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## FROM THE DIRECTOR

Welcome to the first edition of the CTSI News! With great help from one of our partners, the College of Journalism and Communications, UF's new Clinical and Translational Science Institute goes "live" today. In this first edition of our newsletter we'll try to explain who we are, how we came into being and what we intend to accomplish, which is nothing less than a cultural sea-change at UF in the way it conducts clinical and translational research and training. And I used the word "partners" deliberately to emphasize the absolute interdependency of every academic and intellectual element of the Institute in realizing this ambitious goal.



Whenever you make significant changes to an organization, it can become an occasion for both excitement and anxiety. As we look forward to the evolution of the CTSI, I wanted to write about the goals of the Institute and some of the concrete organizational steps we will take to meet those goals. Everything that you'll read about the Clinical and Translational Science Institute will be aimed at furthering its essential mission: to encourage and improve the path of discoveries from basic science to clinical research to the practice of medicine and back again.

More than a generation has passed since the term "bench—bedside interface" was first used to describe the diffusion of information between basic research laboratories and the clinical arena required to translate scientific discoveries into practical advances in the diagnosis, prevention, treatment and cure of human diseases. The explosion over the last decade of new scientific methodologies and technologies, such as the "omics" (genomics, proteomics, metabolomics), stem cell, structural and computational biology, gene transfer and imaging, have transcended individual disciplines and have become powerful incentives for their integration. It's also become obvious that the transfer of new knowledge isn't unidirectional, i.e., from the bench to the bedside, but, at its best, is highly iterative and dynamic. This is particularly so at the initial interface between discovery and development and at the bi-directional interface between the scientific and lay communities.

The University of Florida's General Clinical Research Center (GCRC) has

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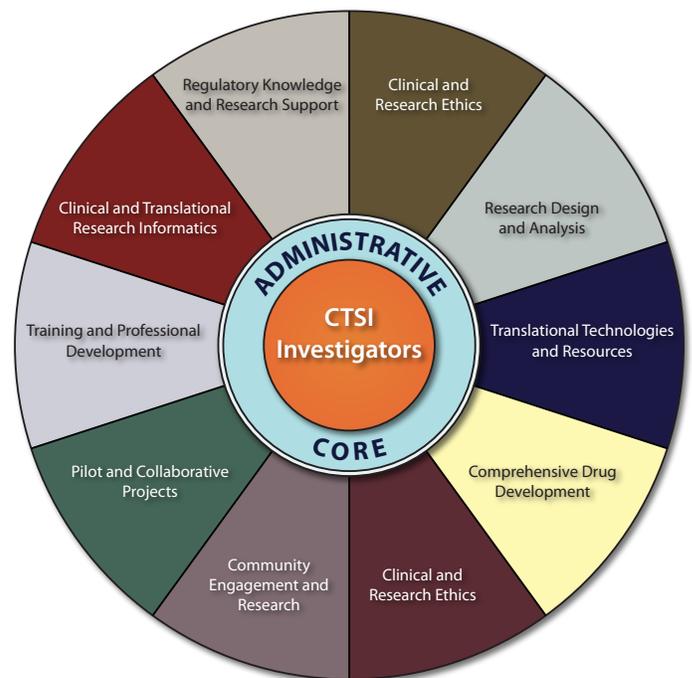
been, since 1962, charged with assisting scientists who want to conduct research in a clinical setting. Established by Congress and funded by the NIH, UF's GCRC (one of about 78 such centers in the U.S.) has provided many types of assistance to the research communities at UF. The CTSI will build on, and vastly expand, the mission of the GCRC.

There are four basic goals that the institute will strive to meet. They are: creating the proper environment for fruitful research, training the individuals who will form research teams, making better technology more available for conducting research and applying the results, and increasing the opportunities for individuals and teams at all stages of research and application to work together to improve health and healthcare throughout the state, the country and the world.

The CTSI will create a better environment for research and practice by helping to eliminate barriers between teams working at different stages of basic research and clinical practice. Through a variety of means, ranging from administrative support to information dispersion, the Institute will help foster inter-team cooperation and the resulting translation of discoveries into products and practices.

