

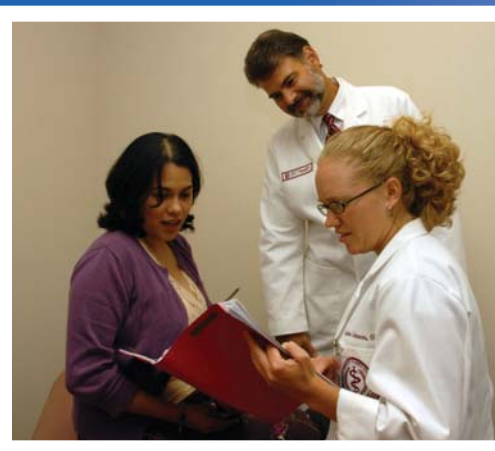
The Osteopathic Research Center



Clinical Trials



Mechanism of Action Studies



Research Training

Annual Report 2007

*Located at the University of North Texas Health Science Center
at Fort Worth*

Many Thanks to Our Sponsors

The Osteopathic Research Center wishes to thank its sponsors for their continued commitment to advancing the osteopathic manipulative medicine research agenda. Their generous support makes it possible for us to meet our research mission on behalf of the osteopathic profession.

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American Osteopathic Association

University of North Texas Health Science Center

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Administrative Director: Cathleen M. Kearns*

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In Retrospect:

2007 was a Momentous Year at The Osteopathic Research Center

The past year has been filled with momentous change for The Osteopathic Research Center (ORC).

In October, John C. Licciardone, DO, MS, MBA, assumed the helm at The Osteopathic Research Center. Dr. Licciardone is the second executive director of The Osteopathic Research Center. He continues the legacy left by Scott T. Stoll, DO, PhD, who resigned his post as executive director of the ORC in September to lead the Physical Medicine Institute and to focus more on his responsibilities as the Osteopathic Manipulative Medicine department chair.

“It is my privilege to lead the ORC through its next period of growth,” Dr. Licciardone said. “Scott has done a tremendous job in establishing the ORC, and is largely responsible for its success to date. I look forward to continuing to build on the past successes, and to expanding the ORC’s role in evaluating the efficacy of osteopathic manipulative medicine.”

“I am also excited about the number of important mechanisms of action studies being conducted at the ORC, and feel this is an area where the ORC and the University of North Texas Health Science Center (UNTHSC) has a great deal to contribute through our strong relationships with basic scientists that allow this critical research to be developed and to thrive,” Dr. Licciardone added.

In addition to the executive director position, other significant personnel changes that occurred in 2007 included des Angles Crusier, PhD, MPA, moving to the research education director position and Cathleen Kearns assuming the administrative director position.

Another major change for the ORC in 2007 was the change in university reporting structure that reaffirmed the ORC’s unique focus on osteopathic manipulative medicine research. Previously, the ORC was under the umbrella of the Physical Medicine Institute (PMI). The PMI will focus primarily on musculoskeletal and biomechanics research.

The ORC will be considered an independent research entity and will report directly to Marc Hahn, DO, the dean of the Texas College of Osteopathic Medicine, and to Thomas Yorio, PhD, the executive vice president for academic affairs and research at UNTHSC.



Stoll



Licciardone

The ORC will continue to collaborate with the Physical Medicine Institute and other UNTHSC institutes and centers on projects of mutual interest.

“This is an exciting move for the ORC,” said Dr. Licciardone. “It illustrates the university’s commitment to the unique mission of the ORC, and positions the ORC to retain its national focus that was deemed critical by the osteopathic profession when it founded the ORC in December 2001.”

An updated organizational chart showing the reporting structure of the ORC within UNTHSC is included on page 4 of this report.

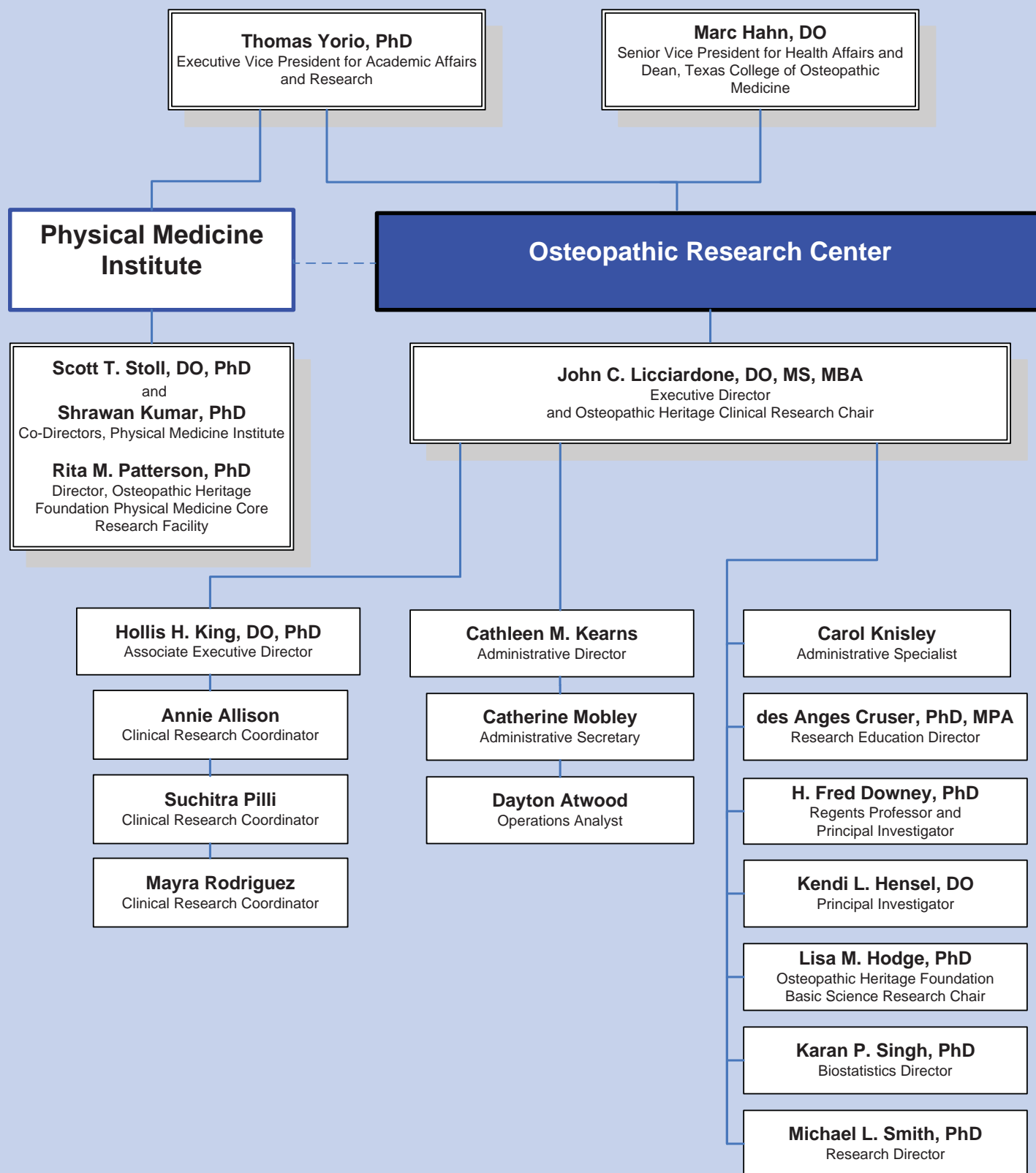
More information about the Physical Medicine Institute may be found on pages 5 and 6 of this report.

