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NEXT MONTH

Next month's newsletter will feature articles about the CTSI's Translational Technologies and Resources Program. This program will integrate several of UF's technology-based cores, add additional relevant resources, make organizational changes, and improve communication in order to enhance the accessibility, quality and quantity of translational technologies and resources available to investigators.

FROM THE DIRECTOR

This edition of the CTSI Newsletter focuses on strategies designed to create career paths for and to build a new cadre of multidisciplinary and interdisciplinary Clinical and Translational Science (CTS) investigators who will become the CTS leaders of tomorrow. Such highly trained and sought-after individuals would integrate at various levels in the CTS workforce, be it in academia, industry or government.

To accomplish this goal, the CTSI has developed a new trans-college program called the Training and Professional Development (TPD) Program. The overarching mission of this initiative is to provide educational opportunities that facilitate the training of clinical and basic science investigators, clinical trialists, laboratory technicians, study coordinators and other key personnel who are required to establish and support multi- and interdisciplinary clinical and translational researchers and research teams. The program is creating the infrastructure for the education of pre-collegiate, undergraduate and graduate students and junior faculty who will comprise this new CTS workforce. It provides a rich portfolio of interdisciplinary educational opportunities across the continuum from preclinical training to community practice (Figure). The director of the program is Dr. Marian Limacher, Professor of Medicine (lmacmc@medicine.ufl.edu).

The trainees chosen by the TPD program are selected from highly motivated, talented individuals who will be mentored at every stage of their early career to become the CTS leaders of tomorrow. The program's curriculum prepares pre- and post-doctoral trainees and faculty for success in conducting multi- and interdisciplinary clinical and translational research.

The basis for all programs is a new three-component core curriculum that all trainees will complete. The new KL2 Program offers Clinical Research (CR) Scholars (mainly junior faculty members in a health-related profession) a comprehensive didactic component that consists of core courses and electives together with extensive practical experiences that will lead to an MS in CTS, an MS in Epidemiology or a Certificate in CTS.

The new T32 Program, which is described further in this newsletter, offers a new minor concentration in CTS for pre-doctoral students who are currently in discipline-focused programs and will also develop a new Ph.D. with a

FROM THE DIRECTOR

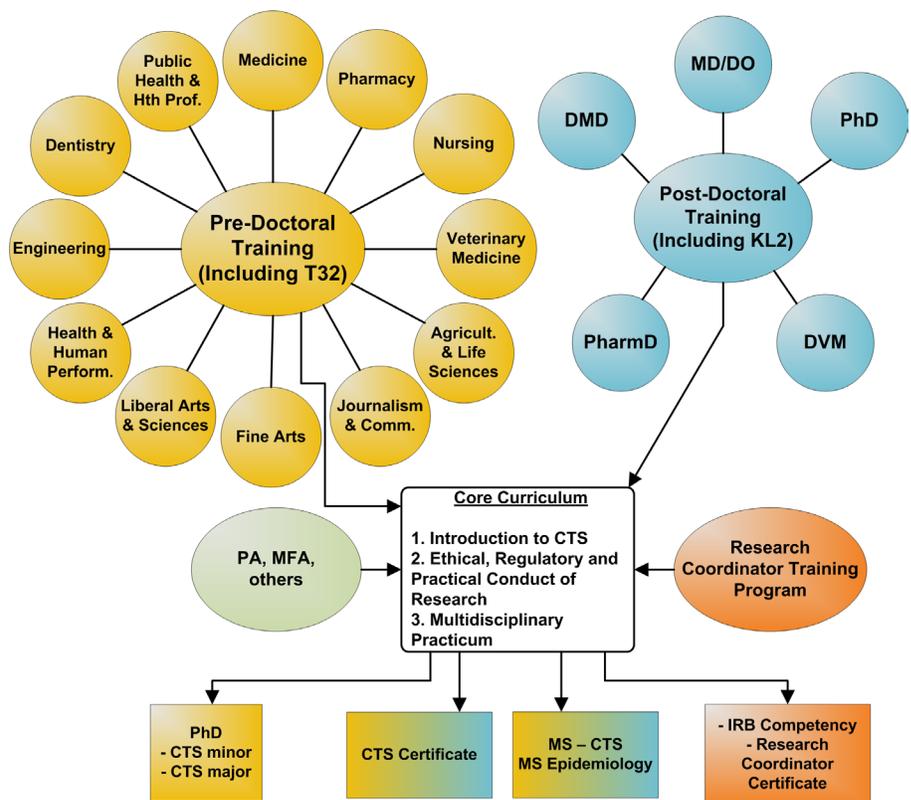
major in CTS. The CTS Ph.D. program crosses department and college boundaries to emphasize the interdisciplinary nature of CTS. Students in professional doctoral programs are eligible to pursue a joint MS or Ph.D. in CTS with their primary MD, DMD, DVM, or PharmD program.

