

4th Annual

Regenerative Medicine Essentials:

From the Fundamentals to the Future

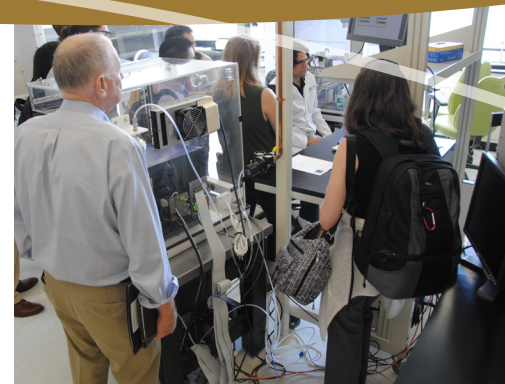
June 5–9, 2017

Wake Forest Bowman Gray Center for
Medical Education, Winston-Salem NC

Official Course of



**REGENERATIVE
MEDICINE**
FOUNDATION



Welcome to Regenerative Medicine Essentials 2017

On behalf of the course organizing committee and our prominent group of course instructors, I welcome all of you to the 4th Annual Regenerative Medicine Essentials: From the Fundamentals to the Future course.

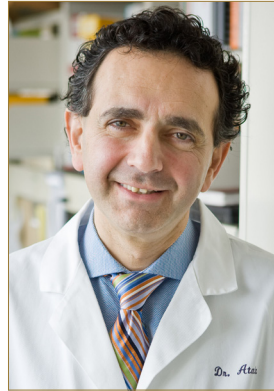
Often referred to as the next evolution of modern health care, regenerative medicine touches many disciplines — from clinical care and engineering to basic science and bioethics. This one-week course — the “official course of the Regenerative Medicine Foundation (RMF)” — taught by prominent experts in the field, addresses the interdisciplinary nature of regenerative medicine and provides attendees a foundation in this exciting field as well as a glance towards the future.

In partnership with RMF, the organizing committee has put together a dynamic and informative course that covers “essential” topics and addresses the fundamental principles and 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, and economic issues critical to the field. Our instructors, which include faculty from the Wake Forest Institute for Regenerative Medicine (WFIRM) as well as distinguished, prominent experts in the field from industry, academia and the government from across the globe, offer a firm foundation with insights into the future directions and potential applications of tissue engineering and regenerative medicine. Further, the course is a dynamic event, providing an ideal setting for academic, clinical and industry professionals to network with colleagues, and encouraging the formation of new exchanges, collaborations and learning opportunities in translational bioscience.

We are also excited to offer three “Into the Lab” workshops that provide hands-on interaction and demonstrations with cutting-edge technologies and techniques for regenerative medicine applications. Participants will have an opportunity to review and interact with these technologies and leading WFIRM researchers at WFIRM. Workshops are also designed to provide translational and commercial insight regarding these technologies and will highlight some of the current challenges and discuss potential approaches to overcome technical hurdles.

We hope this course 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. I look forward to an exciting, enjoyable and productive course for all.

With warmest regards,
Anthony Atala, MD, Director,
Wake Forest Institute for Regenerative Medicine



Welcome to Regenerative Medicine Essentials 2017

Dear colleagues,

On behalf of the Regenerative Medicine Foundation (RMF), I welcome you to RMF’s “official course” — the 4th annual Regenerative Medicine Essentials: From the Fundamentals to the Future. 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.

In my journey, I have found Winston-Salem to be one of the most collegial places on the planet. This week, I assure you, it’s the best place to learn about the future of medicine!

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 2017 Course Director,
Director, WFIRM

Bernard Siegel, JD
RME 2017 Course Co-Director,
Executive Director, Regenerative
Medicine Foundation

Joan F. Schanck, MPA
RME 2017 Course Manager
Academic Research Program Officer,
WFIRM

Joanne Gray
Education and Outreach Coordinator,
WFIRM

Emily McKenzie Gregg
Web and Social Media Manager,
WFIRM

Samantha Sells
RME2017 Program Coordinator,
WFIRM

Workshop Leaders and Committees

Introduction to Translation
Julie Allickson, PhD
Director, Regenerative Medicine
Clinical Center, WFIRM

Rich Payne, PhD
Associate Director, Process
Development, WFIRM

Lisa Hinshaw
Project Manager I, WFIRM

Darren Hickerson, MS, MDiv
Assistant Director, Manufacturing,
WFIRM

Todd Meinecke, MBA
Assistant Director, Quality Assurance,
WFIRM

Bioprinting Basics
John Jackson, PhD
Associate Professor, WFIRM

Daniel Cabrera
Cofounder and CEO, BioBots, Inc.

