonstrate the independent nature of the program's project from their employment responsibilities.

Appendix 1.3: Independent Study Course Syllabus

**Program II-Corporate Internship.** These students will opt to complete an internship with a commercial partner and will be required to register for internship course (RGME 565). Internships will be under the governance of the established criteria for this course and will also require a term summary manuscript outlining the goals and achievements obtained during the internship program.

Appendix 1.4: Internship Course Syllabus

### Example Internship sites

RGME students will have the opportunity to intern at the following sites.

- Cellular Therapy Integrative Services Laboratory, CWRU/University Hospitals
- Cleveland Clinic Innovations
- Athersys
- University Hospitals, Research and Technology
- CWRU, Office of Research and Technology

We are actively working on securing internship sites with the following organizations.

- Cleveland Cord Blood
- Juventas

Students will have the option of taking an elective course along with their internship or independent study to support their need to take a fulltime course load. Students should have no more than one program elective remaining prior to enrolling in the independent study or internship courses.

## VI. Program Admissions

The anticipated annual enrollment for this program is 6-8 students per year. Admissions to the RGME program will follow the guidelines noted in CWRU's General Graduate Programs Bulletin. Students will use the online application platform licensed by CWRU. The RGME admissions committee will comprise of program steering committee members and program mentors.

Candidates will be evaluated based on overall GPA (undergraduate/graduate programs), successful completion of science coursework, and performance on graduate admission exams (i.e. GRE, GMAT, MCAT). Performance on graduate exams may be waived at the discretion of the program admissions committee. Previous research experience will not be required for

admission. All students considered and admitted to the RGME program will have a degree in one of the following disciplines.

- Life Sciences (i.e. cell biology, molecular biology, developmental biology, chemistry, pharmaceutical development or related discipline)
- Biomedical Engineering
- Pre-Medical/Medical studies

Key application materials will also include a personal statement, 3 letters of recommendation, and overall career aspirations. The TOEFL examination will be required for international students.

### VII. Access and Retention/Diversity and Inclusion

NCRM will leverage established and ongoing CWRU recruitment initiatives. The success of CWRU’s recruitment efforts can be attributed to institutional presence at various colleges and universities, scientific conferences and community events organized by underrepresented minority groups. RGME literature and/or personnel will be represented at these ongoing recruitment events. NCRM’s recruitment efforts will be made to enroll people of all racial, ethnic, cultural, socioeconomic, national and international backgrounds, welcoming diversity of thought, pedagogy, religion, age, sexual orientation, gender identity/expression, political affiliation and ability.

The number of students enrolled in graduate programs from underrepresented groups has maintained steady over the last 15 years. In addition, the number of women enrolled in graduate programs at CWRU has been higher than the number of men enrolled over the last 5 years.

### CWRU Diversity Snapshot

Fall 2016																			
School	NatAm	AfAm	Asian	Hawaii	Hisp	Whites	Unkwn	Multi	Intl	Total									
<b>Undergraduate Studies</b>																			
BA, BS, BSN, BSE	4	0%	223	4%	1,015	20%	4	0%	314	6%	2,582	50%	131	3%	238	5%	641	12%	5,152
<b>Graduate Studies</b>																			
MA, MFA, MS, MPH, MEM, ME, DMA, PhD	0	0%	142	5%	250	10%	2	0%	111	4%	1,121	43%	135	5%	46	2%	794	31%	2,601
<b>Applied Social Sciences</b>																			
MSSA, MNO	2	0%	162	25%	10	2%	1	0%	26	4%	377	59%	15	2%	20	3%	30	5%	643
<b>Dental Medicine</b>																			
DMD, MSD	0	0%	15	4%	90	22%	0	0%	16	4%	194	47%	8	2%	8	2%	80	19%	411
<b>Law</b>																			
JD, LLM, MA, SJD	0	0%	39	7%	20	4%	0	0%	20	4%	319	57%	4	1%	3	1%	157	28%	562
<b>Management</b>																			
MAcc, MBA, MPOD, MS, MSM, DMgt	0	0%	40	4%	44	5%	0	0%	15	2%	323	34%	21	2%	5	1%	513	53%	961
<b>Medicine</b>																			
MD, MS, CCLCM	0	0%	42	5%	266	30%	1	0%	28	3%	398	45%	96	11%	18	2%	43	5%	892
<b>Nursing</b>																			
MN, MSN, DNP	0	0%	35	8%	30	7%	1	0%	11	2%	310	70%	35	8%	8	2%	12	3%	442
<b>Graduate / Professional Totals</b>																			
	2	0%	475	7%	710	11%	5	0%	227	3%	3,042	47%	314	5%	108	2%	1,629	25%	6,512
<b>Grand Total</b>																			
	6	0%	698	6%	1,725	15%	9	0%	541	5%	5,624	48%	445	4%	346	3%	2,270	19%	11,664

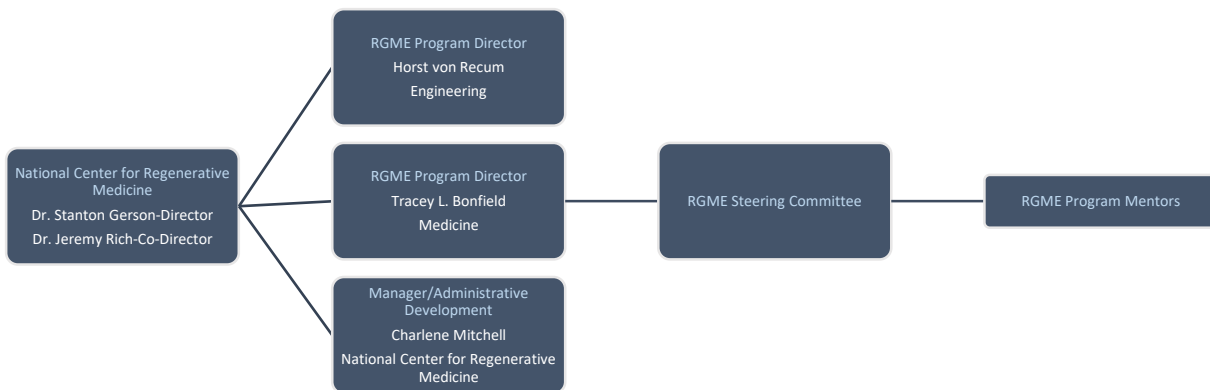
2016 Enrollment by Ethnicity/Race and School  
CWRU, Department of Institutional Research

## VIII. Program Administration

This program will reside in the School of Medicine and NCRM will serve as the home department. The RGME program will be supported by tuition revenue based on six to eight admitted students per year. Department funds will offset any initial program start-up costs.

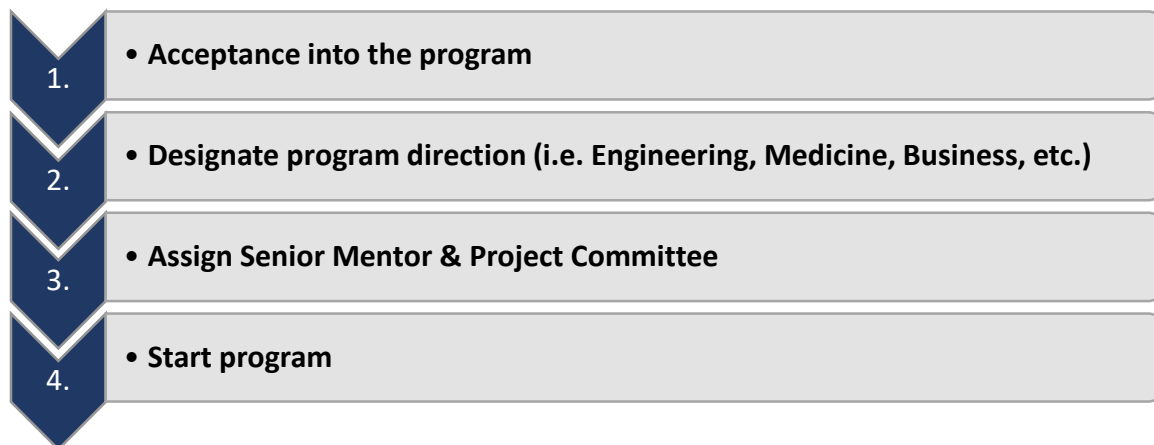
### Appendix 2.1: Program Budget & Assumptions

The budget is set up to account for tuition-sharing both within the School of Medicine and outside the school of medicine as most of the courses are outside the NCRM. Program staff will consist of the following.



NCRM's program manager will work with faculty to track student performance, schedule program events, and maintain appropriate admission and financial records.

