Clinical and Translational Science Institute

CTSI Newsletter

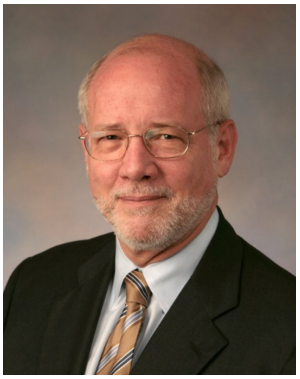
Volume 1, Issue 2 - August 2008

INSIDE THIS ISSUE

NEXT MONTH

The September newsletter will feature articles about the center's Training and Professional Development Program, which will provide educational opportunities for individuals who will comprise the future clinical and translational science (CTS) workforce. These opportunities will be available for highly motivated, talented individuals starting as early as high school, as well as undergraduate and graduate students and junior faculty, who will be mentored at every stage of their early careers to become the investigators, clinical trialists, laboratory technicians, study coordinators and CTS leaders of tomorrow.

FROM THE DIRECTOR



Welcome to the second issue of the new CTSI Newsletter. This will be a short Director's Note because there is so much other information here, and a short time for you to act. The CTSI has grant money available for members of the CTSI community – including many members who have never been eligible for grants before.

In the last newsletter we talked about the ways that the CTSI is different – how its mission and organization are new. With these grants, we're putting real resources behind the talk and working to see the CTSI makes a difference in the work of the research and clinical communities from Day One.

If you have been thinking about translational research, this could be the perfect opportunity for initial funding. Look at the information and examples in this issue, and start working on your proposals now. The staff is here to help, so don't be afraid to call – just don't wait too long.

We're looking forward to a truly superb response to this initial RFA from the CTSI's Pilot and Collaborative Project Program – we know that the members of the research and clinical communities at the University of Florida are among the most creative in the world.

Good luck!

Peter W. Stacpoole, Ph.D., M.D.
Director, CTSI

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A NEW RFA!

The CTSI's Pilot and Collaborative Research Projects Program

How early in the investigation and research process can you decide whether the researcher is on a fruitful path? How does one gauge whether to risk investing in a researcher's idea long before it evolves into a substantive proposal for extramural funding? These questions frame a recurring dilemma for division chiefs, department chairs, center and institute directors and college deans: how to continuously nurture creativity among trainees and faculty while maintaining their fiduciary responsibilities to a broader constituency. These questions are particular relevant to academia today, when federal support for investigator-initiated biomedical research is at low ebb.

Administrators can't afford to let their spending priorities be set by the constantly-shifting winds of extramural funding. Indeed, periods of relative drought in federal awards are precisely those times that demand significant and sustained internal support of faculty and trainees to maximize their competitiveness for extramural funding. Accordingly, UF is committed to encouraging and enabling the development of promising but nascent projects across a broad spectrum of scientific endeavors by CTSI investigators. We intend to grow this program substantially in future years from both institutional and extramural sources through twice-yearly Request for Applications (RFAs) announced through this Newsletter. This fall, we begin by providing seed funds allocated among the following categories:

Category 1: To increase opportunities to transform exciting and innovative CTS ideas by graduate students and junior faculty into proof of concept, we will provide up to $50,000 in new pilot grant awards and encourage competitive proposals from trainees early in their research careers.

Category 2: To encourage development of novel methods and technologies relevant to CTS, the CTSI faculty and mentored trainees will be eligible to compete for awards totaling up to $50,000 to support fundamentally new methodological (e.g., biostatistics, ethics) or technological (e.g., medical device, analytical instrumentation) developments.

Category 3: To stimulate interdisciplinary research in CTS through the CTSI's Major Initiatives Program, by providing up to $150,000 and a new mechanism to forge collaborations among new and established investigators across scientific disciplines. The expectation is that the success of this program will increase UF's ability to garner large extramural grants and contacts based on interdisciplinary CTS.

