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FROM THE DIRECTOR

There have been plenty of good things happening at the CTSI over the summer, including the receipt of the CTSA; the integration of our CTSI members with the NCRR's national CTSA Consortium; UF's position as a founding member of the Society of Clinical and Translational Science; the constitution of both the External Advisory and Translational Science Advisory Committees; the scheduling of our inaugural Research Symposium and Retreat for Feb. 11-12, 2010 (save the dates!); the birth of the Institute's Research Portal (part of the RKRS Program); the issuance of our first TL1 and KL2 mentored awards to an outstanding cohort of inter-college trainees; the imminent publication of the latest Pilot Projects RFA; and the appointment of a new Assistant Director of Administration and Operations for the CTSI, Ms. Marian Boyle.

Several members of the CTSI's leadership have also made recent important contributions to CTS:

Chris Batch, one of the Institute's Associate Directors and its Chief Operating Officer, is co-inventor of Biogard®, a microbacteriacidal polymer chemically bonded to a bandage that traps bacteria and prevents their entry into wounds.

Mike Conlon, our other Associate Director who also heads the CTSI's Biomedical Informatics Program, received very favorable news about a \$12M application to assist researchers nationwide network in conducting collaborative CTS.

Mark Brantly, co-director of the Shands Clinical Research Unit (aka GCRC) reported in *PNAS* preliminary results of a study that could lead to future gene therapy trials in patients with alpha-1 antitrypsin deficiency, a rare, hereditary condition that can lead to fatal lung and liver diseases.

Des Schatz, the Shands CRU other co-director, is principal investigator on a very favorably reviewed NIH competitive renewal application to continue UF's participation in TrialNet, a national consortium of institutions conducting research into the causes, treatment and prevention of type1 diabetes mellitus.

Sara Jo Nixon, the CTSI's director of its Biobehavioral Core, was elected president of the international Research Society on Alcoholism.

Rus Bauer, co-director of the Institute's Tracking and Evaluation Program, was elected president of the international Neuropsychological Society.

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FROM THE DIRECTOR

We're anxious to learn about your success stories, so pass them along! Want to know how your research can be facilitated by the CTSI? Read on about how the Regulatory Knowledge and Research Support Program can help.



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

REGULATORY KNOWLEDGE AND RESEARCH SUPPORT PROGRAM

BY CURTIS
FRANKLIN, JR.

Getting Things Done -- The RKRS Program Brings Research to Life

At many research institutions coming up with good ideas for research projects isn't the toughest piece of the puzzle. The hard part is taking good ideas and putting them into practice – transforming concepts into studies and slide-show bullet points into bricks and mortar. The Regulatory Knowledge and Research Support Group (RKRS) of the CTSI is charged with making the transformation as easy and efficient as possible for all the scientists and researchers working within the Institute.

The RKRS encompasses four areas critical to successful research. The first is regulatory assistance, helping researchers navigate requirements of the FDA and other government regulators. Second is assistance with the process of gaining Institutional Review Board approval, bringing specific expertise and institutional memory to the process of working with the IRB. Next comes research coordination, helping marshal the resources of various units and researchers who can contribute to project success. Finally, there is the biostatistics group to help bring meaning to results and assist in designing and reviewing projects to make sure their design is optimal for proper analysis.

The grant application for the CTSI outlined four goals for the RKRS. They are:

Increase accessibility of information about clinical and translational research and training opportunities, by developing a physical and virtual (Web-based) research portal in the Institute's academic home that will be managed by the RKRS.

Provide expert assistance in the development of research protocols by linking investigators to Research Project Managers (RPMs).

Hold the applicant accountable to the highest standards of scientific and ethical integrity by conducting research protocol reviews in a rigorous, efficient and timely manner.

Ensure rapid activation of outstanding research protocols by providing prompt access to the required research and/or training resources.

Reaching those goals will require the four major components of the RKRS to work closely together while continuing to serve the CTSI research community. I had a chance to sit down this summer with representatives from the

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groups that make up the RKRS. Let's look at how they plan to do things.

The Big Picture

The purpose of the CTSI as a whole is to facilitate research from beginning to end, first research protocol to final clinical trial, and out into the healthcare practice community. The RKRS group is one of the key "pillars" that will support principle investigators and give them the knowledge they need to support clinical and translational research.

The RKRS will provide a uniform "face" of clinical research, helping the PI understand what needs to be done to enable research to begin and proceed, what research-support resources are available at UF, and how they can be used. Many PIs, whether new to UF or with years of experience, may not know about all the resources available. For example, if they want to do research on a particular disease, they can be guided to one of the many clinical research units (CRUs) at UF that offer both inpatient and outpatient facilities.

This group will make the information available to the PI in a "one-stop shop" format, providing information and guidance on issues about which researchers should be aware. Examples of issues RKRS staff can help with include

conflict of interest questions, IRB approval, and FDA regulations – complex areas to negotiate without the kind of expertise and institutional memory found within the RKRS.

