

The Research Notebook

A Publication of the Office of Research

VOLUME 4 ISSUE 1

JANUARY 2009

Inside this issue:

<i>Gerwin Imaging Center Opens</i>	1
<i>Ethics Symposium Held</i>	2
<i>UTRF Honors Patent Recipients</i>	3
<i>Export Control Policy</i>	3
<i>K12 Scholar Grants</i>	4
<i>Clinical Research Certificate Program</i>	4
<i>Translational Application Submitted</i>	5
<i>Innovation Conference</i>	7
<i>Database Available</i>	8
<i>Postdoc Travel Award</i>	9
<i>Adobe and Grants.gov</i>	10
<i>Sending/Receiving Biological Materials</i>	10
<i>IRB Consolidation</i>	11
<i>OHSP Schedule</i>	11
<i>FAQs</i>	13
<i>Contact List</i>	15

Gerwin Small Animal Imaging Center Opens

The Center for Cancer Research is pleased to announce the grand opening of the Gerwin Small Animal Imaging Center in the Cancer Research Building. The goal of the imaging center is to provide UTHSC investigators and external users with a state-of-the-art system capable of measuring luciferase or near-red/infrared fluorophore signals generated from cells implanted into rodents.



Dr. Tiffany Seagroves and Dr. Lawrence Pfeffer in the Gerwin Small Animal Imaging Center..

The Caliper Life Sciences/Xenogen IVIS Lumina imaging workstation is the gold standard in small animal imaging preclinical research, with hundreds of cited publications (<http://www.caliperls.com/products/optical-imaging/>). The IVIS Lumina system includes a highly sensitive CCD camera, a light-tight imaging chamber, filter sets capable of detecting emission spectra from 515-805nm and complete automation and analysis capabilities through the LivingImage software package. The workstation was recently purchased with the generous support of the Gerwin and Muirhead Endowments in conjunction with funds from the United States Department of Energy and the UTHSC Department of Pathology. A XGI-8 isoflurane gas anesthesia module is built into the bio-imager cabinet and is capable of simultaneously anesthetizing 3 mice or 1 rat. The average imaging time of live, anesthetized rodents is under 5 minutes per run, providing high throughput analysis of cohorts.

Use of the Xenogen system will provide investigators with a technology that reliably and reproducibly tracks cell growth and/or metastasis in live whole animals over time without the need to sacrifice animals at intermediate time points to locate the cells. Other applications include calculation of tumor volume before and after drug treatment, *ex vivo* imaging of various tissues post-animal sacrifice to confirm location of cell signals, or the ability to rapidly quantitate changes in fluorophore or luciferase reporter expression in cells that are cultured in standard microplates.

The imaging center will operate as a fee-for-service recovery center under the auspices of both the Office of the Vice Chancellor of Research and

(Continued on page 2)

Gerwin Small Animal Imaging Center Opens (Cntd.)

(Continued from page 1)

Dr. Lawrence Pfeffer, Muirhead Professor of Pathology and Director of Research for the Center for Cancer Research. Questions regarding use of the imaging center and experimental design may be directed to Tiffany N. Seagroves, Ph.D., Assistant Professor of Pathology, service center director (Room 122 CRB, 448-5018, tseagro1@utm.edu). The general fee structure through June 30, 2009 will be \$125/hr for equipment training or use, \$10/hr for use of the anesthesia module and \$100/hr for consultation after 1 hour of complimentary consultation with Dr. Seagroves. The core will provide at a substantial discount sterile aliquots of the luciferin reagent necessary to activate the luciferase signal prior to bio-imaging. In addition, the UTHSC Viral Vector Core has developed lentiviral constructs that express the next generation luciferase (Luc2), which will be available for purchase in the near future in order to assist investigators with modifying cells of interest to use with the Xenogen technology.

Investigators who are interested in using the Gerwin Small Animal Imaging Center at the CRB must meet requirements for housing animals in the CRB facility, receive approval from the UTHSC IACUC to include animal imaging procedures in their relevant animal protocols and receive training in use of the anesthesia module by Lab Animal Care Unit (LACU) staff. Questions regarding animal housing status may be directed to Scott Jackson, DVM or David Hamilton, DVM of the Lab Animal Care Unit. Questions regarding changes to animal protocols may be directed to either Timothy Mandrell, D.V.M., Director, LACU and Chair of Comparative Medicine, or to Thad Nowak, Ph.D., Department of Neurology, IACUC Chair.

