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

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

Mahesh 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

Alekseander 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


Registrants may also email Joan Schanck at jshanck@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

Wake Forest Institute for Regenerative Medicine

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4th Annual
Regenerative Medicine Essentials: From the Fundamentals to the Future

Wake Forest Institute for Regenerative Medicine

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Visitor Information

Directions to the Bowman Gray Center for Medical Education

475 Vine Street
Winston-Salem, NC 27101

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 Reseach 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
- Fairfield Inn & Suites by Marriott 336-714-2800
- Winston-Salem Marriott 800-770-5675
- Embassy Suites by Hilton 336-724-2300
- Hawthorne Inn and Conference Center 877-777-3099

Owned by the Medical Center, the Hawthorne Inn offers special rates for guests.
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.

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
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)

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.

WakeForestInnovations.com
innovations@wakehealth.edu
+1.336.713.1111

Wake Forest Innovations
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
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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 Veiseh, 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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www.StemCellsTM.com
Day 1: Monday, June 5th

9:15am - 10:00am  
Citrate-Based Biomaterials Enabling New Tools for Regenerative Engineering  
Guillermo Ameer, PhD  
5107

10:00am - 10:15am  
Coffee Break and Exhibits

10:15am - 11:00am  
Hydrogel Biomaterials in Regenerative Medicine and Tissue Engineering Applications  
Aleks Skardal, PhD  
5107

11:00am - 11:45am  
Immune Modulatory Biomaterials for Cell-Based Therapies  
Omid Veiseh, PhD  
5107

11:45am - 12:15pm  
Panel and Attendees Discussion

12:15pm - 1:45pm  
Lunch, Career Pathways in Regenerative Medicine Session I (From Postdoc to Faculty), and Exhibits

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

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

5:30pm - 6:15pm  
Refreshments

Day 3: Wednesday, June 7th

7:45am - 8:30am  
Continental Breakfast  
Sign up for WFIRM Tours

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

10:30am - 11:30am  
Scale to Survive: The Future of Cell Therapy  
Robert Preti, PhD  
5107

11:30am - 12:00pm  
Panel and Attendees Discussion

12:00pm - 1:15pm  
Lunch and Exhibits

12:00 pm - 4:00 pm  
RMF Executive Board Meeting (Invitation only)

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, Pharmaceutics and Beyond  
Gabor Forgacs, PhD  
5107

2:45pm - 3:15pm  
Panel and Attendees Discussion

3:15pm - 4:00pm  
Coffee Break and Exhibits
Day 4: Thursday, June 8th

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Speaker(s)</th>
<th>Room</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:45am - 9:15am</td>
<td>Translational Research from Proof-of-Concept to Clinical Trials</td>
<td>Julie Allickson, PhD (Chair)</td>
<td>5107</td>
</tr>
<tr>
<td>9:15am - 10:00am</td>
<td>Think Like a Regulator: US FDA Considerations for Preclinical Studies for Regenerative Medicine Products</td>
<td>Becky Robinson-Zeigler</td>
<td>5107</td>
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<tr>
<td>10:00am - 10:15am</td>
<td>Coffee Break and Exhibits</td>
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<td>5th floor</td>
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<tr>
<td>10:15am - 11:00am</td>
<td>Translation of TERM products into the clinic in US: FDA Perspectives II</td>
<td>Steve Oh, PhD</td>
<td>5107</td>
</tr>
<tr>
<td>11:00am - 11:45am</td>
<td>Regional and Global Perspectives</td>
<td>David Williams, PhD</td>
<td>5107</td>
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<tr>
<td>11:45am - 12:15pm</td>
<td>Panel and Attendees Discussion</td>
<td></td>
<td>5107</td>
</tr>
<tr>
<td>12:15pm - 1:30pm</td>
<td>Lunch, Career Pathways in Regenerative Medicine Session II (Federal Perspectives, and Exhibits)</td>
<td>Kevin Enck and Oula Khoury, Student Chairs/Moderators</td>
<td>5207</td>
</tr>
</tbody>
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Session VII: IRB, Clinical Trials & Bioethics

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Speaker(s)</th>
<th>Room</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:30pm - 2:30pm</td>
<td>IRBs and Translational Research: Overlooking the Cutting Edge</td>
<td>Daniel K. Nelson, MS, CIP</td>
<td>5107</td>
</tr>
</tbody>
</table>

Day 5: Friday, June 9th

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Speaker(s)</th>
<th>Room</th>
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</thead>
<tbody>
<tr>
<td>8:45am - 9:30am</td>
<td>IP 101: Securing IP for Regenerative Medicine Opportunities and Risks in Commercializing Novel Regenerative Medicine Technologies</td>
<td>Julie Watson, JD</td>
<td>5107</td>
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<tr>
<td>9:30am - 10:00am</td>
<td>Coffee Break</td>
<td></td>
<td>5th floor</td>
</tr>
<tr>
<td>10:00am - 10:15am</td>
<td>Commercialization and the Pathways to Market (Case Study)</td>
<td>Doris Taylor, PhD</td>
<td>5107</td>
</tr>
<tr>
<td>11:00am - 11:45am</td>
<td>CIRM 2.0 and Beyond</td>
<td>C. Randal Mills, PhD</td>
<td>5107</td>
</tr>
<tr>
<td>11:45am - 12:00pm</td>
<td>Wrap-Up and Concluding Remarks</td>
<td></td>
<td>5107</td>
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</tbody>
</table>