The Individual Functions

The first function many researchers will tap into when coming to the RKRS is regulatory, especially concerning help dealing with FDA regulations. What kind of questions can the RKRS help with? A young investigator, or even a more experienced PI, may wonder about the necessity of an Investigational New Drug (IND) application. How they go about getting one and even whether one is required are often challenging areas, and this group will guide them through the process. How important is this? Unless the researcher is well versed in the regulations contained within the FDA's guidelines, then the contributions of the RKRS staff can be vital.

Another area researchers need assistance with is the IRB. All protocols involving human subjects must be approved by the IRB, and the RKRS staff can assist investigators campuswide navigate through the process and help them understand the IRB requirements. Each protocol is unique, and RKRS staff can help PIs decide on the type of submission required based on the goals of the research.

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A New RFA

This month's newsletter announces the reissuance of the popular CTSI's RFA that was inaugurated one year ago. In the past, RFA details have been contained within this newsletter, but we have now incorporated all of the pertinent information within our CTSI portal at https://www.ctsi.ufl.edu/?q=current_funding. Simply point your browser to this site to read about the RFA and to download the forms for getting started. Questions? We have the answers; just contact Denise Caswell at dcaswell@ufl.edu.

The application submission due date is October 30, 2009 by 5 pm and the project period award date is anticipated to be November 16, 2009.

Good luck!

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Depending on the type of submission, approval for a protocol typically takes three to six weeks. Assistance is available to improve the quality of the submissions. The goal is to make the process of approval less frustrating for researchers and reviewers alike through education, assistance, and quality improvement. As a result, approval time also could be decreased. The proper balance of expediency, efficiency, and human subject protection is where success lies.

The research support function is perhaps the area to see the most change as it fits within the CTSI. One of the most visible changes will be the creation of a Web portal through which each project initiated when the PI begins working with the CTSI. As features are developed over the next few months, PIs will be able to go to the site (<https://www.ctsi.ufl.edu/>) and get information on the requirements to initiate their research. In addition, RKRS staff will work with researchers on the various things needed for their studies to move forward. The RKRS staff will be able to say, "These are the resources that are available, we can help you with these issues," and then work with the researchers to obtain the necessary help.

That's the crux of the coordination component, to simplify and help navigate through the maze of forms and commit-

tees successfully. It's a huge challenge even for the most experienced researcher to know what's available, and then to figure out the best resources for a study. Keeping track of which units are available for clinical trials, for example, can involve a mind-numbing array of variables and scheduling, and the RKRS staff will be able to look at which unit has which resources and direct investigators so that research doesn't hit any unnecessary delays.

The unit is RK and RS, so there are both regulatory knowledge and research support functions. The two areas are interconnected in how they ultimately work for the researcher as it is important to have both parts working together.

The staff acknowledges that complete integration of the support functions into a single, smoothly functioning unit is a long-term goal. RKRS members estimate that if they can achieve integration within five years it will be a great success. Looking at the records of organizations receiving CTSI grants three years ago, the group feels it has a head start having had the opportunity to learn from the mistakes and successes of those previous grant recipients. However, members note that even the first CTSI recipients are nowhere near final status on bringing the various clinical units under a single umbrella.

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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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The RKRS staff notes there are a lot of challenges in bringing the clinical research units under a single umbrella, because some functions within the units are overlapping and it's important to define which unit will handle which functions. These are critical distinctions to make, not just at this level, but at a much higher level as well. Each process or step will be informed by previous steps and iterations, so the RKRS can achieve the goals established for it.

The fourth major area of the RKRS is biostatistics. Under the CTSI grant, there is a research design and analysis program led by Keith Muller, PhD, and Jonathan Shuster, PhD, which is separate from the biomedical informatics core. Biostatistics has become an important part of the overall research process because a project may be correctly written and ethical as defined by the IRB, but if the proper statistical analysis of the data can't be performed then the research won't be able to answer the questions that were posed.

The biostatistics group will look at studies as they're being formulated. Questions about whether the studies are properly powered, if they have the proper number of subjects proposed for enrollment, and whether the study can be executed properly in order to get a good answer to the question. If the answers to any of those questions is no, then group members may help researchers redesign the study. This puts the biostatistics staff members more in the role of collaborator than simple resource. (repeated from graph above) The goal is to help researchers get to the point of answering the questions they have, do good science and get the results published. This furthers the researcher's career, UF, and science – all goals the biostatistics division wants to help accomplish.

If the study is well designed and clearly laid out on the front end then it clearly makes things much easier for the statistician working with the data on the back end of the study. As the biostatistics staff is fond of saying: "GIGO – Garbage in, Garbage out."

Why Now?

When asked why the CTSI and the RKRS component are so important for today's research, the staff has ready answers. Not just at UF but at almost all CTSI institutions, the problem has been that no one has made common resources available for clinical investigations. This is what the CTSI is going to offer -- a common resource for investigations.