Continued on page 3.

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Translational Funding Opportunities

To receive consideration for funding, research proposals must focus on the translation of pre-clinical studies to humans (T1) or the translation of clinical research/clinical trials to community engagement and clinical practice (T2). Individual pilot proposals from graduate students and Clinical Scholars must reflect a new research approach or direction for the applicant, not originally identified or considered in his or her initial research plan. In other words, the funds sought through this program must help transform the investigator's original scope of research, including its anticipated outcomes. This year's allocation of funds is summarized in Table 1.

Pilot Project Review

Each review will be conducted by primary and secondary reviewers who will be members of the Program's Executive Advisory Committee (Table 2 on page 4).

If an award is made through the Pilot and Collaborative Projects Program, the awardee then works with the Office of Budget Development and Negotiations to finalize the allocation of the awarded funds and sets in place a tracking system to maintain communication with the investigator regarding the timing of the initial of the grant and its progress. Each awardee is required to submit an annual progress report to the Institute, which will consider requests for up to a one year no cost extension of the original award.

Table 1. Funding Categories for CTSI Pilot and Collaborative Projects.

Areas of Support	*Available Funds*[1]	*Funding ceiling/ project*	*Estimated max. # new projects this yr*
Student	$15,000	$7,500	2
Junior Faculty	$35,000	$20,000	2
Novel Methods & Technologies	$50,000	$25,000	2
Major Initiatives[2]	$150,000	$100,000	2

[1] *One year awards, with no-cost carryover in year 2 possible.*

[2] *Minimum of 2 PIs from different colleges.*

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Table 2. Pilot and Collaborative Projects Program Executive Committee.

Member	*Role in CTSI*
Peter Stacpoole (co-director)	Director, CTSI
N. Lawrence Edwards (co-director)	Chair, Scientific Advisory Committee
Christopher Batich	Associate Director, Operations
Michael Conlon	Associate Director, Biomedical Informatics
R. Peter Iafrate	Director, Regulatory Knowledge and Research Support Program
Marian Limacher	Director, Training and Professional Development Program
Jesse Gregory	Director, Translational Technologies and Resources Program

DATES TO REMEMBER

Deadline of Electronic Submission to CTSI (caputcl@medicine.ufl.edu)
September 26, 2008

Proposal Review
September 30, 2008

Award Announcements
October 6, 2008

Earliest Date of Funding
November 1, 2008

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A Familiar Format

Proposals to the Pilot and Collaborative Projects Program will share a common format that is similar to those currently used by the GCRC and the UF Opportunity Fund. An *Abstract* should summarize the proposed work. Proposals can include up to 5 pages, according to the NIH R01 format, to describe:

1. *Hypotheses and Specific Aims;*
2. *Preliminary Studies;*
3. *Design and Methodologies* (including statistical considerations and need for specific CTSI resources (e.g., technology cores; patient research venues, etc.)).

An NIH-formatted list of *References* must be appended, followed by a list of the individuals to be involved in the project and details of their participation. In the case of applicants who are being mentored (graduate students and K 30 Clinical Scholars), a one-half to one page summary of the *Mentoring Plan* and the mentoring environment(s) is required. A detailed *Budget and Justification* of expenses can include all normally allowable costs of research (including meetings with off-campus collaborators) with the exception of faculty salaries, student stipends and indirect costs. A specific start date not later than February 1, 2009 should be given. If none is specified, the Program will assume a start date one month after award notification, or approximately two months after the receipt of applications.

Each applicant must also describe, in up to one page, plans to obtain continuing external support (in the case of Major Initiatives), to use Program funds in furthering career objectives (students and Clinical Scholars), or to develop the commercial potential of new methods or technologies developed with Program support. This latter description should include a statement of potential market size and how funding could increase the marketability of the technology.

