





2022 Virtual Regenerative Medicine Essentials Course & World Stem Cell Summit

June 6–11, 2022 https://rmecoursewscs.com

made possible by the NC Biotech Meeting Grant

North Carolina Biotechnology Center

Welcome to the 2022 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) 9th Annual Regenerative Medicine Essentials: From the Fundamentals to the Future course, which is held in conjunction with the 19th 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 19th Annual World Stem Cell Summit, held on June 10th and 11th.

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 2022 Course Director Joan F. Schanck, MPA Chief Education Program Officer, WFIRM RME 2022 Course Co-Director

Welcome to the 2022 RME & WSCS

On behalf of the Regenerative Medicine Foundation (RMF), I welcome you to the 2022 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

With Special Thanks and Recognition

Organizing Committee

Anthony Atala, MD RME 2022 Course Director; Director, WFIRM

Bernard Siegel, JD RME 2022 Course Co-Director; Executive Director, Regenerative Medicine Foundation

Joan F. Schanck, MPA RME 2022 Course Co-Director; Chief Education Program Officer, WFIRM

Bonnie Davis Chief Communications Officer, WFIRM

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Director of Communications,
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Callie Allen Education and Outreach Coordinator, WFIRM

Emily Gregg Web and Social Media Manager, WFIRM

Kevin McMahon Website Developer, Regenerative Medicine Foundation

Tracy Criswell, PhD Associate Professor, WFIRM

RME 2022 Career Perspectives Committee

Damian Hutchins Pre-Doctoral Fellow

Jao Ruiz Lucio de Lima Parra Pre-Doctoral Fellow

Dariya Lizanet Pre-Doctoral Fellow

Tim Dobroski Pre-Doctoral Fellow

Bradford Kuhlman Pre-Doctoral Fellow

Nicholas Edenhoffer Pre-Doctoral Fellow

Other Contributors

Terri Bowen Administrative Manager, WFIRM

Ernie Lookabill Financial Analyst, WFIRM

Bryanne Peterson Digital Consultant, YNoti Solutions















AR³T is supported by NICHD, NIBIB, and NINDS of the NIH under award number P2CHD086843



RESEARCH SUPPORT & EDUCATION

- Technology Development grants up to \$100,000 each to support the development of novel technologies
- Pilot Grants: up to \$150,000 is distributed each year
- Annual International Symposium on Regenerative Rehabilitation
- Webinar series
- List of publications and resources
- Advanced Training Course

WHAT IS AR³T

A multi-institutional network of laboratories supporting state-of-the-art research in the domains of tissue plasticity and regeneration, mechanobiology, and physical therapeutics

NIH-FUNDED RESOURCE CENTER

Supporting the development of Regenerative Rehabilitation by providing research collaborations and educational opportunities, and supporting technology development

RESEARCH AREAS

Biomaterials, Bioengineering,
Stem Cells, Cellular Therapeutics,
Mechanotransduction,
Mechanosensitive, Biomarkers,
Microtissue Systems, Animal Models,
Gene Therapy, Imaging

Regeneration

$\mathsf{AR}^3\mathsf{T}$ regenerative rehabilitation session tue. Jun 7



3:00 pm to 3:10 pm: Amrita Sahu, PhD, University of Pittsburgh

Regenerative Rehabilitation: An Introduction

3:10 pm to 3:30 pm: Spencer Szczesny, PhD, Pennsylvania State
University
Explant Model for Studying Tendon Degeneration and (Hopefully)





3:30 pm to 3:50 pm: Marian Hettiaratchi, PhD, University of Oregon Development of Mutifunctional Biomaterials Musculoskeletal Tissue Repair

3:50 pm to 4:10 pm: Franklin West, PhD, University of Georgia
Neural Stem Cell Function in a Motor Cortex TBI





4:10 pm to 4:20 pm: Eda Yildirim-Ayan, PhD, University of Toledo Mechanome-Guided Regenerative Rehabilitation

4:20 pm to 4:35 pm: Moderated Panel



Important Information

The RME/WSCS 2022 virtual conference is hosted on http://rmecoursewscs.com. Registered attendees can schedule virtual meetings, network, and interact including LIVE coffee breaks and moderated panels. All registrants received login credentials via e-mail. To request this information, e-mail Emily Gregg at egregg@wakehealth.edu.

