



**SWHR**  
TRANSFORMING SCIENCE

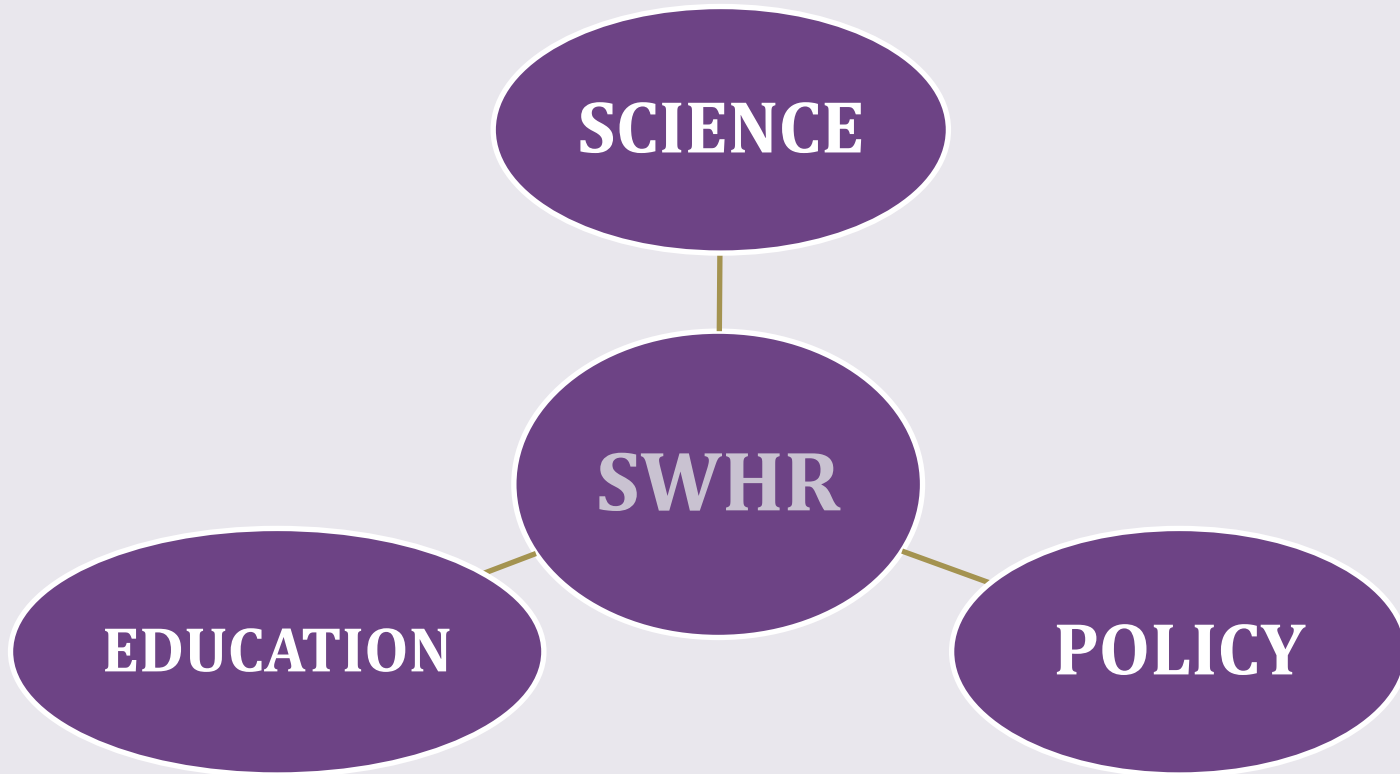
# **Priority Research Roadmap: SWHR's Efforts on Musculoskeletal Health**

