Some things old, some things new, some things yet-to-be….

Most readers of this newsletter have probably heard of the General Clinical Research Center (GCRC), located on the third floor of Shands Hospital. Many may already be veteran investigators of the GCRC as UF’s traditional NIH-funded resource for patient-oriented research (POR). Our Center is one of the oldest in the country, having been continuously funded by NIH since 1962, and the vast majority of successful CTSA applicant organizations have at least one of these institutional resources. Patient-oriented research and training has and continues to be well-served by the GCRC, which has leveraged millions of dollars in extramural funds to supplement investigators’ own grants, and the Center has provided resources to conduct POR in diverse disciplines involving several colleges on campus and has helped launch the careers of innumerable POR investigators.

Upon the anticipated receipt of a CTSA this year, the budget and management of the GCRC will be folded into the CTSI. Moreover, as a way to further enhance the opportunities for POR across campus, the Institute has developed the Clinical and Participant Interactions Program under the direction of Carl J. Pepine, MD, Professor of Medicine in the Division of Cardiovascular Medicine and a preeminent POR investigator and clinical trialist. Under Carl’s direction, this new program will help guide eight Clinical Research Units (CRUs) of which the GCRC will be preeminent in terms of its diversity and direct funding from the CTSI. As described below, the other CRUs will be focused on more thematically discrete areas of research. Some of these units already exist, and our goal is to further enhance their resources for research and training under the auspices of the CTSI; others are still in the planning stages. Thus, the evolution of resources for patient-oriented research and training at both the Gainesville and Jacksonville UF campuses is dynamic and holds promise for providing greater opportunities for our clinical and translational science community.

Read on to find out more about the Participant and Clinical Interactions Program and what it may offer you.

Peter W. Stacpoole, PhD, MD
Director, General Clinical Research Center
Director Clinical and Translational Science Institute
Associate Dean Clinical Research and Training
UF enjoys a wealth of multi- and interdisciplinary extramurally funded programs engaged in patient-oriented research (POR). For 46 years many have utilized the resources of the General Clinical Research Center (GCRC) centered at Shands Hospital. The GCRC has adapted and changed through the years, so it’s no surprise that recent facility renovations, new resources and an ever-expanding portfolio of innovative research and training programs have led to consecutive “outstanding” site visit reviews and five year renewals for the Center.

In order for UF to continue to be a national leader in patient-oriented research, the CTSI will coordinate and implement a unique plan to merge multiple new opportunities available within UF’s expansive academic research setting by forging strong partnerships with the residents of Florida served by statewide healthcare and health delivery systems. As always, the details of how the program will increase its effectiveness are critical. In the case of the GCRC, three goals underlie and guide the transformation:

**Goal 1:** Provide outstanding venues for conducting clinical research and clinical trials in pediatric and adult populations.

**Goal 2:** Ensure that consistently high-quality research is conducted at Clinical Research Units (CRUs).

**Goal 3:** Establish procedural rules and milestones to evaluate resource utilization, research productivity and cost accountability.

Let’s look at each goal in turn and see how the CTSI will meet the challenges of the multiple needs in research….  

**Goal 1: Provide outstanding venues for conducting clinical research and clinical trials in pediatric and adult populations.**

During the planning process, UF, Shands and the Malcom Randall VA Medical Center (MRVAMC) evaluated the current limitations in their ability to serve investigators in POR and training. As a result, the CTSI will transform patient-oriented research at UF by creating a new network of eight Clinical Research Units (CRUs) that together form the venues of the PCIP. These sites and their principal activities are summarized in Table 1.

