

The Research Notebook

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Dear Colleagues,

As the New Year begins, it is a great time to review and check on adherence to research compliance as it relates to our individual research programs. And, it is not so much that we as PIs know our protocols and regulations, but also that our research staff are informed about the details of and are following approved protocols.

Less than a year ago my lab was cited for having animals in the lab for longer than approved in our protocol. We were not thumbing our noses at the policy, but one of the trainees was unaware of the time-in-lab limit. It was easier for him to bring up a batch of mice on Monday and care for them in the lab rather than go down to the facility multiple times in a week. Let me be very clear here, the person at fault was me and not him. It was my responsibility as PI to be sure all were informed and following our approved protocols and policies related to animal handling. To make sure we were not in violation again, we began having short discussions/information pieces on protocols related to animals in our lab meetings. As an aside, out of that grew some very helpful discussions about anesthesia and surgical technique between everyone in my lab.

It should also be noted that compliance with lab animal protocols is not the only area in which research staff can be ill-informed, or protocols subtly or not so subtly change with time. Ensuring compliance with animal, human, and biosafety protocols is the PI's responsibility.

Some of the more common violations related to IRB protocols:

- Failure to properly document the informed consent of subjects, e.g., not securing all the required signatures, failing to retain signed consent forms, or failing to note in the medical record that consent occurred before any research procedures were performed.



Dr. Polly Hofmann

(Continued on page 2)

Research Update (cont.)

- Failure to request IRB approval for all minor changes in the research activity, e.g., accrual of more subjects than initially approved, addition of a research site, or a change in the manner or amount of payment for participation.

Some of the common problems that occur with animal studies are:

- Conducting activities that have not been previously approved by the IACUC. This type of noncompliance can result from not knowing that virtually all animal activities should be previously approved, or thinking that activities were approved when they were not.
- Conducting activities, such as the ordering of animals, under the auspices of one protocol/grant that are actually part of another protocol/grant. This type of noncompliance can result from inadequate information dissemination by the PI or lab members' not following the PI's instructions.

So take a moment to review these issues and, more importantly, your specific protocols with your staff. Please make sure all are on board and following what has been approved. I believe as researchers we should be leaders in advocacy for compliance with animal and human protocols and regulations . . . starting with compliance in our own research.

Happy New Year and may your research advance by leaps and bounds in 2013,
Polly

Polly A Hofmann, PhD
Senior Associate Vice Chancellor of Research

Congratulations to:

- Jeanne Hermann, Director of Electronic Research Administration in the Office of Research, in completing her PhD in Management Information Systems through the University of Memphis.
- Jane Poulos, Senior Business Manager in the Office of Research, for being named a finalist for The Chancellor's Exempt Staff 2012 Employee of the Year.

Congratulations! 

Gene Expression Analysis Available

The J.S. and Bobbi Allen Gene Expression Analysis Laboratory is located in the CRB room 171 and is a fee-for-service facility. The facility includes a Nanostring nCounter gene expression analysis system, which is designed to provide an ultrasensitive, reproducible, and highly multiplexed method for detecting gene expression across all levels of biological expression. This assay provides a method for direct labeling of mRNAs and miRNAs with molecular barcodes called nCounter Reporter Probes without the use of reverse transcription or amplification. The assay can be run on total RNA isolated from any source, including formalin-fixed paraffin embedded (FFPE) samples. For further information on the capabilities of the instrument and technology, please go to the NANOSTRING website. (<http://www.nanostring.com/>).



The following fee schedule applies for UTHSC researchers:

Usage

- For miRNA. Total cost is \$3,360 for analysis of 12 samples on a human miRNA V2 assay (\$280 per sample), which includes a \$50 per sample processing fee.

- For mRNA. There is \$25 per sample processing fee plus the cost of the kit. The cost of kits for analysis of 12 samples varies. For example, the total cost for human cancer-related gene panel kit (230 genes) is \$2,200 for 12 samples. The total cost for human kinase gene panel kit (500 kinase genes) is \$2,900 for 12 samples. Please contact Lawrence Pfeffer for the total cost of other kits (lpfeffer@uthsc.edu)

At least 5µl of total RNA at 40-50 ng/µl is required for profiling.