**Christine Carter, PhD, MPH  
Vice President, Scientific Affairs**

**June 25, 2013**

# Society for Women's Health Research

*Transforming Science*



# SWHR Achievements

## 1990 - 1999

- **SWHR Founded**
- **GAO Audit** - *NIH: Problems in Implementing Policy on Women in Study Populations*
- **ORWH Created** at NIH
- **NIH Revitalization Act** by Congress
- **GAO Audit** - *FDA Needs to Ensure More Study on Sex Differences in Prescription Drug Testing*
- **Women's Health Office Act**
- **IOM Report** - *Sex matters in health from "womb to tomb"*
- **Women's Health Research Coalition**

## 2000 - Present

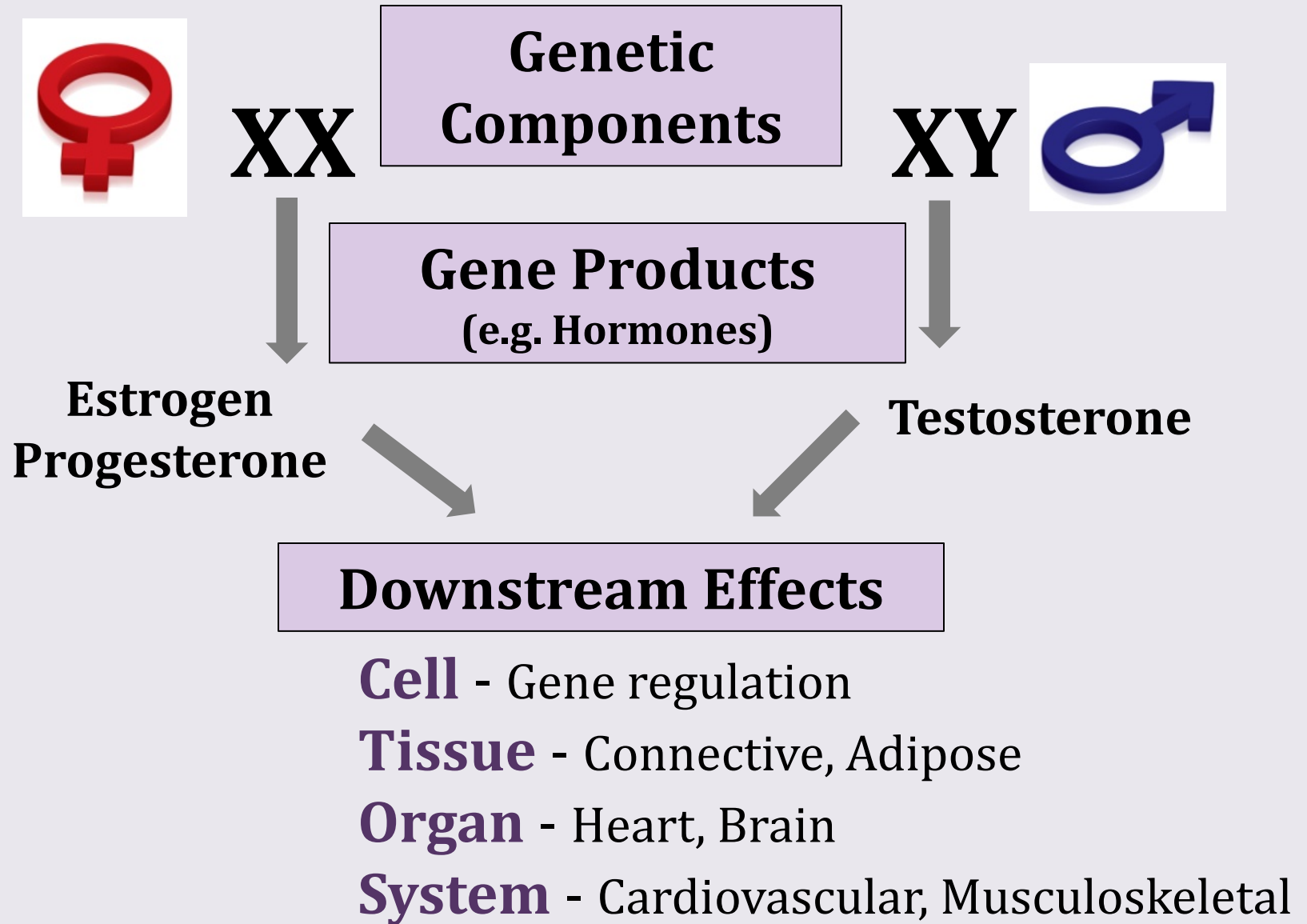
- **NIH Funding** for Research on Sex Differences
- **OSSD** - *Organization for the Study of Sex Differences*
- **SWHR and FDA OWH** host workshop, "FDA and the Critical Path Initiative"
- **ISIS Networks** launched
- **Biology of Sex Differences** – *Open Access Online Journal*
- **SWHR and FDA OWH** collaboration - *conference on women and minorities in clinical trials*
- **HEART Act** Passes the House of Representatives
- **SWHR and WomenHeart** - *2011 10Q Report on Women's Heart Health*
- **FDASIA** - FDA Safety and Innovation Act