Consistent Evaluation

Applications will be scored on the following criteria:

1. *originality and innovation;*
2. *significance in the field of study;*
3. *relationship of the proposal to the current research direction of the applicant;*
4. *likelihood of meeting stated aims within 1-2 years;*
5. *research environment (including qualifications of mentors, if applicable); and*
6. *plans for future funding (not required of graduate students).*

Proposals will be assigned priority scores according to NIH guidelines; the appropriateness of the budget request will not be a factor in determining the priority score. A brief Summary Statement will be provided each applicant that identifies strengths and weaknesses of the application and the allocation of funds, if awarded. A composite priority score is generated that will serve as a means of prioritizing applications. Generally, only those proposals that receive a priority score in the "Outstanding" (≤150) or "Excellent" (151-200) range will be considered for funding. Thus, it is possible that less than the minimum number of awards per category may be made in any year. Revised applications may be submitted twice.

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Students

Graduate students who have been engaged for at least 1 year in a terminal certificate or degree program will be eligible to compete for a one-time individual pilot grant award of up to $7,500 each. Students must be conducting research under the auspices of one or more members of the CTSI's Mentoring Core of faculty who represent the 12 colleges currently participating in the CTSI. Members of the Mentoring Core were carefully chosen by their deans and their college's CTSI Steering and Planning Committee representatives to undertake this mentoring role. The mentors, and their email addresses, can be found in Table 3 on page 11. More faculty undoubtedly will join this core over time.

Individuals seeking a Clinical Research Coordinator certificate or an MS, MPH or PhD with an emphasis in CTS (including those enrolled in a T32 program) are eligible to apply. Moreover, the Program's Mentoring Core of faculty also has one graduate student representative from each participating CTSI college as ex officio members of the Core. For the purposes of pilot project internal award competition, one student representative will be assigned as a tertiary reviewer for each application. This individual will evaluate the mentoring environment of the applicant and the merit of the applicant's use of the requested funds to further his or her research objectives.

The CTSI is committed to providing enhanced opportunities to underrepresented ethnic and racial minorities (women are already extremely well-represented at all levels of graduate study at UF). *Therefore, the Program intends to earmark in future years at least one award per year for talented minority graduate student applicants and at least one award per year for talented minority Clinical Scholar applicants. Furthermore, to encourage and promote community-based studies in pediatrics, the Program will earmark at least one award per year for a graduate student and one award per year for a Clinical Scholar to conduct research in this area.*

An Example of a Student Proposal

For her thesis project, a *graduate student* is conducting T1 (bench to bedside) research by developing a knockdown of a gene, using small, interfering RNA, to create an animal model of an embryonic lethal human genetic disease. During the course of her experiments, she learns of new insights into the behavioral phenotype of affected humans from recently published literature. This causes her to reassess a previously neglected aspect of her original plan to investigate genotype-phenotype relationships in her animal model. From consultation with the CTSI's Biobehavioral Core (contact: Dr. Sara Jo Nixon at: sjnixon@ufl.edu), she learns about validated experimental behavior testing methods that could be applied to extend her characterization of the animals and better determine their applicability as a model of human disease. She applies to the Pilot and Collaborative Projects Program for funding to support the costs of obtaining relevant expert faculty guidance and use of equipment in the Biobehavioral Core to facilitate this new research objective.

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Junior Faculty

Tenure-track faculty at the Assistant or early Associate Professor level who have been enrolled in the CTSI Clinical Research Scholars Program (currently restricted to those enrolled in UF's K30 APPCI Program) for at least 6 months or who have an active NIH 'K' award are eligible to compete for a one-time award of up to $20,000. Clinical Scholars must be conducting mentored research toward an MS, MPH or PhD in CTS. Trainees early in their career gain first-hand experience in the process of grant writing and grant review involving their own research.