Typically, when a researcher begins a project, they must hire a project manager, and laboratory staff, and they'll try to hire a biostatistics person who understands what is being done and can help write a protocol. They are, in essence, building a research silo. The CTSI's goal is to break down silos, creating communities and commonalities in research that are impossible in the silo architecture.

This architecture is part of the academic culture of 'publish or perish,' according to the staff. Investigators needed to concentrate on their own areas of expertise, to publish in their own specialties, and this traditionally runs counter to the needs of interdisciplinary collaboration. In fact, in the past, interdisciplinary collaboration was a distraction from researchers' ability to move their careers forward. Institutions everywhere did not reward the interdisciplinary work, they didn't even recognize it. The RKRS looks then to mark a paradigm shift, not just in the working of science, but also in the institutional cultures ministering to science by acting as agents and champions of change as well as shepherds of investigational support.

MEET THE RKRS TEAM



David Nelson, MD, is Professor of Medicine at the University of Florida where he serves as the Director of Hepatology and Liver Transplantation, and Director of the RKRS program. He received his medical degree from the State University of New York Upstate University in Syracuse, completed a residency in internal medicine at the University of Massachusetts, and obtained fellowship training in gastroenterology and hepatology at the University of Florida. Nelson's area of clinical expertise is hepatology with an emphasis on the management of viral hepatitis and liver cancer. He also has strong basic research interests, focusing primarily on the immunopathogenesis and treatment of chronic hepatitis C and hepatocellular carcinoma. He currently oversees more than 15 active clinical trials and has a 10-year track record of NIH funding. He serves as the principal investigator on both basic science R01 and a T32 training grant in gastroenterology. Nelson has an impressive record of academic achievement

with more than \$8 million in research funding, more than 100 publications, and is currently associate editor for the journal *Hepatology*.

Left to right, the RKRS team members are H. Robert Kolb, Teresa d'Angelo, Douglas Theriaque, Renée Collins and Wajeeh Bajwa.



Robert Kolb RN, BS, CCRC has more than 20 years experience in clinical trials working on NIH-funded, industry-sponsored and VA cooperative studies. He has conducted, managed or consulted on hundreds of protocols in all phases, from international multicenter trials to investigator-initiated studies. A Registered Nurse since 1977, he is a long-standing member of the Association of Clinical Research Professionals (ACRP) and has held a certification as a Clinical Research Coordinator (CCRC) for 17 years. He is a member of the Society of Research Subject Advocates (SRSA), Public Responsibility in Medicine and Research (PRIMER), American Society for Bioethics and Humanities (ASBH) and the Society for Clinical and Translational Science (SCTS).

Teresa d'Angelo, RN, BSN, CCRC is the Director of Research Project Management. She has worked as a Research Coordinator, both at the NIH and for industry-sponsored clinical trials. Teresa also is the nurse manager of the Shands Clinical Research Unit (formerly General Clinical Research Center). Teresa brings more than 30 years of research experience to this position.

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Douglas Theriaque, MS received his degree in statistics from Southern Connecticut State University in 1996. Since 1997 he has served as the Director of Informatics for the GCRC, collaborating with more than 150 investigators and co-authoring 57 peer-reviewed journal articles. During this time he also developed adverse event and subject scheduling software systems as well as more than 50 Web-based electronic data capture (EDC) systems. Theriaque guided the GCRC Informatics Core through two successful competitive renewals, with his core achieving “outstanding” ratings from the NIH review committee each time.

In 2009, Theriaque accepted a position as project manager within the Regulatory Knowledge and Research Support core of the CTSI. In this role he works with investigators in research project development and also develops and supports the CTSI Web portal.

Renée Collins, BS is a Research Program Manager with extensive knowledge of the Institutional Review Board and regulatory issues. She was hired by the IRB in January to assist investigators with submissions. She has more than 15 years of experience as a study coordinator at Vanderbilt University, the University of Arizona, and SUNY at Buffalo. She was also the Administrative Director of Regulatory Services for the departments of Psychiatry and Neurology at the University of Arizona.

Wajeeh Bajwa, Ph.D. received his PhD in Biochemistry from the University of Glasgow, Scotland, in 1981 and did post-doctoral work on yeast expression systems with Albert Hinnen, first at the Freidrich Meschier Institute (Basel, Switzerland) and then at Ciba-Geigy Biotechnology Center (Basel, Switzerland). He joined Hershey Medical Center, Penn State University in 1985. He then moved to a biotechnology company, Strohtech Inc, in Detroit. Bajwa relocated to Durham, North Carolina with this company in 1993, company name also changed to Apex Bioscience, Inc at that time. His group was the first to successfully express functional human hemoglobin in yeast. Bajwa then moved to Duke University Medical Center, North Carolina, in 1998. Based on his work at Duke, the NCRB mandated the Research Subject Advocate program for all GCRCs in 2000.

Bajwa’s work spans a breadth from molecular and genetics work, to animal studies and to human clinical trials. He specializes in GxP regulations and in dealing with the Food and Drug Administration.

Bajwa is currently Director of Regulatory Affairs and Licensing, CTSI, University of Florida.

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