All virtual postings will be offered for 90 days post-event.

We're Social!

Like, follow, and connect with us on social media. Follow along, post pictures, and ask questions.



@WFIRMnews



@RegenerativeMedicineFoundation









We are Students.

We are Educators.



Committed to developing international, intercultural, and interdisciplinary competencies for students and educators.

We are a Global Community.



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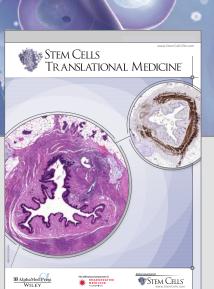
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STEM CELLS TRANSLATIONAL MEDICINE, the official journal partner of the Regenerative Medicine Foundation, publishes high impact articles and concise reviews related to the clinical translation of all types of stem cells, tissue engineering, and regenerative medicine manufacturing and therapies.



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JUNE 6



Anthony Atala MD

Director, Wake
Forest Institute
for Regenerative
Medicine



Joan Schanck MPA
Chief Education
Program Officer,
Wake Forest Institute
for Regenerative
Medicine



Mahendra Rao MD, PhD
CEO, Implants
Therapeutics



Joseph Wu MD, PhD
Director, Stanford
Cardiovascular
Institute; Professor,
Medicine &
Radiology, Stanford



Graca Almeida-Porada MD, PhD Professor, Wake Forest Institute for Regenerative Medicine



Victoria Weis PhD
Instructor, Wake
Forest Institute
for Regenerative
Medicine



Professor, Wake
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Buddy Ratner PhD
Professor, Bioengineering
and Chemical
Engineering, University
of Washington



Elizabeth Cosgriff-Hernandez PhD

Professor, Biomedical Engineering; The University of Texas at Austin



Associate Professor,
Department of
Bioengineering,
MIRM and CTO,
Renerva



Simon Young DDS, MD, PhD Associate Professor, Director of Research, UTHealth, School of Dentistry



John Jackson PhD
Associate Professor,
Wake Forest Institute
for Regenerative
Medicine



Rashid Bashir PhD
Professor,
Bioengineering; Dean,
Grainger College of
Engineering, University
of Illinois at UrbanaChampaign



John Fisher PhD
Professor; Department
Chair, Fischell
Department of
Bioengineering,
University of Maryland



Frank Marini PhD
Professor, Wake
Forest Institute
for Regenerative
Medicine



Christopher Porada PhD
Professor, Wake
Forest Institute
for Regenerative
Medicine



Robert Newman PhD
Associate Professor,
Biology, NC A&T
University

JUNE 6

WELCOME AND OPENING

8:15-8:25am Welcome and Introduction Joan Schanck, MPA 8:25—9:00am Overview/Plenary: Current Concepts and Changing Trends Anthony Atala, MD

Break

SESSION 1: PLURIPOTENT STEM CELLS AND PROGENITORS

9:10—9:30am Regen-MED 2.0 Mahendra Rao, MD, PhD 9:30—9:50am IPSCs for Disease Modeling, Drug Discovery, and Precision Medicine Joseph Wu, MD, PhD 9:50—10:10am Defining Stem and Progenitor Cell Populations for Prenatal Treatment of Graca Almeida-Porada, MD, PhD Genetic Disorders

10:10—10:30am Moderated Panel with Victoria Weis, PhD





SESSION 2: BIOMATERIALS

12:30—12:45pm

10:40—11:00am	The Plasticity of Biocompatibility	David Williams, PhD
11:00—11:20am	Engineering Biomaterials Surfaces for Biocompatibility and Blood Compatibility	Buddy Ratner, PhD
11:20—11:40am	Polymer Strategies to Enhance Bone Regeneration	Elizabeth Cosgriff-Hernandez, PhD
11:40—11:50am	Break	
11:50am—12:10pm	Immunomodulatory Biomaterials for Pelvic Floor Reconstruction	Bryan Brown, PhD
12:10—12:30pm	Biomaterials for Craniomaxillofacial Bone Regeneration	Simon Young, DDS, MD, PhD