**Shands UF CRU.** This traditional GCRC facility will be transformed into a component of the CTSI and will continue to serve as a major resource for clinical research on the Gainesville campus. It will also be the principal venue for small clinical trials involving gene therapy and rare diseases, and will be the major venue for mechanism-based research projects involving pediatric and adult patients whose primary care is rendered by Shands at UF and the North Florida/South Georgia Veteran’s Health System (NF/SGVHS). Several emerging regenerative medicine protocols require telemetry, and UF and Shands will provide telemetry monitoring for the first time in the CRU beginning in early 2009. The transformation from the GCRC into a CRU network and the renovation of facilities in the Shands at UF CRU are particularly timely because of the emergence of cell therapy trials from UF’s Program in Stem Cell Biology and Regenerative Medicine. This program, directed by Edward W. Scott, PhD, is recognized internationally for the quality and
breadth of its research. Initial cell therapy trials are coordinated and led by Carl J. Pepine, MD, in collaboration with John Wingard, MD and Christopher Cogle, MD, of the Shands Bone Marrow Transplant Unit. The Shands at UF CRU will be co-directed by Mark Brantley, MD, professor of Medicine, and Desmond Schatz, MD, professor and vice chairman of pediatrics, both of whom have been associate GCRC program directors for approximately 10 years.

**Shands Jacksonville CRU.** Shands Jacksonville will be integrated directly into the CTSI’s network of CRUs for POR. To transform its ability to conduct cutting-edge POR, the College of Medicine in Jacksonville has renovated existing hospital space and constructed a four-bed inpatient CRU and additional outpatient facilities, with the intention of expanding this resource in future years as demand grows. This transformation enables both Gainesville and Jacksonville campuses to undertake a true sharing of the following resources: 1) administrative, regulatory, biostatistical, and study design and informatics resources aligned with the academic home of the CTSI; 2) on-site research coordinators to assist in CRU studies and link directly to additional research resources at the CTSI in Gainesville; 3) complimentary patient populations relevant to racial, ethnic and socioeconomic demographics; 4) an increased critical mass of clinical investigators able to engage in collaborative clinical

<table>
<thead>
<tr>
<th>CRU</th>
<th>Location</th>
<th>Primary Research and Training Focus</th>
<th>Cachement Area and Patient Demographics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shands UF</td>
<td>GCRC, Shands Hospital</td>
<td>General; rare diseases; gene and regenerative therapy trials; pediatric and early phase trials; cancer trials</td>
<td>International, esp. for rare/genetic diseases and gene therapy; otherwise Alachua County for health subject participants and GA-FL for most other POR protocols</td>
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<td>Shands Jacksonville</td>
<td>Shands Jacksonville/UF campus</td>
<td>Community-based pediatric and maternal-child studies; neurological diseases and stroke, cardiovascular, women’s health</td>
<td>Duval County and S.E. Georgia; esp. underserved populations</td>
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<tr>
<td>Center for Clinical Trials Research</td>
<td>Gainesville campus</td>
<td>Phase 1-2 clinical trials</td>
<td>Regional for studies in healthy subjects; international for studies in patients</td>
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<td>Institute on Aging</td>
<td>Gainesville campus</td>
<td>Observational studies, clinical trials in aging</td>
<td>Elderly populations in GA-FL</td>
</tr>
<tr>
<td>Periodontal Disease Research Center</td>
<td>College of Dentistry</td>
<td>Oral hygiene trials</td>
<td>GA-FL for early-late phase clinical trials; esp. underserved populations</td>
</tr>
<tr>
<td>Comprehensive Center for Pain Research</td>
<td>College of Dentistry</td>
<td>Early-late phase clinical trials</td>
<td>Adult populations in GA-FL</td>
</tr>
<tr>
<td>Cancer Hospital</td>
<td>Shands UF</td>
<td>Cancer trials</td>
<td>Regional or national, depending on specific trial</td>
</tr>
<tr>
<td>A.G. Holley Hospital</td>
<td>Lantana, FL</td>
<td>Multi-drug resistant tuberculosis</td>
<td>International, esp. Central, North and South America</td>
</tr>
</tbody>
</table>
research and clinical trials; 5) closer affiliation through the CTSI’s electronic and videoconferencing facilities to link laboratory scientists in Gainesville with clinical investigators in Jacksonville, thus enhancing opportunities for collaborations; and 6) increasing educational opportunities for fellows and faculty in Jacksonville through distance learning capabilities embedded in the CTSI’s electronic and videoconferencing facilities to link laboratory scientists in Gainesville with clinical investigators in Jacksonville, thus enhancing opportunities for collaborations; and 6) increasing educational opportunities for fellows and faculty in Jacksonville through distance learning capabilities embedded in the CTSI’s academic home and its Training and Career Development Program.

