

## From the Executive Director

Dear Friends,  
Greetings from The Osteopathic Research Center! This spring the ORC continued to make great strides in advancing our core research missions of conducting: mechanistic studies of osteopathic manipulative treatment (OMT), clinical trials of OMT efficacy, and health services research to demonstrate the unique practice characteristics of osteopathic physicians in the United States. You can read updates on the status of our National Institutes of Health - National Center for Complementary and Alternative Medicine (NIH-NCCAM) sponsored clinical trials in this newsletter.

This spring, the ORC applied for “stimulus funds” through several programs announced by NIH as part of the American Recovery and Reinvestment Act of 2009. Together, our NIH proposals during the second quarter of 2009 requested about \$7 million in research funds. More information about one of our proposals involving the Consortium for Collaborative Osteopathic Research Development Practice-Based Research Network (CONCORD PBRN) is provided in this newsletter.

The ORC continues to have a presence at major osteopathic research conferences nationally and internationally. Roberto Cardarelli, DO, MPH, the ORC’s director of translational research, presented during the evidence-based medicine session of the 1<sup>st</sup> Pescara International Conference of Osteopathic Medicine in Italy in May. Steven Berley, DO and I will co-chair the AOA Research Conference this fall, entitled The Translation of Genomic Science into Osteopathic Clinical Practice and Research.

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Licciardone

## ORC to Co-Host AOA Research Conference

The Osteopathic Research Center and Steven Berley, DO, a family physician from Lindenhurst, NY, are teaming up to co-host the 2009 AOA Research Conference November 1-3 in New Orleans.

John C. Licciardone, DO, MS, MBA, the executive director of the ORC and the Osteopathic Heritage Clinical Research Chair, submitted the application to the AOA last fall to lead a conference focused on genomics in osteopathic clinical practice and research.

Martha Felini, PhD, MPH, assistant professor of epidemiology in the School of Public Health at the University of North Texas Health Science Center in Fort Worth, has also been instrumental in helping plan this conference.

In addition to Drs. Berley, Licciardone and Felini, this conference will include many national level speakers such as:

- W. Gregory Feero, MD, PhD, special advisor to the director of genomic healthcare at the National Human Genome Research Institute at the National Institutes of Health. Dr. Feero will deliver the keynote address for the Research Conference;
- Raoul Tibes, MD, PhD, director of the hematological malignancies program at the Translational Genomics Research Institute in Scottsdale, Ariz.;
- David Dooling, PhD, assistant director of the Genome Center, who oversees the Information Systems and Medical Genomics groups at the Washington University School of Medicine;
- Judith Benkendorf, MS, CGC, special assistant to the director of the American College of Medical Genetics;
- Jim Chinitz, BS, chief executive officer of Population Diagnostics, Inc.;

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- Michael Christman, PhD, president and CEO of the Coriell Institute for Medical Research;
- Brandon Colby, MD, MBA, founder and CEO of Existence Genetics;
- George Grills, PhD, director of operations and core facilities and director of advanced technology assessment for the life sciences core laboratory facilities at Cornell University;
- Yumi Kasai, PhD, associate director of the pharmacogenetics program at Mount Sinai School of Medicine;
- Roy Martin, DMin, assistant professor of clinical ethics, Texas College of Osteopathic Medicine, University of North Texas Health Science Center;
- Shannon Kiernan, MS, CGC, genetic counselor at Navigenics;
- David Tegay, DO, assistant professor of medicine and medical genetics at the New York College of Osteopathic Medicine; and
- Michael Terzella, DO, assistant professor of osteopathic manipulative medicine at the New York College of Osteopathic Medicine.

“This conference will contain significant material on genomics for the practicing osteopathic physician and osteopathic clinical researcher,” said Dr. Berley. “Because this conference is designed to impart foundational knowledge in this area that is frequently not addressed at this level in the medical school curriculum, it is appropriate for physicians, medical students, educators and basic scientists.”

