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## FROM THE DIRECTOR

**T**his is crunch time for the CTSI. February 11-12 are the dates of our first annual Research Symposium and Retreat. That's also when our federally-funded CTSA program (awarded only this July!) will undergo its first formal, on-site scrutiny by the National Center for Research Resources, the NIH Center that funds and oversees all CTSA's. As CTSI leadership, including Program, Core and Clinical Research Unit directors, scramble to assemble data regarding traditional metrics of research and training productivity, it's also important for us to reflect on how the Institute can improve the infrastructure for conducting high-quality clinical and translational science across all disciplines represented at UF. At the same time, we must also recognize the impact of our growing participation in the national CTSA Consortium, now numbering 46 institutions and eventually growing to 60 by 2011. Therefore, we need to provide infrastructure not only for intra-institutional research, but also for inter-institutional collaborative clinical and translational investigations.

The first year of our CTSA ends in March 2010; thus, our first "year" ends after only eight months! So as we look forward to our second year of CTSA funding, how can the CTSI better deploy its resources for you, our clients? As a first cut, there are three broad areas:

- **Protocol development.** The CTSI is working hard to improve the efficiency and effectiveness of the development, review and implementation of clinical research protocols, including clinical trials. We are engaged in detailed conversations with Health Science Center leadership about these issues and about how the Institute can provide the infrastructure to facilitate the conduct of essentially all human research conducted at UF. Such infrastructure would include support for study design, biostatistics, informatics, document preparation for IRB and FDA submissions, billing procedures and uniform pricing for clinical trials, among others. We'd all like this to be accomplished yesterday, but we definitely have our sights on having most or all of this infrastructure in place and functional in 2010.
- **Core technologies.** The CTSI has undertaken the development of several new Technology Cores that are designed to support all clinical and translational science, be it in the laboratory, the research clinic or the community. These Cores include Metabolomics, Biobehavior, Biorepository, Comprehensive Drug Development, Human Genotyping and Imaging – all currently in various stages of development. Therefore, one of our goals in year 2 of the CTSA will be to "build out" these Cores so they are sufficiently resourced to appropriately serve your needs.
- **Targeted funding of high-quality research.** We received nearly 50 responses to our latest RFA for funding Pilot and Collaborative Projects. This number is substantially

## FROM THE DIRECTOR

greater than any of our previous RFA announcements and probably reflects, in part, the reworking of unsuccessful applications for American Recovery and Reinvestment Act funding. Undoubtedly, many of the applications we have received are of extremely high quality. However, with currently available funds, we won't be able to make nearly as many awards as we would like. Therefore, the CTSI will be looking in year 2 to enhance our ability to provide greater support for meritorious research proposals, both through our traditional twice-a-year RFA mechanism and by increasing support for investigators who need help in generating preliminary data for responding to time-sensitive RFAs from the NIH, private foundations, etc., that focus on targeted research opportunities. In this regard, an increasing number of NIH RFAs and related funding opportunities emphasize utilizing the institution's own CTSA infrastructure and developing collaborations among CTSA institutions.

Finally, back to metrics and annual reports: One of the most important – and easiest – ways CTSI investigators and trainees can help is to ensure that all publications use the following statement in citing the CTSA award:

This work was supported in part by NIH grant 1UL1RR029890 (Clinical and Translational Science Award).

We'll be adding this reminder to all future newsletters and communications from the CTSI.

Happy Reading!



Peter W. Stacpoole, PhD, MD  
Director, Clinical and Translational Science Institute  
Associate Dean for Clinical Research and Training

### *UF Joins National Recruitment Registry*

The University of Florida has joined with Vanderbilt University and 50 other CTSA institutions to provide a national volunteer registry for recruitment for clinical studies at participating institutions throughout the United States. **ResearchMatch.org** is a Web-based registry for volunteers who are willing to participate in relevant studies conducted by clinical and translational investigators in order to advance the health and well-being of the nation. This electronic volunteer recruitment registry is designed to allow individuals from anywhere in the country an opportunity to securely self-register and express an interest in being prospectively considered for participation in research studies, including clinical trials.



## REGIONAL CONSORTIA: STRENGTH IN NUMBERS

BY PAULA RAUSCH

**U**F's power to speed health improvements to the public got another boost.

In just the span of the past few months since UF received the National Institutes of Health National Center for Research Resources' Clinical and Translational Science Award, the CTSI is already taking steps to partner with other institutions in the Southeast in order to leverage their joint strengths.