Symposium on Scientific Integrity and Prevention of Research Misconduct Held

A one-day conference highlighting scientific integrity and prevention of research misconduct was held on the Memphis campus of UTHSC December 4, 2008. Speakers for the event were Dr. Greg Koski, Associate Professor of Anesthesia at Harvard Medical School and Senior Scientist, Institute for Health Policy, Massachusetts General Hospital, and Dr. Cynthia Ricard, Director of Extramural Research, Division of Education in Integrity, Office of Research Integrity, US Department of Health and Human Services.

Topics discussed included Scientific Integrity, Mentoring in Research, Conflict of Interest, Scientific Misconduct, and Vulnerability in Research and Informed Consent.

Over 100 people attended the symposium, including faculty and staff from UTHSC, St. Jude Children's Research Hospital, The University of Mississippi, Arkansas State University, The University of Memphis, InMotion Musculoskeletal Institute, LeBonheur



Neuroscience Institute, UT Medical Group, Inc., Methodist Healthcare, University Hospital, and The Regional Medical Center.

The symposium was videocast to the UT Graduate School of Medicine in Knoxville and is available on the web at http://www.utm.edu/research/research_administration/Seminar/seminar_info.php

The symposium was sponsored by the UTHSC Faculty Senate and the Office of Research.

UT Research Foundation Ceremony Honors 16 for Inventions in Medicine

Cancer treatments and a new type of X-ray imaging system were among the inventions spotlighted Friday at a ceremony to honor researchers at UTHSC who have had their ideas patented.

"These folks truly are champions of innovation on this campus," said Fred D. Tompkins, president and CEO of the [University of Tennessee Research Foundation](#), a nonprofit group that turns university discoveries into patent-protected ideas it can sell to companies.

The process is necessary for economic development, Tompkins said, because government-issued patents give the holder the right to profit from an invention for a time without fear of interference by a competitor. And that creates incentives for companies to make investments and create jobs.

It's through the patent process that drugs wind up on the pharmacist's shelf and other useful products make their way to the public, Tompkins added.

The recent ceremony honored 16 inventors who have received patents in recent years, including:

- James Dale, for five patents related to his work on a vaccine for group A streptococcus, which causes "strep throat" in children and other diseases. A company called Vaxent is developing these inventions.
- Eldon Geisert Jr., for his work related to anti-brain cancer compounds.
- Dick Gourley and C. Ryan Yates, for work on a rapid genetic test that may have applications for personalized medicine, the concept of adapting a medical treatment to the patient's needs.
- James Johnson and Atul Shukla, for their work on drug delivery systems that could boost the effectiveness of existing drugs.
- Leonard Johnson, Ramesh Ray and Mary Viar, for work on a drug that could help reduce the damage caused by exposure to radioactivity.
- Gabor Tigyi and Ryoko Tsukuhara, for their work on a different method for radioactivity resistance.
- Duane Miller, for 15 patents on different areas, including muscle-building compounds under development by drug company GTx Inc. That company's CEO, Mitchell S. Steiner, was also honored for his patents related to prostate cancer.
- Bob Moore, for work on a cancer treatment plus a method to stabilize a person who has suffered a serious blood loss.
- Andrzej Slominiski, for two patents, including one with applications for skin cancer.
- Herbert Zeman, for a new X-ray method.



UTHSC Export Control Policy Approved

UTHSC has recently approved a policy covering export controls. Export control laws are federal regulations that govern transmission of certain information, technologies, and/or commodities to foreign nationals while they are in the U.S OR overseas to anyone, including U.S. citizens. Penalties for non-compliance with these federal laws are severe and impact the researcher as well as the institution.