During 2007, the ORC made significant progress on the clinical trials it is conducting that are funded by the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NC-CAM). Read more about the clinical trials and other major research studies under way at the ORC beginning on page 8 of this report.

The ORC’s mission to provide research training and education made significant strides in 2007 with the award of a R25 grant from NIH. des Angles Crusier, PhD, MPA, is the principal investigator for the grant. As part of a public/private partnership, the Osteopathic Heritage Foundation contributed additional funding to be used on this project. Read more about the R25 on page 12 of this report.

Finally, learn more about Dr. Licciardone and his vision for the ORC on page 7 of this report.

The ORC Organizational Chart with University Reporting Lines



Physical Medicine Institute:

Institute Enters Growth Phase with President's Commitment and Gift from Foundation

The Physical Medicine Institute (PMI), an interdisciplinary research institute, began to take shape during 2007 with a \$1 million investment by UNTHSC President Scott B. Ransom, DO, MBA, MPH. Musculoskeletal health is one of the five areas of excellence earmarked by Dr. Ransom to receive additional funding from UNTHSC.

The \$1 million from the President's Initiative was primarily used to hire Shrawan Kumar, PhD, and Rita Patterson, PhD. Those funds will also be used to hire a clinical engineer to assist with research in new laboratory space that is being built in the Center for BioHealth on the UNTHSC campus.

In addition to the \$1 million for salaries, the university also committed \$1.5 million in matching funds to support the construction of the Osteopathic Heritage Foundation Physical Medicine Core Research Facility.

The Osteopathic Heritage Foundation (OHF) contributed \$1.1 million to finish out the lab space and \$400,000 to purchase equipment for the lab.

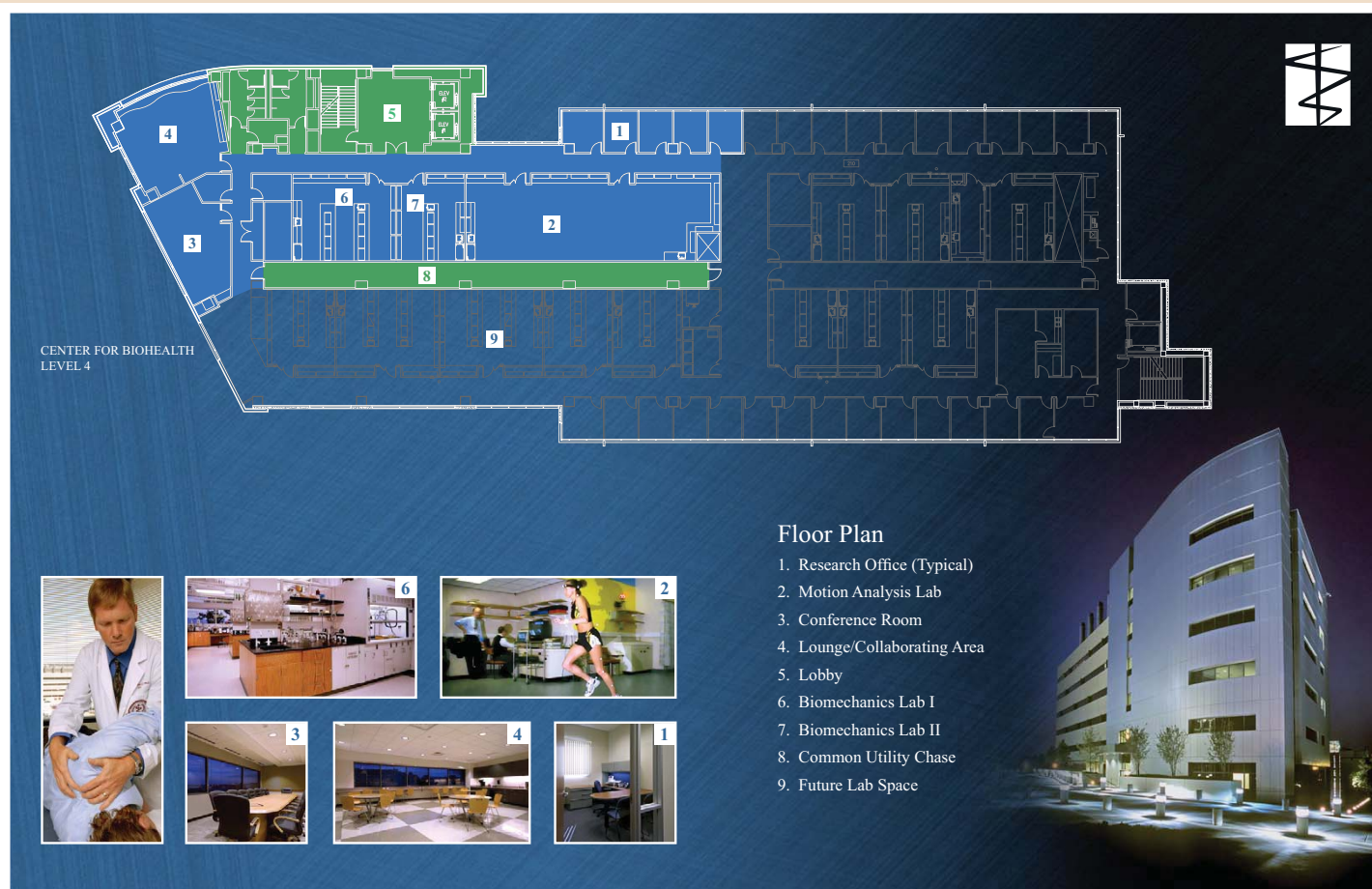
Additional funds needed to complete the facility are being raised from private and public sources.

The OHF Physical Medicine Core Research Facility

will offer collaborative research opportunities for orthopaedic and manipulative medicine specialists in areas such as biomechanics and human performance. The core research laboratory will also support pre- and post-doctoral medical and basic science education in osteopathic manipulative medicine, orthopaedic surgery, and other aspects of musculoskeletal disease and somatic dysfunction.

Scott T. Stoll, DO, PhD, chair of Osteopathic Manipulative Medicine and co-director of the Physical Medicine Institute, Shrawan Kumar, PhD, co-director of the Physical Medicine Institute and David Lichtman, MD, chair of orthopaedic surgery and director of the Bone and Joint Research Center, are working together under the mantle of the existing Physical Medicine Institute to acquire equipment and finalize construction plans. The total cost of the new 7,000-square-foot Core Research Facility, which is under the direction of Rita M. Patterson, PhD, is estimated at \$5 million.