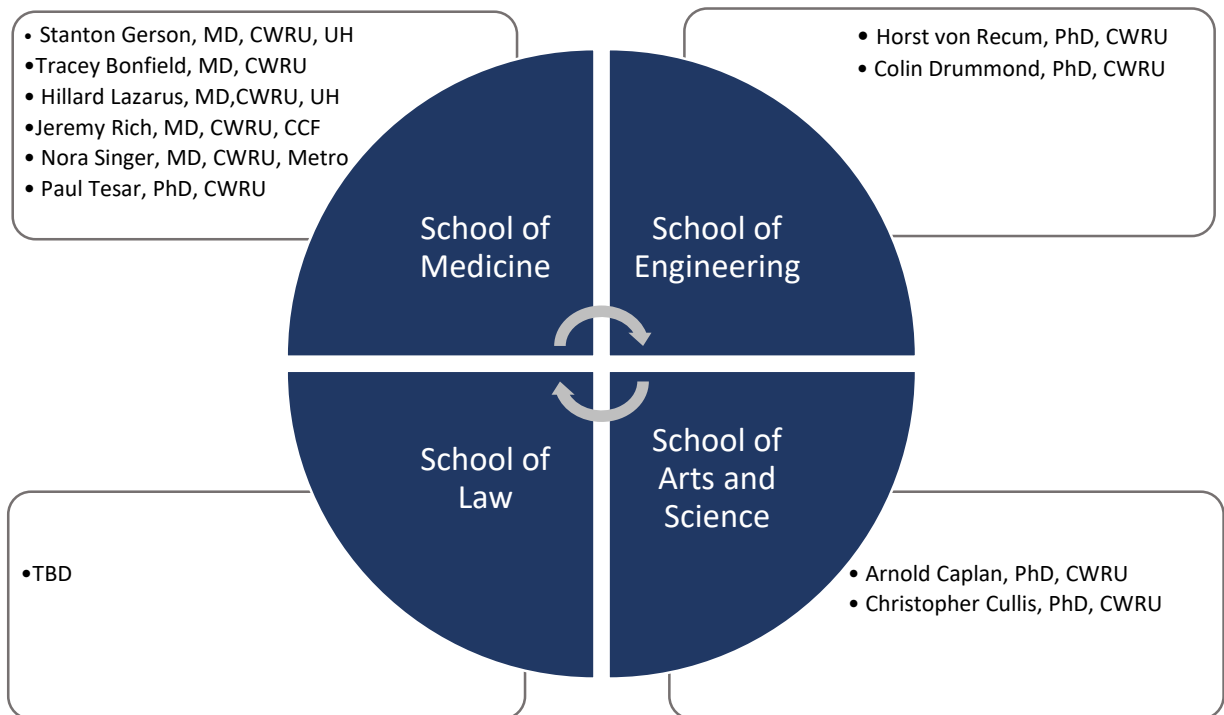
### Program Roadmap for Student



## Program Mentors

Students accepted into the program will be interviewed for specific interest and goals which initiated their application process. This interviewing process will provide the placement of the candidate into the specific field of focus within this multidisciplinary program to begin their connections with the faculty in that discipline. Students will be required to meet with their mentors and discipline leaders at the start of each semester to assure the candidate is on track and in the correct placement. Submission of the final report required for graduation and approval by the committee must be done within 4 weeks of the final semester. The goal of our mentorship program is to streamline the program to meet the specific interests of the candidate and to assure their completion of all of the competencies and transition of their knowledge to the work-place.

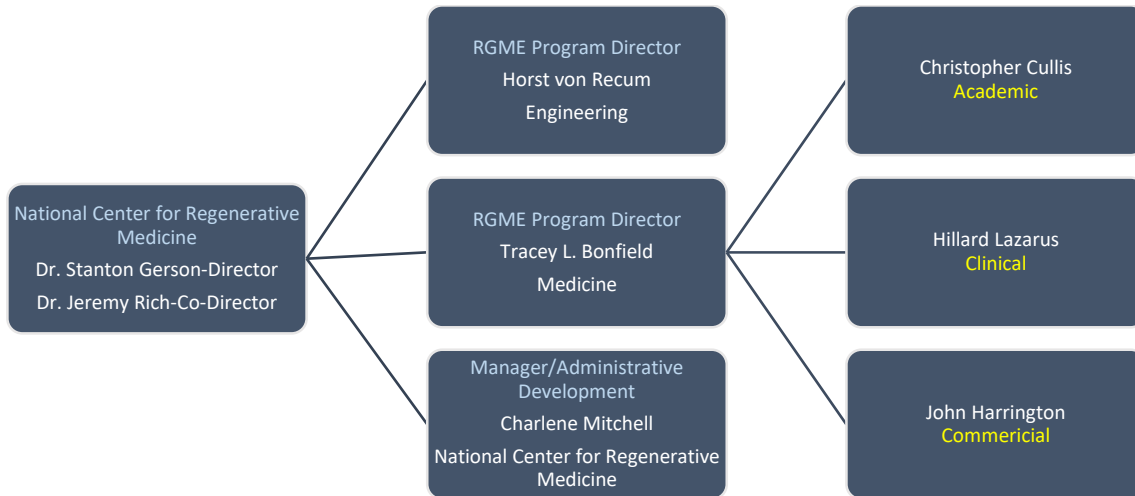
### Appendix 3.1: Program Mentors' Confirmation



## Program Steering Committee

The Steering Committee will consist of faculty from each key discipline contributing to the program core requirements.

## Steering Committee Representation



The program steering committee will be responsible for providing strategic insight regarding overall program administration, execution and expansion. This committee will meet on an annual basis and will be empowered to form subcommittees to support these functions. In addition, the Steering Committee will review and re-appoint all program mentors.

### Appendix 3.2: Steering Committee Members' Confirmation

### Steering Committee's Responsibilities

- **Provide governance and oversight for the RGME program**
- **Strategic Planning (Development & Expansion)**
  - Curriculum updates
  - Recruitment strategies
  - Industry trends (Regenerative Medicine and Biotechnology Innovations)
- **Program Evaluation & Impact**
  - Review program progress against defined metrics
  - Student enrollment
  - Student retention
  - Post program employment

### IX. Faculty Resources

As previously mentioned in this proposal, NCRM will leverage the expertise of faculty from across CWRU. The majority of the required coursework for the RGME program will derive from cross-listing courses from the following academic departments.

- School of Medicine
- Biomedical Engineering
- Weatherhead School of Management

NCRM's Directors will serve as course directors for two of the three RGME courses. As a note, for these two courses (RGME 525/RGME 545), guest lecturers from academic, clinical and commercial entities will present lecture materials. NCRM's training and education program manager will serve as the course director for the independent study (RGME 550).

## APPENDIX 1.1 Core curriculum & Program electives

Required Core Curriculum (18 Credit Hours required)		
Course Number	Course Name	Credits
RGME 525	Foundations in Regenerative Medicine	3
RGME 545	*Stem Cell Biology and Therapeutics	3
EBME 425	Tissue Engineering and Regenerative Medicine	3
ENTP 445	Business Development in the Bioscience Sector	3
ENTP 427	Entrepreneurial Behavior	3
RGME 560	*Independent Study <i>or</i>	3
RGME 565	Internship in Biomedical Science	3

Science Program Electives (6 Credit Hours required)		
Course Number	Course Name	Credits
RGME 550	*Translational Regenerative Medicine & Regulatory Affairs	3
CRSP 412	Communication in Clinical Research - Grant Writing	3
PHRM 409	Principles of Pharmacology	3
PHRM 511	Pharmacology Seminar Series	3
PHRM 520	Basic Cancer Biology and the Interface with Clinical Oncology	3
PHRM 525	Topics in Cell and Molecular Pharmacology	3
PATH 416	Fundamental Immunology	3
PATH 417	Cytokines: Function, Structure, and Signaling	3
CLBY 435	Seminar in Molecular Biology/Microbiology	3
CLBY 450	Cells and Pathogens	3
CLBY 525	Protein Misfolding and Human Disease: Molecular Basis and Clinical Implications	3
EBME 451	Fundamentals in Molecular and Cellular Biology	3
EBME 406	Polymers in Medicine	3

<b>Business Development Program Electives (6 Credit Hours required)</b>		
<b>Course Number</b>	<b>Course Name</b>	<b>Credits</b>
IIME 450	Technology Entrepreneurship: Market Opportunity Analysis	3
IIME 450 B	Technology Entrepreneurship: Managerial Decision-making	3
MEM 475	Technology Marketing	3
LAWS 5366	Venture Finance & Transactions	2
LAWS 5341	Commercialization and Intellectual Property Management	3
LAWS 4302	Patent Law	3
LAWS 4312	Patent Preparation and Prosecution	2
OPMT 420	Lean Six Sigma	3
ENTP 402	Starting and Managing Successful Start-up	3
ENTP 418	New Enterprise Development	3
ENTP 423	Domestic and International Entrepreneurship	3
ENTP 441	Tech-Based Entrepreneurship	3
ENTP 428	Small Enterprise Consulting	3
ENTP 440	Entrepreneurship Finance	3
ENTP 425	Managing Human Resources in Entrepreneurial Firms	3



## APPENDIX 1.2 RGME Course Schedule-SAMPLE

Y1 Fall Semester		
Course Number	Course Name	Credits
RGME 525	Foundations in Regenerative Medicine <b>(Required)</b>	3
ENTP 427	Entrepreneurial Behavior <b>(Required)</b>	3
TBD	Science Elective <b>(Required)</b>	3

Y1 Spring Semester		
Course Number	Course Name	Credits
EMBE 525	*Tissue Engineering and Regenerative Medicine <b>(Required)</b>	3
ENTP 445	Business Development in the Bioscience Sector <b>(Required)</b>	3
TBD	Science Elective <b>(Required)</b>	3

Y2 Fall Semester		
Course Number	Course Name	Credits
RGME 545	*Stem Cell Biology and Therapeutics <b>(Required)</b>	3
TBD	Business Elective	3
TBD	Business Elective	3

Y2 Spring Semester		
Course Number	Course Name	Credits
RGME 560	*Independent Study <b>(Required)</b> <i>or</i>	3
RGME 565	Internship <b>(Required)</b>	3
TBD	Elective (if needed)	3

## APPENDIX 1.3 Independent Study Course Syllabus

### RGME 560 Independent Study in Regenerative Medicine and Entrepreneurship

#### Course Directors:

**Tracey L. Bonfield, PhD D(ABMLI)**

School of Medicine

[tlb7@case.edu](mailto:tlb7@case.edu)

**Horst von Recum, PhD**

School of Engineering

[hav1@case.edu](mailto:hav1@case.edu)

#### Program Manager

**Charlene Mitchell, MBA**

National Center for Regenerative Medicine

[clm25@case.edu](mailto:clm25@case.edu)

#### COURSE DESCRIPTION

The RGME independent study allows students to explore a topic of interest under the close supervision of a RGME program director and mentor. The course may include directed readings, applied work, assisting a faculty member with a research project, carrying out an independent research project, or other activities deemed appropriate. Regardless of the activities, the work must culminate in a formal paper. The specific course requirements are described in the Independent Studies Proposal form to be completed by the student, project mentor and program director.

