THE UNIVERSITY of TENNESSEE Health Science Center

The Research Notebook

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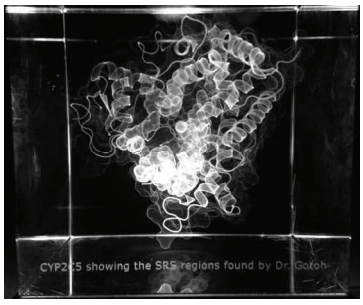
Inside this issue:

Congratulations to UTHSC's "Most Influential Scientists"!

Dr. David Nelson, Professor, Microbiology, Immunology, and Biochemistry, and Dr. Karen Johnson, Professor, Preventive Medicine were recently named among the world's most influential scientists by Thomson Reuters. Researchers earn this distinction by "ranking among the top 1% most cited for their subject field and year of publication—between 2002 and 2012." We have invited each of them to summarize their work, Dr. Nelson in this issue and Dr. K. Johnson in our next issue. We congratulate them both on this recognition.

Dr. David Nelson on Cytochrome P450 Work



A crystal of a mammalian cytochrome P450 laser etched in a 4 inch leaded glass cube.

One wonders sometimes if what you spend countless hours doing has value to anyone except yourself and your three best friends. This recognition seems to say, "Yes, it does." My work on the cytochrome P450 superfamily involves genomics, evolution and bioinformatics. P450 brings me into collaboration with researchers around the world who find this family fascinating. To give a sense of what I do, here is the title of my talk for Kyoto on Sept. 25, 2014: "Filling in the missing colors of our paint-by-number genomes: Game of genes." I am adding detail to Darwin's outline of the evolution of life. Darwin said all of life descended from one common ancestor, and he marshalled his arguments in the *Origin of Species*. The current molecular version of evolution says every gene family is descended from one common ancestor. There are thousands of gene families (14,831 in Pfam); but since 1985, I have chosen one and have been playing this game of genes on cytochrome P450.

My first paper on this subject in 1987 was called "Evolution of cytochrome P-450 proteins" (the dash was eliminated later). There were only 34 P450 sequences in this paper, and they were all that were known to the public at that time. Today, there are more than 26,000 P450 sequences to which I have assigned official names. These sequences are from every branch on the tree of life. The nomenclature is based on the evolutionary relatedness, so sequences in the same family or subfamily are closely related and may carry out similar or identical functions. At the same time as these P450 sequences have been named, I have been tracking the evolution of the superfamily and linking it to known functions. The innovation of new P450

(Continued on page 2)

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families coincides with significant evolutionary novelties in living things. Conquest of the land by plants saw the emergence of many new P450s to cope with life on land. Whole pathways are dedicated to synthesis of signaling, defense and structural molecules for multicellular organisms, whether plant, animal, fungal or protist. P450s are often key players in these pathways.

Researchers around the world send me their sequences for classification and name assignment resulting in a unified standardized nomenclature. This used to be one or two sequences at a time. Now it is whole genomes' worth of P450s. This may mean hundreds to thousands in a set. The lowly potato has 399 named P450s. Wheat in your breakfast cereal probably has more than 1,000 P450s. Working with my collaborator, Dr. Osamu Gotoh in Japan, we have obtained tens of thousands of P450s from hundreds of plant, animal and fungal genomes. Additional work with collaborators in Canada and China has discovered more than 172,000 P450s in more than 1,100 plant transcriptomes.

By studying these sequences, it will be possible to learn much about the evolution of life on earth. Furthermore these sequences can be exploited to make valuable pharmaceuticals (like the anti-malarial drug artemisinin) in yeast or in bacteria, or the P450s can become the targets of fungicides and pesticides or drugs. P450s for making blue pigments have even been used to make the legendary but nonexistent blue rose. It is enough to keep me up at night, working on the next genome.