The Physical Medicine Institute was established in 2000, and provides opportunities and infrastructure for collaborative research in many aspects of musculoskeletal medicine.



CENTER FOR BIOHEALTH
LEVEL 4

Floor Plan

1. Research Office (Typical)
2. Motion Analysis Lab
3. Conference Room
4. Lounge/Collaborating Area
5. Lobby
6. Biomechanics Lab I
7. Biomechanics Lab II
8. Common Utility Chase
9. Future Lab Space

Two New Faculty Members Join Research Team

Shrawan Kumar, PhD

Shrawan Kumar, PhD, DSc, FRSC, has been hired as a researcher for the Health Institutes of Texas (HIT). He serves as co-director of the Physical Medicine Institute, as a professor of osteopathic manipulative medicine and as director of research in the Physical Medicine Institute (PMI).



Kumar

The mission of PMI is to promote research, education and clinical practice in the prevention, diagnosis, treatment and rehabilitation of neuromusculoskeletal disease of all ages.

Dr. Kumar received a doctorate in human biology and an honorary doctorate in sciences in recognition of his lifetime work from University of Surrey in Guildford, U.K., and completed a post-doctoral research

fellowship in engineering sciences at University of Dublin, Trinity College in Dublin, Ireland.

Rita M. Patterson, PhD

Rita Patterson, PhD, has joined the faculty as a researcher for HIT. She also serves as a professor of osteopathic manipulative medicine, and as the director of the Osteopathic Heritage Foundation Physical Medicine Core Research Facility.



Patterson

Dr. Patterson earned a doctorate in biomedical sciences from the University of Texas Medical Branch, a master of engineering degree in bioengineering from Texas A&M University, and a bachelor of science degree in engineering sciences from Baylor University.

Faculty Receive Awards, Serve as Key Consultants

John C. Licciardone, DO, MS, MBA, executive director of the ORC, received the Gutensohn-Denslow Research Award at the American Osteopathic Association Convention in San Diego, Calif. in September. The award was presented as part of the American Osteopathic Foundation's 6th Annual Honors Ceremony.

The award was established in honor of J. Stedman Denslow, DO, a noted researcher in viscerosomatic reflexes and biomechanics, and Max T. Gutensohn, DO, a gifted educator, for their devoted service and contributions to research and education within the osteopathic profession. The purpose of the award is to honor an osteopathic investigator in the areas of research, education, and service.

Dr. Licciardone was also a recipient of the AOA's 2005 Louisa Burns Memorial Lecture Award, which recognizes leadership and contributions in osteopathic research and education.

Dr. Licciardone was recently invited by the World Health Organization (WHO) to serve as a consulting expert on osteopathy. He attended the WHO Consultation on Osteopathy in Milan, Italy, in February. The meeting involved development of WHO guidelines on basic training and safety in osteopathy.

The purpose of the guidelines is to: provide minimum requirements of basic training in osteopathy; present contraindications to the use of specific forms of osteopathic manipulative treatment; serve as a reference for national authorities to establish systems for education, examination, and licensing to ensure the qualified practice of osteopathy; and provide differ-

ent models of training programs for the target trainees with different backgrounds.

Other U.S. osteopathic representatives who served as part of this group include Jane Carreiro, DO, and Kenneth Johnson, DO, from the University of New England College of Osteopathic Medicine; Boyd Buser, DO, from the Pikeville College School of Osteopathic Medicine; Reza Nassiri, DSc, from the Lake Erie College of Osteopathic Medicine; and John Crosby, JD, and Peter Ajluni, DO, representing the American Osteopathic Association.

Hollis H. King, DO, PhD, associate executive director of the ORC, delivered the Thomas L. Northup lecture during the American Academy of Osteopathy meeting at the American Osteopathic Association convention in San Diego, Calif., in October.

Each year, the American Academy of Osteopathy selects an osteopathic physician to deliver this memorial lecture. Dr. King is a past AAO president.

Dr. King also represented the American osteopathic profession at a WHO meeting in Abu Dhabi in the United Arab Emirates on December 10-12.

This diverse working group of international health care representatives were convened to discuss key technical issues and draft new guidelines relating to the design and evaluation of clinical studies of traditional medicine. These guidelines, based on current standards for clinical trials, will help form a benchmark for conducting quality clinical trials in the future.

Charting the Course:

Looking Ahead with the ORC's New Executive Director

In October 2007, John C. Licciardone, DO, MS, MBA, assumed the executive director position at The Osteopathic Research Center (ORC).

Dr. Licciardone has been working with osteopathic manipulative medicine research for over 10 years, and received the first Midcareer Investigator Award from the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NCCAM) in the osteopathic profession.

He earned his doctor of osteopathic medicine degree from the Kirksville College of Osteopathic Medicine. Dr. Licciardone completed a rotating internship at Tulsa Regional Medical Center. He completed a family practice residency at Kennedy Memorial Hospitals in New Jersey and a preventive medicine residency at Ohio State University in Columbus, Ohio, where he also earned his master of science degree in preventive medicine with a concentration in epidemiology. Dr. Licciardone earned his master of business administration degree from Texas Christian University in Fort Worth, Texas.

In addition to serving as the executive director for the ORC, Dr. Licciardone serves as the Osteopathic Heritage Foundation Clinical Research Chair for the ORC.

For the past year, Dr. Licciardone has served as the acting associate dean for clinical research for the Texas College of Osteopathic Medicine at the University of North Texas Health Science Center in Fort Worth.

Dr. Licciardone has a long history of receiving NIH and other federal grants to fund a wide range of research efforts. In the past few years, he has focused on looking at the efficacy of osteopathic manipulation in the treatment of low back pain. In addition to the current K24 Midcareer Investigator Award from NIH-NCCAM, he has completed a meta-analysis of literature to determine the clinical efficacy and cost effectiveness of

osteopathic manipulation in the treatment of various clinical conditions.

Dr. Licciardone serves as editor of London-based BioMed Central's open-access journal *Osteopathic Medicine and Primary Care*.

During his tenure as executive director of the ORC, Dr. Licciardone plans to continue the efforts begun by Founding Executive Director, Scott T. Stoll, DO, PhD, to focus on clinical efficacy studies, mechanism of action studies and on clinical research education and training.

One of his major areas of focus in his first several months as executive director is enhancing and increasing communications from the ORC to the profession and the ORC's sponsors.

"For five years, the ORC has been making great strides in establishing a solid research enterprise, but that has left little time to focus on communicating information about the center, its progress and its mission," Dr. Licciardone said. "We are now at the point in several of our research projects where we can focus on increasing scientific publications and communications.



Carpal Tunnel Syndrome:

Clinical Trial Evaluates Efficacy of OMT

Each year, approximately one million people are diagnosed with carpal tunnel syndrome. Traditional treatment modalities including surgery are often not effective, and many times, leave patients with symptoms that are just as severe as they were before the intervention.