#### COURSE PREREQUISITE

Students must have the Independent Study Proposal Form approved by program director and mentor prior to enrollment.

#### COURSE OBJECTIVE

The primary objective of the course is to provide students with research exploration of a specific topic related to regenerative medicine of interest to the student under the advisement of a program mentor who will monitor and evaluate the student's progress.

#### COURSE CREDIT

The number of credits will depend on the scope of the independent study project. If you register for 3 credits in one semester, you will be expected to work a total of at least 120 hours on the proposed project. Thus, the number of credits registered for should coincide with the agreed upon scope and duration of the independent study project.

## **COURSE REQUIREMENTS**

Requirements will vary depending on the particular project, however, the following requirements will be uniformly applied across independent study projects.

1. Students are expected to identify a potential independent study project that will enhance their area of interest. Students may choose from the resources given by the RGME or provide information regarding an independent opportunity of interest. The independent study opportunity must be identified prior to enrolling in the course. Approval must be granted by the RGME Program Directors prior to committing to the project mentor. An Independent Study Proposal form must be completed.
2. Students must identify a project mentor. The elected mentor must be approved by the Program Directors. A course director will check in with the mentor regularly to ensure students are consulting with them to help guide their project and final paper.
3. For students pursuing an independent study while continuing their work experience as a part-time student, the focus of the independent study project may not be the result of a project in the same laboratory or on a project being undertaken within their specific department.

## **ASSIGNMENTS**

In order to pass this course, students will be expected to complete the following assignments.

### **a. Reflection Log**

Students will keep, and submit weekly, a reflection log. Students will log hours designated to their project. Entries will discuss an overview of the skills and focus for the week, and provide a detailed description of the next steps in the project progression.

### **b. CWRU Research ShowCase**

Students will be expected to submit an abstract to CWRU ShowCase for presentation.

### **c. Final Paper**

Students will be required to submit a final paper. The final paper must be on the approved topic and demonstrate a significant time of investment and research. The final paper will be 20 pages in length. The components of the paper will be defined by the program director.

## **DISABILITIES**

Any student with a documented disability who needs to arrange reasonable accommodations must contact both the program director and project mentor prior to the start of the project.

CWRU provides support services and appropriate accommodations to students with documented disabilities (*e.g.*, mental health, attentional, learning, vision, hearing, physical or systemic). For more information please visit the website at [www.students.case.edu/education/disability/policies](http://www.students.case.edu/education/disability/policies), the office

of Disability Resources is located in Educational Services, 470 Sears Building. Students should call the office at 216.368.5230 and schedule appointments as needed.

### **ACADEMIC INTEGRITY**

The academic community of Case Western Reserve University supports the policy that any form of academic dishonesty is a serious breach of ethics and shall be dealt with appropriately through the Academic Integrity Board. For a full explanation of the policies and procedures that guide academic integrity at Case Western Reserve University, see your Student Handbook and the College's Academic Honesty Policy. (<https://students.case.edu/handbook/policy/integrity.html>)

### **GRADING POLICY**

This course will be evaluated on a pass/fail basis. Grades of "P" or "F" will be given. The assessment will be based on individual meeting participation, assignment completion, and quality of the final paper. The completion of all course assignments will be required for the successful completion of this course.

## APPENDIX 1.4 Internship Course Syllabus

### RGME 565 – Internship in Regenerative Medicine and Entrepreneurial Sciences

#### Course Directors:

##### Tracey L. Bonfield, PhD D(ABMLI)

School of Medicine

[tlb7@case.edu](mailto:tlb7@case.edu)

##### Horst von Recum, PhD

School of Engineering

[hav1@case.edu](mailto:hav1@case.edu)

#### Program Manager

##### Charlene Mitchell, MBA

National Center for Regenerative Medicine

[clm25@case.edu](mailto:clm25@case.edu)

#### COURSE DESCRIPTION

This internship course will provide students with the opportunity to gain practical experience within an industry environment.

#### COURSE OBJECTIVES

- Acquire knowledge of the industry sector in which the internship is completed.
- Translate knowledge and skills learned in the classroom into a work environment.
- Explore additional career options available with the designated industry sector.
- Identify areas for future knowledge and skill development.

#### COURSE PREREQUISITE

Students must submit an Internship Proposal Form. The internship must be approved by both the program mentor and director prior to enrollment.

#### COURSE CREDIT

Students are required to complete 40 hours per week at their internship site. Over the course of the semester, students should roughly complete 620 hours at their hosting site.

#### ATTENDANCE

Attendance will be monitored and required for the program. Any issues of absenteeism, neglect of the required assessments, or issue(s) brought up by the hosting site may result in a failing grade in the course.

## **COURSE REQUIREMENTS**

The following are course requirements for the internship course.

1. Students are expected to identify a potential internship that will enhance their area of focus. Students may choose from resources given by the RGME program or provide information regarding additional sites. The School of Medicine EnRICH (Enhancing Research and Industry Career Horizons) program is also an option to identify internship opportunities. The internship opportunity must be submitted to the Program Directors for approval prior to enrolling in the course.
2. All opportunities must be with an approved site with knowledge of all core competencies to successfully accomplish the requirements for the internship experience.
3. All students must identify an onsite mentor. The elected mentor must to be approved by the Program Directors. The course director will check in with the mentor regularly to ensure students are staying on task, are responsible as well as to ensure an appropriate experience for the student as well as the hosting institution.
4. For students pursuing an internship while continuing their work experience as a part-time student, the internship program may not be in the same laboratory or on the same focused project as the working situation.
5. Students in the RGME internship program will also be given on a monthly basis, specific topics of discussion, to address with their mentor.
6. A monthly assessment will be made by the student's mentor to outline the consistent commitment by the student for the project as well as any exemplary or concerning issues that may come up with regards to the student's contributions to the hosting facility. This will be submitted to the elected Program Director for continuous review.

## **ASSIGNMENTS**

In order to pass this course, students will be expected to complete the following assignments.

### **a. Reflection Log**

Students will keep, and submit weekly, a reflection log. Students will log work hours. Entries will discuss an overview of the skills learned and focus for the week, and provide a detailed description of the next steps regarding internship activities and assignments.

### **b. CWRU Research ShowCase**

Students will be expected to submit an abstract to CWRU ShowCase for presentation.

### **c. Final Paper**

Students will be required to submit a final paper. The final project must demonstrate a significant time of investment and research. The final paper will be 20 pages in length. The components of the paper will be defined by the program director.

### **DISABILITIES**

Any student with a documented disability who needs to arrange reasonable accommodations must contact both the program director and project mentor prior to the start of the project.

CWRU provides support services and appropriate accommodations to students with documented disabilities (*e.g.*, mental health, attentional, learning, vision, hearing, physical or systemic). For more information please visit the website at [www.students.case.edu/education/disability/policies](http://www.students.case.edu/education/disability/policies), the office of Disability Resources is located in Educational Services, 470 Sears Building. Students should call the office at 216.368.5230 and schedule appointments as needed.

### **ACADEMIC INTEGRITY**

The academic community of Case Western Reserve University supports the policy that any form of academic dishonesty is a serious breach of ethics and shall be dealt with appropriately through the Academic Integrity Board. For a full explanation of the policies and procedures that guide academic integrity at Case Western Reserve University, see your Student Handbook and the College's Academic Honesty Policy. (<https://students.case.edu/handbook/policy/integrity.html>)

### **GRADING POLICY**

This course will be evaluated on a pass/fail basis. Grades of "P" or "F" will be given. The final assessment will be based on program mentor's evaluations, assignment completion, and quality of the final paper. The completion of all course assignments will be required for the successful completion of this course.