National Biosafety Stewardship Month and Federal "Safety Stand Down"

In response to several widely publicized incidents at the CDC and the recent report of the Inspector General on these incidents, there has been a renewed focus on Biosafety and Biosecurity at the national level. There are several related developments in this regard. In an August 18th memo, the Whitehouse initiated a "Safety Stand-Down" for all US Government departments and agencies that operate facilities which possess, use, or transfer human, animal, or plant infectious agents or toxins (http://www.absa.org/pdf/140819WhitehouseMemoEnhancingBiosafetyandBiosecurity.pdf). The NIH has also declared National Biosafety Stewardship month which includes reminders for all NIH grantees with respect to laboratory safety and compliance (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-127.html).

The overall goal of these various initiatives is to refocus attention on and to reassess laboratory and biosafety policies, procedures, and training. UTHSC is committed to safety and safety compliance. An independent review of UT safety programs was already underway at the time of this announcement.

An analysis of infectious agent and toxin inventories across the research community is an additional critical component of the stewardship initiative. Investigators are reminded that they are responsible for maintaining inventories of these research materials. Researchers should take the opportunity at this time to review storage locations (freezers, refrigerators, etc.) to ascertain if there are un-inventoried materials present in the research environment.

Welcome Jordan Toutounchian!

UTRF welcomed a new graduate intern in September, Jordan Toutounchian from the Department of Pharmaceutical Sciences. Jordan is a doctoral student in the lab of Dr. Ryan Yates, and will work 8 hours per week at UTRF for the next 6 months learning about technology transfer and assisting in the evaluation, marketing, and licensing of technology developed at UTHSC. Jordan takes over as UTRF graduate intern from Sumana Chintalapudi, who completed her UTRF internship this summer

UTRF Maturation Funding Proposals Due October 13th

The University of Tennessee Research Foundation (UTRF) is announcing a call for submissions for the eighth annual UTRF Maturation Funding program. The program is open to all UTHSC faculty, staff, or students. You do not need to have previously disclosed an invention to UTRF, either existing or new inventions and discoveries are eligible for funding.

Proposals are due into the Office of Research Administration (via PAMS) by close of business October 13, 2014. The program helps UTHSC researchers further develop technologies that have potential for commercial success. Up to $15,000 in direct costs will be awarded to the highest ranking proposals, with four awards anticipated.

Additional information, including the guidelines and proposal requirements, can be found at http://utrf.tennessee.edu/techtransfer/offices/hsc-technology-maturation-fund.shtml. Call or email Richard Magid (rmagid1@uthsc.edu or 901-448-1562) for specific questions about the program.

Biomedical Technician Now Available for Lab Equipment Repairs

The Regional Biocontainment Laboratory is pleased to welcome our newest staff member, Michael Garland, to the University. Mike has been hired as a biomedical technician and will be providing service and repairs for various types of laboratory equipment for the University community. This service is FREE for all UTHSC investigators working in University-owned research facilities! Investigators will only need to pay for any parts required for the repairs. Requests for service can be submitted though email at labfixit@uthsc.edu. Please include the following information with your service request: contact name and phone number, type and location of instrument (building and room number), and nature of the problem. Service will be provided as soon as possible after the request is received. Please note that this service may not be available for all types of equipment, such as refrigerators and -80 freezers. We look forward to having Mike assist the University research community in keeping the lab equipment up and running.

Office of Clinical Research Open for Business!

The Office of Clinical Research (OCR) is officially open for business! OCR hosted an Open House on September 2, 2014, and enjoyed the camaraderie of UTHSC faculty and staff. The OCR provides resources and services to UTHSC researchers performing clinical trials. The OCR will explore opportunities with our health care partners, raise awareness with external sponsors about the UTHSC clinical trial capabilities, and facilitate all levels of clinical trial support for investigators.

Our outpatient clinic is located at 66 N. Pauline, Suite 300. For additional information or inquiries, please contact the Office of Clinical Research at 448-2520, Ari VanderWalde, M.D., Associate VC for Research (avanderw@uthsc.edu), or Risa Ramsey, Ph.D., Associate Professor & Director (rramsey@uthsc.edu).