Ricky Solorzano
Cofounder and CTO, BioBots, Inc.

Carlos Kengla, PhD Student, WFIRM

Ashkan Shafiee, PhD, Post-Doctoral
Fellow, WFIRM

Madeline Winter, VP of Operations,
BioBots, Inc.

Margaret Prendergast
Bioengineer at BioBots, Inc.

Gabe Montoya
Wetware Intern at BioBots, Inc.

Decell/Recell Workshop
Aleksander Skardal, PhD, Assistant
Professor, WFIRM

Sean Murphy, PhD, Assistant Professor,
WFIRM

John Jackson, PhD, Associate
Professor, WFIRM

In Kap Ko, PhD, Assistant Professor,
WFIRM

Julio Aleman, Research Lab Technician,
WFIRM

Matthew Brovold, PhD Student,
WFIRM

Maresh Devarasetty, PhD Student,
WFIRM

Andrea Mazzocchi, PhD Student,
WFIRM

Hema Sivakumar, PhD Student,
WFIRM

Riccardo Tamburrini, MD, Post-
Doctoral Fellow, WFIRM

Jao Paulo Zambon, PhD, Research
Fellow, WFIRM

Cindy Zimmerman, MS, Histology
Core Technician, WFIRM

Cara Cloud, DVM, Research Associate,
WFIRM

Career Perspectives Committee

Kevin Enck, PhD Student, WFIRM

Oula Khoury, PhD Student, WFIRM

Renata Magalhaes, MD, PhD Student,
WFIRM

Peter Prim, PhD, Post-Doctoral Fellow,
WFIRM

Christina Ross, PhD, Post-Doctoral
Fellow, WFIRM

WFIRM Lab Tours

James Yoo, MD, PhD, Professor,
WFIRM

Tracy Criswell, PhD, Assistant
Professor, WFIRM

In Kap Ko, PhD, Assistant Professor,
WFIRM

Sang Jin Lee, PhD, Associate
Professor, WFIRM

Young Min Ju, PhD, Instructor, WFIRM

Aleksander Skardal, PhD, Assistant
Professor, WFIRM

Thomas Eaton, MS, Lab Operations
Manager, WFIRM

Kenneth Gyabaah, Imaging Core
Technician, WFIRM

Ray Johnson, Cell Culture Core
Technician, WFIRM

Tara Jones, Genetics Core Technician,
WFIRM

Cindy Zimmerman, Histology Core
Technician, WFIRM

Other Contributors

Robert Harrison Bardsley IV
Research Lab Technician II , WFIRM

Terri Bowen, Administrative Manager,
WFIRM

Bonnie Davis, Communications
Manager, WFIRM

Sunil George, PhD, Post-Doctoral
Fellow, WFIRM

Ernie Lookabilll, Financial Analyst
WFIRM

Beth Manning, Administrative
Assistant, WFIRM

Karen Richardson, Sr. Manager,
Communications, WFIRM

Donna Tucker, Administrative
Assistant, WFIRM

Norma Zayas, Administrative
Assistant, WFIRM

Important Information

RME 2017 Course Materials Dropbox link: bit.ly/RME17

Registrants may also email Joan Schanck at jschanck@wakehealth.edu to request link be sent to them.

We're Social!

Like, Follow, and Connect with Wake Forest Institute for Regenerative Medicine on social media. We will be live-tweeting and taking questions directed to any of the session and/or individual course instructors. You can submit questions *NOW* and *DURING* the course by using the hashtag **#RMEssentials**. We will also post daily pictures from the course on our Facebook account.