All investigators and coordinators are required to complete an Institutional Review Board (IRB)-based program of competencies. Coordinators may also select additional training and experience under the auspices of the College of Health and Human Performance that will lead to a Certificate in Clinical Research Coordination. Finally, the TPD Program links with current UF programs targeting high school and undergraduate students with interests in science careers to introduce CTS research options and partner with campuswide resources at UF to ensure appropriate enrollment in all programs by women and underrepresented minorities.

We're looking for trainees, so let us know you're interested!



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



Training and Professional Development (TPD) Program. All trainees will participate in the CTSI Core Curriculum (center white box). Predoctoral candidates from 12 colleges (yellow) may pursue a PhD with CTS minor or major emphasis (yellow), CTS certificate or MS degrees (yellow-green). Post-doctoral candidates (blue) and other professionals (green) may pursue the CTS certificate or MS degrees. Coordinator trainees (orange) will complete the Coordinator certificate

Building on success and overcoming barriers to train a new generation of scientists and clinicians

In 1999, UF was awarded funding to establish its *Advanced Postgraduate Program in Clinical Investigation (APPCI)*. This Program provides clinical research training in a mentored research setting. As of Fall 2007, 64 trainees have enrolled in the APPCI, including 30 women and 34 men, 8 Hispanic, 8 Asian, 4 African-American and 1 Pacific Islander. Trainees have included MDs (residents, fellows-in-training, and faculty), PhDs, PharmDs and DMDs, and DOs from 24 departments and 5 colleges across the Health Science Center.

Despite the success of the APPCI Program, several traditional institutional barriers hinder the progress of clinical and translational research and its expansion across multiple disciplines. These barriers include the lack of clear career pathways for junior investigators; the difficulty clinicians have to commit sufficient time to research because of patient care duties; insufficient time for senior faculty to devote to mentoring; insufficient incentive for investigators to apply for and lead training programs; the absence of infrastructure specifically dedicated to clinical research training in multiple disciplines; and importantly a dearth of communication and integration among individual research “silos”.

The major limitation of the APPCI training program has been the inability to provide salary support and protected time for promising trainees as they participate in the structured training and research programs. In addition, resources and offerings available through the existing training programs have no mechanism for integration and

cross-communication.

The strong institutional support committed for the CTSI outlined in letters from Deans of participating colleges, the Senior Vice President for Health Affairs and the Vice President for Research ensures that such barriers will be overcome through the Training and Professional Development (TPD) Program. UF institutional support includes sizeable financial and space resources, new clinical research facilities, the commitment to allocate time to the CR Scholars and mentors for the Program, and the plans for promotion and tenure of CR Scholars, all of which provide the tools and resources to enhance the communication and integration of the multidisciplinary components required for effective training in CTS.

Training and professional development are key to the mission of the CTSI. The goal is providing the sort of training that helps all the individuals working within the CTSI, from support staff through students at various levels, to junior faculty members. To reach this goal the TPD Program will provide educational opportunities and create the infrastructure for the education of pre-collegiate, undergraduate and graduate students and junior faculty who will comprise this new clinical and translational science (CTS) workforce. The Program will not be a simple, one-note training exercise, but will provide a wide variety of interdisciplinary educational opportunities across a continuum from preclinical training to community practice. In order to meet the overall goal of the training program, five individual goals will be accomplished:

Create a curriculum of coursework and practical experience for trainees.

New thinking in clinical research translation requires a new curriculum and the curriculum within TPD will prepare pre- and post-doctoral trainees and faculty for success in conducting multi- and interdisciplinary clinical and translational research. The new coursework will revolve around a new three-component Core Curriculum required of everyone passing through the program.

Institute a new mentored research career development program for junior faculty.

Clinical and Translational Science (CTS) is developing as a collection of disciplines that can be chosen as a professional concentration unto itself. The program for junior faculty will offer Clinical Research (CR) Scholars a comprehensive educational component that consists of core courses and electives together with extensive practical experiences that will lead to an MS in CTS, an MS in Epidemiology or a Certificate in CTS.