Payment for usage fees will be made via transfer vouchers through the CRB into an E-account designated for maintenance of the Nanostring nCounter system.

All users will be required to provide an active R- or E-account to which charges can be assessed.

For more information, please contact Dr. Lawrence Pfeffer (lpfeffer@uthsc.edu).

Cancer Center Initiative Awards

The cancer center initiative launched by the collaboration of The West Clinic, Methodist Healthcare, and the University of Tennessee Health Science Center (UTHSC) has the goal of advancing cancer care, education, and research for the patients we serve in Memphis, the Mid-South, and beyond. Recently, to further the research mission of the cancer center, the partners announced \$200,000 in research grants awarded to four cancer investigators at UTHSC. While this is just a small part of the \$35 million over seven years that the partners have committed to cancer care and innovation on many levels, these grants are an important step.

The following grants provide seed money for new projects involving partnerships between basic/translational investigators and clinicians:

- **Lawrence M. Pfeffer, PhD: *The role of microRNA-21 in human melanoma***
- **Zhaohui Wu, MD, PhD: *Sensitize breast cancer to chemotherapy by inhibiting NF-kB with PARP inhibitors***
- **Tiffany Seagroves, PhD: *The Hypoxic Response as a Driver of Triple Negative Breast Cancer Phenotypes***

Dr. Deborah Smith Named IAAP Executive of the Year

Dr. Deborah Smith, Associate Vice Chancellor, Research Administration, was named the 2012 Executive of the Year by the Memphis chapter of the International Association of Administrative Professionals (IAAP). The IAAP is a not-for-profit association founded in 1942 for office professionals, with approximately 40,000 members and affiliates and nearly 600 chapters worldwide. The Memphis Chapter is the largest of 18 chapters in Tennessee, with over 120 administrative professional members.



Dr. Smith was nominated by Ruthie Ruston, Grants and Contracts Specialist in the Office of Research Administration. There were several executives nominated at the annual Memphis Chapter IAAP event held in October (on National Boss' Day). In addition, Dr. Smith was the first woman to receive this award in the Memphis Chapter's history. Please join us in congratulating Debbie for earning this prestigious award!

Ruthie Ruston, Dr. Deborah Smith, and Rita Jackson, IAAP Chair

Resources Available for Proposal Development



The Office of Research offers many resources which can be found at the side link "Research Resources" http://www.uthsc.edu/research/research_resources/ located within the Research website. Following are a few of these resources:

- Grant consulting - Dr. Israel Goldberg and staff with Health Research Associates, Inc.. For details, go to: http://www.uthsc.edu/research/research_resources/consulting.php
- Copy editing services – visit: http://www.uthsc.edu/research/research_resources/editing_services.php
- Bridge funding is also available if needed. See: http://www.uthsc.edu/research/research_resources/bridge_funding/

Grant Consultant Available to UTHSC Faculty

As a reminder, Dr. Israel Goldberg of Health Research Associates, Inc. is available to assist UTHSC faculty with grant-writing needs. In his previous presentations here on campus, Dr. Goldberg has addressed funding issues related to clinical, basic science, and translational research. We have feedback from a number of our faculty members who felt the previous consultation visits were very beneficial, assisting with approximately \$20 million in anticipated funded grants to the University.

In addition to his visits to campus, Dr. Goldberg is accessible to faculty via long-distance consultation based on available contractual time. To take advantage of this service, e-mail **Dr. Polly Hofmann** at phofmann@uthsc.edu to obtain a request form. Please send any comments regarding your experience with Dr. Goldberg to Dr. Hofmann so we can continue to improve the service he provides to UTHSC.

UTRF Announces 2013 Maturation Fund Recipients

The University of Tennessee Research Foundation (UTRF) Health Science Center office has awarded four teams of inventors in its annual Maturation Funding program. Each team will receive \$15,000 to assist in further developing the technology to improve positioning for licensing and commercialization. Eight award were made state-wide.