@WFIRMNews



@WFIRMNews



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4th Annual

Regenerative Medicine Essentials: From the Fundamentals to the Future

Wake Forest Institute for Regenerative Medicine

With Special Thanks to our Sponsors:

Gold Sponsors:



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NC Biotech Meeting Grant:



Exhibitors:



Contributor:



Workshop Sponsor:



Visitor Information

Directions to the Bowman Gray Center for Medical Education

475 Vine Street
Winston-Salem, NC 27101

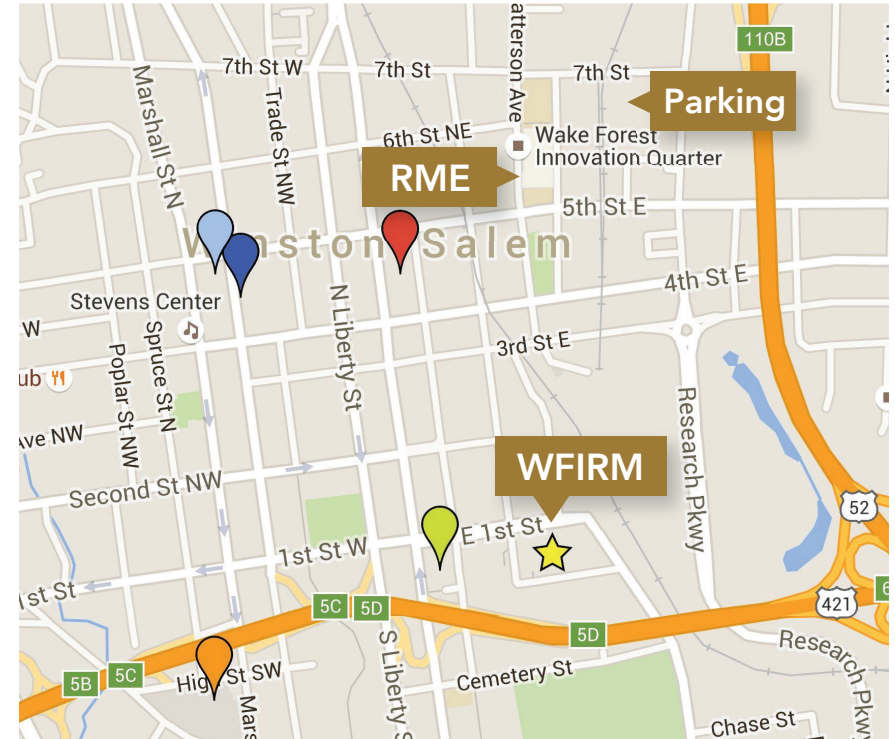



Bowman Gray Center for Medical Education

From the east (Greensboro): Take I-40W/73N toward Winston-Salem. Following 73N, keep left at the fork to continue on, following signs for I-40W. Merge onto I-40W. Use the right two lanes to take exit 206 for I-40W Business toward Winston-Salem Downtown. Take exit 6C toward ML King Jr. Dr./Winston-Salem State University. Turn right onto ML King Jr. Dr. then left onto E. 4th St. Turn right onto Vine St. then turn right onto E. 7th St. Parking lot P8 will be located on the right past Research Parkway. Follow path down E. 7th St. to turn left onto Vine St. to access the Bowman Gray Center for Medical Education.

From the west (Statesville): Take I-40E to Winston-Salem. Keep left to take exit 188 for I-40E Business toward Winston-Salem/Downtown. Take exit 5D and merge onto Main St. Turn right onto E. 4th St. Turn right onto Vine St. then turn right onto E. 7th St. Parking lot P8 will be located on the right past Research Parkway. Follow path down E. 7th St. to turn left onto Vine St. to access the Bowman Gray Center for Medical Education.

Hotels Near the Bowman Gray Center for Medical Education




 The Cardinal Hotel
(a Kimpton property)
336-724-5599

 Embassy Suites by Hilton
336-724-2300

 Fairfield Inn & Suites
by Marriott
336-714-2800

 Hawthorne Inn and
Conference Center
877-777-3099
*Owned by the Medical Center, the
Hawthorne Inn offers special rates
for guests.*

 Winston-Salem Marriott
800-770-5675

Stay An Extra Day: Places To Visit

Old Salem Museums and Gardens

900 Old Salem Rd.,
Winston-Salem, NC
www.oldsalem.org

In the middle of bustling downtown Winston-Salem, you are steps away from the quieter place of the 18th-century Moravian village of Old Salem Museums and Gardens. Enjoy a self-guided walking tour of the historic town. Don't miss a meal at the Tavern or Moravian sugar cake at Winkler Bakery.