**APPENDIX 2.1 RGME Program Budget**

<b><u>FORCASTED EXPENSES</u></b>	<b><u>Start-up Costs</u></b>	<b><u>Y 2017/18</u></b>	<b><u>Y 2018/19</u></b>	<b><u>Y 2019/20</u></b>	<b><u>Y 2020/21</u></b>	<b><u>Assumptions</u></b>
<b><u>Personnel Expenses</u></b>						
Program Director (25 % effort, 3% increase YOY)	42,413	42,413	43,685	44,995	46,345	Assume average faculty salary at \$130K per year with 30.5% fringe rate.
Associate Professor (35% efforts, 3% increase YOY)	54,810	54,810	56,454	58,148	59,892	Assume \$42K per year with 30.5% fringe rate.
Visiting Lecturers (\$250.00 per lecture @30 weeks)	-	3,750	3,750	3,750	3,750	Assume this is honorum (non Case) will be paid by NCRM based on lecture effort (presenting, grading assignment, quiz development).
Administrative Support (50% effort, 3% increase YOY)	20,880	20,880	21,506	22,152	22,816	Assume \$32K per year with 30.5% fringe rate.
<b>Total personnel expenses</b>	<b>118,103</b>	<b>121,853</b>	<b>125,396</b>	<b>129,045</b>	<b>132,804</b>	
<b><u>Operating Expenses</u></b>						
Supplies	5,500	5,500	5,500	5,500	5,500	Assume general office supplies for program administration.
Marketing & Communications (3% increase YOY)	10,000	10,000	10,300	10,815	11,356	Assume digital and print marketing campaigns expenses.
Travel (Department personnel/national conferences)	3,000	3,000	3,000	3,000	3,000	Assume travel to national conferences to promote RGME program.
<b>Total Operating Expenses (Non Salary)</b>	<b>18,500</b>	<b>18,500</b>	<b>18,800</b>	<b>19,315</b>	<b>19,856</b>	
<b>Total Operating Costs</b>	<b>136,603</b>	<b>140,353</b>	<b>144,196</b>	<b>148,360</b>	<b>152,660</b>	
<b><u>NCRM Department Funds-Support Start-up Tuition</u></b>						
Rate		1,770	1,828	1,887	1,948	2 year program
Tuition		254,880	130,771	130,771	130,771	2 year program
Number Cr yr 1		144	144	144	144	Each student will take 9 credits per semester for 3 semesters, 4th semester will take 3 credits.
Number Cr. Yr 2		-	96	96	96	Assumes steady state of 8 students matriculating each fall.
Central & SOM (58%)/T. Dept. (\$250.00/credit/student)		254,880	438,606	452,861	467,579	
<b>Estimated Tuition Returned to Department</b>		<b>135,978</b>	<b>233,996</b>	<b>241,601</b>	<b>249,453</b>	
Estimate Revenue/(Expense)	(136,603)	(4,374)	89,801	93,241	96,794	
<b>Department Program Administration Reserves at end of each fiscal year.</b>	<b>(136,603)</b>	<b>(140,977)</b>	<b>(51,176)</b>	<b>(47,735)</b>	<b>49,058</b>	



## **APPENDIX 3.1: Program Mentors/Support**

**From:** [Cola, Philip](#)  
**To:** [Charlene Mitchell](#)  
**Cc:** [Stanton Gerson](#)  
**Subject:** RE: NCRM Master's Program-Invitation  
**Date:** Friday, March 11, 2016 1:43:58 PM

---

Charlene, my apologies for the delay in responding. I had drafted a response and never finished so it was in my draft box. I would be pleased to participate as a mentor if it's not too late due to my delay in responding. I am happy to be asked and look forward to the opportunity. Phil

Philip A. Cola, Ph.D.  
Vice President, Research and Technology  
University Hospitals Case Medical Center  
Adjunct Assistant Professor  
Case Western Reserve University  
11100 Euclid Avenue  
Cleveland, Ohio 44106-7061  
Phone: (216) 844-5576  
Fax: (216) 844-1547  
[philip.col@uhhospitals.org](mailto:philip.col@uhhospitals.org)

---

**From:** Charlene Mitchell [mailto:clm25@case.edu]  
**Sent:** Tuesday, February 16, 2016 5:16 PM  
**To:** Cola, Philip  
**Cc:** Stanton Gerson  
**Subject:** NCRM Master's Program-Invitation

Dear Dr. Cola,

This is an exciting time for the National Center for Regenerative Medicine. We are nearing the review and approval process for a **Master's of Science Degree program in Regenerative Medicine and Entrepreneurship**. Attached please find a general program outline.

We would like to invite you to serve as a program mentor. As a mentor, you would be expected to participate in the following ways.

- Offer career development support to assigned student (2 times/yr.)
  - Review independent study proposals for students applying for graduation
  - Review project proposals for internship placement
- \*Each mentor will be responsible for 1-2 students per year.*

We anticipate 6-8 students for our inaugural class (Summer 2017). As a recognized expert in the field, we believe your mentorship would be an invaluable asset to our students and overall program. We look forward to your support.

If agreeable, we will include your response along with our program proposal to document support. If

**From:** [Tracey Bonfield](#)  
**To:** [Charlene Mitchell](#)  
**Cc:** [Stanton Gerson](#)  
**Subject:** Re: NCRM Master's Program-Invitation  
**Date:** Wednesday, February 17, 2016 8:35:52 AM

---

Dear Charlene,

This sounds great- I would be happy to be involved in any way to support the NCRM.

Thank you for considering me as a potential mentor-

TLB

On Tue, Feb 16, 2016 at 5:14 PM, Charlene Mitchell <[clm25@case.edu](mailto:clm25@case.edu)> wrote:

Dear Dr. Bonfield,

This is an exciting time for the National Center for Regenerative Medicine. We are nearing the review and approval process for a **Master's of Science Degree program in Regenerative Medicine and Entrepreneurship**. Attached please find a general program outline.

We would like to invite you to serve as a program mentor. As a mentor, you would be expected to participate in the following ways.

- Offer career development support to assigned students (2 times/yr.)
- Review independent study proposals for students applying for graduation
- Review project proposals for internship placement

*\*Each mentor will be responsible for 1-2 students per year.*

We anticipate 6-8 students for our inaugural class (Summer 2017). As a recognized expert in the field, we believe your mentorship would be an invaluable asset to our students and overall program. We look forward to your support.

If agreeable, we will include your response along with our program proposal to document support. If you have any questions regarding this program, please feel free to contact me.

Kind regards,

**From:** [Nora Singer MD](#)  
**To:** [clm25@case.edu](mailto:clm25@case.edu)  
**Subject:** Re: NCRM Master's Program-Invitation  
**Date:** Tuesday, February 16, 2016 10:17:54 PM  
**Attachments:** [IMAGE1.img](#)

---

Hi Charlene,  
Happy to help.

What documents do you need from me?

thanks Nora Singer

Nora G. Singer, M.D.  
Professor of Medicine and Pediatrics  
CWRU School of Medicine  
Director, Division of Rheumatology  
Metrohealth Medical Center  
Vice-Chair for Faculty Development, Dept. of Medicine  
Medical Director, Clinical Trials Unit  
2500 Metrohealth Drive  
Cleveland, OH 44109  
Phone: 216-778-5154  
Fax: 216-778-8376

>>> Charlene Mitchell <[clm25@case.edu](mailto:clm25@case.edu)> 02/16/16 5:23 PM >>>

Dear Dr. Singer,



This is an exciting time for the National Center for Regenerative Medicine. We are nearing the review and approval process for a **Master's of Science Degree program in Regenerative Medicine and Entrepreneurship**. Attached please find a general program outline.



We would like to invite you to serve as a program mentor. As a mentor, you would be expected to participate in the following ways.



- Offer career development support to assigned students (2 times/yr.)
- Review independent study proposals for students applying for graduation
- Review project proposals for internship placement

*\*Each mentor will be responsible for 1-2 students per year.*

We anticipate 6-8 students for our inaugural class (Summer 2017). As a recognized expert in the field, we believe your mentorship would be an invaluable asset to our students and overall program. We look forward to your support.



If agreeable, we will include your response along with our program proposal to document support. If you have any questions regarding this program, please feel free to contact me.



Kind regards,  
Charlene



**From:** [Paul Tesar](#)  
**To:** [Charlene Mitchell](#); [paul.tesar@case.edu](mailto:paul.tesar@case.edu)  
**Cc:** [Stanton Gerson](#)  
**Subject:** RE: NCRM Master's Program-Invitation  
**Date:** Wednesday, February 17, 2016 9:15:38 AM

---

Happy to help as a mentor

--Paul

---

**From:** Charlene Mitchell [mailto:[clm25@case.edu](mailto:clm25@case.edu)]  
**Sent:** Tuesday, February 16, 2016 5:16 PM  
**To:** [paul.tesar@case.edu](mailto:paul.tesar@case.edu)  
**Cc:** Stanton Gerson <[slg5@case.edu](mailto:slg5@case.edu)>  
**Subject:** NCRM Master's Program-Invitation

Dear Dr. Tesar,

This is an exciting time for the National Center for Regenerative Medicine. We are nearing the review and approval process for a **Master's of Science Degree program in Regenerative Medicine and Entrepreneurship**. Attached please find a program outline for your review.

We would like to invite you to serve as a program mentor. As a mentor, you would be expected to participate in the following ways.

- Offer career development support to assigned students (2 times/yr.)
  - Review independent study proposals for students applying for graduation
  - Review project proposals for internship placement
- \*Each mentor will be responsible for 1-2 students per year.*

We anticipate 6-8 students for our inaugural class (Summer 2017). As a recognized expert in the field, we believe your mentorship would be an invaluable asset to our students and overall program. We look forward to your support.

If agreeable, we will include your response along with our program proposal to document support. If you have any questions regarding this program, please feel free to contact me.

Kind regards,  
Charlene

**Charlene Mitchell, MBA** | Training and Education Program Manager | National Center for Regenerative Medicine  
Case Western Reserve University | 10900 Euclid Ave. WRB 2501 | Cleveland, OH 44106 | 216.368.4928  
**Visit us:** [www.ncrm.us/](http://www.ncrm.us/)



## APPENDIX 3.2 Steering Committee/Support

**From:** [Colin K. Drummond](#)  
**To:** ["Charlene Mitchell"](#)  
**Cc:** ["Stanton Gerson"](#)  
**Subject:** Accepted: NCRM Master's Program-Invitation  
**Date:** Friday, February 19, 2016 4:51:47 AM

---

Good morning, Charlene!