**DIRECTOR** ————— *Continued from Page 1* —————

The ORC was also pleased to have Frank Willard, PhD, professor of anatomy at the University of New England College of Osteopathic Medicine, lecture on Pain and the Neuromusculoskeletal System at the University of North Texas Health Science Center in April in conjunction with the ORC initiatives in enhancing education in manual medicine research. Additional details on all of these events are available in this newsletter.

The ORC continues to move forward in many other ways, such as receiving national recognition for its research efforts, publishing in high-impact journals, attracting new members and advisors, and training clinical investigators and research personnel. Learn more about the ORC in this newsletter and via our website at [www.hsc.unt.edu/ORC](http://www.hsc.unt.edu/ORC). As I indicated in kicking off last year’s AOA Research Conference in Las Vegas, this is Your Osteopathic Research Center. As always, I welcome your comments and suggestions, and look forward to your continued support.

The agenda is included on Page 3 of this newsletter. See the AOA website at [www.do-online.org](http://www.do-online.org) for more information and to register for the research conference.



**Berley**



**Felini**



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The Osteopathic Research Center Newsletter is published in electronic format quarterly by The Osteopathic Research Center at the University of North Texas Health Science Center, Fort Worth, Texas.

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# 2009 AOA Research Conference Program

## *The Translation of Genomic Science into Osteopathic Clinical Practice and Research*

**Sunday, November 1, 2009**  
*The Science Behind Genomics*

- 8:00 a.m. - 8:15 a.m.     **Introductory remarks**  
*Steven Berley, DO*  
*Doctors' Care*
- John C. Licciardone, DO, MS, MBA*  
*The Osteopathic Research Center*
- 8:15 a.m. - 9:00 a.m.     **Research Conference Keynote Address:**  
**From genetics to genomics**  
*W. Gregory Feero, MD, PhD*  
*National Human Genome Research Institute*
- 9:00 a.m. - 9:45 a.m.     **The current state of next generation DNA sequencing technologies**  
*George Grills, PhD*  
*Cornell University*
- 9:45 a.m. - 10:00 a.m.     **Q & A**
- 10:00 a.m. - 10:15 a.m.     **Break**
- 10:15 a.m. - 11:00 a.m.     **Osteopathic principles applied in the genomic era**  
*Michael Terzella, DO*  
*New York College of Osteopathic Medicine*
- 11:00 a.m. - 11:45 a.m.     **Bioinformatics**  
*David Dooling, PhD*  
*Washington University School of Medicine*
- 11:45 a.m. - 12:00 p.m.     **Q & A**

**Monday, November 2, 2009**  
*Translational Genomics*

- 8:00 a.m. - 10:00 a.m.     **Convention-wide Keynote Address**
- 10:15 a.m. - 10:55 a.m.     **The Coriell personalized medicine collaborative: examining the utility of genome-informed medicine**  
*Michael Christman, PhD*  
*Coriell Institute for Medical Research*
- 10:55 a.m. - 11:35 a.m.     **Copy number variation (CNV) analysis and causative mutations**  
*Jim Chinitz, BS*  
*Population Diagnostics, Inc.*
- 11:35 a.m. - 12:15 p.m.     **Translating genomic information into personalized medical care**  
*Brandon Colby, MD, MBA*  
*Existence Genetics*

12:15 p.m. - 12:55 p.m.     **Direct-to-consumer genomic medical services**  
*Shannon Kieran, MS, CGC*  
*Navigenics*