“Over the past 5 years UTRF Maturation Grants have led to a number of successful deals, so we have high hopes in this group of investigators,” said UTRF Vice President Richard Magid.

Recipients awarded by the UTRF Health Science Center office include:

- **Renukadevi Patil**, Ph.D., UT Health Science Center, Department of Pharmaceutical Sciences, for further development of novel compounds to treat cancer;
- **Monica M. Jablonski**, Ph.D., UT Health Science Center, Department of Ophthalmology, for nanoparticles to provide extended release drug delivery in the eye for the treatment of glaucoma;
- **Yu Liu, Ph.D. and Randall J. Nelson**, Ph.D., UT Health Science Center, Department of Anatomy and Neurobiology, for clinical trial support for a portable hand rehabilitation device;
- **Tayebeh Pourmotabbed**, Ph.D., UT Health Science Center, Department of Microbiology, Immunology, and Biochemistry, for further development of a novel DNzyme as a new therapy to treat cancer.

The program was open to all University of Tennessee campuses and institutes. The selection process included evaluation of three key areas: (1) demonstration of a path for commercial development, (2) market potential, and (3) stage of development.

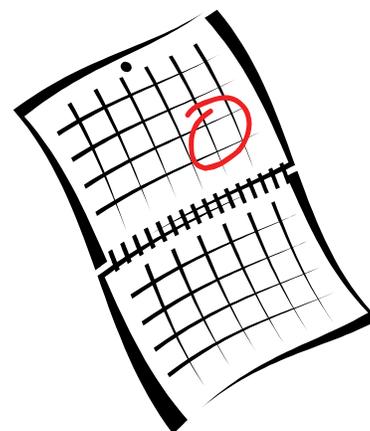
As part of the award process, UTRF will receive interim and final reports from the researchers that will describe increased knowledge and improvements in the subject technology. This information is expected to assist UTRF in better positioning the technologies for licensing.

A call for submissions for next year’s Maturation Funding Program will be announced in October 2013.



How to Post Seminar and Conference Information

Do you have a seminar or conference you would like to have listed on the UTHSC Research home page? Enter the seminar or conference details on the campus calendar through this web interface <http://events.uthsc.edu/events/index.php?com=submit> and choose *Research* as one of the Event Categories. Your seminar or conference will automatically be added to the UTHSC Campus home page calendar as well as the Office of Research home page calendar.



Office of Research Administration

NSF - To Apply or Not to Apply?

NSF generally does not fund medical or health-related research. Faculty who are planning to submit proposals to NSF should carefully read the NSF Proposal Guide (http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/gpg_1.jsp#IB) and be sure that the project you are submitting meets their funding goals. The following is an excerpt from that guide (emphasis added).

*NSF does not normally support technical assistance, pilot plant efforts, research requiring security classification, the development of products for commercial marketing, or market research for a particular project or invention. **Research with disease-related goals, including work on the etiology, diagnosis or treatment of physical or mental disease, abnormality, or malfunction in human beings or animals, is normally not supported. Animal models of such conditions or the development or testing of drugs or other procedures for their treatment also are not eligible for support.** However, research in bioengineering, with diagnosis- or treatment-related goals, that applies engineering principles to problems in biology and medicine while advancing engineering knowledge is eligible for support. Bioengineering research to aid persons with disabilities also is eligible.*

You are encouraged to target your proposal to the funding organization. However, if it's medical or disease-oriented, NIH or one of the health-related foundations may be a better choice than NSF.

Routing Proposals for Private Sponsor Funding

There seems to be some misconception that proposals to private sponsors should not be routed unless they are funded. In fact, all proposals should be routed in PAMS for departmental, college, and institutional approval **prior** to submission to the sponsor. Letters of intent, however, do NOT need to be routed through PAMS unless (1) an institutional signature is required or (2) a budget is required.

This applies whether the application is submitted in paper form, via e-mail, or on a web site.



New ATCC Contract

The University of Tennessee has recently signed a new master agreement with ATCC. Existing customer accounts should not be affected. The UT Customer # is 10670. Please contact ORA if you have any problems in obtaining materials from ATCC under the new agreement.