The Shands Jacksonville CRU will be directed by Alan Berger, MD, Professor of Neurology and Assistant Dean for Research, College of Medicine-Jacksonville. Currently more than 500 clinical trials are underway by College of Medicine faculty located on the Jacksonville campus. The traditional clinical research infrastructure on the Jacksonville campus is integrated into the departments, with many hiring their own staff of research nurses, coordinator and managers.

The Jacksonville campus draws on its vast community-based primary care satellite system that consists of 18 family practice, internal medicine and Ob-Gyn practices distributed geographically across Jacksonville and South Georgia. This system employs more than 65 physicians and mid-level providers and provides primary and specialty care for more than 240,000 patients throughout Jacksonville. Pediatric POR, particularly as it involves community engagement activities, will be led by Mobeen Rathore, MD, Professor of Pediatrics and Director of the UF Rainbow Center in Jacksonville. This Center is the only comprehensive and family-focused NIH-AIDS center in Northeast Florida. Under Dr. Rathore, Jacksonville pediatric researchers will also collaborate with the nearby Wolfson Children’s Hospital’s Community Research Network, a leader in many community-based studies in Northeast Florida and Southeast Georgia. These community-based research activities provide a strong foundation for late-phase clinical trials, particularly in the pediatric population.

Center for Clinical Trials Research (CCTR) CRU. The CCTR was founded in 2001 as a site for industry-sponsored, FDA-compliant early phase clinical trials. The CRU is a 14,000-square-foot, 48-bed unit for conducting inpatient and outpatient clinical trials, and is one of the only free-standing Phase 1-2 clinical research sites based in an academic institution in the U.S. Under the auspices of the CTSI, the CCTR will be transformed into a new resource for training and for conducting investigator-initiated trials, while maintaining an active portfolio of industry-supported studies. The operations and management are under the direction of Constance Stone, DMD. A long-term outcome for faculty participation in the CCTR CRU is developing scientific leaders who can serve as experts to consult and help oversee early phase clinical trials at UF and elsewhere. In turn, using faculty as expert consultants will improve the integrity of trials conducted at the Center and represents a major advantage for UF versus proprietary clinical trial units not affiliated with an academic health center. Faculty also will receive publication opportunities that enhance promotion and tenure.

Training opportunities at the CCTR CRU include lecture-based courses and patient-oriented research experiences overseen by CCTR CRU staff that will involve detailed understanding of investigational new drug applications (IND)s, good clinical practice (GCP), adverse event reporting, intellectual property rights and patent issues, patient and minority recruitment and retention and early clinical phase study design and
analysis, including pharmacokinetics and safety trial design strategies. In this way training involving the CCTR CRU offers an integrated “clinical trials” pathway for physicians, PhDs, dentists, pharmacists and nursing coordinators that will integrate closely with all aspects of the CTSI’s Training and Professional Development Program and to its distance learning resources.

Institute on Aging (IOA) CRU. With the advent of the Claude Pepper Center in 2007, POR in aging at UF has increased exponentially. The transforming aspect of the IOA is its full integration into the CRU network to provide a new venue for investigators interested in mechanism-based and observational studies on aging. It will also be the focal point of early- and late-stage drug and lifestyle interventional clinical trials to improve quality of life in the elderly population. Currently geriatricians are conducting studies on the physiological and biomechanical mechanisms contributing to changes in walking, and secondary analyses of randomized clinical trials and observational studies. The CRU occupies space for outpatient research in the 9,500-square-foot Aging and Rehabilitation Research Center on the Health Science Center campus at UF. Inpatient investigations will utilize the Shands at UF CRU. Marco Pahor, MD, will direct the CRU at the IOA. The PCIP will provide additional administrative and informatics support to the CRU and will ensure the availability of Study Coordinators for protocols relating to aging research.

UF and Shands Cancer Hospital CRU. The Jerry W. and Judith S. Davis Cancer Pavilion and the adjacent Shands Medical Plaza are the locations of several outpatient clinics for pediatric and adult oncology services. Oncologists participate in industry- or NIH-sponsored clinical trials utilizing these outpatient resources and, occasionally, the GCRC for Children’s Oncology Group protocols involving rare pediatric solid tumors. For the most part, however, POR involving cancer patients has not been well organized at UF.