The UTHSC Export Control policy is located at http://www.utmem.edu/policies/w932_document_show.php?p=568. This policy also covers "Deemed Exports," which is the primary export control issue facing universities. Deemed Exports involve the release of covered technology to a foreign national in the United States. Examples of deemed exports include laboratory tours, face-to-face interactions, telephone conversations, e-mails, and sharing computer files with foreign nationals when the technology involved falls under Export Control Regulations. Questions about Export Control Regulations at UTHSC should be directed to Francine Rogers at 901-448-2871. You may read more information about export controls at the federal government website <http://www.bis.doc.gov/licensing/exportingbasics.htm> as well as the UT System web site <http://research.utk.edu/exportcontrol/>.



Hovinga and Jones Awarded K12 Scholar Grants for Translational Research

The Clinical and Translational Science Institute (CTSI) at the University of Tennessee Health Science Center (UTHSC) is pleased to announce recipients of the K12 Scholars grant program. The grants provide direct support for young faculty investigators performing clinical and translational research at the UTHSC.

The K12 Scholars grant involves a competitive process that identifies high quality scholars with outstanding clinical research proposals that can be translated into novel disease treatments, and improvements in community and public health. A CTSI committee reviewed seven applications this spring and two researchers emerged as this year's K12 Scholars grant recipients: Collin A. Hovinga, PharmD, Assistant Professor, UT College of Pharmacy Department of Clinical Pharmacy, and Terreia S. Jones, PharmD, Assistant Professor, UT College of Pharmacy Department of Clinical Pharmacy.

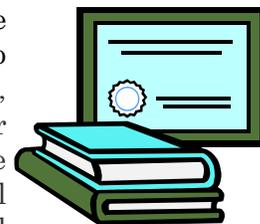
Dr. Hovinga's study will focus on neonatal hypoxia-induced seizures and the identification of genes related to seizure vulnerability and resistance. The genetic data will help identify new, age-appropriate targets at which novel drugs can be aimed. In addition, the research has the potential to identify genes that can predict outcomes of neonatal seizures. An appropriate mouse model will be used for this research, which has the potential to guide clinicians to more aggressive treatments for certain neonatal populations. Throughout the K12 Scholar program, Dr. Hovinga will consult with a mentor team of investigators from UT Health Science Center, other research institutions and the Food and Drug Administration.

Dr. Jones' research will examine how genetic make-up and environment can predict cancer risks in individuals taking anticancer therapies to treat brain tumors. In most cases, these therapies improve cancer survival rates for patients with brain tumors, but some patients end up at risk for secondary cancers. TPMT refers to a gene associated with brain tumor progression. Mice with different TPMT genotypes will be injected with varying doses of specific brain tumor treatments. The goal is to determine the best anticancer drug dose to use and how environmental factors impact negative outcomes, as well as how predisposed genetic factors influence poor results. The research could advance the cure rate for individuals taking anticancer drugs to treat brain tumors while reducing the risk of developing secondary cancers.

"We congratulate Drs. Hovinga and Jones, for their outstanding work and success in being chosen as the inaugural recipients of the prestigious K12 Scholar awards." said Edward Chaum, MD, PhD, Plough Foundation Professor of Retinal Diseases and Director of the K12 Scholars Program for the CTSI. "They represent the next generation of clinician scientists leading the transformation in the clinical research enterprise on campus, and the first of what we envision will be a long line of distinguished K12 Scholars.

Certificate in Clinical Research Program to Consider Applications

The Certificate in Clinical Research (CICR) Program at UT Health Science Center will be reviewing applications in spring 2009 from prospective students who want to be considered for fall 2009 admission to the program. The 12-credit-hour, two-semester program, leading to an awarded certificate, is designed primarily for junior faculty, fellows, and other healthcare professionals who are not in a degree program, who seek initial training in the methods and skills to conduct clinical research, but whose schedules may not accommodate traditional, classroom-based courses. The CICR Program offers online, introductory graduate courses in epidemiology, biostatistics, clinical research design, ethics, and other disciplines related to the effective, efficient conduct of clinical research. More details and an application form are available at <http://www.utmem.edu/prevmed/pm/k30certificateprogram.htm>. The application deadline is May 2, 2009.