Old Salem



Reynolda House

Reynolda House Museum of American Art

2250 Reynolda Rd.,
Winston-Salem, NC
www.reynoldahouse.org

As one considers great homes of the South, few possess more personal appeal than Reynolda House Museum of American Art. Its stellar collections of American art, decorative arts and costumes transport visitors into the era of the early 20th century. Nearby Reynolda Village offers shops and restaurants.

Downtown Arts District & Shopping

400-700 Trade St.,
Winston-Salem, NC (and surrounding areas)
www.dadaws.org

Downtown/Trade Street District has restaurants, retail shops, residences, business offices, and more located in this eclectic area of downtown between 5th and 7th Streets on Trade Street. Many businesses are housed in historic buildings that are characteristic to Winston-Salem's past and present.

For additional ideas visit www.visitwinstonsalem.com.

Stay An Extra Day: Places To Eat

The Tavern in Old Salem - American

736 South Main St.,
Winston-Salem, NC
336-722-1227

Winkler Bakery - Baked Goods

521 South Main St.,
Winston-Salem, NC
336-721-7302

Sweet Potatoes - Southern

529 Trade St.,
Winston-Salem, NC
336-727-4844

Bib's Downtown - Barbeque

675 West 5th St.,
Winston-Salem, NC
336-722-0007

Quanto Basta - Italian

680 West 4th St.,
Winston-Salem, NC
336-893-6144

Krankies - Coffee/American

211 East 3rd St.,
Winston-Salem, NC
336-722-3016

Famous Toastery - Breakfast

770 Liberty View Ct.
Winston-Salem, NC
336-306-9023

Willow's Bistro - American

300 South Liberty Ct.,
Winston-Salem, NC
336-293-4601



The Tavern in Old Salem pecan pie



Bibs Downtown BBQ plate

4th Annual

Regenerative Medicine Essentials:

From the Fundamentals to the Future

Course Instructors



Anthony Atala, MD

Director, Wake Forest Institute for Regenerative Medicine



Julie Allickson, PhD

Director, Regenerative Medicine Clinical Center, Wake Forest Institute for Regenerative Medicine



Graca Almeida-Porada, MD, PhD

Professor, Wake Forest Institute for Regenerative Medicine



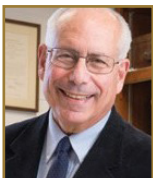
Guillermo Ameer, PhD

Professor, Biomedical Engineering and Department of Surgery at the Feinberg School of Medicine, Northwestern University



Daniel G. Anderson, PhD

Department of Chemical Engineering, Institute for Medical Engineering and Science, Harvard-MIT Division of Health Sciences and Technology; David H. Koch Institute for Integrative Cancer Research



Arnold Caplan, PhD

Professor, Departments of Biology, General Medical Sciences (Oncology), Pathology, and Biomedical Engineering, Case Western Reserve University; Founder of Osiris Therapeutic



Gabor Forgacs, PhD

Professor of Biological Physics, University of Missouri-Columbia; Chief Scientific Officer, Modern Meadows, Inc.



Beth Fordham-Meier

Principal and Founder, NovoCreation Consulting, LLC



Rosemarie Hunziker, PhD

Director of Tissue Engineering and Regenerative Medicine, National Institute of Biomedical Imaging and Bioengineering (NIBIB)

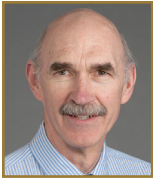
COLLABORATIVE INNOVATION

Wake Forest Innovations improves health through collaborative innovation between industry and the faculty and staff of Wake Forest Baptist Medical Center. We accomplish this through our two centers:

- **Center for Technology Innovation & Commercialization**, which accelerates the development and commercialization of inventions.
- **Center for Industry Research Collaboration**, which expedites access to specialized clinical and research capabilities.