# Why Study Sex Differences?

- Every cell knows its sex. Being male or female is a critical, basic human biological variable.
- ***Biological and physiological differences between men and women at genetic, cellular, tissue and organ levels***
- Understanding the importance of sex differences in disease prevention, diagnosis and treatment will transform disease research to accelerate improved care for all women and men.

# Sex Differences exist at all levels



# Sex and Prevalence in MSK Health

- Women have a higher prevalence of osteoarthritis of the hip and knee and have worse symptoms, compared to men. *(Hawker, G.A., et al., 2000)*
- Osteoporosis affects 8 million women and 2 million men. *(National Osteoporosis Foundation, 2005)*
- Osteoporosis-related fractures are a main cause of disability and mortality in the United States. *(Raisz, L.G., 2005)* One in two women and one in four men over 55 will have this type of fracture. *(National Osteoporosis Foundation, 2005)*
- Pain was greater and more widespread in women than men in ages 72 and older. *(Leveille, S.G., et al, 2005)*

# Sex Differences in MSK Health

- Cells from the bones of women are more susceptible to age-related changes than the same cells from men. *(Katzburg S et. al, 1999)*
- Menopausal hormonal changes attributed to more knee-related complaints in women compared to men (55-75). *(Paradowski PT, et al. 2006)*
- Women begin with less bone mass and lose it at a faster rate than men putting them at risk for Osteoporosis. *(Bone Health and Osteoporosis. A Report of the Surgeon General. 2004)*
- Men endure a greater loss of muscle or sarcopenia than women during aging; however women are more likely to suffer from health problems associated with sarcopenia (Doherty TJ, 2001)

# SWHR's Efforts to Advance MSK Health

- Annual Scientific Conferences
- Hill Briefings
- Educational Campaigns
- Annual Gala: *2012: "No Bones About It: XXcellence in Musculoskeletal Research"*
- **ISIS MSK Network**