An Example of a Junior Faculty Member Proposal

A Clinical Research Scholar in Gainesville is investigating the kinetics and biotransformation of a pro-drug used in the treatment of hypertension. As part of his original proposal for the CR Scholars program, he has identified a novel glutathione transferase (GST) in human liver that is responsible for the conversion of the pro-drug to its active metabolite. During this process, he discovers three isoforms of the gene that, by using the resources of the CTSI DNA/Tissue Bank Core (contact: Dr. James Crawford at: Crawford@pathology.ufl.edu), appear to be unequally distributed among different ethnic and racial groups. Further in vitro studies by the investigator determine significant differences in the K_m and V_{max} for the pro-drug among the 3 GST isoforms. Although his original intent was to conduct limited pharmacokinetic studies in a few subjects in the GCRC at Shands Hospital on the Gainesville campus, he now recognizes the potential of extending these studies across ethnic and racial groups. After consulting with the CTSI's Community Engagement and Research Program (contact: Dr. Elizabeth Shenkman at: eas@ichp.ufl.edu) and the Pharmacogenomics Core (contact; Dr. Julie Johnson at: Johnson@cop.ufl.edu) he submits a proposal to the Pilot and Collaborative Projects Program to fund an extension of his patient-oriented research to the CTSI's Clinical Research Unit on the Jacksonville campus (contact: Dr. Alan Berger at: alan.berger@jax.ufl.edu). This strategy to strengthen his T2 (clinical research to community engagement) investigations will allow him to engage a wide and a diverse community in participatory research involving population genotyping and recruitment of subjects on both UF campuses to examine ethnic and racial differences in drug metabolism.

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Novel Technologies and Methodologies

CTSI faculty and mentored graduate students are eligible to compete for awards of up to $25,000 each. Unlike one-time individual pilot awards to graduate students or Clinical Scholars, an applicant is eligible to receive successive awards to support fundamentally new research projects in methodological (e.g., biostatistical, ethics) or technological (e.g., medical device, analytical instrumentation) development, providing awards are spaced at least 3 years apart.

An Example of a Novel Technologies and Methodologies Proposal

A CTSI *biostatistician* is assisting a Clinical Scholar who is an Assistant Professor in the Department of Anesthesiology. The investigator is PI on a clinical trial designed to shorten hospital stays of patients undergoing total hip replacement surgery by employing a combination of continuous femoral nerve blocks and aggressive physical therapy. This is important T2 research because, as hospitals and outpatient surgical centers become increasingly able to provide 24/7 monitoring for patients, the time to meeting discharge criteria is now a continuous outcome variable. Further, because some patients never meet these discharge criteria (some may need to be discharged before meeting them, some may need further unexpected care, or a small number may die in hospital), the right-censored nature of the data precludes the use of ordinary parametric statistics. Consequently, the biostatistician applies under the auspices of the Novel Methods and Technologies program to fund the development of new software to analyze trial data of this type and to address two previously unsolved problems whose solutions would be important in conducting hospital discharge-related trials: 1) can the proposed methods be extended to account for covariates; and 2) can the methods accommodate random effects? Both problems would make excellent thesis topics for future graduate students who seek PhDs in Biostatistics with an emphasis in CTS (the CTSI's T32 program; Section 12). Thus, such a proposal links the initial investment of support of the biostatistician with new opportunities for training in T2 research.

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Interdisciplinary Research in CTS through the CTSI's Major Initiatives Program

Tenured and tenure-track faculty who form an interdisciplinary collaboration are eligible to compete as multiple PIs for 2-year awards of up to $100,000 in total costs. Applicants are eligible to receive successive awards as PIs to support fundamental new projects in CTS, providing awards are spaced at least 4 years apart.