This R21 clinical research study, funded by the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NCCAM), evaluates the clinical efficacy of osteopathic manipulative treatment to relieve the symptoms of carpal tunnel syndrome and to see if these techniques can actually reverse the pathophysiology of carpal tunnel syndrome.

Under the direction of Scott T. Stoll, DO, PhD, principal investigator, the goal is to have 138 subjects complete the study, which has 12 weekly visits and a followup visit three months after the weekly visits end.

Subjects enrolled in the study must pass a rigorous three-step screening process that includes a phone screening, a nerve conduction study, and a MRI of the wrist. Once enrolled into the study, subjects are

randomly assigned to one of three treatment groups – OMT, placebo ultrasound, or standard care. All subjects receive current perceptual threshold testing and pinch and grip testing at specific intervals to measure their progress. All subjects are also asked to complete a set of questionnaires about symptom severity and function at each visit.



Stoll

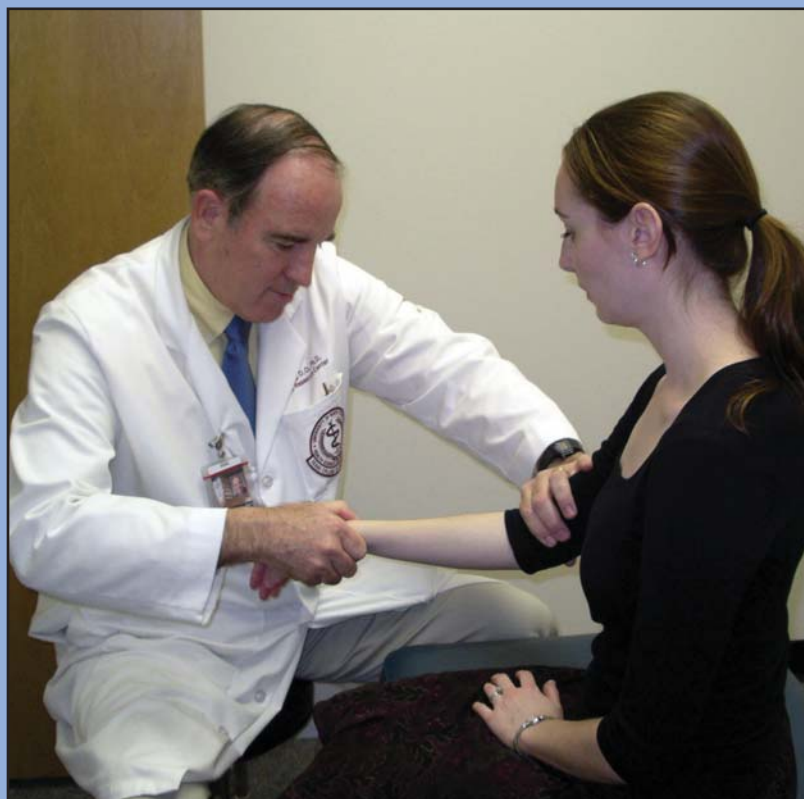
This study is beginning its third and final year.

The R21 grant builds on a successful student project that provided the pilot data to submit the proposal to NIH-NCCAM. This is just one way in which The Osteopathic Research Center involves osteopathic medical students in meaningful research projects, most frequently during their tenure as undergraduate OMM research fellows enrolled in a master of science program.

The OMT protocol developed for the study uses a wide range of manipulative techniques designed to enlarge the carpal tunnel, enhance fluid drainage and reduce fascial and other structural restrictions. The hypothesis for this study is that a standard program of OMT, when used as an adjunctive treatment to the standard medical care of carpal tunnel syndrome, will yield significantly improved physiological and clinical outcomes compared to the usual regimen of standard care.

Measures of physiological function include increased electrophysiologic conduction speed of the median motor and sensory nerves, a decrease in wrist water content (edema), and an increase in the dimensions of the carpal tunnel.

Clinical outcome measurements include reduction of carpal tunnel syndrome symptoms in the hand, wrist, shoulder, and neck, an increase in the patient's functional use of the limb assessed by a function status scale, pain reduction assessed by a symptom severity scale, and an increase in grip strength and sensation.



K24 – Midcareer Investigator Award:

Building on the Evidence Base for OMT in Low Back Pain

Over 30 million ambulatory medical care visits annually in the United States involve low back pain. A majority of such patient visits involve chronic pain, which often is treated using a variety of approaches. However, the research evidence supporting many of these treatments has not been firmly established.

This five-year Midcareer Investigator Award from the National Institutes of Health – National Center for Complementary and Alternative Medicine (NIH-NCCAM) to John C. Licciardone, DO, MS, MBA, provides support to further the evidence base for OMT in chronic low back pain. As part of the award, Dr. Licciardone oversees the **OSTEOPATHic Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial**, a Phase III clinical trial of OMT.

The OSTEOPATHIC Trial will enroll 488 subjects at The Osteopathic Research Center from 2006 through 2010. Using a 2x2 factorial design, each subject will be randomly assigned to receive active or sham OMT. In addition to OMT, the other intervention being studied in this trial is ultrasound physical therapy (UPT). As with OMT, subjects are also randomly assigned to receive active or sham UPT.

Subjects in the trial are screened for chronicity of low back pain (at least three months) and are excluded if they have underlying causes of low back pain, such “red flag” conditions. Subjects are treated and evaluated over a



Licciardone

three-month period to determine the efficacy of OMT and UPT. Major outcomes of interest include pain, physical functioning, general health, work disability, and satisfaction with back care. A study protocol article describing the OSTEOPATHIC Trial will be published in *Osteopathic Medicine and Primary Care* during 2008.

The trial extends previous research conducted by Dr. Licciardone and his team at the ORC. In 2003, a Phase II clinical trial of OMT in chronic low back pain was published in *Spine*. In 2005, a systematic review and meta-analysis of OMT in low back pain published by Dr. Licciardone and his team appeared in *BMC - Musculoskeletal Disorders*. The latter study concluded that OMT provided statistically significant and clinically relevant improvements in low back pain. It also demonstrated that OMT benefits were larger than could be attributed to placebo effects and that OMT effects increased over time. The OSTEOPATHIC Trial is in response to calls for larger, more powerful clinical trials of OMT.

K23 – New Investigator Award:

Assessing the Efficacy and Mechanisms of OMM in the Third Trimester of Pregnancy

For years, osteopathic physicians have recounted numerous clinical cases of positive outcomes in patients who received osteopathic manipulation during their pregnancy.

Now, a five-year project at The Osteopathic Research Center funded by the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NCCAM) begins to scientifically evaluate the efficacy and mechanisms of action of osteopathic manipulation in the third trimester of pregnancy.

Funded as a K23 Mentored Patient-Oriented Research Career Development Award, this project also received financial support from the American Osteopathic Association.

This study looks at physiological and biomechanical changes during pregnancy including increased fluid volume and sympathetic tone that can lead to consequences such as edema, preterm labor and meconium-staining of the amniotic fluid.