Institute a new pre-doctoral training program for highly qualified students seeking either a PhD degree in CTS or a doctoral level professional degree (MD, DMD, DVM, PharmD) combined with a MS or PhD in CTS.

This program will develop a new minor concentration in CTS for pre-doctoral students currently in a discipline-focused program and will also offer a new PhD program with a major in CTS. The CTS PhD program will be independent of department or college and will emphasize the interdisciplinary nature of CTS. Students in professional doctoral programs will be eligible to pursue a joint MS or PhD in CTS with their primary MD, DMD, DVM, or PharmD program.

Establish a Clinical Research Coordinator training program. All Coordinators will be required to complete an IRB-based program of competencies. They may also select additional training and experience under the auspices of the College of Health and Human Performance that will lead to a Certificate in Clinical Research Coordination.

Implement a recruitment and retention plan to develop an outstanding cadre of pre- and post-doctoral trainees of diverse race, ethnicity and gender. In accomplishing this goal, we will reach out to current programs targeting high school and undergraduate students with interests in science careers to introduce clinical and translational research options, and will partner with campus-wide resources at UF to ensure appropriate enrollment in all programs by women and trainees of minority status.

The TPD Program represents a strong added value to UF and allows progress in cross-disciplinary training that otherwise would not be possible. Furthermore, the CTSI centralized Academic Home and communication plans will enhance the effects of the TPD's work and help alleviate the critical deficiencies associated with the current separate and competing departments, schools, and divisions that will together make up the CTSI.

GROWING QUALIFIED FACULTY: THE KL2 PROGRAM

BY CURTIS
FRANKLIN, JR.

Teaching translational science across disciplines will help create a new generation of scientists and health-care professionals

The goal of the *KL2 Program* is to prepare highly motivated and talented junior faculty at UF to work in multidisciplinary teams, to appreciate that collaboration and teamwork are the expected goals and to have the skills necessary to work successfully in multidisciplinary clinical and/or translational research. Trainees of the Program will be known as KL2 Clinical Research (CR) Scholars.

Program Leadership

The *KL2 program* will be directed by Marco Pahor, MD, Professor and Chair, Department of Aging and Geriatric Research and Director of the UF Institute on Aging. Dr. Pahor is a nationally and internationally known scientist in the areas of aging, disability and cardiovascular disease in population-based studies. He has extensive expertise in leading multidisciplinary research and mentoring teams and is the Director of the newly NIH-funded Claude Pepper Older Americans Independence Center (OAIC), which has a major focus on research career development and mentoring of junior investigators. He has a total of 23 years of mentoring and training experience in clinical research in multidisciplinary settings.

The KL2 Director and the Multidisciplinary Advisory Committee (MAC) will provide overall scientific leadership and direction of the Program. They will assure coordination of resources; communicate with other CTSI Programs; facilitate compliance with guidelines and regulations regarding fiscal policy, human subject and animal care and use; set productivity benchmarks; monitor progress; and promote productivity and efficiency.

Requirements for Candidates

We expect that the vast majority of eligible candidates to the KL2 Program will be relatively junior faculty on tenure-track lines. CR Scholar candidates must have a clinical doctorate or PhD degree or its equivalent in health sciences, be a US citizen or permanent resident, be able to commit at least 50-75 percent of full-time professional effort in the Program and its related clinical research activities and not be or have been a Principal Investigator, except for R03 and R21 awards.

The CR Scholar selection process will follow the NIH review format. The Program Director will assign a primary and two secondary reviewers chosen from the MAC. An additional external reviewer may be appointed, if needed. All applications will be discussed and scored according to the following criteria:

(This article continues on Page 6)

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The CR Scholar selection process will follow the NIH review format. The Program Director will assign a primary and two secondary reviewers chosen from the MAC. An additional external reviewer may be appointed, if needed. All applications will be discussed and scored according to the following criteria:

- **Scholarly record: excellence, expertise and multidisciplinary scope in prior training, funded research, publications and other written material (100 points);**
- **Training and mentoring plan: multidisciplinary scope, team approach appropriateness of the career plan, training plan, quality and appropriateness of mentors, personal statement and recommendation letters (100 points);**
- **Career: potential to become an independent investigator, a leader and a team player in multidisciplinary clinical research (100 points);**
- **Research plan: scientific merit, multidisciplinary team clinical research scope, feasibility of the research plan, utilization of resources (100 points);**
- **Departmental support: level of support from the Scholar's home department to develop a career in multidisciplinary clinical research, and laboratory and other infrastructure support (100 points).**

Based on the information provided in the application process, the MAC will assign each CR Scholar a *mentoring team* composed of primary and secondary mentors and at least one MAC member. During the second program year, incoming CR Scholars will also be assigned a *senior CR Scholar* as part of their mentoring team which will ensure that the senior CR Scholar will acquire mentoring expertise, an important part of the training experience.