Moderated Panel with David Williams, PhD Break

SESSION 3: ENABLING TECHNOLOGIES

1:30—1:40pm	Enabling Technologies in Regenerative Medicine Overview	John Jackson, PhD
1:40—2:00pm	Nanotechnology for Regenerative Medicine	Rashid Bashir, PhD
2:00—2:20pm	3D Printing Strategies for Engineering Complex Tissues	John P. Fisher, PhD
2:20—2:30pm	Break	
2:30—2:50pm	Imaging and Regenerative Medicine	Frank Marini, PhD
2:50—3:10pm	Gene Therapy: Getting to the Root of the Disease for a Permanent Cure	Christopher Porada, PhD
3:10—3:30pm	An Integrated Microengineered Organ Equivalent-Based Microfluidics System for Real-Time Detection of Signaling Dynamics and Metabolomics Profiles	Robert Newman, PhD
3:30—3:45pm	Moderated Panel with John Jackson, PhD	



CAREER PERSPECTIVES I

Beyond Academia and Big Pharma: Career Opportunities 4:00—5:15pm

Outside the Role of Primary Investigator with Breanna Deutsch,

Jana Stoudemire, Peter Marks, and Jeanne Loring

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Leaders: Damian Hutchins, Jao Ruiz Lucio de Lima Parra, Dariya Lizanet, Tim Dobroski, Bradford Kuhlman, Nicholas Edenhoffer, Tracy Criswell

JUNE 7



Sean Murphy PhD Associate Professor, Wake Forest Institute for Regenerative Medicine



Shahin Rafii MD Professor Chief and Director, Ansary Stem Cell Institute, Weill Cornell Medicine Graduate School of Medical Sciences



Farshid Guilak MD Professor and Co-Director, Washington University Center of Regenerative Medicine



Matthew Porteus MD, PhD James Yoo MD, PhD Professor, Pediatrics; Institute of Stem Cell Biology and Regenerative Medicine, Stanford



Professor, Wake Forest Institute for Regenerative Medicine



Karen Christman PhD Professor, Department of Bioengineering, Sanford Consortium for Regenerative Medicine



Molly Shoichet PhD Professor and Chair, Chemical Engineering, Donnelly Centre, University of Toronto



Pamela Yelick PhD Professor and Director, Craniofacial and Molecular Genetics, Tufts Graduate School of **Bioomedical Sciences**



Gail Naughton PhD Founder, Histogen, Inc.



Peter Marks MD, PhD Director, Center for **Biologics Evaluation** and Research, FDA



Wilson Bryan MD Director, Office of Tissues and Adv Therapies, Center for **Biologics Evaluation** and Research (CBER)



Sheng Lin-Gibson PhD Chief, Biosystems and Biomaterials Divison, National Institute of Standards and Technology



Amrita Sahu PhD Scientific Coordinator, AR3T, University of Pittsburgh



Spencer Szczesny PhD Assistant Professor, Biomedical Engineering, Pennsylvania State University



Marian Hettiaratchi PhD Assistant Professor, Bioengineering, University of Oregon



Franklin West PhD Associate Professor, Regenerative Bioscience Center, University of Georgia



Eda Yildirim-Ayan PhD Associate Professor, Department of Bioengineering, University of Toledo

9:40—10:00am

SESSION 4: CELL THERAPIES

8:00—8:15am	Opening Comments	Joan Schanck, MPA
8:15—8:35am	Wound Healing Applications of Perinatal Stem Cells and Tissues	Sean Murphy, PhD
8:35—8:55am	HSC's for Inherited Blood Disorders	Shahin Rafii, PhD
8:55—9:15am	Metacells: Re-engineering Living Cells as Therapeutic Delivery Systems	Farshid Guilak, PhD
9:15—9:35am	Genome Editing of Hematopoietic Stem Cells	Matthew Porteus, MD, PhD
9:35—9:40am	Break Sponsored By Phase HOLOGRAPHIC HOLOGRAPHIC	