A K23 award is designed to train beginning clinician investigators to become independent clinical researchers. The grant has two main components: a

training program and a clinical research study.

As part of the research training component, Kendi Hensel, DO, the principal investigator of the study, is completing a PhD in osteopathic clinical research and education.

Dr. Hensel is the first osteopathic physician to receive a K23 award from NIH.

Subjects for the research arm of this study are recruited from specific UNTHSC clinics, and are randomized into one of three treatment groups: osteopathic manipulation, placebo ultrasound or standard care.

The goal is to recruit 400 subjects for the clinical study. One hundred of those subjects will also be recruited to participate in the physiological sub-study.

Dr. Hensel was awarded the grant in 2006.



Hensel



U19 Developmental Center for Research Award: *Mechanisms of Osteopathic Manipulative Medicine*

When The Osteopathic Research Center was founded in 2001, it was charged not only with evaluating the clinical efficacy of osteopathic manipulative medicine (OMM), but also with exploring the mechanisms of action of OMM.

This U19 Developmental Center for Research on Mechanisms of OMM, funded by the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NCCAM) was a giant step forward in bringing basic scientists and clinicians together to investigate the mechanisms of action of OMM.

The \$1.8 million, three-year U19 grant was awarded in September 2004. For the past several months, work on projects under this grant have continued through a no-cost extension. The ORC anticipates receiving additional funding for this research in 2008.

The U19 award encompasses three projects, an administrative core and an osteopathic core.

Paul Standley, PhD, from the University of Arizona College of Medicine in Phoenix, Ariz., is the principal investigator for the first project under this grant which focuses on *Biomechanical Strain Regulation: A Cellular Model of OMM*.

Dr. Standley has developed an innovative model for studying how in vitro cells respond to strains that mimic injury and other strains that mimic osteopathic manipulation.

Dr. Standley and his group found that one minute of simulated indirect counterstrain can reverse the proliferation of pro-inflammatory cytokines caused by eight hours of repetitive strain in an in vitro fibroblast model that mimics fascia and connective tissue.

Project 2 under this grant is led by Fred Downey, PhD. This project focuses on *Lymph Flow Enhancement by OMM in Conscious Dogs*.



Smith



Downey



Standley



Hodge

Through research conducted under this grant, Dr. Downey and his team found that lymphatic pump technique significantly increases canine lymph flow through the thoracic duct and significantly increases immune cell flux approximately eight-fold in the thoracic duct. Dr. Downey and E. Marty Knott, DO, won the George W. Northup, DO, Medical Writing Award of the Journal of the American Osteopathic Association (JAOA) in 2005. Johnathan Tune, PhD, and Scott Stoll, DO, PhD, were co-authors on the award-winning article that focused on portions of this research.

The work to understand the mechanisms of action of lymphatic pump technique is also being explored in a rat model by a research team under the direction of Lisa Hodge, PhD. While the rat studies are not part of the U19 grant, the work is closely related, and is an extension of the work on this U19 project.

The third project under the U19 grant is led by Michael Smith, PhD, principal investigator and research director for the ORC. His project focuses on *Pain-Induced Sympathoexcitation: Effect of OMM*.

Dr. Smith's project evaluates the hypothesis that OMM can reduce pain in certain conditions and that it may also reduce sympathetic neural activity (SNA).

In the first study under project 3, intermittent cold pressor stimulus is used to produce an experimental state of sustained elevation of SNA. Investigators then use this condition to determine whether sympatholytic OMM can decrease a sustained elevation of SNA and whether sustained pain-induced elevations in SNA persist when the stimulus is removed.

In the second study under project 3, Dr. Smith and his research team are looking at whether specific OMM techniques can affect SNA in patients with low back pain and somatic dysfunction.

Current Projects:

ORC Receives Research Education Grant from NCCAM

In August 2007, the ORC received a four-year Research Education Project Partnership Grant (R25) from the National Institutes of Health-National Center for Complementary and Alternative Medicine (NIH-NCCAM). This R25 grant of \$758,000 in total costs will support the integration of biomedical research competencies into the osteopathic medical school curriculum. des Anges Crusier, PhD, MPA, is the principal investigator for the grant.

The grant award is the culmination of a three-year effort to develop a formal research education model to prepare osteopathic medical students to use biomedical research information in a critical, professional manner. The project will also provide opportunities for osteopathic medical school faculty to advance their own mentoring and leadership skills in biomedical research with a focus on manipulative medicine and on several complementary and alternative medicine modalities.

This research education grant forms the centerpiece of a number of other research education and training initiatives at the UNTHSC. The long-range vision includes a greatly enhanced pipeline for pre- and post-doctoral biomedical research training, and greater integration of biomedical research information into the clerkship years. The ultimate goal for this R25 project is to provide a model that all interested osteopathic medical academic institutions will be able to adapt for their students.

Partners in this project include the Texas College of Osteopathic Medicine (TCOM), the Graduate School of Biomedical Sciences (GSBS) at UNTHSC, and the Integrative Medicine CAM Program at the University of Texas Medical Branch at Galveston (UTMB).



Crusier

In addition to the R25 grant received from NIH-NCCAM, Dr. Crusier received an additional \$180,000 over four years from the Osteopathic Heritage Foundation to help improve research training across the osteopathic profession. This is one type of public/private partnership that will enhance the impact of the R25 in support of sister osteopathic institutions. The ORC has been working with NIH, OHF and other osteopathic foundations to develop these types of projects.

With the award of this research education grant, Dr. Crusier assumed new duties as the research education director for the ORC. Dr. Crusier served in the capacity of administrative director of the ORC from June 2002 through August 2007.

Are you interested in learning more about research and training opportunities at The Osteopathic Research Center?

To receive our monthly electronic newsletter and other news or publications from The ORC, please contact Cathleen Kearns, administrative director, at ckearns@hsc.unt.edu

We look forward to hearing from you

Pilot Studies and Student Projects Underway at the ORC

Pilot Studies

The Effects of Osteopathic Manipulative Treatment on Intraocular Pressure in Humans

The purpose of this upcoming study is to determine the effects of osteopathic manipulative treatment (OMT) as an adjuvant modality to standard medical care for the reduction of intraocular pressure in patients suffering from glaucoma; and as an alternative and/or complementary therapy option for patients not responding to current standard treatment options, or for patients for whom current standard treatment options are not appropriate. The use of OMT in the treatment of ocular disorders has a basis in clinical experience as well as being an application of the osteopathic principle to restore the body to its best anatomic state so that self-regulatory and self-healing processes function optimally. Based on the anatomy of the eye and the dysfunctions underlying primary-open angle glaucoma, the presumed mechanism for OMT benefit is the biomechanical restoration of drainage through the trabecular meshwork and Schlemm's canal.

