

The Research Notebook

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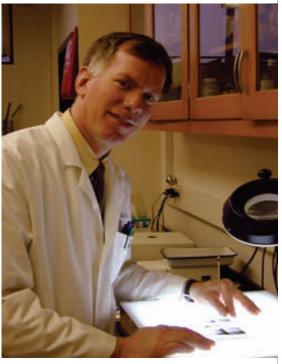
Inside this issue: Thomason heads MRC Τ Research Subjects and Medicare Coverage THA Fall Compliance Conference Chattanooga Vascular Surgery Fellowship Memphis Clinical Trials *Update* Electronic Grant 3 Submission Grant Close-out 3 **Grant Supplements** 4 Subawards 5 OHSP Update Electronic IRB 5 AAALC Site Visit 6 Occupational Health and Safety 6 On-line AALAS Courses Animal Facility Update 7 Microscope Maintenance and Repair 8 FAQs

Special points of interest:

- AAALAC Site Visit Scheduled
- Supplemental Grant Funding

Thomason to Head the Molecular Resource Center

Donald B. Thomason, Ph.D., has been appointed as the new Executive Director of Molecular Resource Center (MRC). Thomason, a Professor the Department in Physiology, was appointed to the position by Dr. Leonard R. Johnson, Vice Chancellor for Research, after being identified by the MRC Internal Advisory Board, which served as search committee for the process. Thomason replaces Daniel Goldowitz, Ph.D., who has accepted a position at the University of British Columbia. Thomason also currently serves as Associate Dean for Student



Affairs in the College of Graduate Health Sciences and has been with UTHSC since 1990 when he joined as an Assistant Professor. Trained as a muscle physiologist Thomason's research interests include, skeletal muscle adaptation and repair, potassium uptake and homeostasis in muscle and, more recently, insulin resistance in skeletal muscle. The MRC, located in the new Cancer Research Building, is one of three THEC centers on campus and is funded as a line item in the state budget. It provides a variety of resources and services to investigators, including DNA sequencing, RT-PCR and RNA quantification. A new Drosophila Transgenic Core encourages investigators to utilize genetic screening tools to examine how individual mutant genes may play a role in disease. The MRC is also an important component of the UT Clinical Translational Science Institute; the CTSI grant that will be submitted to NIH this November. Dr. Thomason brings a great deal of scientific expertise and organizational ability to the MRC, and we are delighted that he has accepted its directorship.

New Medicare Changes for Research Subject Coverage Proposed

On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs ... and costs due to medical complications associated with participation in clinical trials." CMS is now defining the routine costs of clinical trials and identifying the clinical trials for which payment for such routine costs should be made.

The <u>proposed Clinical Research Policy</u> will require principal investigators to submit a letter of self-certification to CMS prior to initiation of a study (for which payment will be sought). Self-certification requires the study be listed on the CMS website, the Federal Register, or <u>ClinicalTrials.gov</u>. In addition this Policy proposes the following standards:

- The research study has a written protocol.
- The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals.
- The clinical research study is registered on the ClinicalTrials.gov website.
- The research study protocol specifies the method and timing of public release of results.
- The research study protocol must explicitly discuss subpopulations.
- The research study protocol must discuss how the results are to be generalized to the Medicare population.

The Final National Coverage Determination will be made on October 17, 2007. Look for more details on how this may impact your submissions to the IRB.

Tennessee Hospital Association Fall Compliance Conference

The Tennessee Hospital Association Fall Compliance Conference, sponsored in part by the UT College of Medicine, Chattanooga, will be held in Chattanooga October 18th and 19th. Program and registration information can be found at http://www.tha.com/pdffiles/compliance-2007-workshop.pdf. Topics will cover current and emerging fraud trends in Tennessee, coordination between entities regarding health care fraud investigations, and case examples. Registration concludes on October 10th.



Chattanooga Vascular Surgery Fellowship Program Approved

On August 27, 2007, the Accreditation Council for Graduate Medical Education and its Surgery Residency Review Committee approved a new Vascular Surgery Fellowship Program for its initial accreditation. The UT COMC program will begin July 2008. Richard Sprouse, MD, will direct the two-year program, sponsored by the UT COMC Department of Surgery. Physicians entering the fellowship program must be board eligible in general surgery and must have completed a Surgery Residency Program prior to beginning the fellowship. The program will offer two positions, one at each level.

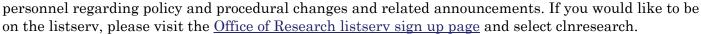
The Surgery Residency Review Committee, "Commended the program for its demonstrated substantial compliance with the ACGME's Requirements for Graduate Medical Education without citations." Congratulations to Surgery department chair, Dr. R. Phillips Burns and to Dr. Sprouse.