Such "team science" is enhanced when all members have access to the training required to improve their job skills and stay abreast of the latest developments in their field. The CTSI will offer a level of training that will not only help individuals become better in their positions, but will enable them to become leaders in their clinical and scientific fields.

Infrastructure is critical to cutting-edge research, and the CTSI will provide superior technology and leader-



**Fig 1. Collaborating Partners in the CTSI**

ship in making new discoveries and removing institutional barriers to their translation into clinical research and practice. Whether the technology involves instrumentation for research or systems for information retrieval and dissemination, the CTSI will act in a critical infrastructure support role.

Information that flows readily between members of the scientific and clinical communities can foster new topics of research and create opportunities for cooperation and collaboration. The CTSI will engage in active outreach to all members of the research and healthcare communities to encourage information exchange and professional collaboration. A Community Advisory Council will help involve community members in the process of improving healthcare for Florida's citizens. Special attention will be given to the needs of children and under-represented minorities.

## FROM THE DIRECTOR

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In order to fulfill the goals of the CTSI, a new organizational structure will be created and housed on campus. The Administrative Core of the institute will provide administration and support for the investigators who are at the heart of the CTSI. Together, they will deliver the major functional components of the CTSI (FIG. 1), which are:

- Research Design and Analysis
- Translational Technologies and Resources
- Comprehensive Drug Development
- Patient-Oriented Research Venues
- Community Engagement and Research
- Pilot and Collaborative Projects
- Training and Professional Development
- Biomedical Informatics
- Regulatory Knowledge and Research Support
- Clinical and Research Ethics

The programs to support these functions and their staffs will constitute the CTSI Commons. These open forums will bring together all members of the CTSI community through programs such as:

- **The CTSI Newsletter**, which will include both a regular publication and electronic chat rooms.
- **CTS Grand Rounds**, modeled on grand rounds of clinical departments, which will include both a talk and a discussion based on the work of a CTS community member or outside investigator.
- **The CTSI Visiting Scientist Program**, which will building on the successful GCRC Visiting Scientist Program.
- **Out-of-the Box Lunches**, for informal meeting and discussion of creative ideas.

- **Annual Research Symposium**, an annual retreat for members of the community to discuss the on-going state of the CTSI.

Obviously, this list isn't exhaustive. It is, however, intended to give an idea of the breadth of programs the CTSI will offer, and the expansive vision that will guide its operation. Governance of the Institute is the charge of a 16-member Steering and Planning Committee made up of representatives of UF's biomedical, healthcare, and other affiliated colleges and communities. The SPC's broad range of collective experience and individual expertise will be tapped to establish principles, strategies, and policies that will make the CTSI an effective instrument for enriching clinical and translational research and training at UF.

Stay tuned for much more to come!