The Mentor's Importance

A *close relationship* between the CR Scholars and their mentors is essential for fostering the development of a successful research career. Mentors play a critical role in transmitting to the CR Scholars the high value placed on scientific integrity through role-modeling. A major factor in the selection of the mentors is their ability to convey the importance of scientific ethics and integrity. The primary mentor will be responsible for:

- advising the CR Scholars about the TPD core curriculum and elective courses and the degree requirements for the KL2 program;
- identifying the resources required for the trainees to accomplish their research;
- helping CR Scholars identify research team members;
- monitoring research progress for critical milestones including course completion, scientific presentations, publications and applying for extramural funding;
- academic strategic career planning; and
- facilitating professional development contacts within the institution and nationally.

The primary mentor will meet twice per month with the CR Scholar and more frequently as needed. The CR Scholar will meet monthly with the full mentoring team including the senior CR Scholar appointed to the team. Primary mentors provide written and verbal input during the final tenure and promotion review.

The new core curriculum for CTS will integrate trainees across disciplines and encourage novel research focusing on medically-important questions. The availability of research experiences and successful mentors

GROWING QUALIFIED FACULTY: THE KL2 PROGRAM

BY CURTIS
FRANKLIN, JR.

will provide high quality experiences for all levels of trainees participating in multidisciplinary research teams. Another innovative feature of the CTSI is the involvement of department chairpersons of the participating colleges in the recruitment, promotion and tenure of the CTSI trainees. Department chairpersons play a critical role in fostering the academic careers of clinical investigators working in multidisciplinary settings. To ensure that the TPD Program is integrated at the departmental level in the colleges of the Health Science Center, the chairs are involved in several

program aspects including: collaborating with the TPD Program in recruiting promising trainees and junior faculty; providing input into the trainees' selection of mentors; and incorporating written and verbal input from mentors and the TOC into the tenure and promotion process for CR Scholars who are junior faculty. All department chairs have agreed to incorporate information about the faculty CR Scholar's performance into the discussion and decision-making about tenure and promotion.

PRE-DOCTORAL T32 TRAINING PROGRAM

BY
PAULA RAUSCH

T*raditionally*, researchers have been involved in only a single aspect of medicine: They have either cared for patients or conducted basic science investigations into the diseases making them ill. Recognizing the need to help speed these basic science investigations into treatments that can be used more effectively in patients, CTSI leaders will launch a new program aimed at training clinical and translational science (CTS) investigators for the dual role they'll play in both facets of this transfer from bench to bedside.

UF and the CTSI are responding to these challenges by creating a foundation on which to build the CTS discipline across campus by instituting a new pre-doctoral T32 training program that will initially include a universitywide doctoral degree interdisciplinary concentration minor in CTS, and a full CTS Ph.D. degree program within five years. Once the CTS minor receives official UF approval, the average amount of time for doctoral students to receive their degrees with the CTS minor will be five to six years.

The goals of the T32 program will be to prepare trainees from departments in 12 colleges campuswide, including many outside the Health Science Center, to work in multidisciplinary teams, to help them embrace the idea of collaboration and teamwork as expected goals, and to provide them with the skills necessary to successfully conduct interdisciplinary CTS research. One of the basic tenants of the CTS model is to train students to consider in more broad terms how their "non-traditional" backgrounds in the arts, humanities and social sciences make them ideally suited to fill an important void in population-based and health policy domains of expertise required to complete the "bench-to-bedside-to-community" mission of translational medicine.

