



AAOS

AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

2009 AAOS/ORS CLINICAL TRIALS IN ORTHOPAEDICS RESEARCH SYMPOSIUM

THURSDAY - SATURDAY, MAY 7 - 9, 2009

Embassy Suites Albuquerque
Albuquerque, New Mexico

Symposium Co-Chairs: Jeffrey N. Katz, MD, MS; Elena Losina, PhD and James G. Wright, MD, MPH

SYMPOSIUM AGENDA

WEDNESDAY, MAY 6, 2009

4:00 – 7:00 PM	Symposium Check In <i>Faculty may load their PowerPoint presentations at this time.</i>	Sage
6:00 – 6:45 PM	Moderator / Breakout Leader / Young Investigator Meeting	Ocotillo I

THURSDAY, MAY 7, 2009

OFFICE HOURS (AGAVE ROOM): 7:00 AM – 5:30 PM

7:30 AM	Breakfast <i>Breakfast will be served in the back of the Ocotillo Room</i>	Ocotillo II
7:55 – 8:00 AM	Overview of Research Symposia <i>Sobail K. Mirza, MD – AAOS Research Development Committee Dartmouth - Hitchcock Medical Center</i>	
8:00 – 8:05 AM	Introduction of ORS Young Investigators <i>Christopher Evans, PhD Harvard Medical School</i>	
8:05 – 8:10 AM	Symposium Structure and Goals <i>Jeffrey N. Katz, MD, MS Brigham and Women's Hospital</i>	
8:10 – 8:40 AM	Keynote Address: Setting the Stage <i>James G. Wright, MD, MPH Hospital for Sick Children</i>	
8:40 – 8:55 AM	Questions and Answers	
SESSION I: CRITICAL RESEARCH QUESTIONS: STATUS REPORT AND AGENDA MODERATOR: JEFFREY N. KATZ, MD, MS		
8:55 – 9:00 AM	Session Introduction <i>Jeffrey N. Katz, MD, MS Brigham and Women's Hospital</i>	Ocotillo II
9:00 – 9:10 AM	1) Upper Extremities <i>Peter C. Amadio, MD Mayo Clinic</i>	
9:10 – 9:20 AM	2) Sports <i>Robert G. Marx, MD, MSc, FRCSC Hospital for Special Surgery</i>	
9:20 – 9:30 AM	3) Pediatrics <i>Unni Narayanan, MBBS, MSc, FRSC The Hospital for Sick Children</i>	