Moderated Panel with Sean Murphy, PhD Break

SESSION 5: TISSUE ENGINEERING MEDICAL PRODUCTS

10:10—10:30am	Considerations for Developing TEMPs	James Yoo, MD, PhD
10:30—10:50am	Injectible Biomaterials for Translational Regenerative Engineering	Karen Christman, PhD
10:50—11:10am	Overcoming Blindness with Regenerative Medicine	Molly Shoichet, PhD
11:10—11:20am	Break	
11:20—11:40am	New Animal Models and Strategies for Craniomaxillofacial Defect Repair	Pamela Yelick, PhD
11:40am—12:00pm	From Concept to Market: The Path, Pitfalls and Progress	Gail Naughton, PhD
12:00—12:20pm	Moderated Panel with James Yoo, MD, PhD	



SESSION 6: REGULATORY, PROCESS DEVELOPMENT & MANUFACTURING

1:15—1:45pm	Future Directions in Cell and Gene Therapy	Peter Marks, MD, PhD
1:45—2:10pm	Regenerative Medicine Advanced Therapy (RMAT) Designation	Wilson Bryan, MD
2:10—2:30pm	Standards to Support Product Development, Manufacturing and Testing	Sheng Lin-Gibson, PhD
2:30—2:45pm	Moderated Panel with Beth E. Roxland, JD, M.Bioethics	

Break

SESSION 7: AR3T

3:00—3:10pm	Regenerative Rehabilitation: An Introduction	Amrita Sahu, PhD
3:10—3:30pm	Explant Model for Studying Tendon Degeneration and (Hopefully) Regeneration	Spencer Szczesny, PhD
3:30—3:50pm	Development of Multifunctional Biomaterials for Musculoskeletal Tissue Repair	Marian Hettiaratchi, PhD
3:50—4:10pm	Neural Stem Cell Function in a Motor Cortex TBI	Franklin West, PhD
4:10—4:20pm	Mechanome-Guided Regenerative Rehabilitation	Eda Yildirim-Ayan, PhD
4:20—4:35pm	Moderated Panel with Amrita Sahu, PhD	

Break

CAREER PERSPECTIVES II

4:45-6:00pm International Careers in Regenerative Medicine: Legal, Regulatory, and Ethical Perspectives on the World-Wide Job Market with

David Williams, Kacey Marra, Steve Lynum, Preveen Ramamoorthy

Sponsored By



Leaders: Damian Hutchins, Jao Ruiz Lucio de Lima Parra, Dariya Lizanet, Tim Dobroski, Bradford Kuhlman, Nicholas Edenhoffer, Tracey Criswell

JUNE 8



Nancy King JD Co-Director, Center for Bioethics, Health and Society, Wake Forest University



Abla Creasey PhD Vice President, Therapeutics Development, CIŔM



Jan Nolta PhD Stem Cell Program Director, UC Davis School of Medicine; Director, Institute for Regenerative Cures



Kacey Marra PhD Professor, Bioengineering; Vice Chair of Research, University of Pittsburgh



Tracy Criswell PhD Associate Professor, Wake Forest Institute for Regenerative Medicine



Milica Radisic PhD Professor, Research Chair, Cardiovascular Tissue Engineering, University of Toronto



Jana Stoudemire Commercial **Innovation Strategy** Lead, Axiom Space



Aletta Schnitzler PhD Chief Scientific Officer, TurtleTree Labs



B.J. Scheessele Chief Commercial Officer, Humacycte



Shay Soker PhD Professor, Wake Forest Institute for Regenerative Medicine



Gary Green EdD Chief Workforce Development Officer, **ReMDO**



Joshua Hunsberger PhD Chief Technology Officer, ReMDO; Executive Director, RMMS



Randy Yerden CEO, BioSpherix Medical



Peter Egelberg PhD CEO and Founder, Phase Holographic Imaging



Karmakar PhD Sr. Operations Research, **SAS** Institute



Jane Scott Head of Global Engagement and Growth, Greater Winston-Salem Oracle for Startups