Critically important to this transformation is that the T32 program will expose graduate students from disciplines across campus to the fundamental principles of CTS. The program, to be co-directed by Drs. Stephen Hsu, M.D., Ph.D., and Wayne T. McCormack, Ph.D., also will augment UF's existing doctoral curricula by affiliating students with a focused group of CTS faculty mentors and by providing advanced courses, journal clubs and seminars aimed at enhancing their translational knowledge and experiences. Hsu, an internationally recognized multidisciplinary clinician and scientist, is the R. Glenn Davis Associate Professor of Clinical and Translational Medicine in the College of Medicine's Division of Nephrology, Hypertension and Renal Transplantation and the director of UF's MD/PhD Program. McCormack has been involved in virtually every facet of graduate program planning, curriculum development, recruiting, admissions and administration, having served as the UF College of Medicine Associate Dean for Graduate Education, as Ph.D. program director and as MD/PhD program co-director. He is also active nationally in biomedical science graduate education, serving in leadership positions in the AAMC Graduate Research, Education and Training (GREAT) Group. Hsu and McCormack will be provided input and guidance on all aspects of the program by a Training Advisory Committee consisting of leadership representatives from all 12 CTSI-affiliated colleges.

The T32 program will train highly qualified students seeking either a Ph.D. in CTS or a dual doctoral level professional degree (MD, DMD, DVM, PharmD) combined with a master's or doctorate in CTS. The MD/PhD program already began implementing the program this summer by enrolling several trainees in an Introduction to Clinical/Translational Science course. Full implementation of and recruitment for the

PRE-DOCTORAL T32 TRAINING PROGRAM

BY
PAULA RAUSCH

T32 program is expected to begin in the summer of 2010 in anticipation of award monies to support four pre-doctoral trainees in the program annually through the National Institutes of Health's CTS funding mechanism. UF will also provide funding to help support those who are selected for the program. Ph.D. students enrolled in the program will be able to apply for T32 funding during their first year of graduate study for support during their second and third years.

Students will be recruited through traditional activities and through special "feeder" programs targeting students in high school and early in their college and graduate educations. Like students participating in other CTSI Training and Professional Development programs, T32 trainees will be required to complete the core curriculum. Advanced elective coursework relevant to CTS will emphasize communication skills and professional development, and trainees will be able to participate in career development seminars and workshops, covering issues such as laboratory management, literature studies, budgeting, conflict resolu-

tion, teamwork, intellectual property, entrepreneurship and mentorship skills.

Most Ph.D. students in the program also will complete rotations in the laboratories of potential mentors, who will be nationally recognized UF faculty members from major disciplines, centers, institutes and programs. Each student will be co-mentored by at least one basic scientist and one clinician-scientist who will serve as co-chairs of the student's graduate supervisory committee. An off-campus expert will be appointed to function as an external member of the trainee's graduate committee and who can serve as a key contact for future study and networking.

The CTSI also hopes to broaden awareness and appreciation of CTS by educating and engaging both non-academic professionals and the public, and in the future will adapt elements of the program for distance education via the Internet in an effort to transfer CTS knowledge and ideals to anyone anywhere in the world.

For more information on these training programs, contact: Dr. Stephen I. Hsu, stephen.hsu@medicine.ufl.edu, (352) 273-7987 or (352) 273-6888; or Dr. Wayne McCormack, mccormac@pathology.ufl.edu, (352) 273-8603.



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A *clinical research trial* aimed at finding a new therapy or a cure for a disease or condition is a complicated, arduous and exacting undertaking. The investigators involved must be experts not only in the science behind what they are testing and in tracking their participants, but they must also carry out a host of time-consuming administrative tasks.

So they can spend more time on the specifics of their trial protocols, researchers hire clinical trial coordinators when possible to assist with some of these duties, including screening, recruitment, submitting required regulatory documents and conducting study visits. However, these highly sought-after coordinators are in short supply at UF and nationwide – a problem CTSI officials expect to address by instituting a new Clinical Research Coordinator Training Program.

The most successful clinical research studies are conducted by researchers who have protected time from clinical responsibilities and researchers who have trained, experienced research coordinators, said Teresa d'Angelo RN, nurse manager of UF's General Clinical Research Center (GCRC) and one of the two people who developed the new training program. "A good study coordinator can make the difference between a successful study and an unsuccessful study."

D'Angelo, who has worked for 5 years managing the GCRC where most of UF's investigator initiated clinical trials are conducted, and James Cauraugh PhD, a professor and the associate dean of research for the College of Health and Human Performance, will oversee the new Clinical Research Coordinator Certificate program. The nine- to 12-month-long curriculum will help ensure the smooth progression

and success of clinical trials by training coordinators in necessary skills, such as screening and recruitment, consenting, budgeting, maintaining source documents, submitting regulatory documents, conducting study visits, preparing laboratory specimens and planning for site visits by trial sponsors and monitors.