Office of Research Administration

Memphis Clinical Trials Update

On September 7th, ORA and its Clinical Trials Office bade farewell to Linda Seely, who retired from UT to return to her home state of Wisconsin. We wish her well in her new ventures.

Until a new Associate Director is identified, Dr. Deborah Smith will be handling contract negotiations. Connie Bozant and Chevella Oliver will assist with follow-up and communication with sponsors and trial personnel. We ask your patience during this period of transition. A clinical trial listserv has been set up to facilitate communication with clinical trial





Electronic Grant Submission

Remember that electronic grant submissions for the October and November deadlines will continue to use the PureEdge software for Windows or Citrix for Mac users. Transition to Adobe has been delayed by Grants.gov and will not occur until after the fall deadlines.

Please be sure you have the latest version of the PureEdge package and/or the RFA/RFP/PA to which you are responding.

Also, remember that the complete, final version of the electronic package routing is due in Research Administration five (5)working days in advance of the agency deadline. You may e-mail the package egrants@utmem.edu or, if the grant is too large to send via e-mail, send a message to that address requesting a URL

where you can post the grant for our retrieval. If your deadline is some time other than the standard deadlines, please give us a heads-up to ensure on-time submission; be sure to put the deadline on the routing sheet.

For additional information about the UTHSC process, please visit the Office of Research Administration web pages.

Grant Close-out: Electronic Close-out is Best

When a grant terminates due to expiration of funding from the sponsoring agency or transfer of the principal investigator to another institution, the PI and the institution are required to submit closeout documents. For NIH grants, three documents are required: (1) the final financial statement (FSR), which is prepared by the Sponsored Programs Office (Gerri Bussell) in conjunction with the departmental business

manager; (2) the final scientific report, which is prepared by the PI; and (3) the final invention statement, which is prepared by the PI and approved by the Office of Research Administration (Debbie Smith). For most NIH grants, all of these reports can be submitted via NIH Commons. It is recommended that if the grant is listed for close-out in Commons that the final scientific (progress) report and the final invention

statement be submitted electronically. In recent months, we have received requests from NIH for close-out documents for grants terminated as long as five or more years ago and for which reports were submitted; but the NIH close-out office could not locate copies. Completing the documents via Commons should ensure that they will be available to the NIH, the PI, and the institution later.

Supplemental Grant Funding Opportunities

All faculty who have existing grants, specifically NIH R01s or other federal grants eligible for supplemental funds, are encouraged to review the applicable guidelines and apply for such supplements. Many of these supplements provide funding for underrepresented or disadvantaged individuals to participate in existing funded projects via additional funds awarded for a related project. Below are some samples of supplements that are available:

Supplements to Promote Reentry into Biomedical and Behavioral Research Careers http://www.nlm.nih.gov/ep/grantsupreentry.html

NIDDK T32 Minority Supplement Program http://www2.niddk.nih.gov/Funding/TrainingCareerDev/T32MinoritySupp.htm

Research Supplements to Promote Diversity in Health-Related Research http://grants.nih.gov/grants/guide/pa-files/PA-05-015.html



Research Grant Subawards

Research grants and often contracts involve collaboration of two or more academic and/or research institutions and mav require subawards once the grant/contract is funded. In some cases. UTHSC is the prime awardee; in other cases. UTHSC is the subawardee. Please remember that all proposals involving subawards must bе approved b v both institutions prior to the submission of the proposal to the agency. In cases where UTHSC is the prime awardee, an institutional letter of support is required along with the grant

application when it is In cases routed. where UTHSC is the sub-awardee. the UTHSC portion of the grant must be routed so that we can provide a support letter to the prime awardee institution prior to submission to the agency. The PI will need to allow additional time collaborator institution support letters when preparing a timeline for the proposal preparation. budgets Subaward must include personnel salary and fringes (if allowable), other costs required complete $_{
m the}$ project (equipment, supplies, etc.),

and applicable institutional F&A. If you have questions about subawards, please send your question to egrants@utmem.edu.



Office of Research Compliance

Office of Human Subject Protections

OHSP recently said goodbye to Janie Gardner who has retired from UTHSC after over 20 years of dedicated service. During the past few years, Janie has been instrumental in organizing several multi-day symposia on various topics pertinent to research involving human subjects. These educational experiences brought together nationally known speakers and our local research community to learn from each other. Sherry Brewer, who represented OHSP in Knoxville at the Graduate School of Medicine (GSM) has also left her position to explore new horizons. Sherry used her training as a lawyer not only to benefit the human subject protection program but also to assist GSM in other areas that had a need for her expertise. Both will be sorely missed as their replacements are sought.