Dr. Ari VanderWalde and Dr. Donna Hathaway

Dr. Risa Ramsey and Dr. Colin Howden

UTCOMC's 2015 Research Week

Information about the UTCOMC's 2015 Research Week—occurring Monday, April 13, through Friday, April 17, 2015—has been posted at www.utcomchatt.org/researchweek. Please see the "2014-2015 Timeline" link (http://www.utcomchatt.org/subpage.php?pageId=715) for important information about November and December submission deadlines for Scientific Review Committee and Institutional Review Board approval of projects. You will also find required forms, presentation tips, and poster guidelines.

2015 Cancer Research Award Funding

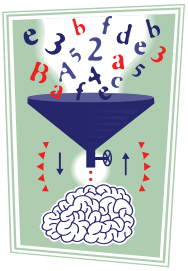
The Executive Council of the UTHSC/ West Cancer Center/ Methodist Healthcare Family has made $200,000 available for research funding to investigators in the cancer research community. This intramural funding will be awarded to investigators based on review of research proposals.

Awards for faculty investigators will be made up to a maximum of $50,000 per project. It is expected that projects funded through this program will be aimed at securing preliminary data to provide the basis of proposals to obtain external funding. Awards may not be received in consecutive cycles. Prior awardees are required to submit a thorough summary of research output from the previous grant.

Download the Research Proposal Format https://www.uthsc.edu/cancer/docs/research-proposal-format.pdf for detailed information to apply for this award.

The research proposal should be completed and submitted in one PDF electronically to Andrea Briggs abriggs3@uthsc.edu by October 31, 2014.

Registries, Databases, and Repositories: Ethical and Regulatory Issues



The Institutional Review Board invites you to attend our quarterly campus IRB Insights training. On Wednesday, October 29, 2014, Dr. Terrence Ackerman will discuss "Registries, Databases, and Repositories: Ethical and Regulatory Issues." Dr. Ackerman will examine a variety of issues. When does the creation of a registry, database, or repository require IRB approval? Do studies conducted with specimens and data maintained in an IRB-approved registry, database, or repository require separate IRB approval? Is the consent of subjects always necessary? How can consent forms be constructed to anticipate currently unforeseeable uses of collected materials? And may the consent process ever be modified to accommodate the accrual of very large numbers of subjects? We look forward to seeing you at 12 p.m. in the GEB, Room A304. HR-128 credit is available.

Need Help with Cage Management?

The LACU has developed a quick reference guide to the cage management functions found in the PI Information area in the lower left of the ACAP home page. These links help the PI or their designee:

- Manage cages - manage cage card requests such as weans, separations, or transfers
- Stale cages- identifies cage cards that may not have been turned in for deactivation
- Pending transactions - print cards for transactions entered at your desk or monitor status of those that LACU must complete
- View Personnel - see personnel on your protocols and their associated roles
- View Inventory - see the cages currently allocated in the system
- View Charges - see pending charges as they accrue along with the underlying cage card number
- View Finalized Statements - see previous months statements in PDF format

The PI Information Section guide is located on the LACU website at http://www.uthsc.edu/research/research_resources/LACU/pi-acap.php.

Conducting or Publishing Human Subjects Research (including "exempt" research) without IRB Approval

The IRB (Institutional Review Board) has recently implemented a new journal surveillance program in order to better ensure that UTHSC complies with its responsibilities for implementing human subjects regulations as a condition of receiving federal research dollars. The program will involve verification that faculty, students, and staff have received prior IRB approval for any human research appearing in journals and other academic publications. This includes publications about projects which are considered "exempt" under the federal regulations. We will also compare the research procedures in your IRB application to the research procedures outlined in the journal article to ensure consistency and therefore confirm that the appropriate category of IRB review for the project was utilized.

In order to receive research dollars from any U.S. federal department or agency, the University has entered into a contractual agreement (called a Federalwide Assurance or FWA) with the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services to observe federal rules for protecting the rights and welfare of human subjects. Under the terms of the FWA, all of our institution's human subjects research activities, regardless of whether they are federally funded, must be guided by appropriate ethical standards recognized by federal departments and agencies and basic regulations known as the Common Rule, (45 CFR 46, Subpart A). The Common Rule includes the requirement that each institution to which the Rule applies must establish an IRB to oversee the application of relevant ethical principles and federal regulations in the conduct of all human research.

