

# 2021 Virtual Regenerative Medicine Essentials Course & World Stem Cell Summit



Institute for Regenerative Medicine

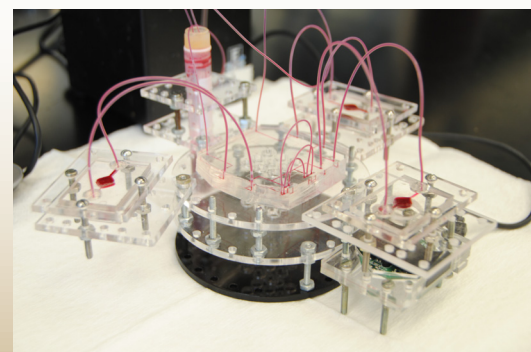


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## June 14-18, 2021

# Welcome to the 2021 RME & WSCS

On behalf of the course organizing committee and a prominent group of course instructors, we welcome all to the Wake Forest Institute for Regenerative Medicine's (WFIRM) 8th Annual Regenerative Medicine Essentials: From the Fundamentals to the Future course, which is held in conjunction with the 18th Annual World Stem Cell Summit. This unique, co-joined event is formatted this year for virtual attendance.

Often referred to as the next evolution of modern health care, the regenerative medicine field touches many disciplines -- from clinical care and engineering to basic science and bioethics. We initiate this co-joined event with the RME "core curricula". The 3-day RME course, taught by leading experts in the field, addresses the multidisciplinary nature of regenerative medicine and provides attendees a firm foundation in this exciting field, insight into the current state of the field encompassing applications, challenges and a prognostic glance to the future.

Our primary objective is to provide an all-inclusive review of various aspects of RM including background material, key scientific components of the RM field, ethical, economic, educational, workforce and other issues important to RM, along with "virtually formatted" opportunities to network and meet leading professionals in the field. Participants are then able to move "beyond the essentials" as they then participate in the 18th Annual World Stem Cell Summit, held on June 17th and 18th.

In partnership with the Regenerative Medicine Foundation, the WFIRM organizing committee has put together a dynamic and informative course that covers the "essential" topics, fundamental principles and current progress in tissue engineering and regenerative medicine, including stem cells and cell therapy, biomaterials, technology-based tissue engineering and enabling technologies, as well as regulatory, ethical, economic issues critical to the field. Our instructors, including faculty from WFIRM as well as distinguished, prominent experts in the field from industry, academia and the government who join from across the globe, provides attendees a strong foundation along with insights into future directions and potential applications of tissue engineering and regenerative medicine.

We hope this distinctive, co-joined virtual event will further interactions among basic scientists engaged in discovery and development, translational researchers who bring laboratory discoveries to the clinical forefront, clinicians and those engaged with funding, regulatory and commercialization endeavors, and further broaden and facilitate interactions with future leaders in the field who join as students.

We look forward to an exciting, enjoyable and productive co-joined event for all.

Anthony Atala, MD  
Director, WFIRM  
RME 2021 Course Director

Joan F. Schanck, MPA  
Chief Education Program Officer, WFIRM  
RME 2021 Course Co-Director

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## Welcome to the 2021 RME & WSCS

On behalf of the Regenerative Medicine Foundation (RMF), I welcome you to the 2021 Virtual Regenerative Medicine Essentials Course and World Stem Cell Summit. We believe the course is a perfect platform for advancing the RMF mission to accelerate regenerative medicine to improve health and deliver cures.

Here at RMF, we recognize that the power of collaboration grows in a nonlinear fashion. One plus one is more than two, and one plus one plus one is much, much more than three — offering explosively positive and unpredictable possibilities. By attending this course, you will expand your knowledge in a totally immersive experience and gain personal connections and collaborations. Be open to all opportunities presented.

Interact with the outstanding interdisciplinary faculty and the superlative researchers of our host institution, the Wake Forest Institute for Regenerative Medicine, led by our treasured friend, Dr. Anthony Atala. We are here for you. Open to your questions and points of view.

This week I urge you to network with fellow attendees. Break bread, make new friends and remember to collect those opportunities.