# **“What a Difference an X Makes: The State of Women’s Health Research”**

***July 18-19, 2013***

***Laura Tosi, MD, George Washington University***

**Sex Differences in MSK Health**

***Saralyn Mark, MD, Solamed Solutions, LLC***

***MSK Health in Space Travel***

***Jan Chambers, National Fibromyalgia and Chronic***

***Pain Association***

**Patient Advocacy**

***Yvonne Lee, MD, Brigham and Women’s Hospital***

**Pain in Rheumatic Diseases**

***Kathleen Sluka, PhD, University of Iowa***

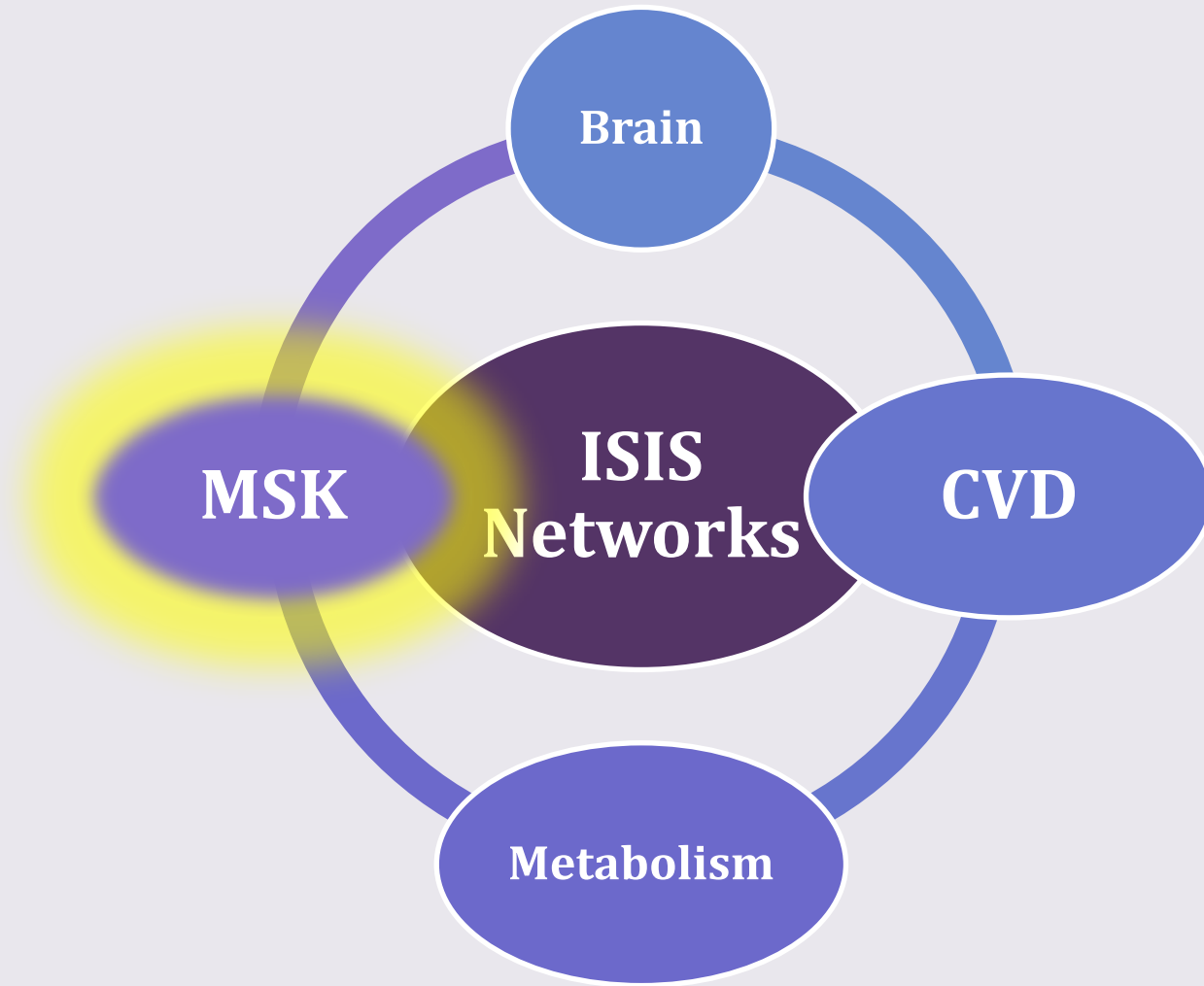
**Chronic MSK Pain**



# Capitol Hill Briefings

- **2000:** *Calcium: News You Can Use*
- **2006:** *Bone Up on Calcium & Vitamin D Facts: Knowledge Is Strength*
- **2007:** *Healthy Bones, Healthy Life*
- **2010:** *Size and Shape Matter: Osteoarthritis and Women*
- **2011:** *Women's Veterans' Health: SeXX Matters*