Mark Owens President and CEO,



Jason Kaplan Associate Vice President, Innovation Quarter



Carrie DiMarzio CEO, BioMedInnovations



Heather Bara PhD Director, Research & Bioanalytics, MIMEDX



Joan Schanck MPA Chief Education Program Officer, Wake Forest Institute for

Regenerative Medicine



Russ Read Executive Director. National Center for the Biotechnology Workforce



Terry Howerton Biotechnology Instructor, Atkins Academic & Technology High School



Manju Bhat PhD Associate Professor and Associate Dean, Winston-Salem State University

JUNE 8

SESSION 8: CLINICAL TRIALS AND BIOETHICS

8:00—8:15am	Opening Comments	Joan Schanck, MPA
8:15—8:30am	Bioethics and Regenerative Medicine: Fundamentals for the Future	Nancy King, JD
8:30—8:50am	Advancing the Regenerative Medicine Ecosystem in California and Worldwide	Abla Creasey, PhD
8:50—9:10am	Cell & Gene Therapy Clinical Trials	Jan Nolta, PhD
9:10—9:40am	Clinical Translation of a Tissue-Engineered Nerve Guide	Kacey Marra, PhD
9:40—9:45am	Break	

9:40—9:45am

9:45—10:05am Moderated Panel with Tracy Criswell, PhD

Break

SESSION 9: COMMERCIALIZATION

10:15—10:35am	Advances in Organ on-a-Chip Engineering	Milia Radisic, PhD
10:35—10:55am	Commercializing Products for Emerging Markets on Earth and in Space	Jana Stoudemire
10:55—11:15am	Moving Toward Commercialization: Product and Process Development Considerations	Aletta Schnitzler, PhD
11:15—11:35am	Commercializing our HAV	B.J. Scheessele
11:35—11:40am	Break	
11:40am—12:00pm	Moderated Panel with Shay Soker, PhD	



SESSION 10: REG MED NEXUS FOR ECONOMIC DEVELOPMENT

12:45—1:00pm	Building a Cytocentric Testing Facility	Randy Yerden
1:00—1:15pm	Advanced Quality Control for Regenerative Medicine	Peter Egelberg, PhD
1:15—1:30pm	Data-Driven Optimization of Biomanufacturing Processes	Nabaruna Karmakar, PhD
1:35—2:05pm	Moderated Panel - Meet Our Test Bed Companies - with Gary Green, EdD	

Break Sponsored By



Co-Chairs: Gary Green and Joshua Hunsberger

SESSION 11: REG MED NEXUS FOR ECONOMIC DEVELOPMENT

RegeneratOR Innovation Accelerator

2:15—2:25pm	Oracle for Startups: Supporting Innovation in Healthtech	Jane Scott
2:25—2:35pm	Greater Winston Salem, Inc. Supporting Innovation	Mark Owens
2:35—2:45pm	Planning for a RegenMed Hub: Short and Long-Term Approaches	Jason Kaplan

RegeneratOR Innovation Accelerator Companies		Co-Chairs: Gary Green and Joshua Hunsberger	
2:45—3:00pm	BioMedInnovations: Breaking Barriers in Organ and Tissue I	Preservation Carrie DiMarzio	
3:00—3:15pm	Accelerating MIMEDX R&D to Expand the Reach of Placent	tal Biologics Heather Bara, PhD	
3:15—3:30pm	Axiom Space - Developing the Commercial Space Economy	y Jana Stoudemire	

Break

SESSION 12: REG MED NEXUS FOR WORKFORCE DEVELOPMENT			
	Co-Chairs:	Gary Green and Joan Schanck	
3:40—3:50pm	WFIRM's Training Ecosystem - Past, Present and Future Gaps	Joan Schanck, MPA	
3:50—4:00pm	Addressing the Gap - Gap 1: Skilled Technicians for Biomanufacturing	Gary Green, EdD	
4:00—4:30pm	NSF ATE Panel: Terry Howerton and Ed Ebert, PhD		
4:30—4:45pm	Addressing the Gap - Gap 2: New WFIRM Masters in Science Degree for Translational Biotechnology	Tracy Criswell, PhD	
4:45—5:00pm	Employers' Perspectives Round Table Discussion	John Moore, President Scientific Bioprocessing, Inc.	