UF has teamed up with seven other CTSA-winning institutions in six states to establish the Southeast Regional Consortium. In addition to UF, it includes the University of Arkansas for Medical Sciences in Little Rock, the Medical University of South Carolina in Charleston – the two other institutions to also be awarded CTSA's in July – the University of Alabama at Birmingham, Emory University and the Morehouse School of Medicine in Atlanta, Vanderbilt University and Meharry Medical College in Nashville, the University of North Carolina at Chapel Hill, and Duke University in Durham, NC. See Figure 1.

Such an extensive partnership with so many other powerhouse institutions is unique for UF, at least on such a comprehensive scale. Up to now, this has occurred investigator to investigator in a very limited way, “but not in terms of a broad programmatic basis,” said UF CTSI Director Dr. Peter Stacpoole, PhD, MD. “There’s been relatively little history of that.”

### *Research Consortia*

The Southeast Regional Consortium makes the sixth such geographic collaboration formed that includes CTSA institutions. The others are the West Coast Consortium, the Midwest Consortium, the Chicago CTSA Consortium for Community Engagement (C3), the East Coast Consortium—NYCON Consortium, and the Upstate New York Translational Research Network.

“The regional consortia were begun as a way to establish geographic connectedness among CTSA organizations that were in a particular region of the United States,” Stacpoole said. When Florida, the Medical University of South Carolina and Arkansas received their awards in July, “it became clear that we had a critical mass to address things.”

The alliance is in its infancy, but members of the Southeast Consortium have held one conference call to discuss areas that “we might wrap our collective heads around,” Stacpoole said, and another is planned for this month.

Collaborators hope to identify areas of shared need regionally on which they can focus their combined expertise and assets in order to improve the health of people in their own areas, as well as those nationally.

“This allows us to pool resources, to collaborate, to determine complimentary resources that we can tap, and this could also result in improved interdisciplinary training across institutions,” Stacpoole said. The consortia also provide increased cooperation among academic institutions, including those that may not have received CTSA's, and their combined infrastructure also will allow them and their investigators to respond to new funding initiatives from both government and non-federal entities. But the bottom line, and the goal of the CTSA's, is to have more impact in communities and among people more quickly, he said.

### *Potential focus area*

One potential area on which the Consortium is considering flexing its collective muscle is research and training opportunities related to health disparities and under-represented minorities.

“It is something we think is highly relevant to our region, and one that I think we are particularly well poised to address if we decide to go forward with this,” Stacpoole said.

## REGIONAL CONSORTIA: STRENGTH IN NUMBERS

This potential focus has been discussed only briefly at an informal meeting Stacpoole and some of the other Consortium's principle investigators had when they attended the annual CTSA meeting in Rockville, Maryland, in mid-October. However, the idea is not a new one for several of the member universities.

Rewind to about five years ago when UF took the lead in assembling a group of institutions in the Southeast

to respond to an NIH request and writing an application for a regional translational research and training planning grant emphasizing under-represented minorities. The group included many of the current southeastern CTSA consortia members. But after considerable time and effort pulling the institutions together and developing the application, the former NIH administration decided not to review any of them because they felt the institutions did not have the proper infrastructure to take such a step.

"That was a heart-stopping moment," Stacpoole said. "There was a collective cessation of heartbeats because a lot of us had put quite a bit of effort into these things."

Despite the setback, he believes that realization by the NIH led to recognition of broader needs. "I think that became the incentive for developing the CTSA's, which was to develop the intra-institutional infrastructure that then would allow inter-institutional agreements and consortia to develop," he said.

Now the CTSA Southeast Consortium, potentially in conjunction with some other non-CTSA institutions including those that may have been part of the original group, will