# Interdisciplinary **S**tudies In **S**ex differences (ISIS)



# ISIS Networks Poster



## The ISIS Networks: A Collaborative Model for Conducting Sex-based Research

Monica P. Mallampalli, PhD, MSc. and Christine L. Carter, PhD, MPH

**Mission: To promote interdisciplinary collaborations to discover new ideas in sex-differences research in a particular disease area consistent with SWHR mission.**

### Abstract

The Society for Women's Health Research (SWHR) has established a collaborative research network for Interdisciplinary Studies in Sex-differences (ISIS) to address cross-cutting research questions that address the biological differences at all levels (genetic, cellular, tissue and organism). These sex-differences have an impact on disease etiology, onset, progression, and treatment, and identifying them has the potential to revolutionize the way in which we understand health and disease for both men and women. The SWHR ISIS Network model facilitates the rapid exchange of data, hypotheses, and research approaches among investigators, and leads to the application of novel, multi-disciplinary, translational strategies for the study of sex-based biology. The SWHR ISIS Networks bring together investigators from diverse disciplines to think, discuss, debate and ultimately plan and conduct network-driven pilot studies. Each Network addresses a specific, but wide-ranging research question. The products developed by the Networks include papers, presentations, conferences, databases, e-content and pilot data applicable for funding larger studies. This poster describes the process, timelines and accomplishments of four successful SWHR ISIS Networks on sex-based biology.

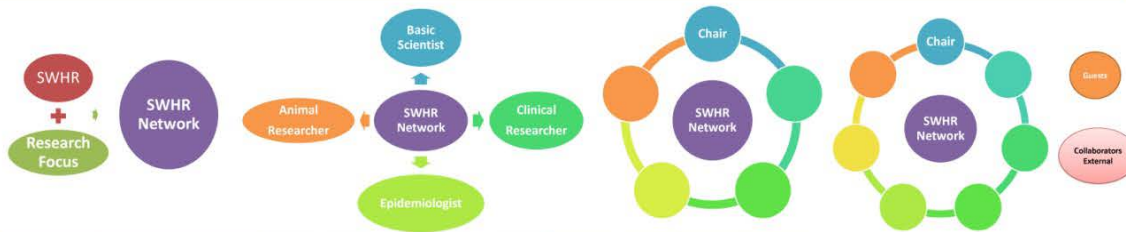
### Lifecycle

Year 1	<ul style="list-style-type: none"> <li>• Network Formation</li> <li>• Elect Chair</li> <li>• Brainstorming ideas, identify research gaps</li> </ul>
Year 2	<ul style="list-style-type: none"> <li>• Focusing research ideas</li> <li>• Planning pilot research projects from ideas</li> <li>• Submitting Network projects for funding</li> </ul>
Year 3	<ul style="list-style-type: none"> <li>• Continuing to plan new studies and developing ideas</li> <li>• Conducting pilot research</li> </ul>
Year 4	<ul style="list-style-type: none"> <li>• Continuing to plan new studies and developing ideas</li> <li>• Conducting pilot research</li> </ul>
Year 5	<ul style="list-style-type: none"> <li>• Presentations</li> <li>• Publications</li> <li>• Apply for external funding</li> </ul>