### **Peter W. Stacpoole, Ph.D., M.D.**

Director, CTSI

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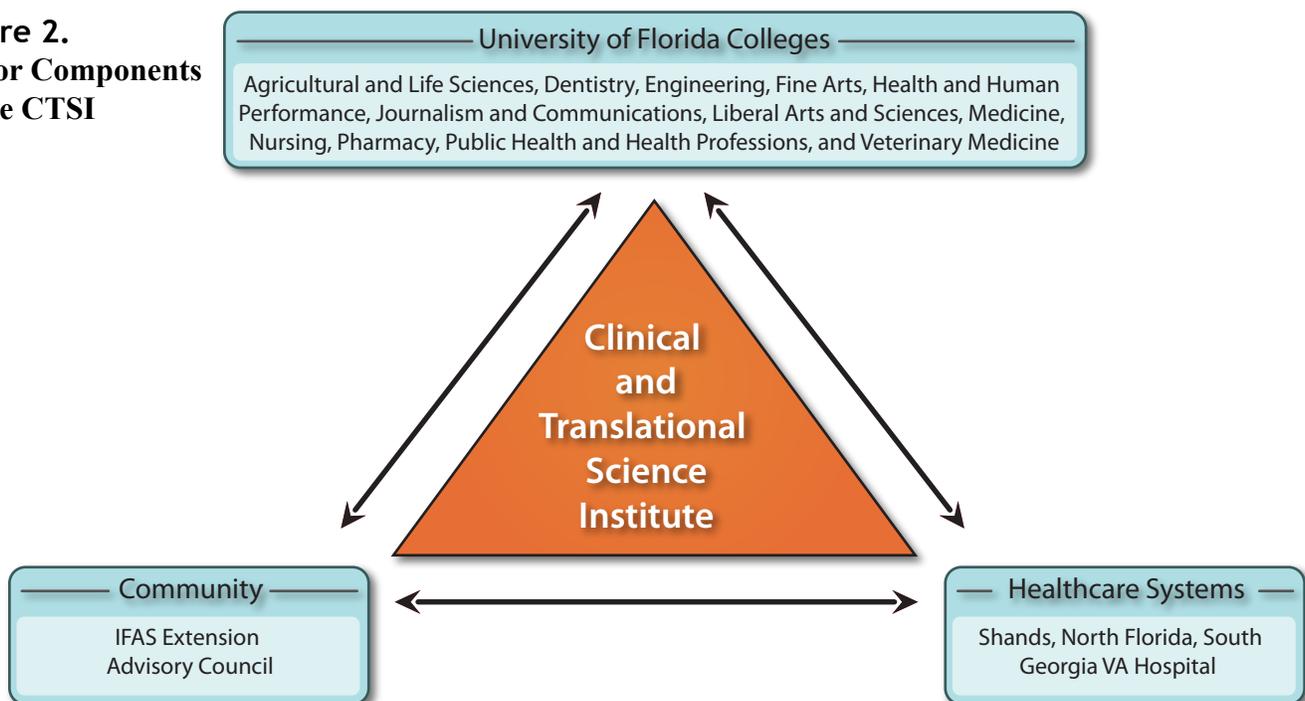
Associate Dean for Clinical Research and Training, College of Medicine

## THE CTSI NEWS

### *Communities Brought Together*

The University of Florida, through the CTSI, will bring together the skills, training and experience of a dozen colleges, two campuses, two regional healthcare systems and all 67 Florida counties (FIG. 2). The colleges involved include Agriculture and Life Sciences, Dentistry, Engineering, Fine Arts, Health and Human Performance, Liberal Arts and Sciences, Journalism and Communications, Medicine, Nursing, Pharmacy, Public Health and Health Professions, and Veterinary Medicine. Both Shands and the North Florida/South Georgia VA Health Systems will be involved in the CTSI, as will the Institute for Food and Agricultural Science's Extension program. It's a huge group of individuals and organizations, but what will the CTSI hope to accomplish by this partnership? Simply stated, the CTSI will work to overcome institutional and cultural barriers to communication and collaboration between scientists and professionals in diverse disciplines to aid in preventing, diagnosing, treating and curing disease. The end result should be nothing short of a transformation of Florida's clinical and translational research enterprise.

**Figure 2.**  
**Major Components**  
**of the CTSI**



The university is not simply waiting for funding from the NIH to begin the transition to the CTSI. UF has already committed thousands of feet of newly-renovated space and millions of dollars in funding to the creation of the new Institute. The Institute will also make seed money available this year to members of the CTSI community who want to develop pilot projects that will lead to new extramural grant applications. More information on these funding opportunities will appear shortly in the next issue of the CTSI News.

## THE CTSI NEWS

### *Communities of Practice*

One of the core issues addressed by the CTSI is that scientists and healthcare professionals tend to spend their time concentrating on the area of their immediate concern. It's widely accepted that members of the research and healthcare communities could learn from one another if given the chance, but, as noted earlier, the infrastructure to facilitate that communication has not been optimal. The CTSI will provide the venues and mechanisms for communication within "communities of practice", assisting in the development of both institutional and cultural means for sharing information. If scientists, healthcare professionals, and the public can be encouraged to share information more broadly, the hope is that new ways of solving problems, new ideas for research topics, and new opportunities for moving scientific discoveries down the path toward new treatments will be found.