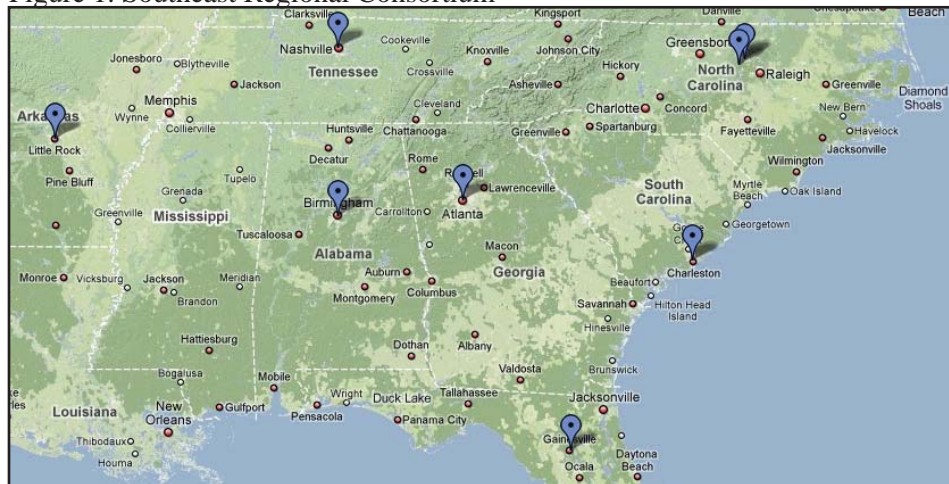
consider whether to concentrate on the matter again. Stacpoole distributed to his Consortium colleagues copies of the two-inch thick binder containing the original application, and they will discuss the prospect of moving forward on it during their next conference call later this month, as

well as other areas of possible concentration.

"It's that type of interaction that you can do more nimbly and perhaps in a more focused theme in these regions than you could on a national level," he said. That's particularly true of this focus area because some of these issues are highly related to geography and to the demographics of that geography. "We have a high population of minorities and they're traditionally under-represented in terms of access to health care, etc., so probably as much or more than any regional consortium, we are best poised to address that issue."

If there is consensus on proceeding with it, the initiative could focus on community-based research and possibly clinical trials that provide rich training grounds for people in a variety of walks of life, including physicians, nurses and other health care professionals, epidemiologists, statisticians, ethicists – the gamut of anyone who might be involved with issues related to health disparities.

Figure 1. Southeast Regional Consortium



## REGIONAL CONSORTIA: STRENGTH IN NUMBERS

The Consortium institutions all will continue to have their various training and funding mechanisms as required by their CTSA's, but focusing jointly on a specific area such as this allows the expertise and foundations from all the institutions to be married, providing trainees interested in doing research in health disparities and under-represented minorities a more fertile environment in which to undertake their research. For example, someone in a CTSA training program at one Consortium institution might need to receive focused training in a related area at another member institution and vice versa.

"It's a complimentary relationship that really is a synergistic process," Stacpoole said. "Trainees are often the bridges to collaborative and interdisciplinary research, whether you're within the same institution or between institutions."

### *National benefits*

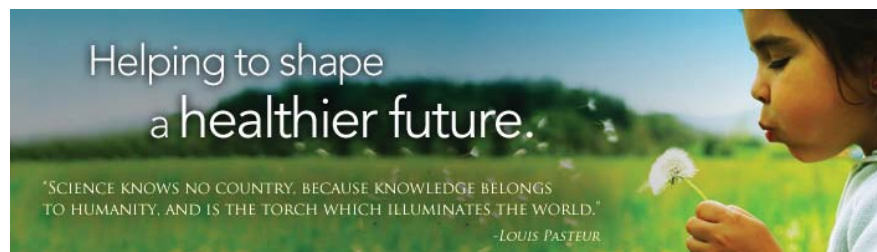
Combining the collective strengths of researchers, disciplines and institutions nationwide to leverage their combined strengths in order to more quickly get health care and medical improvements to the public is what the CTSI concept is all about, and UF already is participating in two of the ongoing national consortium-wide clinical trials. One has to do with a randomized controlled trial of a drug to treat pediatric and adult patients admitted to an intensive

care unit with influenza. The second involves a device used to treat cardiac arrhythmias.

And despite their community-based focus, the lessons learned from the work undertaken by these regional consortia can also be applied nationally. In addition to the hands-on participatory research that is done in communities, more directed hypotheses could also be tested in traditional research-intense academic settings. For example, biological tissues and fluids could be obtained that would then be studied in laboratories to gain insight into the mechanisms underlying problems – knowledge that would be valuable much more broadly. These efforts are also meant to be multi-disciplinary, and so could involve a broad spectrum of activities and researchers that aren't necessarily aligned with clinical science or laboratory science, such as social scientists, educators, and economists.

But addressing needs that may be more pressing among people closer to home is also key, including in areas on which the Southeast Regional Consortium and other potential partners may concentrate their considerable strengths.

"There really are no boundaries here except the limits of your own imagination and your ability to cooperate," Stacpoole said. "It's so early, I think the book is wide open and the pages still need to be written."



