

# 5th Annual Regenerative Medicine Essentials

## Course Schedule

Day 1: Monday, June 4th		
11:45am - 1:15pm	Arrival and Registration	
1:15pm - 1:30pm	Welcome and Opening Remarks	Joan Schanck MPA, WFIRM
Session 1: Pluripotent Stem Cells and their Progenitors		
1:30pm - 2:15pm	<i>Introduction and Background: Current Concepts and Changing Trends</i>	Anthony Atala, MD, Director, WFIRM
2:15pm - 3:00pm	<i>Stem Cells, Basic Biology, Therapeutics, and Vehicles for Gene Delivery</i>	Graça Almeida-Porada, MD, PhD, WFIRM (Chair)
3:00pm - 3:15pm	Coffee Break	
3:15pm - 4:00pm	<i>Stem Cell-Derived Retinal Pigmented Epithelium: Translation of a Cellular Therapy for Age-Related Macular Degeneration</i>	Dennis Clegg, PhD, UC Santa Barbara
4:00pm - 4:30pm	Panel and Attendees Discussion	Bernard Siegel, JD, Executive Dir, Regenerative Medicine Foundation (Moderator)
	Brief Closing Remarks	
4:30pm - 6:00pm	Opening Reception (Heavy Hors D'oeuvres and Beer/Wine)	
Day 2: Tuesday, June 5th		
7:45am - 8:30am	Networking and Continental Breakfast	
Session 2: Biomaterials		
8:30am - 9:10am	<i>Essential Biomaterials Science</i>	David Williams, PhD, WFIRM (Chair)
9:10am - 9:50am	<i>Engineering Naturally Derived Hydrogels for Applications in Regenerative Medicine</i>	Aleks Skardal, PhD, WFIRM
9:50am - 10:10am	Break - 20 mins. (Coffee Break and Exhibits)	
10:10am - 10:50am	<i>Engineering and Applications of Biomaterials in 3D Printing</i>	John Fisher, PhD, U of Maryland
10:50am - 11:30am	<i>Synthetic biomaterials for engineering bone and cartilage implants</i>	Anthony Melchiorri, PhD, Rice University
11:30am - 12:00pm	Panel and Attendees Discussion	
	Lunch and Exhibits	
12:00pm - 1:15 pm	Lunch Break and Exhibiting - Career Pathways Lunch Session I (for Grads/Fellows)	PhD Candidates: Kevin Enck and Andrea Mazzocchi
Session 3: Enabling Technologies		
1:15 pm – 2:00 pm	<i>Overview of Enabling Technologies in Regenerative Medicine (w/ Gene Therapy Applications)</i>	Christopher Porada, PhD, WFIRM (Chair)
2:00 pm – 2:45 pm	<i>Tracking Stem Cells Anywhere in the Body - A Look at Regenerative Imaging</i>	Frank Marini, PhD, WFIRM
2:45 pm – 3:00 pm	Coffee Break and Exhibits	
3:00 pm - 3:45 pm	<i>Bioprinting: Enabling Technology for Tissue Engineering and Regenerative Medicine</i>	John Jackson, PhD, WFIRM
3:45 pm - 4:30 pm	<i>Genome Editing for Research and Therapeutic Applications</i>	Kiran Musunuru, MD, PhD, MPH, FAHA, U of Pennsylvania
4:30 pm – 4:45 pm	<i>Flexcell's Dynamic 2 and 3D culture Systems for Stem Cell Tissue engineering</i>	Albert J. Banes, PhD, President, Flexcell
4:45 pm - 5:00 pm	Panel and Attendees Discussion	
5:00 pm – 6:00 pm	Refreshments and Networking	
Day 3: Wednesday, June 6th		
8:00am - 8:45am	Networking and Continental Breakfast	
Session 4: Cell Therapies		
8:45am - 9:30am	<i>Overview w/Applications of Perinatal Stem Cells</i>	Sean Murphy, PhD, WFIRM (Chair)
9:30am-10:45am	<i>Stem Cell Therapies for Human Heart Disease</i>	Joshua Hare, MD, U of Miami

10:45am - 11:05am	Coffee Break and Exhibits	
11:05am - 11:50 am	<i>Game Changers: Using Cord Blood to Help the Brain</i>	Joanne Kurtzberg, MD, Duke Medical Center
11:50am - 12:20pm	Panel and Attendees Discussion	
12:20pm - 1:30 pm	Lunch Break and Exhibiting	