9:30 – 9:40 AM	4) Spine <i>David Coben, MD, MPH</i> <i>Johns Hopkins University</i>	Ocotillo II
9:40 – 10:00 AM	Questions and Answers / Discussion	
10:00 – 10:10 AM	BREAK	
10:10 – 10:20 AM	5) Lower Extremity Reconstruction <i>Daniel J. Berry, MD</i> <i>Mayo Clinic, Rochester</i>	
10:20 – 10:30 AM	6) Foot and Ankle <i>Judith F. Baumbauer, MD</i> <i>University of Rochester</i>	
10:30 – 10:40 AM	7) Tumors <i>John H. Healey, MD, FACS</i> <i>Memorial Sloan Kettering Cancer Center</i>	
10:40 – 10:50 AM	8) Trauma <i>Mohit Bhandari MD, MSc, FRCSC</i> <i>McMaster University</i>	
10:50 – 11:00 AM	9) Translational Research: Basic Discoveries to Clinical Trials <i>Christopher Evans, PhD</i> <i>Harvard Medical School</i>	
11:00 – 11:30 AM	Questions and Answers / Discussion	
11:35 AM – 1:10 PM	<u>Breakout Session One/ Working Luncheon</u> Identification of Research Questions	1A) Pinon
	<u>Group 1A: Upper Extremity / Sports</u> Moderator: <i>Peter C. Amadio, MD</i> Young Investigator: <i>John Claude Elfar, MD</i>	1B) Agave
	<u>Group 1B: Pediatrics / Spine</u> Moderator: <i>Andrew Howard, MD</i> Young Investigator: <i>Quanjun Cui, MD, MS</i>	1C) Ocotillo I
	<u>Group 1C: Lower Extremity / Foot and Ankle</u> Moderator: <i>Daniel J. Berry, MD</i> Young Investigator: <i>Hassan M.K. Ghomrani, PhD, MP</i>	1D) Sage
	<u>Group 1D: Tumor / Trauma</u> Moderator: <i>John H. Healey, MD, FACS</i> Young Investigator: <i>Wakenda Tyler, MD, MPH</i>	
1:15 – 1:45 PM	Report of Breakout Groups	Ocotillo II
SESSION II: OVERCOMING METHODOLOGICAL CHALLENGES MODERATOR: ELENA LOSINA, PHD		
1:45 – 1:50 PM	Session Introduction <i>Elena Losina, PhD</i> <i>Brigham and Women's Hospital</i>	Ocotillo II
1:50 – 2:20 PM	10) Overview of Key Methodological Challenges I <i>John A. Baron, MD</i> <i>Dartmouth Medical Center</i>	
2:20 – 2:50 PM	11) Overview of Key Methodological Challenges II <i>Tor Devin Tosteson, ScD</i> <i>Dartmouth-Hitchcock Medical Center</i>	
2:50 – 3:05 PM	12) Prognostic Factors and Subgroup Analysis in Clinical Trials <i>Elena Losina, PhD</i> <i>Brigham and Women's Hospital</i>	

3:05 – 3:20 PM	13) Equipoise (what it means, willingness to acknowledge uncertainties) <i>Bruce A. Levy, MD</i> <i>Mayo Clinic</i>	Ocotillo II
3:20 – 3:35 PM	Questions and Answers / Discussion	
3:35 – 3:50 PM	BREAK	
3:50 – 4:05 PM	14) Blinding / Concealment / Sham Control / Placebo Effect <i>Bruce Moseley, MD</i> <i>The Methodist Hospital</i>	
4:05 – 4:20 PM	15) Creating Collaborative Teams: Multicenter/Multinational Trials <i>Mobit Bhandari MD, MSc, FRCSC</i> <i>McMaster University</i>	
4:20 – 4:35 PM	16) Standardization Proficiency / Protocols <i>Judith L. Forman, MPH</i> <i>Dartmouth Medical School</i>	
4:35 – 4:50 PM	17) Research from a Chair's Perspective <i>Daniel J. Berry, MD</i> <i>Mayo Clinic, Rochester</i>	
4:50 – 5:05 PM	Questions and Answers / Discussion	
5:05 – 6:05 PM	Breakout Session Two Designing Proposals – Part I	2A) Pinon
	Group 2A: Moderator: <i>Robert G. Marx, MSc, FRCSC</i> Young Investigator: <i>John Claude Elfar, MD</i>	2B) Agave
	Group 2B: Moderator: <i>Sobail K. Mirza, MD</i> Young Investigator: <i>Quanjun Cui, MD, MS</i>	2C) Ocotillo I
	Group 2C: Moderator: <i>Ranjan Gupta, MD</i> Young Investigator: <i>Hassan M.K. Ghomrami, PhD, MP</i>	2D) Sage
	Group 2D: Moderator: <i>Mobit Bhandari, MD, MSc, FRCSC</i> Young Investigator: <i>Wakeanda Tyler, MD, MPH</i>	
7:00 PM	Opening Reception and Dinner <i>The Zinc Wine Bar is located 2 miles from the hotel. Please plan to take a taxi to the restaurant. Save your receipts for reimbursement.</i>	Zinc Wine Bar Private Balcony 3009 Central Ave NE Albuquerque, NM