To address these shortcomings and to meet the growing need for outstanding clinical resources for the care of oncology patients, members of the CTSI and UF and Shands Cancer Hospital are working towards the development of a CRU for early phase oncology trials at this new hospital. However, use of the Shands at UF CRU as a site for cancer clinical research studies will continue even after the Cancer Hospital CRU opens, because of the focused resources at the Shands UF CRU for undertaking around-the-clock monitoring and conducting precise pharmacokinetic investigations. To assist in this effort, the entire nursing staff of the Shands UF CRU has received certification in administering cancer chemotherapy.

Periodontal Disease Research Center CRU. The PDRC directed by Ingvar Magnusson, PhD, DDS, has been a central venue for industry-sponsored clinical trials in the College of Dentistry since 1985. Many protocols have dealt with control of plaque formation and gingivitis. PDRC staff routinely develop standard operating procedures concordant with FDA and European guidelines for good clinical practice and good laboratory practice standards. Clinical staff of the PDRC includes two full-time and four part-time registered dental hygienists as well as a patient coordinator. The PDRC also has laboratory facilities available for conducting small-scale pilot studies and/or for determining the effects of various compounds on oral flora.

The PDRC occupies dedicated clinical research space...
in the College of Dentistry and contains nine fully equipped dental operatories. Despite this invaluable resource, the PDRC was not formerly incorporated fully into the academic environment at UF. Thus, it has not traditionally served as a venue for conducting investigator-initiated clinical trials or for facilitating training in patient-oriented research relating to oral hygiene. Like the CCTR, the PDRC will transform into one of the CTSI’s CRUs in collaboration with Dr. Magnusson and the College of Dentistry. Accordingly, the PDRC CRU will continue to serve as a venue for industry-driven clinical trials but will expand its mission to encourage investigator-initiated, extramurally-funded POR. In addition, it will serve as a site for training dentists and dental hygienists in Phase 1-3 dentistry-oriented clinical trials. The CTSI will provide enhanced biostatistical, study design, bioethics and informatics support from its other cores for the PDRC CRU investigators and trainees.

Comprehensive Center for Pain Research (CCPR) CRU. The CCPR is a university wide Center directed by Robert Yezierski, PhD, that represents the scientific home for the extensive translational pain research community at UF. Utilizing resources within the six colleges of the Health Science Center (HSC), the McKnight Brain Institute and the GCRC, this multidisciplinary initiative provides pain research, education and training programs in a wide range of pre-clinical and clinical disciplines, including molecular and cell biology, physiology, pharmacology, psychology, sociology, epidemiology, research theory and design and clinical pain management. Moreover, the CCPR is the home for UF’s NIH-funded training program in Integrative and Translational Pain Research.

The CRU, which opened July 2008, under the direction of Roger Fillingim, PhD, represents the most recently developed entity within the CCPR. This CRU will be affiliated with the CTSI’s Biobehavioral Core, given its mission of providing expertise and resources to support human studies involving pain assessment. The CCPR’s CRU will transform POR at UF by providing for the first time a centralized venue dedicated to hypothesis-driven research and training in the causes and treatment of pain.

The CCPR CRU facility includes two private rooms devoted to quantitative sensory testing (QST), which are equipped with state-of-the-art psychophysical testing devices for assessment of sensory responses to thermal, mechanical, cold, ischemic and electrical stimuli. Also, each room includes cardiovascular monitors. An additional private room is available for conducting physical and dental exams. Dr. Fillingim and other affiliated faculty will be able to provide expert consultation to CTSI investigators to assist with implementing optimal pain assessment methods into their protocols.

A.G. Holley Hospital CRU. A.G. Holley is the only state tuberculosis (TB) hospital in Florida and one of only two in the US. Its mission is to provide state-of-the-art inpatient care for the most challenging cases of TB in the state. It receives national attention as a model facility dedicated to curing the most complicated and difficult tuberculosis cases that have failed treatment in the community. Approximately half of all patients admitted to A.G. Holley are there by court order because of non-adherence to therapy. The other half of patients are hospitalized voluntarily because they could not be managed adequately in the outpatient setting due to the complexity of their disease, such as multi-drug resistance or complications.
related to HIV infection. For these patients, the hospital offers complete medical care with extensive support services. The Southeastern National Tuberculosis Center (STNC) is located in Gainesville and its clinical campus is at the A.G. Holley State Tuberculosis Hospital located in Lantana. Because of the Center’s juxtaposition to both academia and public health, it can serve as a catalyst for multidisciplinary and interdisciplinary translational research.