UT Clinical and Translational Science Institute Submits Second Application to NIH

The CTSI submitted its second application to the National Institutes of Health requesting \$20 million for the next 5 years to support the new UT Institute. Scores of UTHSC and affiliate faculty and staff devoted hundreds of man hours to prepare the 650 page application, which describes a comprehensive strategy to fully implement the Institute as well as a description of progress to date. Dr. James Dale, the Executive Director of the UT CTSI and the P.I. on the application, stated, "This application is much stronger than our initial submission last year. The institutional funds provided in July by the UTHSC administration have allowed the CTSI leadership to implement key programs and functions of the Institute. We believe that we will be a serious contender for NIH funding based on the significant progress made and our clear and focused plan for growth."

The application was submitted on October 21st and will be reviewed by the NIH study section in February, 2009. Applicants will most likely receive summary statements and priority scores in April, 2009.

Our CTSI is still young in comparison to some larger institutions; however, we are well into the growth phase of our Institute even prior to receiving CTSA funding. In a relatively short time, we have made significant progress in implementing key functions and building programs. A brief progress report follows:

- The Institute web site has become the focal point of communication and information exchange. It is extensively used by faculty and students as the foundation of the Institute "Front Porch," the point of entry and source of information for Institute members and partners.
- In February, 2008 we inaugurated an Institute-wide \$300,000 Pilot Projects Program. The initial RFA energized the entire CTSI community. In response we received 39 letters of intent and subsequently invited 18 complete applications. Most applications were excellent multidisciplinary translational projects with innovative approaches that covered the spectrum of Clinical and Translational Science (CTS). In July, 2008 we funded the four most outstanding projects.
- Recognizing the importance of expanding our training and career development activities, the Research Education Unit of the Institute implemented institutional K-like and T-like Awards funded by the CTSI. In July, 2008 we funded 2 Clinical Scholars (K) and 3 Pre-doctoral Scholars (T) that were selected from an excellent pool of applicants. Mentoring of these new scholars is taking place under the auspices of our innovative UT/St. Jude/U of Memphis Mentoring Academy.
- We have also developed a novel multidisciplinary graduate program that will offer M.S. and Ph.D. degrees in CTS.
- Our plan to integrate the activities and personnel of the GCRC into the Clinical Research Unit (CRU) of the Institute is well underway. As of December 1, 2008 the current staff and operating budget of the GCRC is fully supported by the CTSI and by July, 2009 new projects will begin to conform to the new business and operating models of the CRU.
- Regulatory compliance and ethics support have been totally revamped under the direction of Terrance Ackerman, Ph.D. who also chairs our Department of Human Values and Ethics and heads our IRB. The functions and personnel of the Regulatory Compliance and Research Ethics Unit (RCAREU) will meet the needs of Institute investigators and participants and provide the highest standards for the ethical conduct of research. For the sake of efficiency, these functions rely heavily on the existing regulatory, IRB and research support services of the academic health center.

(Continued on page 6)

UT Clinical and Translational Science Institute Submits Second Application to NIH (Cntd.)

(Continued from page 5)

- The Biomedical Informatics Unit has created critically needed infrastructure with our web-based Slim-Prim System that provides a platform for data entry and integration of data from multiple sources.
- We are collaborating with the informatics team of the Vanderbilt Institute for Clinical and Translational Research to fully utilize the data available in the MidSouth eHealth Regional Health Informatics Organization (RHIO), which is based in Memphis and is one of only several fully operational RHIOs in the country.
- The leadership of our Research Technologies Unit has successfully integrated 9 key core laboratories, including the Molecular Resource Center, Imaging Core, Viral Vector Core and Flow Cytometry Core, among others, to meet the needs of Institute investigators. We have recently established two new CTSI core services, the Tissue Services/Biorepository (TSB) Core and the Human Genetics Core. The CTSI has made major financial as well as informatics investments in the TSB Core, a fundamental component of our overall CTS research strategy. Creation of these cores has also helped to establish the process by which new cores will be developed and are the models of the dynamic process for identifying and meeting translational needs.
- The Institute's Design, Biostatistics, and Epidemiology Unit (DBEU) has formed formal, contractual partnerships with the Department of Mathematics and the Program in Bioinformatics at the University of Memphis to establish faculty commitment to the education, research, and service mission of the DBEU. The Department of Biostatistics and Department of Epidemiology and Cancer Prevention at St. Jude Children's Research Hospital will continue as affiliated members of the DBEU.
- Pediatric research is a prominent component of our Institute. The partnership of the UTHSC Department of Pediatrics with Le Bonheur Children's Medical Center (LBCMC) and the Children's Foundation Research Center of Memphis has produced a robust research platform for basic, clinical and translational research in children. The recent successful integration of CTSI resources and expertise with those of the pediatric program has resulted in a synergy that will take pediatric clinical and translational research to a new level. In addition to the generous support for construction of new laboratory space and recruitment of new faculty committed to the Institute by LBCMC, the Children's Foundation of Memphis has recently donated \$2.5 million for the construction of a 10,000 sq ft 12-bed pediatric clinical research unit in the new children's hospital presently under construction that will be dedicated to the Institute Pediatric CRU.
- The Institute activities in community engagement and research have been bolstered by the recent Robert Wood Johnson Foundation award Aligning Forces for Quality (AF4Q) to the Healthy Memphis Common Table (HMCT) and UTHSC. The Institute is now focusing some of its community research strategies and data support on the well-defined needs of HMCT and AF4Q.
- The members of the leadership team and other key personnel have joint faculty appointments in the Institute and now receive direct salary support from the Institute.
- The Institute has recruited new staff in the Clinical Research Unit, Research Education Unit, Biomedical Informatics Unit, Community Engagement Unit, Finance Office, and the Executive Director's office.