FRIDAY, MAY 8, 2009		
OFFICE HOURS (AGAVE ROOM): 8:00 AM – 5:30 PM		
8:00 AM	Breakfast <i>Breakfast will be served in the back of the Ocotillo Room.</i>	Ocotillo II
SESSION III: CULTURAL AND PRACTICAL BARRIERS / ISSUES MODERATOR: JAMES G. WRIGHT, MD, MPH		
8:15 – 8:20 AM	Session Introduction <i>James G. Wright, MD, MPH</i> <i>Hospital for Sick Children</i>	Ocotillo II
8:20 – 8:35 AM	18) Overview of Clinical Trials: A Regulatory Perspective <i>Jonette Foy, PhD - U.S. Food and Drug Administration</i>	
8:35 – 8:50 AM	19) Culture of Orthopaedics <i>Marc F. Swiontkowski, MD</i> <i>University of Minnesota</i>	

8:50 – 9:05 AM	20) Training from an Investigator’s Perspective <i>Robert G. Marx, MD, MSc, FRCSC</i> <i>Hospital for Special Surgery</i>	Ocotillo II
9:05 – 9:20 AM	21) Infrastructure of Clinical Trials <i>Michael J. Bosse, MD</i> <i>Carolinas Medical Center</i>	
9:20 – 9:35 AM	22) Myths and Realities of Data Management for Clinical Trials <i>Christine Chaisson, MPH</i> <i>Boston University</i>	
9:35 – 9:50 AM	Questions and Answers / Discussion	
9:50 – 10:05 AM	23) Funding: NIH and Multinational <i>James Panagis, MD, MPH</i> <i>National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)</i>	
10:05 – 10:20 AM	24) Institutional Review Boards <i>Jeffrey N. Katz, MD, MS</i> <i>Brigham and Women’s Hospital</i>	
10:20 – 10:35 AM	25) Role of Journals in Printing Evidence Based Medicine <i>James D. Heckman, MD</i> <i>Journal of Bone and Joint Surgery</i>	
10:35 – 10:50 AM	Questions and Answers / Discussion	
10:50 – 11:00 AM	BREAK	
11:00 AM – 12:40 PM	Breakout Session Three/ Working Luncheon Designing Proposals – Part II Group 3A: Moderator: <i>Jeffrey N. Katz, MD, MS</i> Young Investigator: <i>John Claude Elfar, MD</i> Group 3B: Moderator: <i>Elena Losina, PhD</i> Young Investigator: <i>Quanjun Cui, MD, MS</i> Group 3C: Moderator: <i>John A. Baron, MD</i> Young Investigator: <i>Hassan M.K. Ghomrami, PhD, MP</i> Group 3D: Moderator: <i>Tor Devin Tosteson, ScD</i> Young Investigator: <i>Wakenda Tyler, MD, MPH</i>	3A) Pinon
		3B) Agave
		3C) Ocotillo I
		3D) Sage
12:45 -2:35 PM	Presentation of Breakout Groups / Questions and Answers	Ocotillo II
2:35 – 2:50 PM	BREAK	
SESSION IV: ECONOMIC EVALUATION: CONCEPTS AND METHODS MODERATOR: ELENA LOSINA, PHD		
2:50 – 2:55 PM	Session Introduction <i>Elena Losina, PhD</i>	Ocotillo II
2:55 – 3:15 PM	26) Overview of CEA (Measuring Costs and Effectiveness, Perspectives, Examples of CEA in Orthopaedics) <i>Anna Tosteson, ScD</i> <i>Dartmouth-Hitchcock Medical Center</i>	
3:15 – 3:35 PM	27) Cost-Effectiveness Analysis Alongside Clinical Trials <i>Alvin Mushlin, MD, ScM</i> <i>Weill Cornell Medical College</i>	
3:35 – 3:55 PM	28) Economic Evaluation Beyond the Timeline of the Clinical Trials <i>Elena Losina, PhD</i> <i>Brigham and Women’s Hospital</i>	