Nurses and other health professionals, such as dietitians, psychologists, respiratory therapists, exercise physiologists and health educators, with undergraduate degrees are eligible to be trained under the program. In addition, the curriculum will be made available to coordinators hired to work with CTSI projects and to investigators. As the program develops, nurses and other health professionals with associate's degrees will also be able to enroll in the curriculum.

"People fall into these coordinator positions and don't have the necessary training" because opportunities for training are lacking, d'Angelo said. They learn the job through "trial by fire" and that's not the best way.

"And we can make it easier for them" through this program, Cauraugh said.

The training has already begun with a pilot project d'Angelo instituted in January 2007 with one of her nurses. Three nurses have now completed the curriculum and have worked part time as coordinators with UF investigator-led trials while also continuing to work part time as nurses caring for research subjects on the GCRC.

(This article continues on Page 11)

All coordinators and investigators working with CTSI-funded projects will be required to complete a new IRB Competency Program. This Collaborative IRB Training Initiative (CITI) is an Internet-based program developed with NIH funds that addresses Good Clinical Practice in research. Coordinators participating in the Clinical Research Coordinator Certificate Program must take additional training. Trainees must participate in the UF course called "Introduction to Clinical and Translational Sciences," one of the CTSI's core classes, as well as an 8 - 10 week evening course in "Research Methods and Experimental Design" offered by the College of Health and Human Performance. These trainees also will participate in laboratory experiences in one of several of the College of Health and Human Performance's motor behavior and physiology laboratories. Finally, trainees will become involved in a mentored internship/practicum in one of the CTSI's Clinical Research Units (CRUs). An important goal of this program is to match a trainee's interests to the experiences offered by a UF mentor.



Pamela Schreck RN, MSN (left) functioned as a mentor to Janet King RN (seated) and Glenna Paguio RN, BSN, while they were enrolled in the Clinical Research Coordinator Training Program. Schreck is the assistant director for clinical programs for Pulmonary and Critical Care Medicine at UF. King and Paguio are both staff nurses on the General Clinical Research Center.

Through this training program we'll be able to facilitate the interaction of research being conducted all across UF, Cauraugh said, "and then maybe the science will go quicker from this research arena out into the community."

OTHER ANNOUNCEMENTS

New NIH Initiative: Translational RO1s

As part of its Roadmap for Biomedical Research, the National Institutes of Health announced on September 9 it was accepting applications for transformative Research Project Grants (R01) for exceptionally innovative, high risk, original and/or unconventional research with the potential to create new or challenge existing scientific paradigms. Projects must clearly demonstrate potential to produce a major impact in a broad area of biomedical or behavioral research. The NIH intends to commit \$25 million dollars in FY 2009 to fund up to 60 applications submitted in response to this FOA. Application deadline is January 29, 2009. Additional general information can be found at <http://www.grants.gov/search/search.do?&mode=VIEW&flag2006=true&oppId=18350>, and the complete announcement is available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-029.html>.

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For a few months now the Newsletter has been sent out to many faculty and staff. While we will continue to do this for a while, you can ensure that you receive future editions of the Newsletter by subscribing to the CTSI-ANNOUNCE-L Listserv. It's quick and easy to do and will ensure that you also receive other CTSI announcements as they are distributed. To subscribe, simply send an email to listserv@lists.ufl.edu with the message:

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NIH Peer Review Improvement Timeline Announced

The National Institutes of Health announced on Friday its initial implementation timeline for various initiatives aimed at enhancing the NIH peer review system. The initiatives are a result of a process begun in June 2007 involving external and internal working groups. Among the initiatives and their implementation dates:

- Review criteria-based scoring on a 1 to 7 scale will commence in May 2009
- A shorter (12-page research plan) R01 application (with other activity codes scaled appropriately) will be restructured to align with review criteria for January 2010 receipt dates.

The NIH notice also reported, "To ensure that the largest number of high quality and meritorious applications receive funding earlier and to improve system efficiency, NIH is considering separate percentiling of new and resubmitted applications and permitting one amended application."

Lastly, the NIH announced it will establish an Early Stage Investigator (ESI) designation. In 2009, NIH will evaluate clustering ESI applications for review. The same approach will be considered for clinical research applications. The Advisory Committee to the Director recommended piloting the clustered review and ranking of early investigator applications. The ACD did not recommend clustering clinical research applications and the consideration of such a move surprised some observers.

For more information, visit: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-118.html>