Electronic IRB Nearing Completion

The project to convert the IRB application and review process to a fully electronic, webbased system is nearing completion. Over the past 18 months, the staff of the UTHSC IRB has joined with Research Administration Informatics personnel to adapt the iMedRIS research data management software to the needs of the IRB. During the fall months, the system will be placed on a test server and its use by selected research groups in key clinical departments will

permit additional evaluation and fine-tuning of its operation. Implementation of the system for all clinical investigators will occur at the beginning of 2008. The new IRB application forms will involve answering a series of objective questions, attaching pertinent documents, and submitting all items electronically. Most of the narrative components of the old application will be eliminated,. Applicants will be guided through

the process by the computer program to assure that all relevant questions are answered, and the preparation of paper copies of submitted document will no longer be necessary. The exclusive use of electronic communications between the IRB and investigators will further enhance the speed and efficiency of the review and approval process.

While the new application system undergoes final testing, construction is under way on an electronic conference room that will host IRB meetings. The electronic conference room will include thin clients at each work station for the paperless review of applications,

voice and video conferencing capabilities for interacting with investigators, projection screens for reviewing key documents, and built-in equipment for recording committee proceedings. Completion of the conference room is expected by the beginning of 2008 and will coincide with full implementation of the electronic application process.

Plans for training of all key research personnel in the use of

electronic system will be announced later in the fall, once the date for its implementation is finalized.



AAALAC Site Visit Scheduled for November 13th and 14th

UTHSC will be visited on November 13-14 by a team from the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. UTHSC's animal care and use program historically has been re-accredited every three years. During this year's visit, members of the site visit team will talk with members of the Institutional Animal Care and

UTHSC Use Committee, and administrators, our scientific community. Thev also tour research laboratories as well as animal facilities. For information about what might be expected during laboratory visits, please contact Mary Frances Braslow in the Office of Research Compliance at 901-448-3904 or via email at mbraslow@utmem.edu.



Occupational Health and Safety

When contacted by the Occupational Health and Safety (OHS) Coordinator and asked to participate in follow-up screenings, we strongly encourage you to complete this follow-up at your earliest convenience. These follow-up sessions are the second part of our Occupational Health and Safety program and are

designed to provide you with the opportunity to receive the health screenings, medical assessments and training that you need to safely and effectively carry out your work involving the use of animals in research and teaching.

Failure to complete this portion of the program will result in access to animal facilities being inactivated. Completion of the screenings will help ensure that our research programs, and especially those involving animals, are safe, effective and productive.

On-Line Educational Opportunities

UTHSC has purchased enough memberships to the American Association Laboratory Animal Science (AALAS) Learning Library for all those who work with animals to have access to the 120 on-line courses over available. Courses range from those covering relatively general matters of regulatory compliance to species-specific and technique-specific presentations designed to provide easy access to information about best practices

research and animal care. Current federal regulations require that the IACUC be able to determine that investigators have been



trained and have the expertise conduct the proposed studies. On-line educational opportunities, and the certificates of completion that they generate, serve as an efficient means to obtain this documentation. You encouraged to contact Mary Frances Braslow in the Office of Research Compliance at 901-448-3904 or via email at mbraslow@utmem.edu obtain the web address, a username, and a password for the AALAS Learning Library.

Research Support Services

Regional Biocontainment Laboratory and Nash Animal Facility Renovation Construction Update

On or about January 2, 2008, Inman Construction, the general contractor for the Regional Biocontainment Laboratory, will begin demolition for access to the Nash Annex. This phase of the project will include making an opening in the exterior wall of the Nash Annex for RBL demolition access and certain interior walls and floors in the containment area and soiled side of the cage wash in the Nash building. The area affected is the northwest corner of the Nash Annex animal facility. The demolition should be complete within 30 days of the start date and all of the Nash Annex remodeling should be completed within 90 days. During this demolition phase

there will be unavoidable noise and vibration that will likely affect the first floor of the Nash Annex animal facility. We are working closely with the contractor to minimize the actual demolition time and amount of disruption.

A separate animal facility renovation project will also begin around the same time. That project will involve replacement of the Nash tunnel washer, leveling of animal room floors in the distribution area, electrical modifications in animal rooms. and renovation of certain animal rooms in the Coleman building. As soon as contractor has been identified, this work will be coordinated with the RBL construction

manager to occur within the same time frame as the Nash containment area demolition and renovation.

A town hall meeting will be scheduled in the near future to provide information on the RBL and Nash Annex construction project, as well as information on the RBL operations.