Cordially,

Bernard Siegel, JD  
Executive Director, Regenerative Medicine Foundation  
Founder & Chair, World Stem Cell Summit



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# With Special Thanks and Recognition

## Organizing Committee

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RME 2021 Course Director;  
Director, WFIRM

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RME 2021 Course Co-Director;  
Chief Academic Program Officer,  
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Alyssa Rudinsky  
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Regenerative Medicine Foundation

## RME 2021 Career Perspectives Committee

James Poteracki  
Pre-doctoral Fellow, WFIRM

Bradford Kuhlman  
Pre-doctoral Fellow, WFIRM

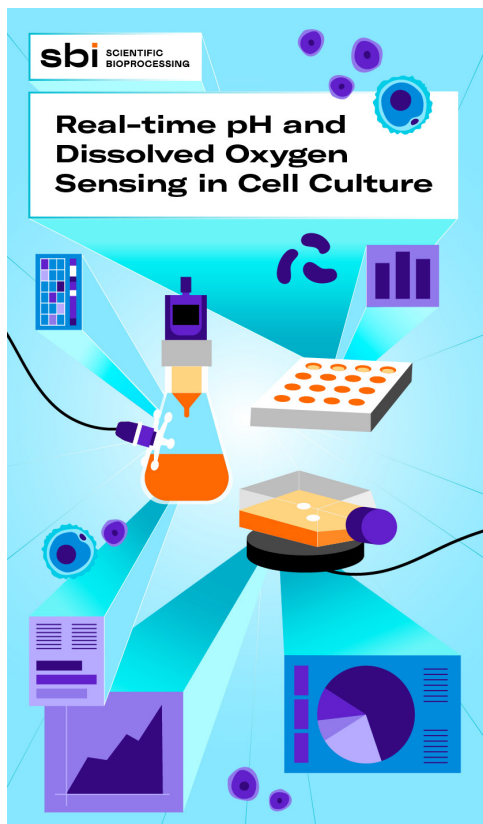
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The RME/WSCS 2021 conference is powered by the Jujama Networking Partnering App. Registered attendees can schedule virtual meetings, network, interact like never before through industry-leader Jujama partnering technology. The Conference App is accessible on iPhones, Android and any web-enabled device.

Registrants may also email [support@jujama.com](mailto:support@jujama.com) to request link be sent to them.

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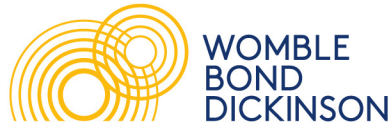
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## Course Instructors



**Anthony Atala, MD**

Director, Wake Forest Institute for Regenerative Medicine



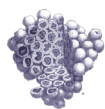
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**Graca Almeida-Porada, MD, PhD**

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Heather Hatcher, Ph.D.

Regulatory Scientist

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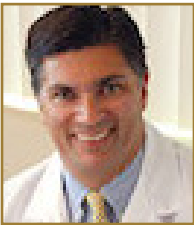
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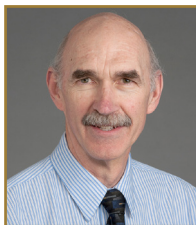
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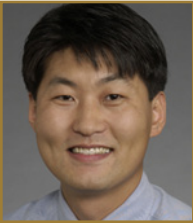
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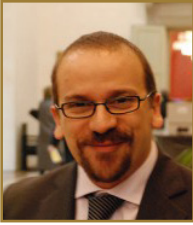
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**Delivering on the promise of regenerative medicine requires significant progress in manufacturing to scale up technologies and make them affordable.**

Making this progress a reality is the focus of the Regenerative Medicine Development Organization (ReMDO) – a non-profit organization that manages a consortium of more than 60 industry and academic members. The ultimate goal is to accelerate the transition of regenerative medicine technologies to the global market.



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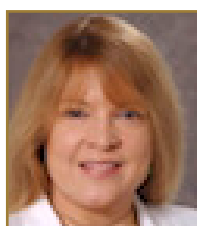
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**Thomas Tubon, PhD**

CoPI, NSF ATE InnovATEBIO, National Center  
for Biotechnology, Madison College



**Bill Wagner, PhD**

Director, McGowan Institute for Regenerative  
Medicine

## 2021 RME COURSE & WORLD STEM CELL SUMMIT AGENDA

### Regenerative Medicine Essentials Course

Monday, June 14

#### Session 1: Intro and Background; Pluripotent Stem Cells and Progenitors

8:15-8:30am	RME Course Welcome	Joan Schanck, MPA
8:30-9:00am	Current Concepts and Changing Trends	Anthony Atala, MD
9:00-9:10am	BREAK	
9:10-9:40am	RegenMed 1.0	Mahendra Rao, MD, PhD, Chair
9:40-10:00am	Regenerative Medicine's First Biomarker for Predicting Responsiveness to Stem Cell Therapy Based on Mechanism-of-action: Evidence from Cerebral Injury	Evan Snyder, MD, PhD, FAAP
10:00-10:20am	Development of an iPSC-derived Neuron Replacement Therapy for Parkinson's disease	Jeanne F. Loring, PhD
10:20-10:30am	BREAK	
10:30-10:50am	Live Panel Discussion	Moderator: Victoria Weis, PhD
10:50-11:00am	BREAK	