Although federal regulations provide for exemption from IRB oversight for certain kinds of research involving minimal risk, OHRP policy guidance requires that the determination that a study qualifies for exempt status be made by an entity *other than the investigator*. UTHSC IRB policy requires that the determination of whether a study qualifies for exempt status must be made by the Chair or other senior member of the IRB. This determination is made through your submission of a Form 1 Application via iMedRIS, the IRB electronic system. Examples of possible "exempt" projects are retrospective chart reviews, even when the data is de-identified; surveys where the subject matter is not sensitive (*i.e.,* could be damaging in any way if the participants' identities were revealed); case studies of 5 or fewer cases; projects where public behavior is only observed; quality improvement research in the classroom involving normal educational practices; and simple taste and food evaluation studies. Even though these types of projects may be "exempt" under the federal regulations, OHRP guidance, our FWA, and our corresponding IRB policies require UTHSC faculty, students, or staff to receive IRB determination of exempt status and approval before beginning these research projects. (IRB approval is also obviously needed before beginning any expedited and full board research.) Note that the IRB does not provide "retrospective" approval for research that has already been initiated, completed, and/or submitted for publication.

Lastly, the IRB has the authority to place research activities on hold, as well as to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies or federal regulations for the protection of human subjects. Additionally, the IRB must also report to appropriate institutional officials and agency heads any serious or continuing noncompliance of investigators with federal regulations and local IRB policy, and any suspension or termination of research studies resulting from noncompliance.

If you have any questions about this article or the IRB process, or you wish to request IRB policy and procedure training (including iMedRIS training), please contact Kimberly Prachniak, Associate Director of the IRB, at 448-5060. You may also consult our Authority policy at http://www.uthsc.edu/research/research_compliance/IRB/docs/policies/sop-irb-authority-membership-permanent-positions.pdf , our Exemption policy at http://www.uthsc.edu/research/research_compliance/IRB/docs/sops/sop-exempt-research.pdf , and our Noncompliance policy at http://www.uthsc.edu/research/research_compliance/IRB/docs/sops/SOP29.pdf .

Private Grantmaker Limited Submissions Aren't for Everyone

Thanks to technological advances, millions of grant applicants can blanket funders will multiples of applications. Private grantmakers are overwhelmed, especially since the flow of federal dollars has diminished. To address this onslaught, private grantmakers created the Limited Submission (LS) process. Through the Limited Submission process, the grantmaker restricts the number of applications, full proposals, or letters of intent (LOI) it will it accept from one institution or from one researcher. Some LS competitions also restrict the number of applications submitted for similar projects or research.

LS programs usually allow only one or two full proposals or LOIs per application cycle per higher education institution (or campus system). LS grant opportunities are internally directed to ensure that the higher education institution submits only the number of proposals allowed. Internal review criteria usually include: (a) the quality of the project description, (b) the relevance or "match" between the LS requirements and proposed project, (c) the impact and/or outcomes of the proposed project, (d) the PIs qualifications in the specific area of research, and (e) other factors specific to the private grantmaker.

LS private grantmaker opportunities are often announced either by the UTHSC Office of Development and Alumni Relations, Corporate and Foundation Relations (CFR), or the UTHSC Office of Research Administration. The actual LS "internal selection" process is handled by the Interim Vice Chancellor for Research and/or the Office of Research Administration. All of the above work together.

The UTHSC LS process sets an internal submission deadline in advance of the funder's deadline. The Interim Vice Chancellor for Research usually requests a "pre-proposal" submission accompanied by the PI's curriculum vitae, and then works to initiate an internal selection review committee to assess each "pre-proposal" package. Once the internal applicant or applicants are selected by the committee, they are notified by the Interim Vice Chancellor for Research, who also contacts the Corporate and Foundation Relations Director and the Office of Research Administration. The CFR Director will then work directly with internally selected applicants to follow the usual ORA procedures for submission of either the full proposal or LOI to the private grantmaker by the external due date.