Microscope Repair and Maintenance Services

Biomedical Instrumentation provides services to assure that the sophisticated scientific instruments and computer systems on campus function in top form. Biomedical Instrumentation provides a variety of services including computer enhancement, maintenance and repair, scientific instrument design, fabrication and repair, machine shop facilities, electromechanical design, and optical instrument service and repair. The microscope repair unit offers services unique among UT's peer institutions as well as to the city of Memphis:

- Service and repair of most makes and models of laboratory microscopes.
- Preventive maintenance for a flat fee to ensure savings of time and money
- Customer service reports
- Replacement lights and specialty bulbs
- Only local provider of optical services in greater Memphis area

Mr. Glen Dawkins, a certified Olympus service provider, has over 25 years of optical repair experience. He can be reached at 901-448-5267 for a quote or additional information.



Frequently Asked Questions

Did You Know?

Research Administration

Q: When submitting an electronic grant application, is it okay if I send a partial package to Research Administration by the internal deadline date and then send additional sections later, to allow more time for me to write/review/correct the scientific sections or get collaboration letters, etc.?



A: No. If the package is not complete and in final form by the internal deadline date, wait until it is final to send it to ORA. The risk is that you may miss a deadline. On any given deadline, ORA has many grant applications, and does not have sufficient time to review two or three versions of each nor, unfortunately, is there time to insert the various scientific portions in the proper places of the package without neglecting review of other grants proposals that have been submitted correctly.

Q: How do I know if I have the correct grant application package?

A: The best way to be sure that you have the latest version of the grant application package is to go to either grants.gov or the agency web site and pull down the package from there. Attempting to "revise" a package that was submitted earlier is risky since: (1) the package and/or some of the imbedded forms may have changed; and (2) you may forget to make changes on some pages and submit forms or data that have not been updated.

Clinical Trials Unit

Q: Who is handling negotiations for industry-sponsored clinical trials?

A: Debbie Smith is handling negotiations until a new Associate Director is named to fill the position vacated by Linda Seely.

Q: Who do I contact to follow up on an industry-sponsored clinical trial document?

A: Please contact Chevella Oliver at 901-448-3126 to inquire about the status of these documents. She will coordinate with Debbie Smith and/or Connie Bozant to determine the status and provide a response. Please provide the name of the PI, name of the coordinator, name of the sponsor and/or CRO, and protocol designator.

Institutional Review Board

Q. My research project has been declared exempt by the IRB, and I have a letter that I need to include with a grant application indicating the exemption number. Can I mark "no" to the human subjects question and still include my exemption letter?

A: No. If you are conducting research that has been declared exempt, you must mark "yes" to the human subjects question on the NIH grant application package, then include UT's FWA# and the IRB exemption # and approval date.

Frequently Asked Questions (cont.)

Research Compliance

Q: If I'm using human cell lines purchased from a commercial vendor, why must I obtain IRB approval to have them declared exempt from human subjects protection regulations? Federal regulations protecting human subjects research (i.e., 45 CFR Part 46) clearly state that the use of cell lines purchased from commercial vendors such as the American Type Culture Collection is not considered to be human subjects research. Neither is research that involves cells from a donor whose identity cannot be readily ascertained by the investigator (http://grants.nih.gov/grants/policy/hs/faqs-specimens.htm#Q1). However, the Office of Human Research Protections (OHRP) states that investigators not be given the authority to make an independent determination that human subjects research is exempt but should consult with the appropriate institutional authority to help make that determination. University policy has assigned that authority to the Chair of the IRB. Investigators should contact the IRB office for help in completing the single page form used in establishing that cell lines are exempt from consideration as human subjects research.

Q. How can I receive approval of my protocol or registration more quickly?

Investigators may request a pre-review of their animal use protocol or their IBC registration. Pre-reviews are conducted by members of the appropriate compliance committee. They may involve the Institutional Biosafety Officer when required. There are several things to keep in mind regarding pre-reviews. First, they must occur prior to the deadline for submission, which usually means a week or two before protocol deadlines. Second, they represent the views of the reviewer; additional clarification may be requested once the protocol is discussed in committee. Third, they are most effective when the investigator has undertaken significant preparation of the protocol prior to requesting the pre-review. Please contact the support staff of the appropriate compliance committee for details about requesting protocol pre-review.

Research Resources

$oldsymbol{Q}$: Who should we call to relocate our lab equipment: Biomedical Instrumentation or the UT Movers?

A: Both. Biomedical Instrumentation's role in relocating lab equipment is to prepare the equipment for moving by performing tasks such as disconnecting gas lines, draining water jacketed incubators, locking down balance mechanisms, and advising the UT Movers of any necessary precautions that should be taken with a particular piece of equipment during the move. Adequate notice must be received prior to the move for Biomedical Instrumentation to complete these tasks in coordination with the UT Movers.

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