Kinematics of the Body

The purpose of this research study is to generate an interaction between the fields of osteopathic manipulative treatment, rehabilitation science, and biomechanical engineering in order to gain an accurate understanding of the musculoskeletal system in states of health and after injury. The first aim in this study is to determine hand movement patterns (normal synergies) of healthy subjects. Their kinematics will be measured while performing gross grasp and fine prehension. The second aim is to determine pathological hand movement patterns (pathological synergies) of a person with carpal tunnel syndrome. Kinematics will be measured in persons with carpal tunnel syndrome while performing gross grasp and fine prehension. These aims will be addressed by measuring hand kinematics in patients enrolled in the current NIH-sponsored carpal tunnel study at the ORC.

Student Projects

Prior Osteopathic Palpatory Training and the Accuracy of Clinical Breast Exams

The purpose of this student research study was to evaluate whether there is an association between osteopathic palpatory training and increased accuracy of clinical breast exams. Incoming first-year medical

students, second-year medical students, and physician assistant students participated in this study. During the study, 105 students palpated six silicone breast models with lumps of varying sizes, depths and hardness. Accuracy was measured by mean sensitivity, specificity and positive predictive value. The results of this study showed that there were no statistically significant differences in accuracy between the three student groups.

Osteopathic Manipulative Treatment for Post-Operative Nausea and Vomiting

The purpose of this student research study was to assess the efficacy of osteopathic manipulative treatment (OMT) for post-operative nausea and vomiting (PONV). The goal of using OMT was to return post-operative patients' to autonomic homeostasis and improve anatomic maladies that may impair proper physiologic functioning. Individuals undergoing orthopaedic surgery under general anesthesia were recruited. Seventeen subjects were randomized and completed the study. Eight subjects received treatment immediately following emergence from anesthesia, nine subjects comprised the non-treatment control group. Treatment and control groups were well-matched with respect to all demographic variables, risk factors for PONV, and baseline vital signs and visual-analog scales. Incidence of PONV was low in both treatment and control groups, presumably because of the liberal use of prophylactic antiemetic medication. Future studies should work toward enrolling more subjects, including those at greater risk for PONV.

Effect of Craniosacral Manipulation on Sleep Architecture

The purpose of this student research study is to test the hypothesis that craniosacral manipulation improves parameters of sleep quality in subjects with documented sleep impairment accompanying a persistent stress state. Craniosacral manipulative techniques used by osteopathic physicians are recognized to have significant relaxing effects, but are also hypothesized to affect neural and visceral function. Two recent studies have shown that craniosacral manipulation can decrease sympathetic neural activity, increase parasympathetic neural activity and accelerate sleep latency in healthy individuals. However, it is not known whether these manipulative techniques can produce benefits to sleep architecture throughout the night or improve the impaired sleep architecture associated with acute and

Continued on page 19

Publications and Presentations by ORC Faculty in 2007

Full Length Publications

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Hodge LM, King HH, Williams AG, Reder SJ, Belavadi T, Simecka JW, Stoll ST, Downey HF. Abdominal lymphatic pump treatment increases leukocyte count and flux in thoracic duct lymph. *Lymphatic Research and Biology*. 2007; 5: 127-133.

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Licciardone JC. Secondary Analysis of Data on Osteopathic Manipulative Treatment (OMT): Systematic Review and Meta-Analysis of Osteopathic Manipulative Treatment. Technical Report prepared for AOA, March 2007.

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Sanderlin BW, Licciardone JC. Osteopathic manipulative treatment for pandemic influenza: many questions, few answers. *Osteopathic Medicine and Primary Care*. 2007; 1:12. <http://www.om-pc.com/content/pdf/1750-4732-1-12.pdf>

Manuscripts – In Review

Downey HR, Durgam P, Williams AG, Rajmane A, King HH, Stoll ST. Lymph flow in the thoracic duct of conscious dogs during lymphatic pump treatment, exercise, and expansion of the extracellular fluid volume. *Lymphatic Research and Biology*.

Eagan T, Meltzer K, Standley PR. Heterobiaxial and equiradial strain models of manual medicine techniques: dichotomous regulation of fibroblast morphology, growth and cytokine secretion. *Journal of Biomechanics*.

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Meltzer K, Schad J, King H, Stoll S, Standley P. In vitro strain-mediated injury and myofascial release in human fibroblasts: role of inflammatory cytokines. *American Journal of Physiology*.

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Clearfield D, Licciardone JC, Fulda K. Attitudes, knowledge, and use of osteopathic manipulative treatment by osteopathic sports medicine physicians. *Osteopathic Collaborative Clinical Trials Initiatives Conference VIII, Colorado Springs, CO, 2007*

Giles P, Hensel K, Smith M. The effects of upper cervical spine manipulation on vagal tone. *Osteopathic Collaborative Clinical Trials Initiatives Conference VIII, Colorado Springs, CO, 2007*

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S. Osteopathic manipulative medicine in pregnancy: physiologic and clinical effects. *Osteopathic Collaborative Clinical Trials Initiatives Conference VIII, Colorado Springs, CO, 2007*

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Schrick-Senasac S, Sprys MJ, King HH. Adjunct osteopathic manipulative treatment as possible prophylaxis for post-operative nausea and vomiting in patients receiving inhalation anesthesia. Osteopathic Collaborative Clinical Trials Initiatives Conference VIII, Colorado Springs, CO, 2007

Steele K, Carreiro J, CIPHER D, Crusier dA, Stoll ST. Multicenter osteopathic otitis media study: a proposed clinical trial. Osteopathic Collaborative Clinical Trials Initiatives Conference VIII, Colorado Springs, CO, 2007

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Downey F, Knott EM. Developing a Successful and Meaningful Animal Research Project during Undergraduate and Residency Training. Osteopathic Collaborative Clinical Trials Initiatives Conference VIII, Colorado Springs, CO, March 2007.

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Hensel K. The Effect of OMM on Autonomic Control.

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King HH. OMT of the Cervical Spine: Research Conundrums. Osteopathic Collaborative Clinical Trials Initiatives Conference VIII, Colorado Springs, CO, March 2007.

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King HH. Initiatives in Research on Cranial Osteopathy. The Cranial Academy Conference, Tucson, AZ, June 2007.

King HH. Progress, Challenges, and Potential for OMM/OMT Research. Second Osteopathic Medical Student Research Conference. Michigan State University College of Osteopathic Medicine, East Lansing, MI, July 2007.

King HH. Osteopathy: Art and Science - Truth or Consequences (Northrup Memorial Lecture). American Academy of Osteopathy. American Osteopathic Association Convention, San Diego, CA, October 2007.

King HH. Cranial Fascia: Continuity and Motion Characteristics. International Fascia Research Congress: Basic Science and Implications for Conventional and Complementary Health Care, Harvard University, Boston, MA, October 2007.

King HH. Research into Sleep and Osteopathy: CV4 and Sleep and Progress in OMM/OMT Evidence-Based Research. Sutherland Cranial Teaching Foundation Continuing Studies Course, University of New England College of Osteopathic Medicine, Biddeford, ME, October 2007.