I apologies for the delayed response; was a hectic week and my email backlog built up a bit.

Thank you for the kind invitation and I would be pleased to serve on the committee. Serving can be mutually beneficial in several ways, I believe.

Again, I thank you for reaching out.

Respectfully,  
Colin

---

From: Charlene Mitchell [<mailto:clm25@case.edu>]  
Sent: Tuesday, February 16, 2016 5:17 PM  
To: Colin Drummond  
Cc: Stanton Gerson  
Subject: NCRM Master's Program-Invitation

Dear Dr. Drummond,

We would like to thank you for your previous support of allowing our prospective students to enroll in your courses.

However, we would like to circle back and extend an invitation to serve on our program steering committee. Attached please find a general program outline. Please note the listed courses will be adjusted as we work through the approval and feedback process.

As a potential committee member, you would be expected to participate in the following ways.

- . Provide governance and oversight for the RGME Master's Program
- . Program Strategy (Development & Expansion)
- o Curriculum

**From:** [Christopher Cullis](#)  
**To:** [Charlene Mitchell](#)  
**Subject:** Re: Biotechnology Internships-Inquiry  
**Date:** Thursday, February 11, 2016 12:56:41 PM

---

Hi Charlene,

I am happy to serve on the steering committee. If it has to meet before I return (in early May) I can always join through Skype.

Regards,

Christopher Cullis  
Francis Hobart Herrick Professor of Biology  
Case Western Reserve University  
10900 Euclid Avenue  
Cleveland, Ohio 44106-7080  
Phone: 1 216 368 5110  
Fax: 1 216 3689 4672  
e-mail: [cac5@case.edu](mailto:cac5@case.edu)

On Thu, Feb 11, 2016 at 6:54 PM, Charlene Mitchell <[clm25@case.edu](mailto:clm25@case.edu)> wrote:

Hi Dr. Cullis,

I hope you are enjoying your time in France.

Your response was helpful and it will help me get started for now. At some point, I would like to circle back with you to find out best practices for selecting a company and pitching an internship opportunity.

I have another question for you. Would you be interested in serving on our program steering committee? The committee will meet once a year for a strategic planning and program evaluation session. However, we may require the group to convene if there's a pressing issue or major program change. We are trying to roll out this program around Fall 2017.

Let me know your thoughts regarding this opportunity.

Thank you.



**From:** [Horst von Recum](#)  
**To:** [Charlene Mitchell](#)  
**Subject:** Re: NCRM Master's program  
**Date:** Tuesday, February 23, 2016 1:10:35 PM

---

Hi Charlene,

I'd be glad to be on the steering committee.

In the future we can discuss other positions (e.g. director) if it still makes sense.

On a different note, I'd been meaning to pass on a couple other courses which might be a good/easy addition to the possible list of courses students can take.

one is a course I helped develop in the Department of Pharmacology (although they run it entirely independently of me now),

PHRM 409 Principles of Pharmacology.

Another two courses are ones taught in my department.

EBME 451 Fundamentals in Molecular and Cellular Biology

EBME 406 Polymers in Medicine

The advantage of both of the above courses is that they are taught entirely online, so they would be very easy for students both on and off campus to take. Also I teach the above two courses so I know their content, and know that the content would be suitable for the students we were discussing.

Horst

---

Horst von Recum  
Associate Professor  
Department of Biomedical Engineering  
Case Western Reserve University  
Cleveland, OH 44106  
216-368-5513  
<http://bme.case.edu/cdmc>

On Tue, Feb 23, 2016 at 10:33 AM, Charlene Mitchell <[clm25@case.edu](mailto:clm25@case.edu)> wrote:

Dear Horst,

Thank you for your insight during last week's call...most helpful.

**From:** [Lazarus, Hillard MD](#)  
**To:** [Charlene Mitchell](#)  
**Cc:** [Stanton Gerson](#); [Hillard Lazarus](#)  
**Subject:** RE: NCRM Master's Program-Invitation  
**Date:** Wednesday, February 17, 2016 12:43:41 AM

---

An interesting concept.  
Yes, I am pleased to participate.  
Please indicate the specific times when I will be needed.

Hillard M. Lazarus, MD, FACP  
The George & Edith Richman Professor and Distinguished Scientist in Cancer Research  
Professor of Medicine, Case Western Reserve University  
Director, Novel Cell Therapy  
telephone (216) 844-3629  
FAX (216) 844-5979  
Editor-in-Chief, *Bone Marrow Transplantation*  
Editor-in-Chief, *Blood Reviews*

---

**From:** Charlene Mitchell [clm25@case.edu]  
**Sent:** Tuesday, February 16, 2016 5:13 PM  
**To:** Lazarus, Hillard MD  
**Cc:** Stanton Gerson  
**Subject:** NCRM Master's Program-Invitation

Dear Dr. Lazarus,

We would like to invite you to serve on the RGME program steering committee. Attached please find a general program outline. Please note the listed courses will be adjusted as we work through the approval and feedback process.

As a potential committee member, you would be expected to participate in the following ways.

- **Provide governance and oversight for the RGME Master's Program**
- **Program Strategy (Development & Expansion)**
  - Curriculum
  - Student recruitment/retention
  - Industry trends (Clinical Innovations & Business Development)
- **Program Evaluation**
  - Review program progress against defined milestones
  - Evaluate program impact
    - Program graduates
    - Collaborative partnerships (academic, clinical and corporate)
    - Brand awareness

We believe your participation would be invaluable for the development and growth of this program. If agreeable, we will include your response along with our program proposal to document support. If you have any questions regarding this program, please feel free to contact me.

**From:** [Insoo Hyun](#)  
**To:** [Charlene Mitchell](#)  
**Cc:** [Stanton Gerson](#)  
**Subject:** Re: NCRM Master's Program-Invitation  
**Date:** Wednesday, February 17, 2016 12:21:11 PM

---

Dear Charlene,

I would be happy to serve on the steering committee.

Insoo

On Tue, Feb 16, 2016 at 5:17 PM, Charlene Mitchell <[clm25@case.edu](mailto:clm25@case.edu)> wrote:

Dear Dr. Hyun,

We would like to invite you to serve on the RGME program steering committee. Attached please find a general outline of our program. Please note the listed courses will be adjusted as we work through the approval and feedback process.

As a potential committee member, you would be expected to participate in the following ways.

- **Provide governance and oversight for the RGME Master's Program**
- **Program Strategy (Development & Expansion)**
  - Curriculum
  - Student recruitment/retention
  - Industry trends (Biotechnology & Societal Issues)
- **Program Evaluation**
  - Review program progress against defined milestones
  - Evaluate program impact
    - Program graduates
    - Collaborative partnerships (academic, clinical and corporate)
    - Brand awareness

**From:** [John Harrington](#)  
**To:** [Charlene Mitchell](#)  
**Cc:** [Stanton Gerson](#)  
**Subject:** RE: NCRM Master's Program-Invitation  
**Date:** Wednesday, February 17, 2016 10:44:53 AM

---

Charlene,

I would be happy to serve on the RGME program steering committee. If you need anything else, in addition to this email, please let me know.

Best regards,

John

---

John Harrington, Ph.D.  
Executive Vice President and Chief Scientific Officer  
Athersys, Inc.  
3201 Carnegie Avenue  
Cleveland, OH 44115-2634  
Phone: 216-431-9900  
Fax: 216-361-9495

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**From:** Charlene Mitchell [mailto:clm25@case.edu]  
**Sent:** Tuesday, February 16, 2016 5:24 PM  
**To:** John Harrington <jharrington@athersys.com>  
**Cc:** Stanton Gerson <slg5@case.edu>  
**Subject:** NCRM Master's Program-Invitation

Dear Dr. Harrington,

We would like to invite you to serve on the RGME program steering committee. Attached please find a general program outline. Please note the listed courses will be adjusted as we work through the approval and feedback process.

As a potential committee member, you would be expected to participate in the following ways.