This year the CTSI will occupy renovated space in the Health Science Center campus to establish its new academic home that will provide the leadership, infrastructure and resources to oversee and guide the transformation of CTS at UF. It will house offices for the Administrative Core of the Institute and for many of the faculty and staff associated with the component programs identified in FIG. 2 that will be discussed in subsequent issues. The plans for the CTSI recognize that working in cross-disciplinary teams may require training that most laboratory-based scientists and healthcare professionals have never received. That's why funding for new training programs is included within the CTSI. This funding recognizes the importance of training future leaders in the communication, management and research skills that will allow them to make use of the practices and processes embodied in CTS.

### *An Aggressive Timeline*

The transition to the CTSI will begin this year in tangible ways with the inauguration of pilot project grants this fall; a Visiting Scientist Lecture series (Jeremy Nicholson and Elaine Holmes from the U.K. speaking on July 24 about the new field of Metabolomics); development of new technology cores in Metabolomics and Biobehavior; the beginnings of a major initiative in Biomedical Informatics; opening within the next few months of the Institute's Office of Regulatory Affairs for assistance in circumnavigating local and federal regulations in areas such as investigational drugs and devices; and a centralized Research Portal (both physical and electronic) through the Administrative Core for CTSI protocol development. Mechanisms for tracking the milestones and outcomes of each new program will come on line within the next year and will continue through the Institute's five-year planning window.

The objectives are aggressive and ambitious. However, they speak to the critical need to integrate UF's rich environment of distinguished colleges, state-of-the-art research facilities and statewide health education and health delivery systems in a manner that will place our institution at the forefront of the new discipline of Clinical and Translational Science.

## THE CTSI NEWS

### *No Longer Lost in Translation: the New Discipline of CTS and the Transfer of Information*

To improve the process by which scientific discoveries become tools for healthcare professionals and to enhance communications between members of the scientific and healthcare communities, the National Institutes of Health launched a new initiative in 2005 called the Clinical and Translational Science Award (CTSA) program. CTSA's are designed to incorporate and expand upon the funding provided General Clinical Research Centers (GCRCs) that for almost 50 years have been the principle venues at academic health centers in which hypothesis-driven research using human subjects is carried out. UF's GCRC, located in Shands hospital, began in 1962 and is one of the country's oldest continuously federally funded Centers.

When one four-letter acronym becomes another, it's tempting to think that nothing but the letters are changing. In the case of our GCRC's transition to the CTSI, the name is the least of the changes involved. Indeed, on a national level the move to CTSA's will be accompanied by consolidation, as approximately 78 GCRCs become 60 CTSI's. The shift to the CTSI model is intended to build on the success of the traditional GCRC program while improving key areas in process and communications among the various communities that make up the CTSI. In particular, the Institute is structured to target what NIH defines as the two "nodes" of translational science: the translation of laboratory discoveries to "first-in-human" clinical trials and the translation of clinical research to community practice, through new treatments, healthcare policies and healthcare delivery.

## SEED MONEY AVAILABLE

The CTSI benefits are about to begin. A pool of seed money for grants under the CTSI is being made available by the university, with initial grants for graduate students and faculty anticipated by the end of September 2008. Be watching for the next issue of the newsletter for details on the proposal process and more information on the precise amounts available. The time-line is short, so start thinking about the projects that you would like to see funded under these initial CTSI pilot project grants.

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## CTSI Biomedical Informatics Program

by Paula Rausch

In the not too distant past, clinicians and researchers felt they didn't have enough data at their fingertips to find answers to many of the deepest questions they had about diseases and the best ways to treat them in their patients.

That problem of too little data has disappeared, replaced by perhaps an even weightier issue: How to adequately sort out and pull together the appropriate strands of data from among the heaps being created these days so they can be used to translate basic research studies into new and better disease treatments more quickly and improve the care that patients receive in the meantime.