The STNC is federally funded through the Centers for Disease Control and Prevention (CDC) and it is based at UF and the A.G. Holley State TB Hospital. It is charged with providing training, education and expert medical consultation for the TB programs of the southeastern U.S. and U.S. territories in the Caribbean. It is one of four national TB Centers nationwide. Although funding for these centers specifically excludes research or clinical activities, guidance from the CDC encourages developing the Center as the Center leadership sees fit including seeking additional outside funding for TB-related research activities.

The STNC is directed by Michael Lauzardo, M.D., MSc, and co-directed by David Ashkin, MD. Both are full-time employees of the Department of Health with joint appointments in UF’s Division of Pulmonary and Critical Care Medicine.

One of the most significant aspects of the State of Florida TB Program incorporated into the STNC is the TB Physicians Network. This is a network of pulmonologists that was created nine years ago to provide medical consultation and programmatic assistance to the county health departments throughout Florida. The Network has full access to the TB Information Management Systems database that contains clinical and demographic information on more than 15,000 patients during the last 10 years—a tremendous research resource that has been underutilized but could provide a valuable entrée to community-based public health programs.

The STNC with the TB Physicians Network provides access to an underserved population, approximately 80 percent of whom are from minority groups. Under the CTSI, the A.G. Holley Hospital will undertake a transformation of its mission to be included as a 50-bed inpatient CRU for conducting POR in patients with TB. The CRU at A.G. Holley would function as both an inpatient resource for studies of multi-drug resistant or other complex cases of TB and as a venue for outpatient studies in the community. The hospital’s location 300 miles south of the Gainesville UF campus might be considered a major drawback for linking with the CRU network. However, disparate sites give CTSI investigators and trainees access to a diverse population of mostly underserved individuals from a wide variety of backgrounds that are not usually represented in traditional biomedical research. Distance communications and learning opportunities will be facilitated by the CTSI’s Administrative Core. In turn, A.G. Holley has recently invested resources to create seven sleeping rooms in the hospital to accommodate researchers overnight or for extended periods of stay. Dr. Lauzardo will serve as program director of the A.G. Holley CRU with Dr. Ashkin assisting as codirector.

**Goal 2: Ensure that consistently high-quality research is conducted at CRUs.**

Accessing PCIP’s CRUs. The CTSI will create a physical and virtual research portal in its academic home. The portal has been developed by the Biomedical Informatics Program and will be managed by the Regulatory Knowledge and Research Support (RKRS).
Program under the direction of David Nelson to facilitate project development, review and implementation. The intent of the Program is to decrease the time required for a CTS research project to be reviewed and ultimately approved. The CTSI staff estimate 1-2 months will be required for bringing protocols from concept to the point of scientific and regulatory review. This timeline could be shortened considerably depending on how much prior knowledge the investigator has about the general project development process and the types of resources available through the CTSI.

Scientific review of research involving humans and/or vertebrate animals will be administered by the Scientific Advisory Committee (SAC), chaired by N. Lawrence Edwards, MD, professor of medicine. The SAC reflects a broad range of scientific expertise and representation by faculty from the colleges affiliated with the CTSI. Protocols submitted to the SAC will be divided into those involving human research and animal research.