1:15 p.m. - 2:30 p.m.     **COM Alumni Luncheons**

**Tuesday, November 3, 2009**  
*Clinical Genomics*

- 8:00 a.m. - 8:30 a.m.     **An osteopathic primary care model for integrating genomic medicine into clinical practice**  
*Steven Berley, DO*  
*Doctors' Care*
- 8:30 a.m. - 9:00 a.m.     **Genomic factors as predictors of response to osteopathic manipulative treatment among low back pain patients**  
*John C. Licciardone, DO, MS, MBA*  
*The Osteopathic Research Center*
- 9:00 a.m. - 9:40 a.m.     **Oncogenomics in clinical practice**  
*Raoul Tibes, MD, PhD*  
*The Translational Genomics Research Institute*
- 9:40 a.m. - 10:20 a.m.     **Pharmacogenomics and the promise of personalized medicine**  
*Yumi Kasai, PhD*  
*Mount Sinai School of Medicine*
- 10:20 a.m. - 10:30 a.m.     **Break**
- 10:30 a.m. - 11:10 a.m.     **Clinical neurogenomics**  
*David Tegay, DO*  
*New York College of Osteopathic Medicine*
- 11:10 a.m. - 11:40 a.m.     **The role of the genetic counselor**  
*Judith Benkendorf, MS, CGC*  
*American College of Medical Genetics*
- 11:40 a.m. - 12:10 p.m.     **Public health issues in genomic medicine**  
*Martha Felini, PhD, MPH*  
*University of North Texas Health Science Center*
- 12:10 p.m. - 12:50 p.m.     **Social and ethical issues pertaining to genomic medicine**  
*Roy Martin, DMin*  
*University of North Texas Health Science Center*
- 12:50 p.m. - 1:00 p.m.     **Wrap-up**
- To learn more about the conference, or to register for this conference, please visit the AOA website at [http://www.do-online.org/index.cfm?PageID=res\\_conf](http://www.do-online.org/index.cfm?PageID=res_conf). Information is also available on the ORC website at <http://www.hsc.unt.edu/ORC>.**

## ORC Internal Advisory Committee Meets



**Bastida**



**D'Agostino**



**Dubin**



**Kurz**

The Osteopathic Research Center convened its semi-annual Internal Advisory Committee (IAC) meeting in June. New members of the IAC were recently appointed and charged with helping to develop the strategic direction for the ORC's future research endeavors, including securing the resources to implement such research.

In addition to John Licciardone, DO, MS, MBA, executive director and Cathleen Kearns, administrative director of the ORC, the other voting members of the IAC include:

- Elena Bastida, PhD, is the associate dean for research for the School of Public Health, and interim chair of social and behavioral sciences. She earned her PhD in medical sociology from the University of Kansas in Lawrence, KS;
- Darrin D'Agostino, DO, MPH, is the chair of internal medicine at the Texas College of Osteopathic Medicine. He is a diplomat of the American Board of Internal Medicine, and is board certified in neuromusculoskeletal medicine. He earned his DO degree from the New York College of Osteopathic Medicine, and his MPH from the University of Connecticut;

- Bruce Dubin, DO, JD, serves as the interim dean for the Texas College of Osteopathic Medicine. He earned his DO degree from the Kirksville College of Osteopathic Medicine and his juris doctor from the University of Detroit College of Law;
- Richard Kurz, PhD, is the dean of the School of Public Health, and interim chair of health management and policy. He earned his PhD from the University of North Carolina at Chapel Hill;
- Kristine Lykens, PhD, MPA, is an assistant professor of health policy and management. She earned her PhD in political economy, and her master of public affairs at the University of Texas at Dallas;
- Jerry Simecka, PhD, is the chair of molecular biology and immunology. He earned his PhD at the University of Alabama-Birmingham;
- Jamboor Vishwanatha, PhD, is the dean of the Graduate School of Biomedical Sciences, the director of the Texas Center for Health Disparities, and the scientific director for the Institute for Cancer Research. He earned his PhD from the University of South Carolina-Columbia.



**Lykens**



**Simecka**



**Vishwanatha**

# Academic Medicine Publishes Osteopathic Medicine and Medical Education Theme Issue

The Osteopathic Research Center and several of its members were prominently represented in the Osteopathic Medicine and Medical Education theme issue of Academic Medicine in June. Marc Hahn, DO, former dean of the Texas College of Osteopathic Medicine at the University of North Texas Health Science Center, served as the guest editor for the issue, which included 14 articles with an osteopathic theme.