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John Jackson, PhD

Associate Professor, Wake Forest Institute for Regenerative Medicine



Nancy King, JD

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



Joanne Kurtzberg, MD

Director, Pediatric Blood and Marrow Transplant Program, Duke University Medical Center



Frank Marini, PhD

Professor, Wake Forest Institute for Regenerative Medicine



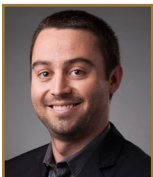
Antonios G. Mikos, PhD

Louis Calder Professor of Bioengineering, Chemical and Biomolecular Engineering, Director for Center for Excellence in Tissue Engineering, Director for J.W. Cox Laboratory for Biomedical Engineering, Rice University



C. Randal Mills, PhD

President & CEO, California Institute for Regenerative Medicine (CIRM)



Sean Murphy, PhD

Assistant Professor, Wake Forest Institute for Regenerative Medicine



Daniel K. Nelson, MS, CIP

Professor and Director of U.S. Environmental Protection Agency and University of North Carolina - Chapel Hill



Steven Oh, PhD

Chief, Cell Therapies; Office of Tissues and Advanced Therapies, FDA, CBER



Chris Porada, PhD

Associate Professor, Wake Forest Institute for Regenerative Medicine



Robert Preti, PhD

President & CEO, PCT



Becky Robinson-Zeigler, PhD

Chief of Pharmacology/Toxicology Branch 2 in CBER/OTAT



Bernie Siegel, JD

Executive Director, Regenerative Medicine Foundation



Aleksander Skardal, PhD

Assistant Professor, Wake Forest Institute for Regenerative Medicine

**Igor Slukvin, MD, PhD**

Professor, Department of Pathology and Laboratory Medicine, University of Wisconsin

**Rachel Smith, PhD**

Research Scientist and Faculty, Cedars Sinai Heart Institute; Vice President of Research and Development, Capricor Therapeutics

**Doris A. Taylor, PhD, FAHA, FACC**

Director, Regenerative Medicine Research, Texas Heart Institute; Director, Center for Cell and Organ Biotechnology at Texas Heart Institute and TAMU College of Veterinary Medicine

**Omid Veisheh, PhD**

Assistant Professor of Bioengineering, CPRIT Scholar in Cancer Research, Rice University

**Julie Watson, JD**

Special Counsel, Marshall, Gerstein & Borun, LLP; Intellectual Property Director and Legal Counsel, WFIRM

**David Williams, DSc**

Professor and Director of International Affairs, Wake Forest Institute for Regenerative Medicine

**James J. Yoo, MD, PhD**

Associate Director and Chief Scientific Officer, WFIRM

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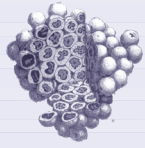
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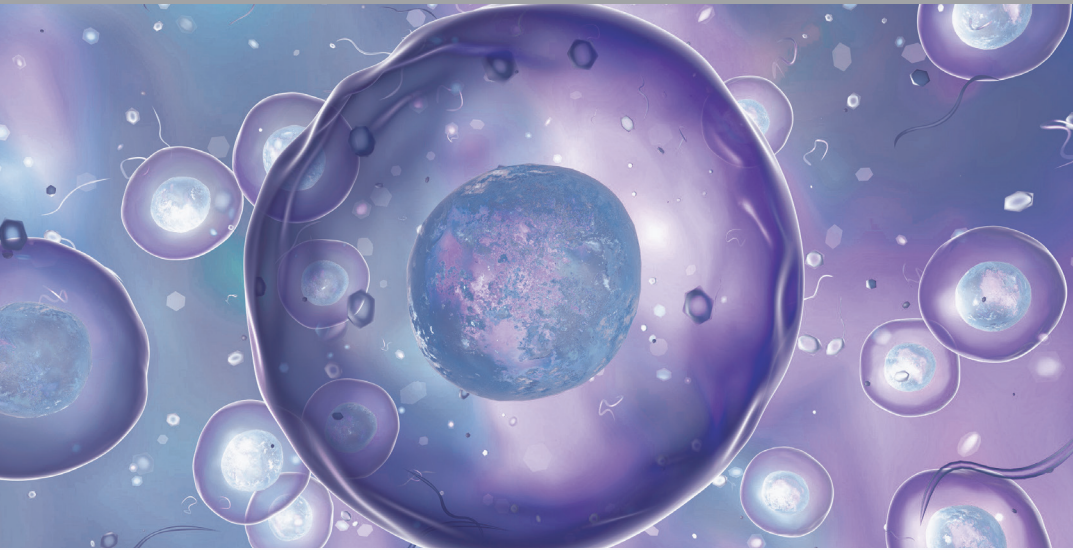
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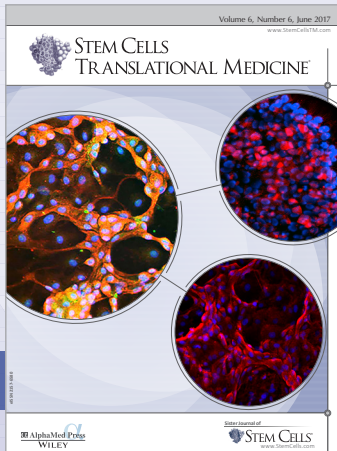