The RKRS program is working with CRU leadership to transform the process by which CTSI protocols will be reviewed. The following changes are being addressed: First, the meetings of the SAC and IRB will be coordinated so that they occur separately but on the same day every other week. Second, all submissions will be made electronically and reviewers assigned to specific protocols will be encouraged to address questions or concerns with applicants prior to formal committee review. Third, all three review groups will utilize the same five-page mini-R01 protocol format employed by the SAC. Fourth, regulatory issues contained in the IRB Introductory Questionnaires will be reformatted to include queries relevant to the other regulatory review boards (e.g. radiation, gene therapy committees), thus eliminating the need for investigators to submit separate applications to these groups. The Introductory Questionnaire, protocol description, CTSI resource utilization section and the informed consent form will constitute a single, electronically submitted research project document available simultaneously to the SAC and IRB/IACUC. CTSI staff estimates this procedure, coupled with the frequency of reviews, will result in at least a 30 to 50 percent reduction in the approximately 28-day time required currently for combined GCRC/IRB review. Collectively, the entire process of project development, submission, review and implementation should average two to three months or less, depending on the experience of the applicant and the complexity of the research study.

Integration with Biomedical Informatics. Previous efforts to integrate clinical data in support of research have focused on case-by-case extractions of data from the clinical systems using manual methods. Through the CTSI’s Biomedical Informatics Program the units will alter their strategy to one of creating persistent technical interfaces using a variety of approaches as needed. These approaches include extract-transform-load, access in place and messaging. Each has been used successfully in previous work. The clinical interface effort will be focused on EpicCare. Interfaces will include de-identification and data models optimized for research database construction and patient eligibility alerts within EpicCare, supporting the CRUs. The UF Faculty Group Practice has begun designing these interfaces. Star schema will be used where appropriate. Data from clinical systems will be made available on a cost recovery basis using strict access control technology meeting all applicable regulatory and ethical restrictions.
**PARTICIPANT AND CLINICAL INTERACTIONS PROGRAM**

**Goal 3: Establish procedural rules and milestones to evaluate resource utilization, research productivity and cost accountability.**

**Organization and Governance of the PCIP.** The PCIP will be led by Dr. Carl Pepine, who has a long and distinguished career as a clinical investigator. He has conducted numerous federally and industry-funded, multi-center or international clinical trials in areas of cardiovascular medicine. Dr. Pepine will chair the advisory committee of the PCIP. The committee is comprised of the program directors of each of the Clinical Research Units and Michael Conlon, PhD, CTSI Associate Director for Biomedical Informatics. Dr. Pepine and the committee will have the authority to appoint Rapid Action Teams to define, implement and ensure best clinical practices and to address particular areas of opportunity or concern. Dr. Pepine will report his findings to the Steering and Planning Committee which will have overall governance of the PCIP and the other cores and programs of the CTSI. The SPC will have the authority to recommend and enforce changes in the organization, governance and activities of the PCIP, but will work in consultation with the Translational Science (internal) Advisory Committee and the External Advisory Committee of the CTSI.

It will be essential for the PCIP to receive feedback from the individuals participating as research study subjects in the CRUs and investigators and trainees who utilize these resources. Anonymized questionnaires will be distributed to subject participants and investigators through the Institute’s Translational Science Advisory Committee, which conducts the tracking and evaluation of all CTSI functions. This information will be used by Dr. Pepine, the CRU program directors, and the SPC in rendering evaluations of the effectiveness of the program.

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The March edition of the Newsletter contained an RFA for seed money support through our new Pilot and Collaborative Projects Program. We received nine proposals by the April 30 deadline for receipt of applications. The Programs’ Executive Committee made the following awards on May 7, 2009 with funding available by June 1.

CTSI Pilot and Collaborative Project Program Awards (May, 2009).

<table>
<thead>
<tr>
<th>Category</th>
<th>Awardee</th>
<th>Academic Affiliation</th>
<th>Title of Project</th>
<th>Award</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graduate Student</td>
<td>Amber Van Matre, MS</td>
<td>College of Liberal Arts and Sciences</td>
<td>Pharmacological Treatment of Repetitive Behavior: Targeting Adenosine, Dopamine, and Glutamate Heteromeric Receptor Complexes</td>
<td>$ 7,508</td>
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<tr>
<td>Junior Faculty</td>
<td>Benjamin G. Keselowsky, PhD</td>
<td>College of Engineering</td>
<td>Dendritic Cell Arrays for Type I Diabetes Microparticle-Based Vaccines</td>
<td>$ 15,000</td>
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<td></td>
<td>Baharak Moshiree, MD</td>
<td>College of Medicine</td>
<td>Comparison of Two Macrolides, Azithromycin and Erythromycin, for Symptomatic Treatent of Gastroparesis</td>
<td>$ 20,000</td>
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<tr>
<td>Novel Methods* and Technology</td>
<td>Michael A. Crary, PhD</td>
<td>College of Public Health and Health Professions</td>
<td>Development and Initial Validation of a Swallow Frequency Meter</td>
<td>$ 24,720</td>
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</tbody>
</table>

Total $ 67,228

*Multiple co-investigators and/or colleges were represented by these proposals, but only the PIs and their colleges are listed.