Dr. John Licciardone, Michael Clearfield, DO, dean of the Touro University College of Osteopathic Medicine-California, and V. James Guillory, DO, MPH, vice president for research for the Kansas City University of Medicine and Biosciences, contributed an original research article on the clinical practice characteristics of osteopathic and allopathic primary care physicians at academic health centers based on an estimated 4.5 billion physician office visits in the United States from 2002 through 2006. The authors concluded that osteopathic physicians in a non-academic health center (non-AHC) setting (i.e., community-based physicians) offered a more

distinctive osteopathic approach to primary care than osteopathic physicians at AHCs. For example, osteopathic physicians in the community ordered fewer drugs and more often performed osteopathic manipulative treatment than their osteopathic counterparts at AHCs.

The findings generally refuted the hypothesis that osteopathic physicians at AHCs, including the colleges of osteopathic medicine, are more likely to be role models of the osteopathic philosophy than osteopathic physicians in the community setting.

Other articles with an ORC connection included: a point-counterpoint piece by Kenneth Veit, DO, member of the ORC's External Advisory Committee, on osteopathic medical graduates in ACGME residencies; an article by Don Peska, DO, MEd, faculty member of the ORC, and colleagues on osteopathic postdoctoral training institutions; and an article by Scott Stoll, DO, PhD, former executive director of the ORC, and colleagues involving an historical view of osteopathic research.

## Cardarelli Represents ORC at Conference in Pescara, Italy



Roberto Cardarelli, DO, MPH, director of translational research for The Osteopathic Research Center and the executive director of the Primary Care Research Institute at the University of North Texas Health Science Center, was invited to speak at the

1<sup>st</sup> Pescara International Conference of Osteopathic Medicine in Italy on May 23.

His presentation entitled, An Evidence-based Approach to Better Understand Methodological Issues in Conducting Osteopathic Research, focused on issues that are faced in conducting research on osteopathic manipulative treatment (OMT). The discussion identified challenges related to placebo effects, control groups and methods to reach valid conclusions. An important distinction between efficacy and effectiveness research created the underpinning for future discussions on OMT research. Dr. Cardarelli is collaborating with John C. Licciardone, DO, MS, MBA, executive director of The Osteopathic Research Center, on new research initiatives to study the effectiveness of OMT as a complementary treatment for chronic low back pain.

The conference session evolved into exciting discussions assessing the possibility of future international collaborative projects. Congratulations to our colleagues in Italy for organizing a wonderful and successful event!

## ORC to Develop Nationwide OMM Practice-Based Research Network

The Osteopathic Research Center (ORC) is developing a nationwide network of osteopathic physicians to conduct osteopathic manipulative medicine research.

Through this project, the ORC would recruit two cohorts of 12 physicians annually. The training portion of the cohort experience would last for one year, during which time, each physician would receive research training over six extended weekend sessions in Fort Worth. Both cohorts would work with the ORC to collect data from their practices for a nationwide osteopathic manipulative medicine (OMM) research project that is designed to help the physicians learn to implement the knowledge they have gained during the extended weekend sessions.

The training component of the grant would include 184 hours of instruction on clinical research design and conducting clinical research. Over the course of the year, each cohort of 12 physicians will receive instruction as follows: 24 hours of clinical epidemiology, 24 hours of biostatistics, 16 hours of data management, 16 hours of evidence-based medicine, 8 hours of genetics, 8 hours of immunology, 10 hours of

human subjects training, 16 hours of training specific to conducting research on low back pain and other musculoskeletal conditions, 26 hours on practice-based research networks, 12 hours on The Osteopathic Research Center and the research conducted there, 8 hours on psychosocial aspects of chronic pain, and 16 hours on conducting research on manipulation (including developing protocols for studies).