Visit the newly designed CTSI web page at <https://ctsi.utmem.edu> and provide feedback and comments via the email contacts listed. The Executive Management Board of the CTSI welcomes your input and suggestions as we continue to implement this important research resource.

UT Researchers Present at Innovation Conference

Several University of Tennessee researchers from Knoxville, the UT Health Science Center (UTHSC) and the UT Space Institute presented their technologies at the inaugural Tennessee Innovation Conference in Nashville on November 21. Sponsored by the Tennessee Technology Development Corporation (TTDC), the conference highlighted researchers from across the state whose efforts have the potential to help transform the state's economy through potential commercialization efforts.

Using guidelines from TTDC, the University of Tennessee Research Foundation selected the researchers based on their current research efforts in high impact areas such as clean energy, medical technologies and pharmaceuticals. The event was designed to facilitate early stage dialogue between scientists and 25 venture capitalists from across the country. The objective was to help researchers receive useful data – strategy input and feedback, referrals to potential partners or investors, ideas on how to estimate the size of the potential market opportunity, awareness of potential competitors -- so that they can make better decisions during their technology development that may positively affect commercial success.

One of the highlights for the researchers was a case study of BioMimetic Therapeutics. Founder, president and CEO Sam Lynch shared his story of developing a high-growth, venture-backed biotechnology business in Tennessee with technology licensed from Harvard University.

There were several positive outcomes. Researchers said they learned a lot about the commercialization process and how their efforts can influence it. One venture capitalist has offered help to start a new business based on one of the technologies, and another was so impressed by the capabilities at UTHSC that he is planning a visit to the campus in January. Yet another offered to present one of the technologies to some of their portfolio companies.



The participating researchers from UTHSC were:

- Monica Jablonski - treatment for age-related macular degeneration.
- Duane Miller - treatment for prostate and skin cancer.
- Jim Johnson - sustained release injectable analgesics.
- Denis DiAngelo - spine implant testing system.
- George Wood - targeted drug delivery system for cancer.

The participating researchers from UTK were:

- Dayakar Penumadu - more environmentally friendly Styrofoam alternative.
- Jimmy Mays - high performance and lower cost fuel cell membrane.
- Bill Hamel - new imaging device for examining skeletal joints during movement.

The participating researcher from UTSI was:

- Ying Ling Chen - eye evaluation system for children.

The event was such a success that the TTDC is considering hosting this event on an annual basis.

Research Database for Laboratory and Patient Information Management Available

As in many other research communities, basic and clinical studies at UTHSC are often conducted independently of each other. Awareness of another researcher's data or current projects can significantly affect experimental design or aid in the clinical application of data. Sharing data can enhance the quality of health care offered by our medical community, and helps accelerate progress in biomedical sciences. With the current national emphasis on translational research, data exchange systems are needed that bridge the gap between basic science and clinical research.