- **Provide governance and oversight for the RGME Master's Program**



NATIONAL CENTER FOR  
REGENERATIVE MEDICINE

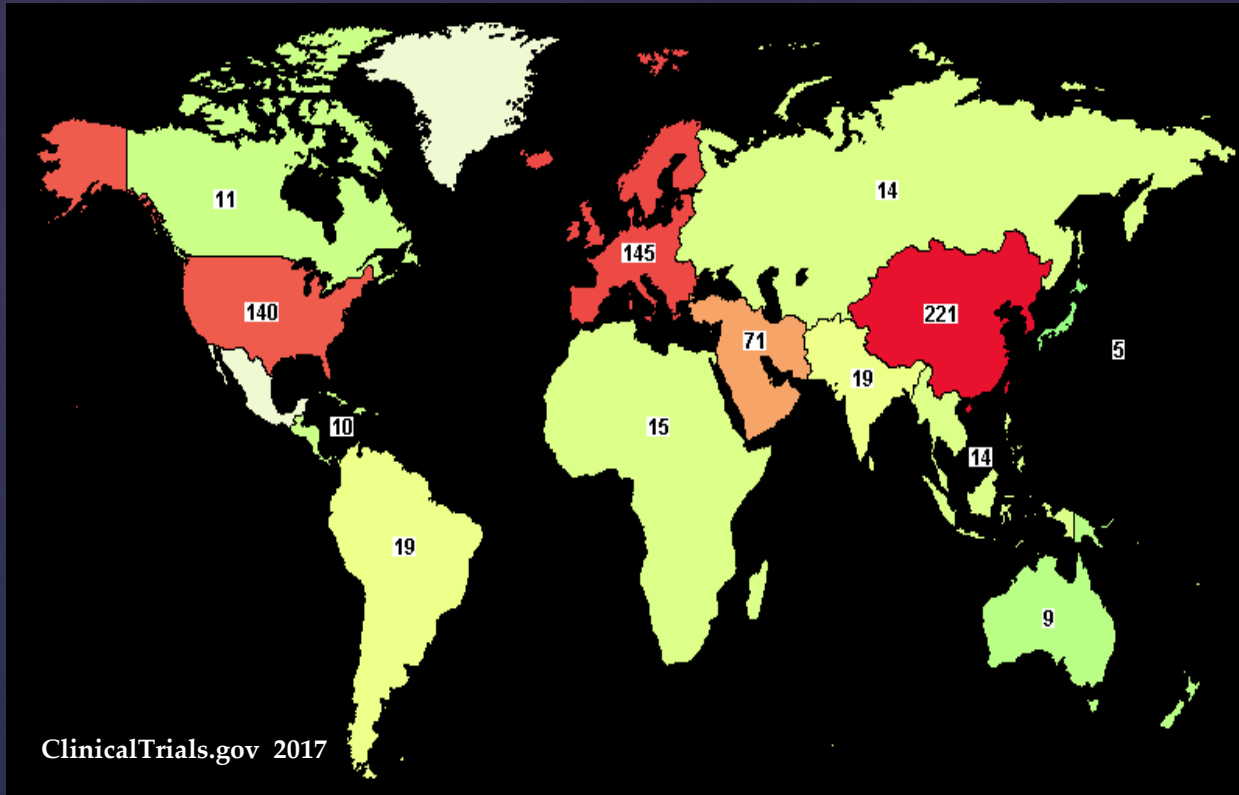
# Master's of Science in Regenerative Medicine & Entrepreneurship (RGME)

Tracey L. Bonfield, PhD. D(ABMLI)

Associate Professor, Department of Pediatrics  
Case Western Reserve University  
School of Medicine  
Program Director



# 730+ MSC-CLINICAL TRIALS 6110+ Studies for “Stem Cells”



~50%



from 2014

## Industry Overview

**672+**

Regenerative Medicine Companies Worldwide,  
Including Gene and Cell Therapies

**185**  
Europe  
& Israel

**112**  
Asia

**349**  
North  
America

**10**  
South  
America

**1**  
Africa

**15**  
Australia &  
New Zealand

Development

Research

GMP Compliance

Development Cell Source

Potency Testing

Cost Assessment

Patient Advocacy

# REGENERATIVE MEDICINE

Management

Applications

Efficacy Testing

Clinical Trials

Commercialization

Engineering Principles

Intellectual Property

Investment

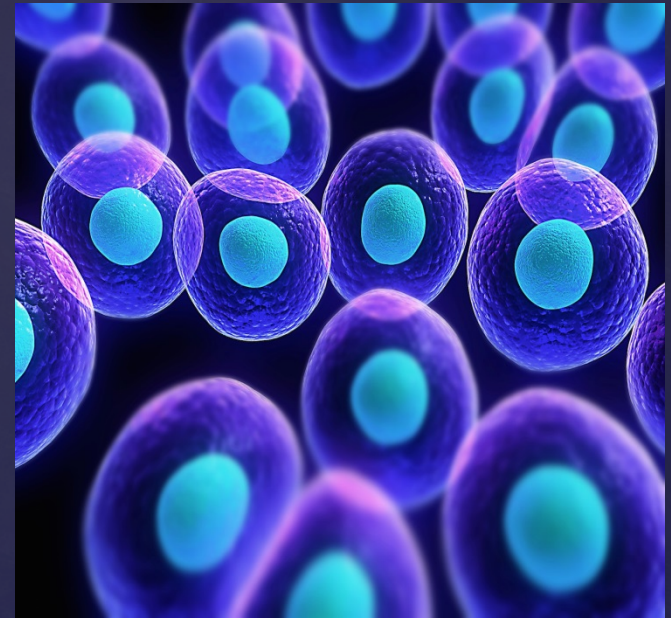
Strategies

Engineering Practices

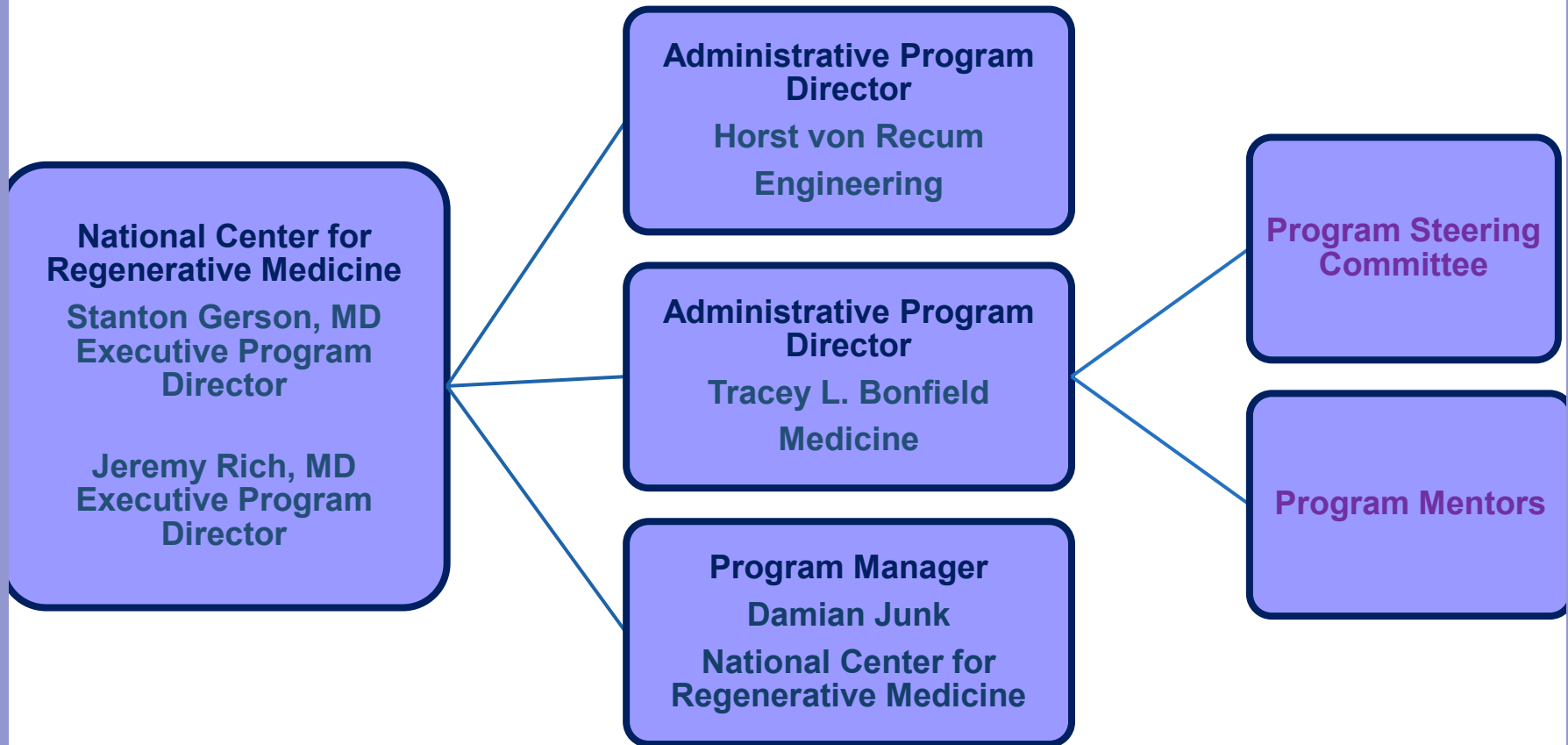


# Program Rationale

- ❖ To address the diversity in the knowledge gap associated with regenerative medicine.
- ❖ To develop a forum by which innovative contributors to regenerative medicine can be trained for a specialized workforce with a unique interdisciplinary focus.



# Program Organization



# Program Infrastructure

## Steering Committee

- Stanton Gerson, MD, CWRU, UH
- Tracey Bonfield, MD, CWRU
- Hillard Lazarus, MD, CWRU, UH
- Jeremy Rich, MD, CWRU, CCF
- Horst von Recum, PhD, CWRU
- Christopher Cullis, PhD, CWRU
- John Harrington, PhD, Athersys, Inc.