### Networks and Accomplishments

Research Focus	Drugs and Brain (Jan 2002-Sept 2007)	Metabolism (Aug 2003- Mar 2009)	Musculoskeletal Health (2007-Present)	Cardiovascular Disease (2009-Present)
<b>Mission</b>	Develop collaborations for exploratory and hypothesis-driven research on sex differences in nervous system function, and to translate the results of this research into new and/or improved therapies for advancing human health.	Advance the understanding of sex-dependent differences in energy homeostasis and metabolic disorders.	Advance translational research on musculoskeletal health in women and men.	Promote interdisciplinary and translational research that defines sex and gender differences in pathophysiology, health care delivery, and treatment effectiveness to reduce cardiovascular disease burden.
<b>Accomplishments</b>	<ul style="list-style-type: none"> <li>• 1 Book</li> <li>• 3 Review articles</li> <li>• 1 Meeting abstract</li> <li>• 14 Peer-reviewed publications</li> <li>• 4 ISIS pilot projects</li> <li>• 2 NIH funded projects</li> <li>• 8 Symposia at scientific meetings.</li> </ul>	<ul style="list-style-type: none"> <li>• 7 Peer-reviewed publications</li> <li>• Web portal</li> <li>• 5 Funded pilot projects</li> <li>• 2 Symposia at scientific meetings</li> </ul>	<ul style="list-style-type: none"> <li>• 5 Peer-reviewed publications</li> <li>• 1 Meeting abstract</li> <li>• 1 Advocacy document</li> <li>• 4 ISIS pilot project</li> <li>• 1 Follow-on grant</li> <li>• 4 Symposia at scientific meetings</li> <li>• 1 Workshop</li> <li>• 4 Symposia at scientific meetings</li> </ul>	<ul style="list-style-type: none"> <li>• 1 Review article</li> <li>• 6 Peer-reviewed publications</li> <li>• 2 Meeting abstract</li> <li>• 1 Advocacy document</li> <li>• 8 ISIS Pilot project</li> <li>• 1 Report (the 10Q)</li> <li>• 1 Podcast</li> <li>• 1 Workshop</li> <li>• 4 Symposia at scientific meetings</li> </ul>
<b>Highlighted Products</b>	<i>Sex differences in the brain from genes to behavior.</i> Edited by Becker JB, Berkley KJ, Geary N, Hampson E, Herman JP and Young E, Oxford University Press. 2007.	<b>The Adipose:</b> A web portal for researchers on obesity and adipose tissue. <a href="http://www.adipose.org">www.adipose.org</a>	<b>Addressing the gaps: sex differences in osteoarthritis of the knee.</b> Boyan B, Tosi L, Coutts R, Enoka EM, Hart DA, Nicoletta DP, Berkley KJ, Kwok K, O'Connor M, Kohrt W, Sluka KA and Resnick E. <i>Biology of Sex Differences</i> Journal. December 2013, 4:4.	<b>Strategies and Methods to Study Sex Differences in Cardiovascular Structure and Function: A Guide for Basic Scientists.</b> <i>Biology of Sex Differences</i> Journal. December 2011, 2:14.
<b># of members</b>	11	11	11	12
<b>Network Chair</b>	Jill Becker, PhD, University of Michigan, Ann Arbor, MI	Joel K. Elmquist, DVM, PhD, University of Texas Southwestern Medical Center, Dallas, TX	Barbara Boyan, PhD, Virginia Commonwealth University, Richmond VA	Noel C. Bairey-Merz, MD, FACC, FAHA; Cedars-Sinai Medical Center, Los Angeles, CA