Congratulations to the awardees! Competition was stiff and many meritorious proposals could not be funded. For those who did not apply or who were unsuccessful this round, we plan to announce the next RFA in the September, 2009 Newsletter.
Carl J. Pepine, MD, is Eminent Scholar Emeritus and Professor of Medicine, Division of Cardiovascular Medicine at the University of Florida College of Medicine. He is a graduate of the University of Pittsburgh and the College of Medicine of New Jersey.

When asked about the CTSI, Pepine said that the individual units are running separately and successfully now but tending to function entirely separately from one another. The goal of the CTSI is that they can be brought together in a matrix of research units sharing information and training opportunities.

How does Pepine see the interaction between units taking shape? He sees two broad areas for obvious cooperation. He says, “The first [area for cooperation] that I’m proposing is that we simply track projects in an informational tracking program across the units so each would know what others are doing.” For the benefits of this information sharing he gives the example of a new drug that cardiovascular researchers have discovered and have in Phase 1 trials might be relevant to sleep researchers if they have access to the compound and its sponsor so that Phase 2 studies might be done in one of our units. According to Pepine, “At present there’s no knowledge of the trials going on in the various units. You can play out the advantages in any of the units. Just the information and tracking structure will add tremendous value.”

The second area for training, Pepine says, is training. Through the coordination of the CTSI, all of the units are now available for training individuals across the participating schools and organizations. Mentors and researchers now have access to a host of clinical trial units, so a trainee could select one or several of the units to do projects in or select a mentor out of any of the units.

Pepine says, “These are the first two things that could be rolled out, and there would be others in subsequent areas so we could streamline processing and IRB hurdles that are significant issues here.”

Asked about the difference that the CTSI will make for the individual units, Pepine says, “They grew up in their own little specialized niches, and there was no intent or stimulus on a larger level until just a few years ago when the NIH put forth the money to stimulate the program.” Now the structures will be in place to help the units look beyond the confines of their own specialty to think of research in a larger context, he says.

The difference for the units will be echoed in the difference the CTSI will make in Pepine’s own work. “It takes me out of my focused niche in ischemic disease in cardiovascular to take a broader view. It’s refresh-
MEET THE PCIP DIRECTOR

Pepine is an internationally recognized leader in both the clinical and scientific areas of cardiovascular medicine. His major interests focus on the pathophysiology of ischemic heart disease and coronary and systemic vascular hemodynamic mechanisms underlying the disease. He is principal investigator for the UF center for the National Heart Lung and Blood Institute (NHLBI)-funded Women’s Ischemia Syndrome Evaluation (WISE) and the UF center for the Cardiovascular Cell Therapy Research Network (CCTRN). He has been or is the PI for many investigator-initiated clinical trials. He is past president of the American College of Cardiology (ACC), the professional organization for cardiovascular physicians. He currently serves on the Board of Trustees of the ACC and many committees and task forces and is the founder and overall Project Chair for the Vascular Biology Working Group (VBWG).

Dr. Pepine’s clinical interests include ischemic heart disease, heart disease in women, cardiovascular cell therapy, preventive cardiology, genetic cardiology and clinical trials in cardiovascular disease.

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E-mail: pepincj@medicine.ufl.edu

Employment
Did you know that there are multiple venues through which both internal and external jobs are posted?

For Job Seekers
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http://www.union.ufl.edu/jobs/ - Reitz Union student job listings.
http://www.sfa.ufl.edu/programs/ops.html - Other Personnel Services jobs.
http://www.sfa.ufl.edu/programs/oece.html - Off-Campus jobs.
http://www.sfa.ufl.edu/programs/vaworkstudy.html - Veteran’s Affairs Work-Study.