If you discover a private grantmaker with an LS grant opportunity that has not been announced by either CFR or the ORA, immediately contact Denise Rivers, CFR Director via cfr165@uthsc.edu. The CFR Director will then route the LS grant opportunity to the Interim Vice Chancellor for Research to initiate an appropriate internal LS submission competition.

Note: When LS opportunities are limited from the entire UT system, a system-wide selection process is used.

Freedom of Information Act and Tennessee Public Records Act Requests

Occasionally, requests are made to UTHSC for release of UTHSC grant or contract information under either the Freedom of Information Act (FOIA) or the Tennessee Public Records Act (TPRA). Faculty who receive notices of FOIA requests from federal agencies should contact Debbie Smith (dsmith@uthsc.edu) prior to responding (we usually have a couple of weeks to respond). Faculty who receive requests for release of information under the TPRA should contact Sheila Champlin (schamplin@uthsc.edu) prior to responding. Because such requests may involve sensitive information and may require considerable time and effort, we need to be sure that we have a coordinated response.

Postdoc Office and Postdoctoral Research Trainee Update

There are some changes/updates that affect the Postdoc Office and Postdoctoral Research Trainees on the UTHSC campus, effective July 1, 2014:

Change in title of Postdoctoral Research Trainees

- Both Postdoctoral Research Trainees and Postdoctoral Fellows will now be titled, "Postdoctoral Fellows"
- All Postdoctoral Fellows will be under the umbrella of the Postdoc Office
- Health insurance for all Postdoctoral Fellows will be handled as it has been for Postdoctoral Research Trainees
- Cost for single health insurance coverage will come from the grant(s) that pay the stipend
- Coverage for dependents will be cost-shared by the Postdoctoral Fellow

Grant writing incentive program for Postdoctoral Fellows

- Postdoctoral Fellows will receive a $200 stipend bonus for submitting a fellowship application, funded by CGHS; name CGHS as primary or secondary department in PAMS for tracking purposes

Affirmation of Research Trainee Status

- Postdoctoral Fellowship appointments are for additional training beyond the terminal degree and thus are of a temporary nature
- Former postdoctoral fellows who have advanced in their career (*e.g.,* Research Associate, Asst. Professor) may not return to fellow status unless there is a clear training benefit to the individual in question (*e.g.,* retooling, complex skill development)

Postdoctoral Fellow Term Limits

- All Postdoctoral Fellowships will now have 5-year/8-year term limits that follow the same guidelines as NIH and St. Jude
- The Postdoc Handbook lists a five-year limit in each lab already, so this is not a major modification from current rules
- Postdocs who are already on campus will be required to leave their current labs (or be promoted to a staff position) at the 5-year mark
- If, after 5 years, a current postdoc moves to a new lab, he/she can only remain there for only 3 additional years, up to the 8-year maximum
- The Postdoc Office will inform the principal investigator and postdoc as the time to transition approaches; the path that the postdoc takes will be the decision of the mentor and the postdoc

Certificates of completion

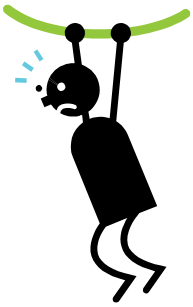
- Certificates of completion will automatically be generated for all Postdoctoral Fellows when they leave the UTHSC postdoctoral fellow program
- The certificate will state the Postdoctoral Fellow's name, department, and the dates that they were a Postdoctoral Fellow on the UTHSC campus

Family Medical Leave Act (FMLA)

- Postdoctoral Fellows are covered by the FMLA
- To be eligible for FMLA, a Postdoctoral Fellow must have worked 1250 hours during the previous 12 months
- If eligible, Postdoctoral Fellows will be guaranteed up to 12 weeks of unpaid leave
- All FMLA paperwork must be processed through Human Resources