PUBLICATIONS AND PRESENTATIONS ——— Continued ———

Licciardone JC. Osteopathic Research: A Strategic Tool for Defining and Promoting Osteopathic Medicine. Grand Rounds at the University of North Texas Health Science Center (UNTHSC), Fort Worth, TX, May 2007.

Licciardone JC. Evidence-Based OMTology (Keynote Address). Symposium on Advances in Osteopathic Research, 10th International Congress of the German Osteopathic Association, Schlangenbad, Germany, October 2007.

Licciardone JC. Osteopathic Research: A Strategic

Tool for Defining and Promoting Osteopathic Medicine. Grand Rounds at the Kansas City University of Medicine and Biosciences, Kansas City, MO, November 2007.

Licciardone JC. The Evidence Base for Osteopathic Manipulative Treatment. Research Seminar at the A.T. Still University. Kirksville, MO, November 2007.

Stoll ST. Strategies for Selecting Adaptive Aids. 21st Annual Dallas Family Medicine Update, Dallas, TX, April 2007.

ORC Fosters Research Training and Collaboration

When The Osteopathic Research Center was founded in December 2001, one of the main charges to the center was to help facilitate research training and collaboration across the profession.

The ORC uses a number of methods to attain this goal including coordinating a research conference each spring, partnering with other institutions in multi-center clinical trials and mechanism of action research, working with individual researchers across the country to conduct research studies and assisting individual researchers in developing and completing their own projects where feasible.

On an individual level, some of the most frequent questions posed to ORC faculty and staff include assistance with biostatistical analysis, research study design, institutional review board issues and guidance, publicizing research articles and customizing rotations for students interested in learning more about research.

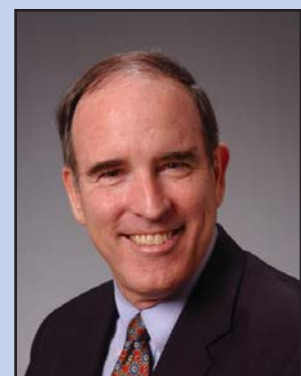
Two years ago, the ORC assumed the responsibility for coordinating and managing the Osteopathic Collaborative Clinical Trials Initiatives Conference (OCCTIC) series. This series of research conferences has continued to evolve since its inception in 1998.

Leading osteopathic medical organizations such as the American Academy of Osteopathy, the American Association of Colleges of Osteopathic Medicine, the American Osteopathic Association, the Osteopathic Heritage Foundation and The Osteopathic Research Center continue to fund this series of conferences, which alternates annually between research training conferences and research symposia on hot topics in manual medicine research.

The conference is typically held in conjunction



Kearns



King

with the American Academy of Osteopathy Convocation each March to maximize attendance by those students and physicians who are most likely to be interested in conducting osteopathic manipulative medicine research.

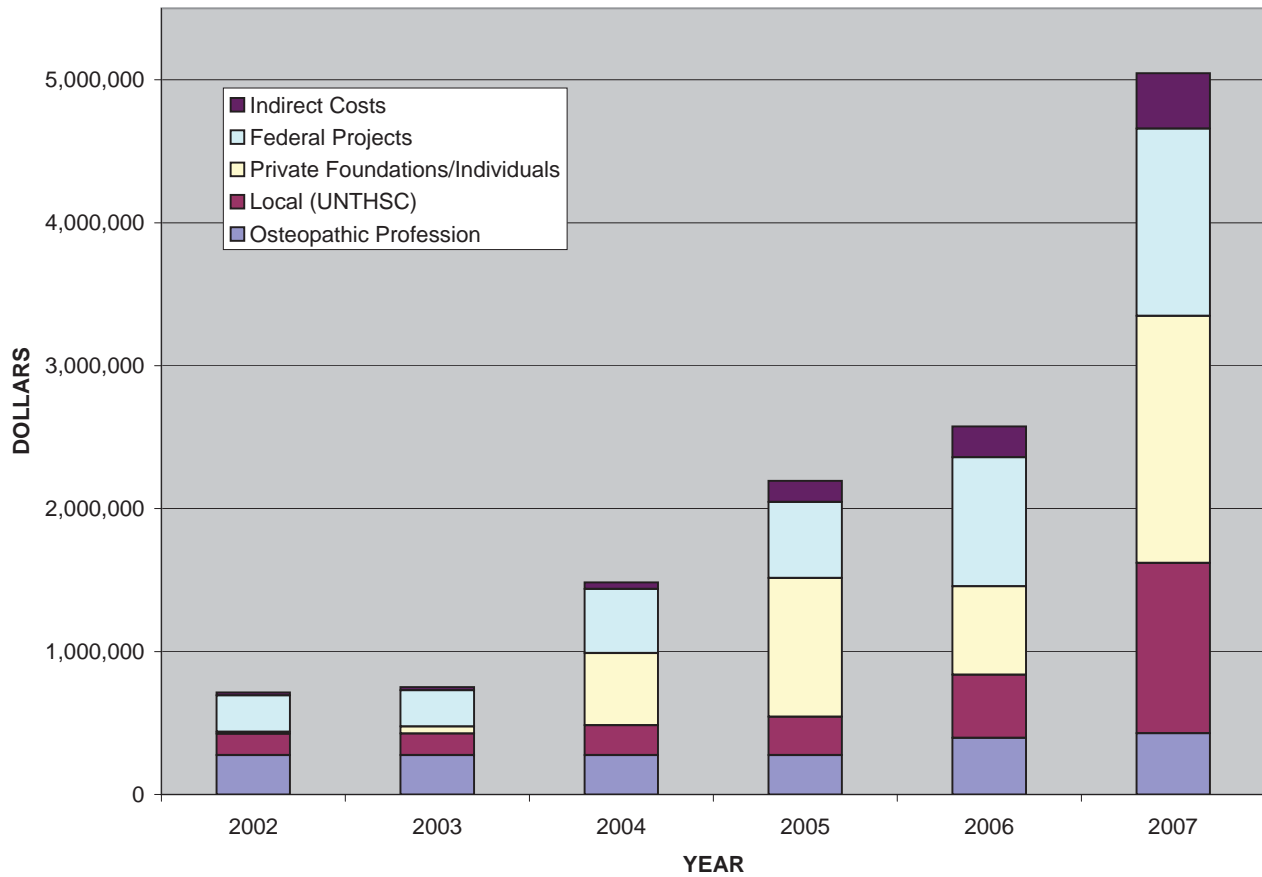
Cathleen Kearns, ORC administrative director, and Hollis King, DO, PhD, ORC associate executive director, manage the conference on behalf of the center.

In addition to providing individual assistance with research projects, fostering collaboration and managing an annual research conference, the ORC facilitates research education and training through graduate degree programs that have been developed at the University of North Texas Health Science Center.