#### Session 2: Biomaterials

11:00-11:20am	Principles of Biomaterials: Specifications and Selection	David Williams, PhD, DSc, Chair
11:20-11:40am	Biomaterials for Biomolecule and Cell Delivery in Tissue Engineering	Tony Mikos, PhD
11:40am-12:00pm	Hydrogel Bioinks for Cell-Based Extrusion Bioprinting	Sang Jin Lee, PhD
12:00-12:20pm	Clinical Applications of 3D Printed Biomaterials	John Fisher, PhD
12:20-12:40pm	Regenerative Engineering of Bone: A Thirty Year Experience	Cato T. Laurencin, MD, PhD
12:40-12:50pm	BREAK	

#### Session 3: Enabling Technologies

2:10-2:30pm	Enabling Technologies Overview and Bioprinting: An enabling technology for tissue engineering and regenerative medicine	John Jackson, PhD, Chair
2:30-2:45pm	In Vivo Delivery of RNA and Genome Editing Tools	Daniel Anderson, PhD
2:45-3:00pm	Imaging and Regenerative Medicine	Frank Marini, PhD
3:00-3:15pm	Gene Therapy: Getting to the Root of the Disease for a Permanent Cure	Chris Porada, PhD
3:15-3:30pm	Genome Editing for Protection Against Heart Attack	Kiran Musunuru, MD, PhD, MPH, ML
3:30-3:40pm	BREAK	
3:40-4:00pm	Live Panel Discussion	Moderator: John Jackson, PhD
4:00-4:15pm	Closing Comments	Course Directors
4:15-4:30pm	BREAK	

4:30-5:30pm	Career Perspectives I: Creating The Right Career for You – A roundtable discussion Student Chairs: Bradford Kuhlman, Diana Lim, James Poteracki	Jamie Garza, MD, DDS, FACS; Graca Almeida-Porada, MD, PhD; Gary Green EdD, Beth Roxland, JD
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## Tuesday, June 15

### Session 4: Cell Therapies

8:00-8:10am	RME Course Day 2 Opening Comments	Joan Schanck, MPA
8:10-8:40am	Overview MSCs/COVID, Opioids, and More	Arnold Caplan, PhD
8:40-9:10am	Cell and Gene Based Biologic Therapies	Graca Almeida-Porada, MD, PhD, Chair
9:10-9:40am	Amniotic Epithelial Stem Cells for Lung and Wound Healing	Sean Murphy, PhD
9:40-9:45am	BREAK	
9:45-10:00am	Live Panel Discussion	Moderator: Graca Almeida-Porada, MD, PhD
10:00-10:15am	BREAK	

### Session 5: Tissue Engineered Medical Products/Temps and Biofabrications

10:15-10:35am	Considerations for Developing TEMPs	James Yoo, MD, PhD
10:35-10:55am	Soft Tissue Construct Development by Electrohydrodynamic Processing	Bill Wagner, PhD
10:55-11:15am	Glance into Biofabrication for TERM: Past, present and future	Lorenzo Moroni, PhD
11:15-11:35am	From Concept to Market: The Path and Pitfalls	Gail Naughton, PhD
11:35-11:45am	BREAK	
11:45am-12:05pm	Live Panel Discussion	Moderator: James Yoo, MD, PhD

### Session 6: Regulatory Policy, Process Development and Manufacturing

1:00-1:20pm	Regenerative Medicine Clinical Translation in Academia: How do we accelerate the technology to first-in-man?	Julie Allickson, PhD, Chair
1:20-1:40pm	FDA Perspectives on Characterization of Cell Therapies	Steve Bauer, PhD
1:40-2:00pm	From Business Card to IND: A CAR-T Case Study	Gary Pigeau, PhD
2:00-2:20pm	Addressing Cell Therapy Hurdles Through Cell Characterization and Innovation	Steve Becker, PhD
2:20-2:30pm	BREAK	
2:30-2:50pm	Live Panel Discussion	Moderator: Julie Allickson, PhD
2:50-3:00pm	BREAK	