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Agenda

Day 1: Monday, June 5th	
11:45am - 1:15pm	Arrival and Registration
1:15pm - 1:30pm	Welcome and Opening Remarks
1:30pm - 2:15pm	Session I: Pluripotent Stem Cells and their Progenitors
2:15pm - 3:00pm	<i>Introduction and Background: PAST, PRESENT, FUTURE - The Evolution of Regenerative Medicine</i>
3:00pm - 3:15pm	<i>Stem Cells, Basic Biology, Therapeutics, and Vehicles for Gene Delivery</i>
3:15pm - 4:15pm	Coffee Break
4:15pm - 5:15pm	<i>MSC's are not SC's</i>
5:15pm - 5:45pm	<i>Cord-Blood Derived Stem Cells</i>
5:45pm - 7:00pm	Panel and Attendees Discussion
	Brief Closing Remarks
	Opening Reception
	(Heavy Hors D'oeuvres and Beer/Wine)
Day 2: Tuesday, June 6th	
7:45am - 8:30am	Continental Breakfast
8:30am - 9:15am	Session II: Biomaterials
	<i>Essential Biomaterials Science</i>
	David Williams, PhD (Chair)

5th floor
5107

5107

Anthony Atala, MD

5107

Graca Almeida
Porada, MD, PhD
(Chair)

5th floor

5107

Arnold Caplan, PhD

5107

Joanne Kurtzberg, MD

5107

Bernard Siegle, JD

5107

(Moderator)

1st floor

courtyard

5th floor

5107

David Williams, PhD

(Chair)

5107

9:15am - 10:00am	Citrate-Based Biomaterials Enabling New Tools for Regenerative Engineering Coffee Break and Exhibits	Guillermo Ameer, PhD	5107
10:00am - 10:15am			5th floor
10:15am - 11:00am			5107
11:00am - 11:45am	Hydrogel Biomaterials in Regenerative Medicine and Tissue Engineering Applications	Aleks Skardal, PhD	5107
11:45am - 12:15pm	Immune Modulatory Biomaterials for Cell-Based Therapies Panel and Attendees Discussion	Omid Veisesh, PhD	5107
12:15pm - 1:45pm	Lunch, Career Pathways in Regenerative Medicine Session I (From Postdoc to Faculty), and Exhibits	Christina Ross, PhD, Peter Prim, PhD and Renata Magalhaes, MD, Student Chairs/Moderators	5207
Session III: Enabling Technologies			
1:45pm - 2:30pm	Overview of Enabling Technologies in Regenerative Medicine (w/ Gene Therapy Applications)	Christopher Porada, PhD (Chair)	5107
2:30pm - 3:15pm	Tracking Stem Cells Anywhere in the Body - A Look at Regenerative Imaging	Frank Marini, PhD	5107
3:15pm - 3:45pm	Coffee Break and Exhibits		5th floor
3:45pm - 4:15pm	Bioprinting and Processes 101	John Jackson, PhD	5107
4:15pm - 5:00pm	CRISPR-Cas9 in the Clinic	Daniel G. Anderson, PhD	5107
5:00pm - 5:30pm	Panel and Attendees Discussion		5107
5:30pm - 6:15pm	Refreshments		5th Floor