Office of Research Administration

Upcoming Changes in Regulations Affecting Federal Awards - The Uniform Guidance



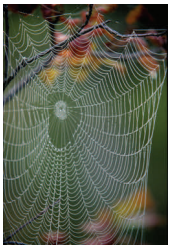
If you hear colleagues at meetings or business folks on campus talking about "changes in the circulars," "A-81," "uniform guidance" or the "omni circular," here's what they're talking about. Federal awards and spending on federal awards are governed by various federal regulations that have been summarized by the federal Office of Management and Budget in publications called "circulars." Over the years, you may have heard of "Circular A-21" or "A-122" or "OMB Circular A-133." In the spirit of streamlining and transparency, eight of the most commonly used circulars have now been combined into one, which is being called the "Uniform Guidance." It is codified at 2 CFR 200 (link to here: http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CCAQFjAA&url=http%3A%2F%2Fwww.gpo.gov%2Ffdsys%2Fpkg%2FFR-2013-12-26%2Fpdf%2F2013-30465.pdf&ei=ovgFVIq8NZLNggSQlIGIDQ&usg=AFQjCNHRYhdqCR_bICBVcrocELsU0Wz0bw&bvm=bv.74115972,d.eXY) , and is great for reading on those nights when you suffer from insomnia.

We want to let you know that UT is fully aware of the upcoming changes in the regulations scheduled to take effect December 26, 2014, for new awards and incremental funding issued on or after that date. A number of UT personnel, both at the campus and system level, are participating in working groups, both internally and with colleagues from other institutions, in order to fully understand the implications of the changes and to review and revise any affected policies.

Many of the Uniform Guideline changes are administrative and may not change the way you conduct daily business. But there are several ways in which the changes may affect you and your federal awards or subawards; here are some of them:

1. More time to prepare applications. The UG requires that federal agencies post funding opportunities at least 60 days before a deadline.
2. More F&A recovery. Federal agencies must accept an institution's negotiated F&A rate unless the head of the agency approves otherwise.
3. Changes in procurement and direct charging. Some procurement and direct charging requirements may change (e.g., computers and support staff), but we are still awaiting clarification on some of these issues and will keep you posted as we know more.
4. More subrecipient information. Subrecipients will be subject to a risk assessment prior to award and increased monitoring post-award, so more information will likely be required from potential subrecipients at the time of proposal submission and award. More reporting may also be required of subrecipients during the project.
5. Effort reporting. Requirements for effort reporting to the feds have changed, but we do not expect to see major changes in UT policy or practice regarding effort reporting since UT's current system is in compliance with the new guidance.

Changes to ORA Web Pages



ORA is updating its web pages and invites you to check them out and to let us know if you have suggestions for additional information that should be added or if you see outdated information that needs to be revised. http://www.uthsc.edu/research/research_administration/

Office of Research Administration

eRA Commons Username Required for Sponsor in Individual Fellowship Grant Applications to NIH and AHRQ

In order to facilitate the electronic processing of Individual Fellowship grants, NIH & AHRQ now require a valid eRA Commons Username to be included for the primary Sponsor designated on competing Individual Fellowship grant applications. Including the eRA Commons IDs for personnel designated as Co-sponsors remains optional.

The primary Sponsor must be listed on the R&R Senior/Key Person Profile form of the Fellowship grant application as follows:

- List the Sponsor as Senior/Key Person 1.
- Use the 'Other' or 'Other Professional Role' in the Project Role field and provide the text 'Sponsor' in the other Project Role Category field.

Provide a valid Commons Username with the 'Sponsor' role in the Credential field. Note that if the sponsor has an existing eRA Commons account with the PI or other scientific roles, the 'Sponsor' role should be added to the existing account rather than creating a new account.

Failure to properly identify the Sponsor on an application may result in an error preventing successful application submission.