### Session 5: Tissue Engineered Products & Technologies (TEMPS)

1:30pm - 2:10pm	<i>Tentative: Considerations for Developing Tissue Engineered and Regenerative Medicine Products (TEMPS) (Intro to include overview of examples?) Session Chair</i>	James Yoo, MD, PhD (Chair)
2:10pm - 2:50pm	<i>Translational Effort: Bringing a Regenerative Medicine Product to Patients (tentative)</i>	Saverio La Francesca, MD, Founder and CEO Orgagen, Inc.
2:50pm - 3:10 pm	Coffee Break and Exhibits	
3:10pm-3:50pm	<i>Regenerative Skin Substitutes: Discovery to Phase III Trial in Burns</i>	Allen Comer, PhD, Director of R&D, Stratatech
3:50pm- 4:20 pm	Panel and Attendees Discussion	
4:20pm - 5:00pm	Coffee Break and Exhibits	
4:30pm - 5:45pm	WFIRM "Into the Lab" Tours (Shuttle Service or Walk. Van shuttle to WFIRM from WF Medical Education Center from 3:15 pm to 5:45 pm).	<i>Tours begin at 4:30; 4:50 and 5:10 pm</i>
4:30pm - 6:00 pm	Social Networking at WFIRM with Refreshments (Light Hors D'oeuvres and Beer/Wine)	

### Day 4: Thursday, June 7th

7:45am - 8:30 am	Networking and Continental Breakfast	
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### Session 6: Regulatory, Process Development & Manufacturing

8:30 am - 8:45 am	<i>Presenting Sponsor: Nordmark Biochemicals Collagenase: The Key Enzyme in the Process of Cell Isolation</i>	Johanna Moench, PhD, Head of Nordmark Biochemicals
8:45 am - 9:15 am	<i>Intro to translation in Academia: Challenges and Possible solutions</i>	Julie Allickson, PhD, WFIRM (Chair)
9:15 am - 9:50 am	<i>Evolution of the Regulatory Framework for Regenerative Medicine</i>	Peter Marks, PhD, Director, CBER, FDA
9:50 am - 10:05 am	Coffee Break and Exhibits	
10:05 am - 10:40 am	<i>Topics Covered: How Federal Funding Agencies Interdigitate w/FDA, 21<sup>st</sup> Century Cures Act, New RM Biofab, etc.</i>	Martha Lundberg, PhD, NIH
10:40 am - 11:15 am	<i>Advocacy and the 21st Century Cures Act - Perspectives??</i>	Robert Klein, President and Founder, Americans for Cures
11:15am - 11:45am	Panel and Attendees Discussion	
11:45 am 12:45 pm	Lunch Break and Exhibiting - Career Pathways Lunch Session II (for Grads/Fellows)	Peter Prim, PhD, Postdoctoral Fellow and Renata Magalhaed, MD, Pre-doctoral Fellow


### Session 7: Clinical Trials & Bioethics

12:45pm - 1:15 pm	<i>Translational Regenerative Medicine Research: Ethics Overview</i>	Nancy King, JD, Wake Forest
1:15 pm - 1:55 pm	<i>Clinical Trials Case Studies: Commercial and Ethical Considerations for Execution and Reporting of Clinical Trials</i>	Todd McAllister, PhD, Amnion Foundation
1:55 pm - 2:15pm	Focus Break with Synapse and Exhibits	



2:15 pm - 2:45 pm	<i>IND/IDE: The Good, the Bad and the UGLY!</i>	Richard Clark, PhD, Stony Brook
2:45 pm - 3:10 pm	Panel and Attendees Discussion	
3:10 - 3:30 pm	Coffee Break and Exhibits	

### Session 8: Regenerative Rehabilitation

3:30 pm - 4:05 pm	<i>TBC - Introductory lecture w/foundational info on Reg Rehab</i>	Nick Willett, PhD, Emory
4:05 pm - 4:40 pm	<i>Interactive Effects of Rehabilitation and Cell Therapy to Treat Brain Damage</i>	Michel Modo, PhD, University of Pittsburgh
4:40 pm - 5:15pm	<i>Musculoskeletal</i>	George Christ, PhD, University of Virginia
5:15 pm - 5:30 pm	Panel and Attendees Discussion	
5:30pm - 6:45pm	NC BBQ ft. Sonny's BBQ and Social Networking	

### Day 5: Friday, June 8th

8:00 am - 8:45 am	Continental Breakfast	
<b>Session 9: Commercialization</b>		
	Session Moderator	Bernard Siegel, JD, RMF (Moderator)
8:45 am - 9:25 am	<i>IP 101: Securing IP for Regenerative Medicine</i>	Julie Watson, JD, WFIRM
9:25 am - 10:00 am	<i>Opportunities and Risks for Commercializing Novel RM Technologies</i>	Julie Watson, JD, WFIRM
10:00 am - 10:20 am	Coffee Break	
10:20 am - 11:00 am	<i>TBC - Commercialization in Action</i>	Gail Naughton, PhD, Histogen
11:00 am - 11:45am	<i>Patient Perspectives w/Americans for Cures Pt. Advocate(s)</i>	Adrienne Bell-Cors Shapiro, Patient Advocate, w/Bernard Siegel, JD, RMF (Moderator)
11:45 am - 12:00 pm	Wrap-Up and Concluding Remarks	Joan Schanck, MPA, WFIRM