Each physician selected to participate in the program will receive travel reimbursement, clinical research training, access to data entry tools and databases, assistance with data entry, mentoring in research and support in collecting data and managing OMM protocols for use in research studies. The Texas College of Osteopathic Medicine will offer a certificate to those individuals who successfully complete the program.

Watch the ORC website at <http://www.hsc.unt.edu/> ORC for more information about this project and to apply to the program. The first cohort of 12 physicians could begin as early as December 1, depending on funding for the project being finalized.

### Willard Speaks at UNTHSC

Frank Willard, PhD, professor of anatomy at the University of New England College of Osteopathic Medicine in Biddeford, Maine, was on the University of North Texas Health Science Center campus April 8 to present a lecture on basic mechanisms of pain and the neuromusculoskeletal system.

He will be working with several UNTHSC faculty to deliver a special seminar series to students and pre-doctoral fellows that incorporates research education, manipulative medicine and gross anatomy.

The presentation was supported by a NIH-NCCAM R25 research education grant for which des Anges Cruser, PhD, MPA, executive director of the Mental Sciences Institute and research education director for the ORC, is the principal investigator. The Osteopathic Heritage Foundation also provides funding to extend the R25 grant to other osteopathic medical schools in the U.S.

Dr Willard's visit was in conjunction with ORC initiatives in enhancing education in manual medicine research. For more information about the R25, visit the ORC website at <http://www.hsc.unt.edu/orc/education.htm>.

### ORC Clinical Trials Update

The Osteopathic Research Center (ORC) is conducting the largest osteopathic manipulative medicine (OMM) clinical trials in the world. All clinical trials underway at the ORC are funded by the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NCCAM).

The OSTEOPATHic Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial is the largest OMM clinical trial ever. It will evaluate osteopathic manipulation as a treatment for non-specific chronic low back pain. This research is funded under a K24 Mid Career Investigator Award. Targeted enrollment for this study is 488 subjects. As of June 27, 356 subjects have been enrolled in this study and 267 of those subjects have completed the study.

Another clinical trial underway at the ORC focuses on the use of osteopathic manipulation to reduce back pain, improve function, and improve delivery outcomes in the third trimester of pregnancy. This study aims to recruit 400 subjects. Currently, there are 130 subjects that have been enrolled in the study, with 106 of those subjects having completed the study.

## ORC Helps Interns Experience the Real World of Clinical Research

The Osteopathic Research Center is pleased to provide research internships for graduate students seeking a degree in Clinical Research Management. Debbie Lewis, RN, clinical research supervisor for the ORC's Clinical Research Unit, works closely with Patricia Gwartz, PhD, assistant dean of the Graduate School of Biomedical Sciences and professor of integrative physiology, to identify candidates best suited for working with the ORC's diverse subject population.

During the six-month internship, students are immersed in ongoing research projects in the Clinical Research Unit as valued members of the research team. Under the oversight of Ms. Lewis and the coordinator of the clinical trial to which they are assigned, the students receive hands-on experience in all aspects of conducting human subjects research.

In addition to the hands-on experience of helping to manage a clinical trial, the students develop their own research project. Applying concepts learned in class, the interns identify a research question, usually directly related to the study to which they are assigned, and develop that question into a research project. They then design the methods and select the appropriate data collection tools for their project. They are also responsible for submitting all the necessary documents to the Institutional Review Board (IRB) for approval. Once IRB approval is received, the students



Ebo



Ya

collect and enter their data in addition to performing their usual tasks as members of the research team.

Joy Ebo, one of our current interns, is conducting a project to study factors associated with adherence to protocol visits within the context of an osteopathic clinical trial involving pregnant women.

Chai Ya, our newest intern, is interested in developing a standardized protocol for detecting undiagnosed hypertension among subjects of a randomized control trial of osteopathic manipulative treatment and ultrasound physical therapy for chronic low back pain.