To meet this challenge a database system called "Slim-Prim" was developed by the Biomedical Informatics Unit (BMIU) of the UTHSC Clinical Translation Science Institute (CTSI). This "integrated data system" collects, processes, archives, and distributes basic, clinical, and translational research data. Slim-Prim provides de-identified, HIPAA-compliant information via web-based applications, which facilitates data sharing and analysis across campus and serves as a laboratory management interface and archival data repository. "Slim-Prim is an example of bridging the gap between laboratory discovery and practice using database technology," said Professor Chanchai McDonald, Co-Director of the BMIU and lead developer of Slim-Prim. The Slim-Prim interface may be found at <https://ctsi.utmem.edu/gateway.php>.

'Slim-Prim' stands for Scientific Laboratory Information Management – Patient-care Research Information Management (Slim-Prim), and as of December Slim-Prim was already central to several clinical studies at UT, including providing a storage system and database functions for a pharmacogenetic tissue repository at the Cancer Institute, and managing an interactive searchable database for pediatric hospital admission data from the Healthcare Cost and Utilization Project (HCUP).

"The ultimate goal of Slim-Prim is to create scientific and patient-care information tools for data collection and entry, storage, and retrieval," said McDonald, adding, "The Slim-Prim system isn't designed to just facilitate data collection, but because it uses web-applications it can be used to recruit patients too." The system allows collaborators to share data across studies, and also supports complex queries targeting specific data sets. For example, the system can create a data bank for reagents, create a laboratory equipment inventory, or manage data from all core facilities at UTHSC. Some of the clinical projects Slim-Prim supports are highlighted below.

Patient recruitment: Slim-Prim has received over 400 visitors on the Urban Child Institute sponsored "Conditions Affecting Neurocognitive Development and Learning in Early Childhood" (CANDLE) study web-site. Each visitor is a potential clinical trial subject. This tool identifies suitable subjects, allowing recruiters more time to speak with participants who qualify.

Content Management System: An NIH funded Post-Transplant Obesity study is using Slim-Prim to create patient screening and enrollment forms, as well as a repository for genetic, environmental and lifestyle data, and tools to assist in basic data analysis. The versatility of the system means that these forms and features can be adapted easily for other studies.

Collecting Research Data: Slim-Prim provides an application to collect data in different formats and forms to support research specific aims. For example, the NIH funded Post-Transplant Obesity study headed by Dr. Ann Cashion (Director of the Community Engagement and Research Unit) is currently using Slim-Prim to create a complex patient screening form, enrollment form, a repository



Slim-Prim User Login Screen

(Continued on page 9)

Research Database Available (Cntd.)

(Continued from page 8)

for genetic, environmental and lifestyle data, and tools to assist in basic data analysis. The Slim-Prim application for this study includes the following features: 1) a complex patient screening-report form to collect prescreening data from prospective patients; 2) complex enrollment patient report forms incorporated with existing information from screening report records used to collect patient demographic data; 3) simple, quick self-test measures of patient depressive feelings and behaviors during the past week (Center for Epidemiologic Studies Depression Scale (CES-D) survey form) for determining depression level; 4) SF-36v2 Health Survey report form designed to collect patient health information for data analysis purposes; and 5) a report generator system for prescreening data analysis and preparing any nutrition data analysis. These forms and features can be easily adapted for other future studies.

Data aggregation: The Slim-Prim system supports data migration from other database systems and transforms the data into standardized formats, allowing researchers to review data in different ways according to their needs. For example, the BMIU has migrated data for the Division of Pediatric Surgery, which currently uses the Kids' Inpatient Data (KID) from the Healthcare Cost and Utilization Project (HCUP). This decade of triennial hospital admissions data will allow pediatric epidemiological studies to be carried out using Slim-Prim.

Clinical and translational research communities need web applications granting access to data and data-sharing across labs and institutions—not just at UT, but at other sites around the country. Because of data sharing issues, Slim-Prim has been designed strictly with research compliance and security in mind. “One of the greatest assets of Slim-Prim is its sheer versatility,” said Professor McDonald. “The system uses patient-care information tools like online screening forms, online applications, and medical forms, but importantly we can also store radiology image-files and DNA sequencing files.”