### Session 7: Regenerative Rehabilitation with AR3T

3:00-3:20pm	Engineering The Regenerative and Rehabilitative Response to Musculoskeletal Trauma	Karina Nakayama, PhD, Chair
3:20-3:35pm	Predicting the Effects of Rehabilitation on Cartilage Repair	Riccardo Gottardi, PhD
3:35-3:50pm	Mechanical Regulation of Cartilage Repair: Relevance for Tissue Engineering and Rehabilitation	Sibylle Grad, PhD, PD
3:50-4:05pm	Cell Therapy for Spinal Cord Injury	Wenchun Qu, MD, PhD
4:05-4:20pm	Regenerative Rehabilitation of Complex Musculoskeletal Injuries	Robert Guldberg, PhD
4:20-4:30pm	BREAK	
4:30-4:45pm	Live Panel Discussion	Moderator: Karina Nakayama, PhD

4:45-5:00pm	Closing Day Comments	Joan Schanck, MPA
5:00-5:15pm	BREAK	
5:15-6:15pm	Career Perspectives II: Biotech Startups: Perspectives from New Investigators to Established Founders Student Chairs: Bradford Kuhlman, Diana Lim, James Poteracki	James Kovach, MD, JD, Mahendra Rao, MD, PhD, Andrea Mazzocchi, PhD

### Wednesday, June 16

#### Session 8: Clinical Trials and Bioethics

8:15-8:30am	RME Course Day 3 Opening Comments	Joan Schanck, MPA
8:30-8:45am	Bioethics & Regenerative Medicine: Basics & Beyond	Nancy King, JD
8:45-9:05am	Cord Blood and Cord Tissue Therapies in Children	Joanne Kurtzberg, MD
9:05-9:25am	MSC Clinical Trials	Joshua Hare, MD, FACC, FAHA
9:25-9:45am	Cell and Gene Therapy Clinical Trials	Jan Nolta, PhD
9:45-9:55am	BREAK	
9:55-10:15am	Live Panel Discussion	Moderator: Tracy Criswell, PhD
10:15-10:30am	BREAK	

#### Session 9: Commercialization

10:30-10:50am	Engineering Human Tissues for Medical Impact	Gordana Vunjak-Novakovic, PhD
10:50-11:10am	Translating Immunoengineering for Regenerative Medicine	Jennifer Elisseeff, PhD
11:10-11:30am	Commercial Planning of a Biotech Product – REACT Case Study	Deepak Jain, PhD
11:30-11:40am	BREAK	
11:40am-12:00pm	Live Panel Discussion	Moderator: Shay Soker, PhD
12:00-12:45pm	Lunch and Social Networking	

#### Session 10: Regenerative Medicine Hub

##### Business Development, Incubation, and Acceleration

12:45-12:52pm	ReMDO Overview	Rick Blume, Chair
12:52-12:59pm	Agile City Overview	Karen Barnes
12:59-1:06pm	Greater Winston-Salem Overview	Laura Lee
1:06-1:13pm	Winston Salem Starts Overview	Robert Boles
1:13-1:25pm	LIVE Panel Discussion	Moderator: Rick Blume
1:25-1:40pm	BREAK	

##### Workforce Development and Training – Defining an Ecosystem for RM Workforce

1:40-1:50pm	Needs and Gaps	Gary Green, EdD
1:50-2:00pm	Common Employability/Beta Skills	Russ Read, CPP (LERN), MA
2:00-2:10pm	Perspectives	Tom Tubon, PhD
2:10-2:20pm	WFIRM Training Ecosystem	Joan Schanck, MPA
2:20-2:30pm	LIVE Panel Discussion	Moderator: Tracy Criswell, PhD
2:30-2:45pm	BREAK	

Session 11: RMMS and SCTM

2:45-2:55pm	Introduction and Background	Joshua Hunsberger, PhD and Ann Murphy, PhD
2:55-3:15pm	RMMS Working Groups: Getting Involved, Progress, and Future Aspirations	Zohreh Izadifar, PhD and Shannon Eaker, PhD
3:15-3:30pm	BREAK	
3:30-4:30pm	Innovative Tech for Regenerative Medicine Manufacturing <ul style="list-style-type: none"><li>• PHC/Epredia: Digital Pathology for Regenerative Medicine - Steven Lynam, BCMAS</li><li>• Biospherix: Cytocentric - Alicia Henn, PhD, MBA</li><li>• SBI: Optical Sensing and Cell Culture - Jake R. Boy</li><li>• PHI: Non-invasive live cell imaging - Kersti Alm, PhD</li><li>• CellBox: Shipping and Logistics - Corné Swart, PhD</li><li>• Technical Break, followed by LIVE Panel Discussion</li></ul>	Joshua Hunsberger, PhD and Gary Green, EdD
4:30-5:00pm	Resources for Enabling a Regenerative Medicine Ecosystem	Ann Murphy, PhD and Joshua Hunsberger, PhD
5:00-5:15pm	RME Closing Remarks	Joan Schanck, MPA