## Established Mentors

- Stanton Gerson, MD, CWRU, UH
- Tracey Bonfield, MD, CWRU
- Hillard Lazarus, MD, CWRU, UH
- Jeremy Rich, MD, CWRU, CCF
- Nora Singer, MD, CWRU, Metro
- Paul Tesar, PhD, CWRU
- Horst von Recum, PhD, CWRU
- Colin Drummond, PhD, CWRU
- Arnold Caplan, PhD, CWRU
- Christopher Cullis, PhD, CWRU

# Program Scope

- ❖ **The RGME program will expose students to the following:**
  - ❖ **Academic Research**
  - ❖ **Commercial Entrepreneurialism**
  - ❖ **Business development**
    - ❖ **Intellectual Property**
    - ❖ **Commercialization**
    - ❖ **Marketing**
  - ❖ **Biotechnology Support**
  - ❖ **Regulatory and Compliance Training**

# Multidisciplinary Training Platform: Program Metrics



School of Medicine



School of Engineering



School of Law



School of Management

- ❖ 6-8 students/year
- ❖ Program Requirements
  - ❖ 18 required core credits across the disciplines
  - ❖ 12 required elective credits in the area of specific designated interest

# Course Options: Diversity in Perspective

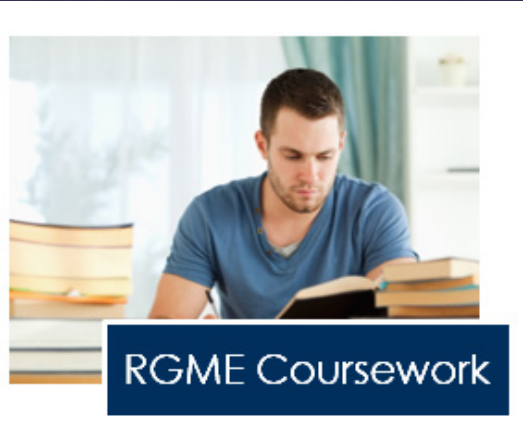
<b>Business Development Program Electives (6 Credit Hours required)</b>		
<b>Course Number</b>	<b>Course Name</b>	<b>Credits</b>
<b>IIME 450</b>	Technology Entrepreneurship: Market Opportunity Analysis	3
<b>IIME 450 B</b>	Technology Entrepreneurship: Managerial Decision-making	3
<b>MEM 475</b>	Technology Marketing	3
<b>LAWS 5366</b>	Venture Finance & Transactions	2
<b>LAWS 5341</b>	Commercialization and Intellectual Property Management	3
<b>LAWS 4302</b>	Patent Law	3
<b>LAWS 4312</b>	Patent Preparation and Prosecution	2
<b>OPMT 420</b>	Lean Six Sigma	3
<b>ENTP 402</b>	Starting and Managing Successful Start-up	3
<b>ENTP 418</b>	New Enterprise Development	3
<b>ENTP 423</b>	Domestic and International Entrepreneurship	3
<b>ENTP 441</b>	Tech-Based Entrepreneurship	3
<b>ENTP 428</b>	Small Enterprise Consulting	3
<b>ENTP 440</b>	Entrepreneurship Finance	3
<b>ENTP 425</b>	Managing Human Resources in Entrepreneurial Firms	3

# Graduation Requirements

Academic

Clinical

Industry



# RGME Internships

- ❖ Cellular Therapy Integrative Services Laboratory, University Hospitals
- ❖ Cleveland Clinic Innovations
- ❖ Athersys, Inc.
- ❖ Research and Technology, University Hospitals
- ❖ Office of Research & Technology, CWRU
- ❖ Nationwide Children's Hospital
- ❖ TrailHead, Incorporated





# Job Placement

- ❖ Utilize the Internship Program for potential job placement.
- ❖ Mentor resources for potential connections.
- ❖ Student presentations at MSC 2017, Cancer Stem Cell Retreat, The Business of Regenerative Medicine and other National and Local Meetings (Research, Management and Compliance Programs)
- ❖ Program specific integrations programs through the Ohio Frontier.

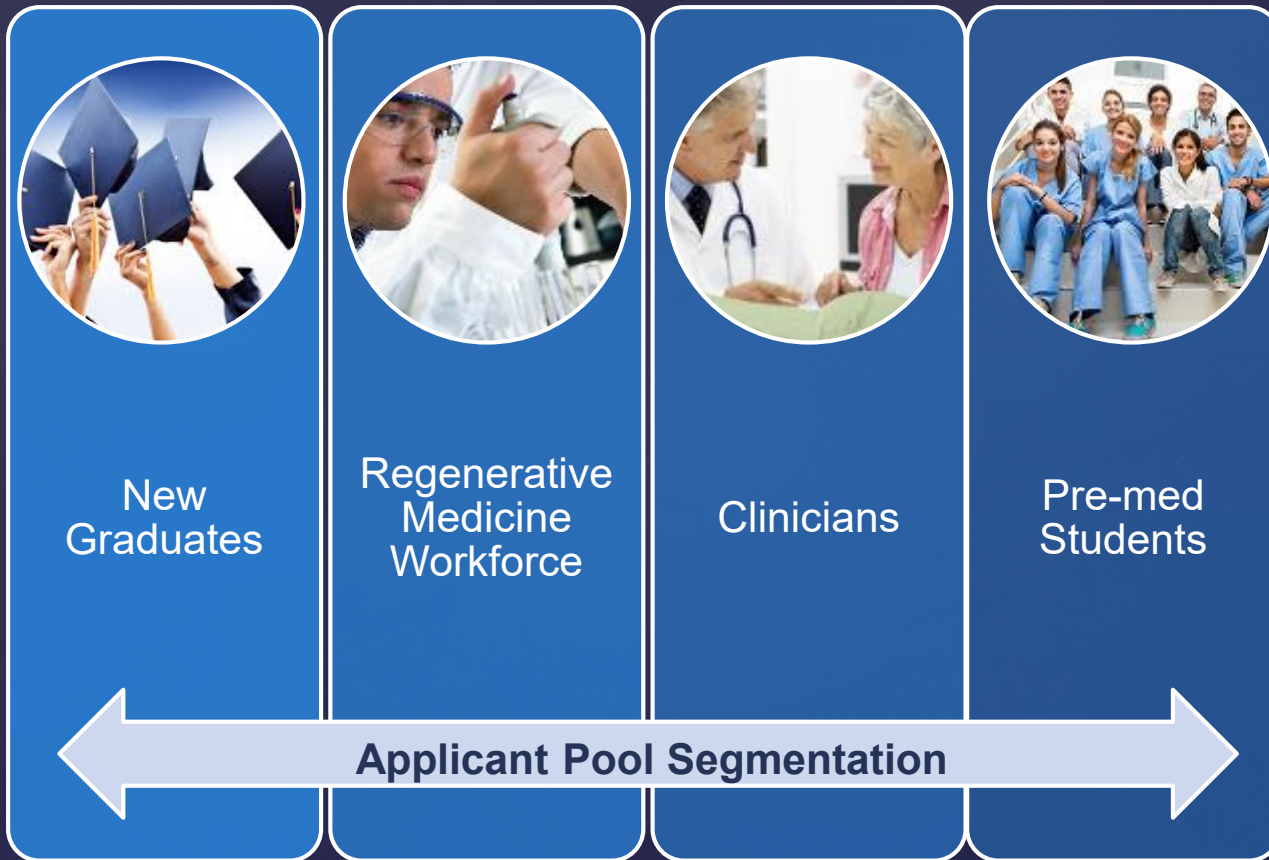
GPA and completion of  
Science Coursework

# Program Applicants

3-Letters of  
Recommendation

Recruitment Strategy

Research Experience



Career  
Statement

Personal  
Statement

Graduate Proficiency Exam Scores

TOEFL examination for international students.

# What is Innovative about this MS Program?

- ❖ It will be **FIRST** Master's of Science Program that will cover 4 different schools and perspectives at CWRU
- ❖ It will be the **FIRST PROGRAM** of its kind in the United States

# A MASTERS OF SCIENCE IN RGME

**Integrative interdisciplinary training program aimed at generating a workforce capable of participating in the facilitation of stem cell based applications from “bench-side” research to clinical and commercial applications with an effort to optimize success.**

Memorandum

To: Pamela B. Davis, MD, PhD  
Dean, School of Medicine  
Case Western Reserve University

From: Maureen W. McEnery, PhD, MAT  
Chair of the Faculty Council

Re: "Master's of Science in Regenerative Medicine and Entrepreneurship"

Date: Jan. 30, 2017

At its regular January 23, 2016, meeting, the Faculty Council voted unanimously to recommend approval of a "Master's of Science in Regenerative Medicine and Entrepreneurship" to your office.

In accordance with our SOM practices, an ad hoc committee composed of members of the Faculty Council Steering Committee, Graduate Directors, the SOM members of the Faculty Senate's Committee on Graduate Programs, and the Associate Dean for Graduate Education was created to review the program proposal. The ad hoc committee was chaired by Nicholas Ziats. The ad hoc committee reviewed the document, discussed the proposal, and engaged with the program presenter. After discussion, the ad hoc committee approved the reviewed proposal and it was sent to the Faculty Council for a vote.

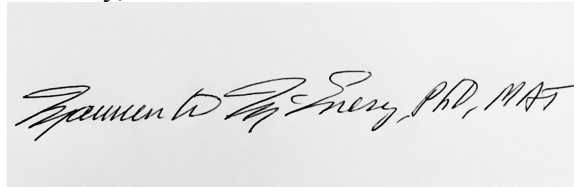
Charlene Mitchell, Training and Education Program Manager at the National Center for Regenerative Medicine, presented the proposal to Faculty Council. Stanton L. Gerson, MD Director, Case Comprehensive Cancer Center and Seidman Cancer Center and Director at the National Center for Regenerative Medicine, Asa & Patricia Shiverick (Tripp) Professor of Hematological Oncology, Distinguished University Professor and Vice Dean of Oncology, was on hand to answer additional questions. After some discussion, a motion to recommend was accepted by a unanimous vote.

After your review, I hope you will join me in recommending the proposal for a "Master's of Science in Regenerative Medicine and Entrepreneurship" for approval by the Faculty Senate, as required by the Faculty Handbook.

Please let me know if I can provide any additional information.

Thank you for your consideration.