- See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-129.html#sthash.DVv6aK2Z.dpuf

Check Out PubMed Commons

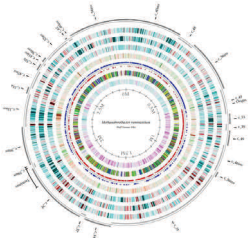
NIH has recently developed PubMed Commons, which "enables authors to share opinions and information about scientific publications in PubMed." Anyone who is an author of a publication in PubMed can use PubMed Commons to comment on other publications and to view comments on his/her own publications and respond to those comments. In his article in *Government Executive*, NIH Director, Dr. Francis Collins, says, "Authors of biomedical research papers can update and receive feedback on their papers from fellow scientists around the globe. Comments can guide further research by identifying and sharing links to other relevant papers, linking to datasets, replication efforts, or blogs. Researchers can also link to articles in non-biomedical journals that might otherwise be overlooked." He says it "is a great tool to bring scientists together to share resources and knowledge, boost collaboration, and enhance our efforts to advance biomedical knowledge—with the ultimate goal of improving human health." http://www.ncbi.nlm.nih.gov/pubmedcommons/

Recommended Browsers for eRA Commons

The NIH eRA Commons Help Desk recommends using Internet Explorer for Windows users and Safari for Mac users. If you try to upload documents using another browser and get a "null" error message, try switching browsers before you contact the NIH Help Desk.

Office of Research Administration

NIH Announces New Genomic Data Sharing Policy



The National Institutes of Health (NIH) has announced the final Genomic Data Sharing (GDS) Policy that promotes sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research.

The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support). The Supplemental Information to the NIH Genomic Data Sharing Policy (Supplemental Information) provides examples of research projects involving large-scale genomic data that are subject to the Policy. NIH Institute or Centers (IC) may expect submission of data from smaller scale research projects based on the state of the science, the programmatic priorities of the IC funding the research, and the utility of the data for the research community. - See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html#sthash.h2GJClwg.dpuf

NIAMS Policy for Submission of Applications Containing Clinical Trials

Effectively immediately, NIAMS will not accept investigator-initiated R01 applications that include clinical trials under PA-13-302. A clinical trial is a prospective biomedical or behavioral research study of human subjects designed to answer specific questions about the safety, tolerability, efficacy and/or effectiveness of pharmacologic, behavioral, biologic, surgical, or device (invasive or non-invasive) interventions.

- This policy applies only to clinical trials submitted to PA-13-302 for investigator-initiated R01 applications and subsequent reissuances. This policy does not apply to other NIAMS-specific announcements that specifically solicit clinical trials.
- Applicants submitting investigator-initiated applications to NIAMS that contain a clinical trial must submit to one of the following NIAMS FOAs specifically designed for clinical trials:
- PAR-14-192 Exploratory Clinical Trial Grants in Arthritis and Musculoskeletal and Skin Diseases (R21)
  PAR-14-060 Pilot and Feasibility Clinical Research Grants in Arthritis and Musculoskeletal and Skin Diseases (R21)
  PAR-14-200 NIAMS Clinical Trial Implementation Cooperative Agreement (U01)
  PAR-14-199 NIAMS Clinical Trial Planning Cooperative Agreement (U34)
- More about NIAMS clinical trials policies can be found at: Policies and Guidelines for Investigator-Initiated Clinical Trials

See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-AR-14-021.html#sthash.P07AbJtE.dpuf

Invite Us Over!

ORA is happy to come to departmental meetings upon request. We will provide specific training for groups or individuals (your place or ours), and we will be happy to attend faculty meetings to provide information or answer questions about our services. Please contact Debbie Smith (dsmith@uthsc.edu) to make arrangements.

Office of Research Administration

How Do Multi-PI Applications Fare?

Reprinted from the July 11, 2014 post by Sally Rockey

A question that I hear often from investigators is: are my chances of funding increased or decreased by submitting a multi-PI application? It was seven years ago that NIH implemented the Multiple Principal Investigator Policy to encourage interdisciplinary and team approaches to biomedical research, and give scientists the option to apply with their peers and allow for equal credit for leadership of the research program. While the single-PI model works well, and continues to be the model for most of NIH's research grants, the multi-PI option recognizes that as health research grows in scale and complexity, scientific teams may better reflect the intellectual and scientific leadership within a given grant application.