3:55 – 5:15 PM	Questions and Answers / Panel Discussion	Ocotillo II
5:15 PM	Evening Assignment Instructions <i>Jeffrey N. Katz, MD, MS; Elena Losina, PhD and James G. Wright, MD, MPH</i>	
7:00 PM	Dinner (Off Site) <i>The Los Equipales Restaurant is located 3 miles from the hotel. Please plan to take a taxi to the restaurant. Save your receipts for reimbursement.</i>	Los Equipales Restaurant 4500 Silver Ave SE Albuquerque, NM

SATURDAY, MAY 9, 2009

OFFICE HOURS (AGAVE ROOM): 7:00 AM – 12:00 PM

7:30 – 8:00 AM	Career Development Breakfast: <i>Please join us in this breakfast geared toward interacting with the Young Investigators.</i>	Ocotillo II
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SESSION V: CLINICAL PRACTICE / POLICY IMPLICATIONS: LOOKING FORWARD
MODERATOR: JAMES G. WRIGHT, MD, MPH

8:00 – 9:00 AM	PANEL DISCUSSION: <i>Bridging the Gap Between Policy Makers, Researchers, and Sponsors</i> <ul style="list-style-type: none"> ➤ Marc F. Swiontkowski, MD – <i>Journal of Bone and Joint Surgery</i> ➤ Joan McGowan, PhD – <i>NLAMS</i> ➤ Dan Schultz, MD – <i>Director, Center for Devices and Radiological Health - U.S. Food and Drug Administration</i> ➤ Paul Voorhorst - <i>DePuy Orthopaedic / AdvaMed</i> ➤ Kristy Weber, MD – <i>AAOS</i> ➤ Christopher Evans, PhD – <i>ORS</i> ➤ Thomas A. Einhorn, MD – <i>OREF</i> 	Ocotillo II
9:00 – 9:30 AM	Questions and Answers	
9:30 – 9:50 AM	Final Breakout Group Presentation: Group A	
9:50 – 10:10 AM	Final Breakout Group Presentation: Group B	
10:10 – 10:25 AM	BREAK	
10:25 – 10:45 AM	Final Breakout Group Presentation: Group C	
10:45 – 11:05 AM	Final Breakout Group Presentation: Group D	
11:05 – 11:40 AM	Wrap Up and Conclusion / Program Evaluation	
11:45 AM	Symposium Adjournment	
12:30 PM	Co-Chair Debriefing / Luncheon	

Young Investigator Attendees

Quanjun Cui, MD – Department of Orthopedic Surgery, University of Virginia School of Medicine
John Claude Elfar, MD – University of Rochester/Strong Memorial Hospital and Highland Hospital
Hassan M.K. Ghomrawi, PhD, MPH – Weill Cornell Medical College/ Hospital for Special Surgery
Wakenda Tyler, MD, MPH – Memorial Sloan-Kettering Cancer Center

U.S. Food and Drug Administration (FDA)

Dan Schultz, MD – Director, FDA Center for Devices and Radiological Health (CDRH)
Jonette Foy, PhD – Orthopedic Joint Devices Branch, Division of General, Restorative and Neurological Devices

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

James S. Panagis, MD, MPH – Director, Orthopaedics Program
Joan McGowan, PhD – Director, Musculoskeletal Diseases Branch

National Center for Medical Rehabilitation Research (NCMRR)

Nancy Shinowara, PhD (TBD) – Health Scientist Administrator, The Eunice Kennedy Shriver National Institute of Child Health and Human Development

Research Development Committee (RDC)

Ranjan Gupta, MD - Chair, Department of Orthopaedic Surgery, University of California, Irvine
Terri A. Zachos, DVM, PhD – Assistant Professor of Orthopaedic Surgery, Michigan State University

Society of Military Orthopaedic Surgeons (SOMOS)

Anthony E. Johnson, MD – McDonald Army Hospital

AAOS/ORS Clinical Trials in Orthopaedics

Meeting Room Guide