Collaboration in this internship program serves both to augment ORC resources and to provide the real world experience that facilitates the development of researchers who are committed to excellence.

## Elsevier to Publish Proceedings from Somato-Visceral Conference

In 2010, the international publishing company, Elsevier, will publish the proceedings of the 2008 international, interdisciplinary conference on somato-visceral interactions that was hosted by The Osteopathic Research Center in Fort Worth, Texas. The book will be titled, *The Science and Clinical Application of Manual Therapy*.

Editors for the text are Hollis H. King, DO, PhD, FAAO, former associate executive director of the ORC, Wilfrid Jänig, MD, PhD, from Germany, and Michael M. Patterson, PhD. The book will be published by Elsevier's Amsterdam division.

The book is being authored by many of the key speakers from the conference including Dr. King, Dr. Jänig, Dr. Patterson, Joel Pickar, DC, PhD, Brian S. Budgell, DC, PhD, Michael L. Smith, PhD, Jay Triano, DC, PhD, Robert D. Foreman, PhD, Charles H. Hubscher, PhD, Kerstin Uvnäs-Moberg, MD, PhD, Lisa E. Goehler, PhD, Cheryl Hawk, DC, PhD, Steven

George, PT, PhD, and Janet Kahn, PhD, NCBMT.

Major sections headings in the book are:

- Peripheral and Spinal Viscero-Somatic Mechanisms
- Segmental and Suprasegmental Mediation of Somato-Visceral Interactions
- Clinical Impact of Manual Therapy on Physiologic Functions and Systemic Disorders
- Consensus statements on
  - Basic Science on Somato-Visceral Interactions – Peripheral and Central: Evidence Base and Implications for Research
  - Clinical Applications of Manual Therapy on Physiologic Functions and Systemic Disorders: Evidence Base and Implications for Research

For a complete table of contents, please visit the ORC website at <http://www.hsc.unt.edu/orc/events.htm>

## ORC Welcomes Two New Members

Steven Berley, DO, and Xiangrong Shi, PhD, were appointed as members of The Osteopathic Research Center during the second quarter of 2009.

Dr. Berley is a 1982 graduate of the Kansas City University of Medicine and Biosciences, and currently practices primary care in Lindenhurst, NY. Dr. Berley has a strong professional interest in the evolving field of genomics, and recently represented the American Osteopathic Association at the Developing a Blueprint for Primary Care Physician Education in Genomic Medicine meeting June 8-9 in Bethesda, MD. He will co-chair, along with Dr. Licciardone, the 2009 AOA Research Conference, entitled The Translation of Genomic Science into Osteopathic Clinical Practice and Research. The research conference program is provided in this newsletter. Dr. Berley was appointed as a national member of the ORC.

Dr. Shi received a PhD in environmental physiology from Yale University in 1989. He is currently an associate professor in the Department of



Berley



Shi

Integrative Physiology within the Graduate School of Biomedical Sciences at the University of North Texas Health Science Center. He is also a fellow of the American College of Sports Medicine. Dr. Shi's research interests include the role of osteopathic manipulative treatment, specifically cranial techniques, in preventing or managing disorders involving cerebral tissue oxygenation deficits. Dr. Shi was appointed as a faculty member of the ORC.

# Support uniquely osteopathic research with a donation to



*Where Science Meets Practice™*

**Now more than ever, your contribution helps us conduct clinical trials that look at the efficacy of osteopathic manipulative treatment, basic science research that explores the underlying mechanisms of action of OMT, and health services and policy research that helps highlight the distinctive ways in which osteopathic physicians provide patient care.**

**Please send contributions to The Osteopathic Research Center, UNTHSC, 3500 Camp Bowie Boulevard, Fourth Floor, Center for Bio-Health, Fort Worth, TX 76107. Attn: Cathleen Kearns**