So, let's look at some data on how multi-PI applications fare in comparison to single-PI applications. Looking at data on new competing research project grant applications from 2010 through 2013, overall we see no significant difference in the award rates of single-PI applications versus multi-PI applications:

Type 1 Research Project Grant Applications* and Award Rates by Multi-principal Investigator (MPI) Status

	Single PI		MPI		
FY	# of Applications	Award Rate	# of Applications	Award Rate	P-Value
2010	39,186	15.3%	5,318	16.2%	--
2011	41,140	13.8%	7,258	13.6%	--
2012	42,572	14.0%	8,300	13.7%	--
2013	40,496	13.2%	8,275	14.1%	*p<0.05*
2010-2013	163,394	14.0%	29,151	14.2%	--

*includes all research project grant activities.Two-tailed proportion z-test with the null hypothesis that single PI and MPI award rates are equal. P-values less than 0.05 are significant at the 95% confidence level. One test is statistically significant at the 95% confidence level.

Only in 2013 is there a significant difference in award rate between single PI and multi-PI award rates, and this is in favor of multi-PI awards. But for most years, and overall, there doesn't seem to be a trend indicating that multi-PI applications are more (or less) likely to be awarded than single PI applications.

So, when you're applying to NIH for research funding, while there are many other considerations to take into account in deciding whether to submit a multiple-PI application, preference for funding is not one of them. As always, the key questions to ask is: what would best address the science being proposed? Would a single- or multiple-PI model best ensure optimal leadership of this research project? Additionally, when considering the multi-PI option, be sure to consider how you will structure the roles of the investigators to meet the goals of your proposed research.

If you're looking for more information on the multi-PI policy and how it works, visit our website and frequently asked questions on the multi-PI policy. See more at: http://nexus.od.nih.gov/all/2014/07/11/how-do-multi-pi-applications fare/?utm source=rss&utm medium=rss&utm campaign=how-do-multi-pi-applications fare#sthash.EaMsu14u.dpuf

Reminder from ORA: For MPI applications, both PIs are equally responsible for the scientific and budgetary portions of grant; so be sure you know and can trust your colleague before you agree to be an MPI with him/her. Please see the ORA website for sample MPI plans.

Proposal Development Funding

Funding has been established for small pilot project expenses (up to $5,000). Funds can be requested via e-mail to Jane Poulos jpoulos@uthsc.edu and should include specific needs of the project, the name of the proposed grant that this funding will support, and the date the proposed grant is to be submitted. Fund requests are reviewed and approved by the Interim Vice Chancellor for Research.

Copy editing services are also provided by the Office of Research, and can be requested via e-mail to Jane Poulos (jpoulos@uthsc.edu). Requests are reviewed by the Interim Vice Chancellor for Research.

For more details, please see:
http://www.uthsc.edu/research/research_resources/editing_services.php

Grant Incentive Funding

Grant Incentive Funding is available in the amount of $25,000 or less to UTHSC faculty who have recently submitted a new R01, R15, R21, or equivalent grant, were not funded, but received a percentile score of 30 or less. A Principal Investigator who meets the Grant Incentive Fund criteria should submit an application to the Office of Research. An internal review committee will evaluate applications and make recommendations to Dr. Larry Pfeffer, Interim Vice Chancellor for Research.

The deadline for applications is **December 30, 2014.** For more details, visit: http://www.uthsc.edu/research/research_resources/docs/Grant_Incentive_Program_Guidelines.pdf

Bridge Funding

The Office of Research encourages faculty to apply for Bridge Funding. Funding is currently available to individual applicants in $75,000 or less. Any full-time faculty member, tenured or tenure-track, who is a principal investigator on a grant funded for at least three consecutive years by a national funding agency (e.g., NIH, NSF, American Heart Association) and whose application for continued support from that or another national funding agency has not been funded, shall be eligible for Bridge Funding. This funding is intended to provide University of Tennessee Health Science Center faculty members with temporary, reduced support in order to retain key personnel and continue laboratory or research operations while full support is being sought from outside agencies.

Deadline for applications is **December 15, 2014**. For details regarding eligibility and the application process, go to: http://www.uthsc.edu/research/research_resources/bridge_funding/

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