ResearchMatch.org

## OTHER CTSA REGIONAL CONSORTIUMS

The Southeast Regional Consortium, which includes UF, is the newest regional consortium and is in its earliest stages of partnership and exploration. According to the CTSA's official Web site ([ctsaweb.org](http://ctsaweb.org)), the other regional consortia and their respective members include:

*West Coast Consortium*

- Oregon Health & Science University
- Stanford University
- University of California, San Francisco
- The Scripps Research Institute
- University of California, Davis
- University of Washington

*Midwest Consortium*

- Mayo Clinic College of Medicine
- University of Wisconsin
- University of South Dakota \*
- University of Kansas \*
- University of Iowa
- Washington University in St. Louis
- University of Nebraska-Lincoln \*
- University of Minnesota \*

*Chicago CTSA Consortium for Community Engagement (C3)*

- Northwestern University
- University of Illinois \*
- University of Chicago

*East Coast Consortium - NYCON Consortium*

- Albert Einstein College of Medicine
- Rockefeller University
- Weill Cornell Medical College
- Mount Sinai School of Medicine
- Columbia University
- University of Rochester
- Yale University
- New York University School of Medicine

*Upstate New York Translational Research Network (UNYTRN)*

- Albany College of Pharmacy \*
- Bassett Healthcare System in Cooperstown, NY \*
- Cornell University Division of Nutritional Sciences
- Ordway Research Institute \*
- Roswell Park Cancer Institute in Buffalo, NY \*
- University at Buffalo \*
- University of Rochester
- Albany Medical College \*
- Binghamton University \*
- Guthrie Healthcare System in Sayre, PA \*
- Rensselaer Polytechnic Institute in Troy, NY \*
- SUNY Albany School of Public Health \*
- Upstate Medical University in Syracuse \*

\* Non-CTSA Institution

## CHANGES IN NIH GRANT APPLICATIONS

**P**lease take the time to learn about the upcoming changes to the NIH grant application process.

Applications submitted for due dates on or after January 25, 2010, using incorrect forms or following old instructions will result in applications being returned prior to review.

What's happening?

Due to changes resulting from the Enhancing Peer Review initiative, applications for due dates on or after January 25, 2010, require:

- Restructured application forms
- New instructions including shorter page limits

These changes affect ALL applications (new, renewal, resubmission, and revision).

- Applicants who are eligible for continuous submission may continue to use current forms and instructions through February 7, 2010, for R01, R21, and R34 AIDS applications that would otherwise have been due on January 7, 2010.

In December, you will need to download the new application forms (applies to both electronic SF 424 [R&R] and paper PHS 398). When the time comes, be sure to choose the correct application package:

- SF 424 (R&R): ADOBE\_FORMS\_B
- PHS 398: Revision date "June 2009"

### *Steps for Success*

1. Read about requirement changes **now** to be able to begin writing the Research Strategy section of the application.
2. In **December**, go back to the updated FOA or reissued Parent Announcement and download the new application

package and instructions.

3. Read the new application instructions **carefully**.

4. For **due dates on or after January 25**, submit applications using the new application forms and instructions.

### *How to Get Informed!*

To better understand the new requirements, the Enhancing Peer Review Website has a page dedicated to the application changes and has made available to you a number of resources on the Training and Communications Resources page including:

- A flyer
- A one-page update
- PowerPoint presentations describing the changes

Additional information is also available throughout the website including:

- FAQs
- List of policy notices
- Timeline of changes

A video overview of the changes will be available in mid-November on the Enhancing Peer Review Web site under Training and Communication Resources.

The Enhancing Peer Review Website will continue to be updated with additional resources as they are developed. To be notified when new application packages become available, sign up on the Enhancing Peer Review LIST-SERV or look out for an announcement in the NIH Guide for Grants and Contracts.

Please note that in addition to the new page limits there are significant changes to the Biosketch!

## THE LAST PAGE . . . .

### *Employment*

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

### *For Job Seekers*

<https://jobs.ufl.edu> - University of Florida jobs postings.

<http://www.union.ufl.edu/jobs/> - Reitz Union student job listings.

<http://www.sfa.ufl.edu/programs/workstudy> - Federal Work-Study Program.

<http://www.sfa.ufl.edu/programs/ops.html> - Other Personnel Services jobs.

<http://www.sfa.ufl.edu/programs/oce.html> - Off-Campus jobs.

<http://www.sfa.ufl.edu/programs/vaworkstudy.html> - Veteran's Affairs Work-Study.

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### *Publication Acknowledgement*

For all publications, CTSI investigators and trainees should remember to acknowledge the CTSI thusly:

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