Day 3: Wednesday, June 7th

7:45am - 8:30am	Continental Breakfast <i>Sign up for WFIEM Tours</i>		5th floor
Session IV: Cell Therapies			
8:30am - 9:15am	Overview w/Applications of Perinatal Stem Cells	Sean Murphy, PhD (Chair)	5107
9:15am - 10:15am	iPSC-based blood regenerative therapies	Igor Slukvin, MD, PhD	5107
10:15am - 10:30am	Coffee Break and Exhibits		5th floor
10:30am - 11:30am	Scale to Survive: The Future of Cell Therapy	Robert Preti, PhD	5107
11:30am - 12:00pm	Panel and Attendees Discussion		5107
12:00pm - 1:15pm	Lunch and Exhibits		5th floor & 5203, 5205
12:00 pm - 4:00 pm	RMF Executive Board Meeting (Invitation only)		5402
Session V: Tissue Engineered Products & Technologies (TEMPs)			
1:15pm - 1:45pm	Considerations for Developing Tissue Engineered and Regenerative Medicine Products	James Yoo, MD, PhD (Chair)	5107
1:45pm - 2:15pm	Biomaterials Commercialization	Tony Mikos, PhD	5107
2:15pm - 2:45pm	Commercial Applications of Bioprinting in Regenerative Medicine, Pharmaceuticals and Beyond	Gabor Forgacs, PhD	5107
2:45pm - 3:15pm	Panel and Attendees Discussion		5107
3:15pm - 4:00pm	Coffee Break and Exhibits		5th floor

3:30pm - 5:30pm	WFIRM Lab Tours (<i>Shuttle Service or Walk.</i> <i>Van shuttle to WFIRM from WF Medical Education Center from 3:15 pm to 5:45 pm).</i>		<i>Tours begin at 3:30; 3:50 and 4:10 pm</i>	Outside main lobby entrance
4:00pm - 5:30pm	Social Networking at WFIRM with Refreshments <i>WFIRM Patio</i>			WFIRM
Day 4: Thursday, June 8th				
8:00am - 8:45am	Continental Breakfast			5th floor
Session VI: Regulatory, Process Development & Manufacturing				
8:45am - 9:15am	<i>Translational Research from Proof-of Concept to Clinical Trials</i>		Julie Allickson, PhD (Chair)	5107
9:15am - 10:00am	<i>Think Like a Regulator: US FDA Considerations for Preclinical Studies for Regenerative Medicine Products</i>		Becky Robinson-Zeigler, PhD	5107
10:00am - 10:15am	Coffee Break and Exhibits			5th floor
10:15am - 11:00am	<i>Translation of TERM products into the clinic in US: FDA Perspectives II</i>		Steve Oh, PhD	5107
11:00am - 11:45am	<i>Regional and Global Perspectives</i>		David Williams, PhD	5107
11:45am - 12:15pm	Panel and Attendees Discussion			5107
12:15pm - 1:30pm	Lunch, Career Pathways in Regenerative Medicine Session II (Federal Perspectives), and Exhibits		Kevin Enck and Oula Khoury, Student Chairs/Moderators	5207
Session VII: IRB, Clinical Trials & Bioethics				
1:30pm - 2:30pm	<i>IRBs and Translational Research: Overlooking the Cutting Edge</i>		Daniel K. Nelson, MS, CIP	5107

2:30pm - 3:00pm	Translational Regenerative Medicine Research: Ethics Overview			Nancy King, JD	5107
3:00pm - 3:15pm	Coffee Break and Exhibits				5th floor
3:15pm - 3:45pm	Understanding NIH Funding of Regenerative Medicine (WebEx)			Rosemarie Hunziker, PhD	5107
3:45pm - 4:45pm	Cardiac Regenerative Medicine (Clinical Trials Case Studies)- Tentative Title			Rachel Smith, PhD	5107
4:45pm - 5:00pm	Panel and Attendees Discussion			Bernard Siegel, JD (Moderator)	5107
5:00pm - 5:30pm	Refreshments				5th floor
5:30pm - 6:45pm	NC BBQ and Social Networking				Bailey Park
Day 5: Friday, June 9th					
8:00am - 8:45am	Continental Breakfast				5th floor
Session VIII: Commercialization					
8:45am - 9:30am	IP 101: Securing IP for Regenerative Medicine			Julie Watson, JD	5107
9:30am - 10:00am	Opportunities and Risks in Commercializing Novel Regenerative Medicine Technologies			Beth Fordham-Meier	5107
10:00am - 10:15am	Coffee Break				5th floor
10:15am - 11:00am	Commercialization and the Pathways to Market (Case Study)			Doris Taylor, PhD	5107
11:00am - 11:45am	CIRM 2.0 and Beyond			C. Randal Mills, PhD	5107
11:45 - 12:00pm	Wrap-Up and Concluding Remarks				5107