Sincerely,



Maureen W. McEnery, Ph.D, MAT  
Chair of the Faculty Council  
Associate Professor of Neurology  
Associate Professor of Neuroscience  
University Hospitals of Cleveland Medical Center  
Case Western Reserve University School of Medicine

## Memorandum

cc: Nicole Deming, JD, MA, Dan Anker, JD, PhD

**Pamela B. Davis, MD, PhD**  
**Dean**  
**Senior Vice President for Medical Affairs**  
**Office of the Dean**

10900 Euclid Avenue  
Cleveland, Ohio 44106-4915

Visitors and Deliveries  
Biomedical Research Bldg., Room 113

phone 216.368.2825  
fax 216.368.2820

casemed.case.edu

January 30, 2017

Peter Harte, PhD  
Chair, Faculty Senate  
c/o Rebecca Weiss, Secretary of the University Faculty  
Adelbert Hall  
7001

Dear Professor Harte:

As noted in the accompanying memo from Dr. Maureen McEnery, Chair of the School of Medicine's Faculty Council, the Faculty Council has recommended approval of a new degree program for a Master's of Science in Regenerative Medicine and Entrepreneurship in the School of Medicine.

This two-year Master's of Science degree is a collaborative effort among four schools: the College of Arts and Sciences, the Case School of Engineering, the Weatherhead School of Management, and the School of Medicine. This program will recruit those interested in regenerative medicine including clinician-investigators, pharmacy students, and the biotechnology/regenerative medicine workforce. The program will cross-train students in business development, communication skills, public policy, entrepreneurship, and regenerative medicine.

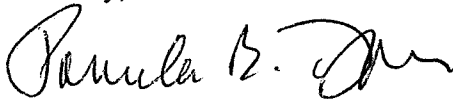
The proposal approval process is outlined in Dr. McEnery's memo. An ad hoc Committee was convened to review this new program and after revisions, the program was approved by the School of Medicine's Faculty Council.

I concur with the Faculty Council and recommend approval of this proposed graduate program.

Please submit the proposed degree program to the appropriate committees for their review at their earliest opportunity. I would be pleased to answer any questions that might arise during the review process.

Thank you.

Sincerely,



Pamela B. Davis, MD, PhD

c: Dr. Maureen McEnery, Chair, Faculty Council  
Nicole Deming, Assistant Dean for Faculty Affairs and Human Resources, SOM

enclosures



SCHOOL OF MEDICINE  
CASE WESTERN RESERVE  
UNIVERSITY



CASE SCHOOL  
OF ENGINEERING

CASE WESTERN RESERVE  
UNIVERSITY

Stanton L. Gerson, MD  
Director, Case Comprehensive Cancer Center and Seidman Cancer Center  
Director, National Center for Regenerative Medicine  
Asa & Patricia Shiverick (Tripp) Professor of Hematological Oncology  
Distinguished University Professor  
Vice Dean of Oncology

Jeffrey L. Duerk  
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10900 Euclid Avenue  
Cleveland, Ohio 44106-7220  
Visitors and Deliveries  
Nord Hall 500  
Phone 216.368.4436  
Fax 216.368.6939  
[www.engineering.case.edu](http://www.engineering.case.edu)

March 24, 2017

Dear Stan:

On behalf of the School of Engineering, it is my pleasure to endorse the proposed Master of Science program in Regenerative Medicine & Entrepreneurship.

Moving forward, we will work together to expand the RGME program and further build a partnership between NCRM and the School of Engineering. As discussed, we agreed to the following:

**NCRM/School of Engineering Partnership**

- RGME students will be permitted to take School of Engineering courses as outlined in the program development proposal
- Horst von Recum, PhD will serve as a co-program director and represent the School of Engineering
- To drive program growth, a dual admissions track will be established by the School of Engineering to recruit graduate school applicants specifically interested in regenerative medicine and biomedical engineering
  - NCRM and the College of Engineering will work with Dean Rozek to formalize a dual admissions track to meet state guidelines and approval
  - Tuition return: Revenue generated from students admitted to the RGME program under the School of Engineering will remain with Engineering
  - Tuition revenue from this point of entry will complement Horst von Recum's activities as a co-program director
- NCRM will also support program directors' activities from tuition return and a formal percent effort will be confirmed once program is established and generating tuition revenue
- Co-branding and marketing campaigns will be established to promote student enrollment through the School of Engineering pipeline

Sincerely,

Jeffrey Duerk, PhD  
Dean, Case School of Engineering  
Leonard Case Professor of Engineering





Jessica W. Berg, Dean  
 Tom J.E. and Bette Lou Walker  
 Professor of Law

February 21, 2017

Michael P. Scharf, Dean  
 Joseph C. Hostetler - BakerHostetler  
 Professor of Law

Stanton L. Gerson, MD  
 Director, Case Comprehensive Cancer Center and Seidman Cancer Center  
 Director, National Center for Regenerative Medicine  
 Asa & Patricia Shiverick (Tripp) Professor of Hematological Oncology  
 Distinguished University Professor  
 Vice Dean of Oncology

11075 East Boulevard  
 Cleveland, Ohio 44106-7148

phone 216.368.3283  
 fax 216.368.1277  
 lawdeans@case.edu

Dear Stan:

law.case.edu

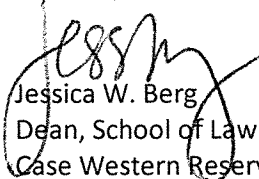
On behalf of the School of Law, it is my pleasure to endorse the proposed Master's of Science program in Regenerative Medicine & Entrepreneurship. I am pleased that you selected courses from the School of Law to serve as electives for this unique and innovative program. In an effort to support this multidisciplinary training platform, I would like to grant approval for your students to enroll in the following School of Law courses.

Course Number	Course Name	Credits
LAWS 5366	Venture Finance & Transactions	2
LAWS 5341	Commercialization and Intellectual Property Management	3
LAWS 4302	Patent Law	3
LAWS 4312	Patent Preparation and Prosecution	2

The selected courses will help your students better understand business activities supporting product development, commercialization, and working in entrepreneurial environments. As the RGME program expands, we will assess course enrollment by your students to ensure access for students in other School of Law programs as well as appropriate compensation for teaching efforts.

In closing, I wish to emphasize my commitment and support for this new graduate program.

Sincerely,



Jessica W. Berg  
 Dean, School of Law  
 Case Western Reserve University



CASE WESTERN RESERVE  
UNIVERSITY

COLLEGE OF ARTS AND SCIENCES

April 18, 2017

Stanton L. Gerson, MD  
Director, Case Comprehensive Cancer Center  
and Seidman Cancer Center  
Director, National Center for Regenerative Medicine  
Asa & Patricia Shiverick (Tripp) Professor of Hematological Oncology  
Distinguished University Professor  
Vice Dean of Oncology

Cyrus C. Taylor, Dean  
Albert A. Michelson Professor in Physics

College of Arts and Sciences  
Crawford Hall, Room 712  
Case Western Reserve University  
10900 Euclid Avenue  
Cleveland, Ohio 44106-7068

Phone 216-368-4437  
Fax 216-368-3842  
1-800-515-2774  
cyrus.taylor@case.edu

Dear Professor Gerson:

I am writing to express my support of the proposed Master of Science Program in Regenerative Medicine & Entrepreneurship. This program will offer a distinct multidisciplinary training platform at Case Western Reserve University. As you move forward with the program development process, I look forward to meeting with you to explore potential opportunities for collaboration. I believe our students would mutually benefit from courses and training opportunities offered by each of our respective areas. In addition, I support College of Arts and Sciences representation on the program steering committee as well as among the program mentorship group.

In closing, I would like to reiterate my general support and wish you much success in the development and implementation of this new graduate program.

Sincerely,

A handwritten signature in black ink, appearing to read "Cyrus C. Taylor".

Cyrus C. Taylor  
Dean and Albert A. Michelson Professor in Physics  
College of Arts and Sciences



August 22, 2017

Stanton L. Gerson, MD  
Director, Case Comprehensive Cancer Center  
Director, National Center for Regenerative Medicine  
Asa & Patricia Shiverick (Tripp) Professor of Hematological Oncology  
Distinguished University Professor  
Vice Dean of Oncology

Dear Stan:

On behalf of Weatherhead, it is my pleasure to endorse the proposed Master of Science program in Regenerative Medicine & Entrepreneurship. I am pleased that you selected courses from the Entrepreneurship program to serve as electives for this innovative program. It is my understanding that there will be some variability in course offerings in the future, which will provide some diversity in the electives aspect of our program. A snap-shot of some of the courses that may provide the foundation of the program's structure are listed below.

Entrepreneurship Electives		
Course Number	Course Name	Credits
ENTP 478	Entrepreneurship and Innovation	3
BAFI 444	Entrepreneurial Finance	3
DESN 419	Entrepreneurship and Personal Wealth Creation	3
ENTP 501	Topics in Entrepreneurship	3
ENTP 428	Small Enterprise Consulting	3
MGMT 495 A&B	AMES Business Models	3
ENTP 425	Managing Human Resources in Entrepreneurial Firms	3

Since formal tuition-sharing negotiations are underway between the Graduate and Professional schools of Case Western Reserve University, we will use that as the basis of an agreement for tuition. We will re-visit tuition sharing once we can better gauge the courses utilized and after having a better appreciation of the interest of our students and the number of courses pursued.

In closing, I look forward to integrating into your Master's Program, with an exciting perspective on this multidisciplinary study towards regenerative medicine and business.

Sincerely,

A handwritten signature in blue ink, appearing to read "Simon Peck".

Dr Simon Peck  
Associate Professor of Strategy; Associate Dean  
Weatherhead School of Management  
Case Western Reserve University