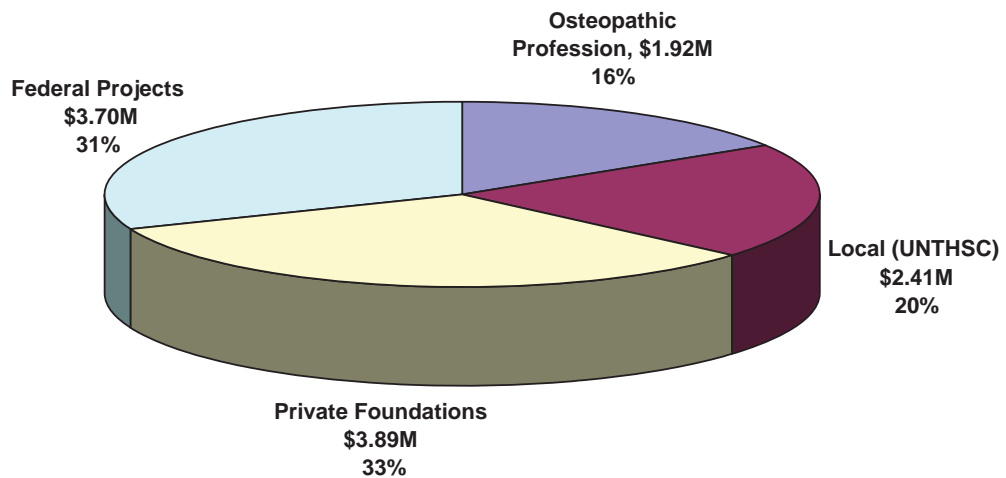
Since its inception, the ORC has been integral in developing a master of science degree and a doctoral degree in osteopathic clinical research and education.

For more information about conferences, research training opportunities and research education tools, please visit the ORC website at <http://www.hsc.unt.edu/orc>.

**THE OSTEOPATHIC RESEARCH CENTER
FUNDING BY SOURCE 2002 - 2007**



**ORC SUPPORT (DIRECT \$)
ACTUAL FUNDING
2002 - 2007
\$11.92M**



Looking Back:

A Brief History of the ORC

Founded in December 2001, The Osteopathic Research Center was the culmination of efforts by members of several groups to develop a national osteopathic research center dedicated to osteopathic manipulative medicine.

Representatives from key osteopathic associations were brought together as the Osteopathic Research Task Force, which was charged with facilitating an OMM research agenda for the profession.

Organizations represented on the task force included the American Association of Colleges of Osteopathic Medicine (AACOM), the American Osteopathic Association (AOA), the Louisa Burns Osteopathic Research Committee of the American Academy of Osteopathy, the American College of Osteopathic Family Physicians, the former American Osteopathic Healthcare Association and several colleges of osteopathic medicine. Basic scientists, researchers, clinicians and academic faculty members served on the task force.

Based on discussions that grew out of the task force, AACOM, AOA and the American Osteopathic Foundation (AOF) committed \$1.1 million to create this research center through a competitive bid process.

In 2001, the center was awarded to the Texas College of Osteopathic Medicine at the University of North Texas Health Science Center under the guidance of Scott T. Stoll, DO, PhD, the founding executive director of the ORC.

Each year, the ORC continued to expand the number of grants it received, the number of faculty and staff employed and its sphere of influence within the profession.

In 2005, the ORC received a second four-year award totaling \$900,000 from AACOM, AOA and AOF.



To date, the ORC has received the first K23 Mentored Patient-Oriented Research Career Development Award for new physician investigators and the first K24 Midcareer Investigator Award in the profession.

Faculty and staff at the ORC have a strong track record of receiving awards from federal research funding agencies including the National Institutes of Health, the Department of Defense, the Health Resources and Services Administration and the U.S. Department of Education.

PILOT STUDIES AND STUDENT STUDIES ————— **Continued** —————

chronic stress. This study has been approved by the IRB, but has not yet begun to actively recruit participants.

The Use of Osteopathic Palpatory Findings in Screenings for Nephropathy in Type 2 Diabetes Mellitus

The purpose of this student research study was to evaluate the efficacy of osteopathic palpatory findings in screening for diabetic nephropathy (kidney disease) in patients known to have type 2 diabetes mellitus. The first aim of the study was to assess whether osteopathic palpatory findings are associated with diabetic nephropathy. The hypothesis tested was that osteo-

pathic palpatory findings at the thoracolumbar level T10-L2 will be associated with type 2 diabetes mellitus and the development of renal disease. The second aim of the study was to assess whether osteopathic palpatory findings will be more often associated with type 2 diabetic subjects than with non-diabetic subjects. The second hypothesis tested was that the osteopathic palpatory findings at the thoracolumbar level of T10-L2 will be more prevalent in subjects with type 2 diabetes mellitus than in subjects without disease. All of the data have been collected for the study and the results are currently being analyzed.

the 1990s, the number of people with a mental health problem has increased in the UK, and the number of people with a mental health problem who are in contact with mental health services has also increased (Mental Health Act 1983, 1990, 1994, 1997, 2003, 2007, 2012, 2017, 2020).

The current study was part of a larger project that aimed to explore the experiences of people with a mental health problem who are in contact with mental health services. The project was funded by the National Institute for Research in Drug Addiction (NIDA) and the National Institute for Mental Health (NIMH). The project was led by Professor John M. S. P. et al.

The current study was a qualitative study that aimed to explore the experiences of people with a mental health problem who are in contact with mental health services. The study was conducted in the UK and involved 10 participants. The participants were recruited through a range of sources, including mental health services, community groups, and social media.

The data were collected through semi-structured interviews. The interviews were conducted by a researcher who had experience of conducting qualitative research and had not been involved in the design or delivery of the mental health services that the participants were in contact with. The interviews lasted between 30 and 60 minutes and were audio taped.

The data were analysed using a grounded theory approach. This approach involves identifying themes in the data that are related to the research question. The themes are then used to develop a theory that explains the data. The grounded theory approach is a common approach for qualitative research and is well suited to exploring the experiences of people with a mental health problem who are in contact with mental health services.

The findings of the current study suggest that people with a mental health problem who are in contact with mental health services experience a range of challenges. These challenges include difficulties with accessing services, difficulties with understanding services, and difficulties with engaging with services. The findings also suggest that people with a mental health problem who are in contact with mental health services experience a range of benefits. These benefits include improved mental health, improved social support, and improved access to services.

The findings of the current study have implications for mental health services. They suggest that mental health services should be designed to address the challenges that people with a mental health problem who are in contact with mental health services experience. This could involve providing more information about services, providing more support with accessing services, and providing more support with engaging with services.

The findings of the current study also have implications for research. They suggest that further research is needed to explore the experiences of people with a mental health problem who are in contact with mental health services. This research could involve exploring the experiences of people with a mental health problem who are in contact with mental health services in different countries, exploring the experiences of people with a mental health problem who are in contact with mental health services in different settings, and exploring the experiences of people with a mental health problem who are in contact with mental health services in different ways.

The findings of the current study are limited by a number of factors. These factors include the small sample size, the lack of diversity in the sample, and the lack of control over the data. Despite these limitations, the findings of the current study provide valuable insights into the experiences of people with a mental health problem who are in contact with mental health services.