Those who know the problem most intimately say these are lofty goals, but that endeavors to accomplish them at a time when data issues have become extremely complicated will be significantly enhanced by establishing a biomedical informatics program at UF's proposed Clinical and Translational Science Institute to assist researchers and clinicians from across campus do just that.

Particularly in the two decades since the invention of the personal computer, collection of data of all kinds is ubiquitous. Technology-

enabled machine production of data has also exploded with the capabilities to sequence genes, automate patient monitoring in hospitals and clinics, and create immense digital images. Consider as an example the seven terabytes of data generated by a single genetics-based pharmacy study at UF. Seven terabytes is equivalent to about 200 laptops worth of data, about 3.5 million pages of text, or enough books to line the home team sideline of more than three Gator football fields.

"It's very easy to make data these days," said Michael Conlon, Ph.D., UF's director of data infrastructure and interim director of biomedical informatics. "It's not very easy to use it, and biomedical informatics is about using it."

And it's about using it in two important ways, according to Conlon. The first is to assemble all the appropriate components from what are now disparate basic science research studies in a variety of disciplines so that, as a whole, the information can improve the understanding of diseases and translate that knowledge sooner into new and better disease treatments.

Second, biomedical informatics works to bring together all the existing data about each patient so that

his or her clinician, and the patient as well, will have it all available in one place – information, for example, from various doctors, clinics, hospitals, pharmacies, imaging centers, and even genetic sequencing – in order to ensure the best possible treatment and care decisions.

"Data about you is everywhere, and bringing it together in some reasonable way is important to you and it's important to your caregivers," Conlon said. "We're looking at a very holistic view."

Not only does BMI hold promise for significantly improving research and patient care, but it has potential for creating a more efficient health care system in which clinicians would know the genetic makeup of their patients and could use that information to determine specifically which therapies would work for each person.

"But you can't do any of this without informatics because you've got to hook all this stuff up, otherwise it's just data in a drawer – it's data in a drawer, data in a hard drive somewhere – it's not a part of the environment that you can use to do this work," Conlon said.

## CTSI Biomedical Informatics Program

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by Paula Rausch

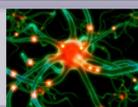
BMI is a complex field in which informaticians like Conlon often think in terms of “stacks” of data-related work segmented by layers. The stack’s top layer contains the lofty goals of improving scientific research and patient care. The bottom layer consists of infrastructure or hardware – all the networks, computers, storage devices and other components where data is held.

Sandwiched in between are two giant – but often overlooked – layers in which biomedical informaticians are working to figure out how to make the data useful. The layer directly above the infrastructure is data management. It involves all of the effort, engineering, utility and thinking that go into efficiently storing the information in ways that allow it to be easily accessed for later use. The next layer up, falling just below the lofty goals, comes the challenge of finding ways to display the thousands or even millions of pieces of data so it can be analyzed.

“We used to display 100 data points, now we’ve got 5 million,” Conlon said. “So we have to have visualization techniques that are optimized for handling massive amounts of data, and those tech-

### The Computational “Stack”

Each layer is challenged by massive data



Science – Questions to be answered about the natural world



Data Analysis – Modeling and Inference, Patterns, Visualization



Data Management – Informatics Algorithms, Methods, and Tools to move and manage massive data



IT Infrastructure – High Speed Networks, Large Scale Storage, HPC

niques cannot obscure any important scientific features of the data.”

The use of biomedical informatics is in its earliest stages at UF and worldwide, but it underpins the university’s large-scale research initiatives, Conlon said. He foresees a program that will one day become a distinct academic department with as many as 30 biomedical informaticians involved in scientific research across all disciplines at UF.

Previously the problems being investigated at UF did not require the kind of complex data that are

now commonplace in research and patient care, Conlon said. “We’re now creating the capability that we need now and forever to address the ever-increasing complexity of data in the modern science world.”