An Example of a Major Initiatives Program Proposal

A group of faculty members from various disciplines in the Departments of Food Science and Human Nutrition, Biomedical Engineering, Pediatrics and Chemistry decide to collaborate on a study of the neurological basis, metabolic profile and treatment of refractory epilepsy in children. The engineer has patented a new instrument for recording electrical brain activity that provides superior computer-assisted discriminatory power in differentiating subtle epileptiform spikes from other wave patterns. The pediatric neurologist runs a regional clinic for epilepsy and has conducted prior research on patients using the sleep-study room in the GCRC (contact: Dr. Peter Stacpoole at: stacpool@gcrc.ufl.edu). The food scientist has also used the GCRC to investigate the effects of ketogenic diets of various fatty acid compositions on patient tolerability and seizure frequency by collaborating with the neurologist. The analytical chemist has developed novel mass spectrometric techniques to create metabolite 'platforms,' by which quantitative information can be obtained from plasma and skin fibroblasts or other tissues regarding mitochondrial pathways of fuel metabolism.

Although distinguished in their own fields of T1 research, previous interactions among these investigators have been limited. The engineer uses the registry of faculty researchers maintained by the CTSI's Research Portal (still a work in progress!) to initiate contact with the other investigators. The team eventually develops a proposal for a Major Initiative submission to the Pilot and Collaborative Projects Program to generate preliminary studies and to show a track record of collaboration in preparation for an eventual Program Project or large R01 application. In their proposal they request support to conduct proof-of-concept studies in the GCRC on the application of the new electroencephalographic device and on the effects of ketogenic diets on seizure activity in relation to both dietary fatty acid composition and metabolic changes in patients' plasma and cultured cells. Funds are requested for consultative support from the CTSI's Research Design and Analysis Program, the Clinical and Research Ethics Program and the Metabolomics Core (contact: Dr. David Powell at: (powell@chem.ufl.edu) and funds to hire a part-time Clinical Research Coordinator (contact: Ms. Teresa D'angelo, RN, at: danget@shands.ufl.edu), purchase laboratory supplies and cover routine ancillary patient care costs. They also request travel funds to present their initial findings at a national pediatric neurology meeting.

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SOME HELPFUL RESOURCES

Useful CTSI Programs for Grant Proposals

In the first CTSI Newsletter, we summarized the various programs that are coming on-line to facilitate CTS research. For the purposes of this inaugural CTSI Request For Applications (RFA), some relevant Institute resources include the following:

The *Office of Regulatory Affairs and Licensing* provides for assistance in facilitating research and training in FDA-compliant matters of investigational drugs, biologics, nanoparticles and devices. This office provides full-service consultations on all regulatory matters and will assist the investigator in writing appropriate IND and IDE applications, when required. Contact Dr. Wajeeh Bajwa at: bajwaw@gcrc.ufl.edu.

The applicant may also engage the resources of the *Office of Budget Development and Negotiations*. This office will assist in constructing a budget for the proposal within the guidelines established by the Pilot and Collaborative Projects Program. Contact Ms. Candy Caputo at: caputcl@medicine.ufl.edu.

If the proposed pilot project includes research involving vertebrate animals or clinical research (as defined by NIH guidelines), the investigator may solicit advice from the *Clinical and Research Ethics Program*. This program includes experts in all aspects of the ethical conduct of animal and human research; the ethics of drug production, distribution and use; the practices and procedures of IRBs and IACUCs; and related information essential to crafting a proposal and consent form consistent with local and federal ethical and regulatory guidelines. Contact Bob Kolb, RN, CCRC at: kolbb@gcrc.ufl.edu.

In addition, the applicant may also require further consultation from the *Research Design and Analysis Program (RDAP)* and the *Biomedical Informatics Program (BMIP)* to ensure hypotheses are based on valid study design and biostatistical considerations and that appropriate informatics resources are available for the acquisition, management and analysis of data. Contact Dr. Keith Muller at: keith.muller@biostat.ufl.edu for the RDAP and Dr. Mike Conlon at: mconlon@ufl.edu for the BMIP.

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WHO'S ELIGIBLE? (CONTINUED)

CTSI S&P Committee Program and Core Directors Mentors (Table 3)

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