MTA Follow-up

Some of you may have noticed over the past several months that ORA is attempting to close out some old MTA files. You may have been contacted by Carlisa Smith, asking for information about your MTAs, or, if you are a department head, about MTAs for faculty in your department who have left UTHSC.

ORA has no way of knowing when material is received, when a project is complete, or when material is used up in the course of research. We retain records for as long as the contract indicates, then follow up to see if there is a reason for retaining the records further. If the material was never received, or has been destroyed or used up in the course of the research, we can close out the file.

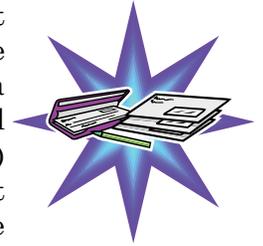
When faculty leave UTHSC, we try to pull all of their active grant and contract files (including MTAs) to ensure that they are properly closed out. However, in some cases, people leave without our ever knowing what happened to materials in their labs.

We appreciate your cooperation in responding to the best of your knowledge with regard to materials you may have received under an MTA.

Office of Research Administration

Grant Close-out Procedure

We are always excited when we receive new grant funding, but sometimes find it a burden when the project is complete and those nasty close-out documents must be filed. Most sponsors (NIH, in particular) will require three final reports when a grant ends: (1) final financial report; (2) final progress report; and (3) final invention report. The office of Sponsored Projects Accounting (Gerri Bussell's office) will complete the final financial report, but they need the PI and department business manager to be sure that all appropriate charges have been made to the account prior to close out. The PI is responsible for the final progress report, which, in the case of NIH, is submitted via eRA Commons. Both the PI and ORA are responsible for the final invention report, which also is submitted via eRA Commons. The PI should indicate in Commons whether any inventions arose from the project and, if any, list them. ORA will review the report, enter the date(s) on which the inventions were reported to the NIH; and complete the submission. Or if no inventions were reported, ORA will confirm and submit the report. All final reports are due within ninety (90) days of termination of the grant.



Please read your grant notices of award carefully for information on filing close-out reports and be sure to submit them timely. PIs are also reminded that they must comply with the NIH Public Access Policy, which requires that all peer-reviewed manuscripts arising from NIH funding must be submitted to PubMed Central. Additional information is available at <http://publicaccess.nih.gov/>.

Uncertain Extramural Budgets

At press time, the recent Congressional action regarding budgets had just occurred, and it is yet unclear as to the impact on extramural funding. Most NIH awards that UTHSC has received during the current federal fiscal year have been funded at around 90% of the recommended amount; however, we have received some NIH notices of award for non-competing grants with only six months of funding and a note that the budget will be adjusted after the federal budget is finalized. While we are optimistic that the grants will ultimately be funded at the recommended amount, we urge investigators to spend judiciously.



Outside Interest Disclosure & CITI Conflict of Interest Training Requirements

Faculty and others involved in sponsored projects are encouraged to complete the new Outside Interest Disclosure forms required as of August 24th (See UTHSC Fiscal Procedure F125 http://www.uthsc.edu/policies/w932_document_show.php?p=155) and to complete the CITI Conflict of Interest training module (http://www.uthsc.edu/research/research_compliance/OHSP/register.php). Both are required for all documents routed in PAMS. In order to avoid delays in signatures on grants, research agreements, and other documents (including CDAs and MTAs), please be sure that these requirements have been met prior to submission.

Location Entry in PAMS - Off-Campus Studies

For off-campus studies, please be sure that the location selected in PAMS matches both the location indicated on the grant proposal and the F&A rate. Off-campus locations in the state should be listed under "In-State County Locations"; then, choose the county and identify the facility. E.g., if work is being done at the MED, choose Shelby County and The MED. UT does lease space in some facilities that would otherwise be considered off-campus; e.g., VAMC, UHS, LeBonheur. However, if the work is not being done in UT-leased space, do not select the on-campus location at that facility. If work IS being done in UT-leased space, you should use the on-campus F&A rate.

Contact List



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vacant	IBC Admin Res Asst	448-2871
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