<b>Network Members</b>	<ul style="list-style-type: none"> <li>• Art Arnold, PhD, University of California, Los Angeles, CA</li> <li>• Karen J. Berkley, PhD, The Florida State University, Tallahassee, FL</li> <li>• Jeffrey D. Blaustein, PhD, University of Massachusetts, Boston, MA</li> <li>• Elizabeth Hampson, PhD, University of Western Ontario, London, ON, Canada</li> <li>• James P. Herman, PhD, University of Cincinnati Medical Center, Cincinnati, OH</li> <li>• Wolfgang Sadleir, D. rer. nat., Ohio State University, Columbus, OH</li> <li>• Meir Steiner, MD, PhD, FRCP, McMaster University, Hamilton, ON, Canada</li> <li>• Jane Taylor, PhD, Yale School of Medicine, New Haven, CT</li> <li>• Elizabeth Young, MD (deceased), University of Michigan, Ann Arbor, MI</li> <li>• Steve Zalman, PhD (deceased), University of Medicine and Dentistry- New Jersey Medical School, Newark, NJ</li> </ul>	<ul style="list-style-type: none"> <li>• R. Jeffrey Chang, MD, University of California, San Diego, CA</li> <li>• Deborah Clegg, PhD, University of Texas Southwestern Medical Center, Dallas, TX</li> <li>• Susan K. Fried, PhD, Boston University, Boston, MA</li> <li>• Neri Geary, PhD, Swiss Institute of Technology, Zurich, Switzerland</li> <li>• Kevin Grove, PhD, Oregon Health and Science University, Portland, OR</li> <li>• Jennifer C. Lovisio, PhD, University of Washington, Seattle, Washington</li> <li>• Randy Seeley, PhD, University of Cincinnati, Cincinnati, OH</li> <li>• Philipp E. Scherer, PhD, The University of Texas Southwestern Medical Center, Dallas</li> <li>• Richard B. Simerly, PhD, University of Southern California, Los Angeles, CA</li> <li>• Steven R. Smith, MD, Louisiana State University System, Shreveport, LA</li> </ul>	<ul style="list-style-type: none"> <li>• Karen Berkley, PhD, Florida State University, Tallahassee, FL</li> <li>• Richard Coutts, MD, University of California, San Diego, CA</li> <li>• Roger M. Enoka, PhD, University of Colorado, Boulder, CO</li> <li>• David A. Hart, PhD, University of Calgary, Calgary, Canada</li> <li>• Wendy Kohrt, PhD, University of Colorado, Boulder, CO</li> <li>• Henri Kwok, MD, University of Pittsburgh, Pittsburgh, PA</li> <li>• Daniel Nicoletta, PhD, Research Institute, San Antonio, TX</li> <li>• Mary O'Connor, MD, Mayo Clinic, Jacksonville, FL</li> <li>• Phyllis Shukla, PT, PhD, University of Iowa, Iowa City, IA</li> <li>• Laura Tosi, MD, Children's National Medical Center, Washington, DC</li> </ul>	<ul style="list-style-type: none"> <li>• Sarah L. Berga, MD, Wake Forest University School of Medicine, Winston-Salem, NC</li> <li>• Jane Kaplan, PhD, Wake Forest School of Medicine, Winston-Salem, NC</li> <li>• Melissa M. Miller, PhD, MBA, Mayo Clinic, Rochester, MN</li> <li>• Phyllis Quyang, MBBS, Johns Hopkins University, Baltimore, MD</li> <li>• Joe F. Reckelhoff, PhD, University of Mississippi Medical Center, Jackson, MS</li> <li>• Janet Rich-Edwards, ScD, MPH, Harvard Medical School, Boston, MA</li> <li>• Leslie J. Shaw, PhD, Emory University School of Medicine, Atlanta, GA</li> <li>• Meir Steiner, MD, PhD, FRCP, McMaster University, Hamilton, ON, Canada</li> <li>• Doris A. Taylor, PhD, Texas Heart Institute, Houston, TX</li> <li>• R. Clinton Webb, PhD, Georgia Regents University, Augusta, GA</li> <li>• Nanette Wenger, MD, Emory University School of Medicine, Atlanta, GA</li> </ul>

### Network Formation



### Network Initiation (Network Administrator)

### Formation of Core Group (Members 3-5)

### Network Growth and Selection of Chair

### Final Network (Members 12)

### Administrator Role

- Plans and coordinates Network meetings;
- Prepares meeting agenda and assesses Network's progress;
- Facilitates communication with and among the Network members;
- Prepares and distributes meeting minutes;
- Provides Network progress and fiscal reports to funders when requested;
- Prepares financial reports and evaluates fiscal expenditure.

### Chair Role

- Execution of meeting agenda;
- Gather Network's consensus at the meeting;
- Communicate effectively with the Network Administrator and other Network members on relevant issues pertaining to minutes, meetings, Network Products;
- Assist Network Administrator in planning meeting agenda.

### Network Criteria

- Knowledge of sex differences to the relevant field;
- Established senior investigator with fully-funded research programs;
- High level of success and leadership;
- Commitment to Network participation;
- Commitment to collaborative research;
- Cross-disciplinary representation.

SWHR is a national non-profit organization based in Washington DC and founded in 1990, is widely recognized as the thought leader in research on sex differences and is dedicated to improving women's health through advocacy, education, and research.

Fundings: The SWHR ISIS Networks are funded by philanthropic donors, industry, or foundations.

# ISIS MSK Network: A Case Study

## Knee Osteoarthritis



## Members

- **Barbara Boyan**, PhD, *Virginia Commonwealth University, Richmond VA*
- **Karen Berkley**, PhD, *Florida State University, Tallahassee, FL*
- **Richard Coutts**, MD, *University of California, San Diego, CA*
- **Roger M. Enoka**, PhD, *University of Colorado, Boulder, CO*
- **David A. Hart**, PhD, *University of Calgary, Calgary, Canada*
- **Wendy Kohrt**, PhD, *University of Colorado, Boulder, CO*
- **Kent Kwoh**, MD, *University of Pittsburg, Pittsburg, PA*
- **Daniel Nicollela**, *Southwest Research Institute, San Antonio, TX*
- **Mary I. O'Connor**, MD, *Mayo Clinic, Jacksonville, FL*
- **Kathleen Sluka**, PT, PhD, *University of Iowa, Iowa City, IA*
- **Laura Tosi**, MD, *Children's National Medical Center, Washington, DC*

# ISIS MSK Network - *Reviews*

- Nicolella DP, Enoka RM, Boyan BD, Hart DA, Resnick E, Berkley KJ, Sluka KA, Kwoh CK, Tosi LL, O'Connor MI, Coutts RD, and Kohrt WM *Mechanical contributors to sex differences in knee osteoarthritis. Biology of Sex Differences 2013, 3:28*
- Sluka KA, Berkley KJ, O'Connor MI, Nicolella DP, Enoka RM, Boyan BD, Hart DA, Resnick E, Kwoh CK, Tosi LL, Coutts RD and Kohrt WM *Neural and psychosocial contributions to sex differences in knee osteoarthritic pain. Biology of Sex Differences 2013, 3:26*
- Boyan BD, Hart DA, Enoka RM, Nicolella DP, Resnick E, Berkley KJ, Sluka KA, Kwoh CK, Tosi L, O'Connor MI, Coutts RD and Kohrt WM *Hormonal modulation of connective tissue homeostasis and sex differences in risk for osteoarthritis of the knee. Biology of Sex Differences 2013, 4:3*
- Boyan BD, Tosi LL, Coutts RD, Enoka EM, Hart DA, Nicolella DP, Berkley KJ, Sluka KA, Kwoh CK, O'Connor MI, Kohrt WM, and Resnick E *Addressing the gaps: sex differences in osteoarthritis of the knee. Biology of Sex Differences 2013, 4:4*

# ISIS MSK Network - *Projects*

- Determination of Sex Differences, Heritability, and Sex-specific Genetic Effects on Knee Arthritis in a Non-human Primate Model

*Daniel Nicolella, Richard Coutts and Lorena Havill\**

- An Analysis of Sex Differences in Knee Osteoarthritis

*Mary O'Connor, Karen Berkley, Barbara Boyan and David Hart*

- Genetic Architecture of Knee OA: Lessons from Healthy Joints in Animals of Advanced Age

*Richard Coutts, Daniel Nicolella and Lorena Havill\**

- Association of Vitamin D Status with Pain Reporting in the Health ABC Study

*Laura Tosi, Kent Kwoh and Jane Cauley\**

**\*External collaborators**

# SWHR's Next Steps

- Continue to address research gaps and tackle policy issues
- Focus on MSK-related patient centered research
- Foster public-private partnerships
- Develop Public educational campaigns





# SWHR Program & Policy Staff

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