At the time of going to press Slim-Prim just seems to keep on growing. The web functionality has been expanded to help maintain the Faculty Senate, and Faculty Portal web sites, and more clinical investigators are contacting the BMIU about using Slim-Prim in their research. “Even at this difficult time for our university, the research is just pushing ahead,” said McDonald. “Basic scientists and clinicians are working closer together than ever before.”

UTPhDA and Postdoctoral Office Travel Award Winners

It is my great honor to announce the first and second place travel award winners for the first annual UTHSC Postdoctoral Association (UTPhDA) and Postdoctoral Office (PDO) Travel Award Competition. Dr. Thirumalini Vaithianathan's submission has been awarded first place and Dr. Christopher Hoehamer's submission has been awarded second place. Dr. Vaithianathan is a postdoctoral fellow in the Department of Pharmacology and plans on attending the 2009 Biophysical Society Meeting in Boston, MA. Dr. Hoehamer is a postdoctoral fellow in the Department of Clinical Pharmacy and has recently attended the 48th annual ICAAC/IDSA conference in Washington, DC. These two winners will receive up to \$2000 for reimbursement of travel related expenses. The UTPHDA and PDO are indebted to the generosity of the UTHSC Office of Research for supplying the necessary funds for these travel awards. In addition, I would like to sincerely thank the authors of our other travel award submissions for making this year's travel award competition a success as well as all of our judges for their critiques and scoring. All of the submissions were very well presented and planned. I wish you all best of luck in your travels.

Sincerely,

George Howell III, Ph.D

UTPhDA President



Office of Research Administration

Important Reminder: Adobe and Grants.gov

Most Grants.gov applications are now being submitted using Adobe forms. As you may know, Grants.gov is phasing out PureEdge software and is converting to Adobe forms, which are platform-independent. Beginning in January, we can expect most, if not all, NIH electronic submissions to use Adobe format; other agencies are also converting to Adobe. Positive Adobe features:

- Many people are already familiar with Adobe.
- The Adobe forms look very much like the old PureEdge forms, but are easier to use in some ways.
- Adobe works equally well on PCs or Macs.
- The entire package (except for secondary pages and attachments) can be printed without the extra blank pages common with PureEdge.
- Adobe allows the user to scroll through the entire package (except for secondary pages or attachments) instead of opening each form separately.

A word of caution: Be sure you have Adobe 8.1.3 or higher; opening the package with an earlier version of Adobe will corrupt the package . . . and the corruption can not be detected until after submission, at which time the entire package will have to be re-done. If the error is not detected until after submission and the deadline has passed, the sponsor may not accept the package.

Also, when you open an Adobe package, be sure to move all forms to the right before you begin. Otherwise, the forms will be rearranged in the order in which they were moved. You may make changes after the forms are moved to the right. Also, please be patient with the Adobe forms . . . the Adobe package is a bit slower than the PureEdge package.

BE SURE EVERYONE WORKING ON THE ADOBE GRANTS PACKAGES HAS ADOBE 8.1.3 OR HIGHER INSTALLED AND OLDER PACKAGES REMOVED FROM THE COMPUTER.

Tips for Grant Submissions to Agencies other than NIH:

NSF - Unless the program announcement specifies the use of Grants.gov, plan to submit NSF applications in FastLane. If you do not have a FastLane account, please contact the Office of Research Administration (egrants@utmem.edu), and one will be set up for you.

Army - The Army is VERY strict about its deadlines. The Army requests that all grants be submitted 48 hours prior to its published deadline to allow Grants.gov time to get the package to the Army. Grants that are received by the Army past the deadline will be returned without review or consideration.

HRSA - Most--but not all--HRSA applications require submission of several forms via Grants.gov; then, the remainder of the application is handled via the HRSA Electronic Handbook (EHB). HRSA applications are fairly complex, so be sure to read and follow the instructions carefully. Questions about HRSA applications can be directed to Connie Bozant (cbozant@utmem.edu).

Sending and Receiving Biological Materials

No biological material should be sent out of UTHSC without prior review by the Institutional Biosafety Officer and, if applicable, the Office of Research Administration. In some instances, a Material Transfer Agreement (MTA) may be required in order to send material to another institution. The Office of Research Administration and the UT Research Foundation will negotiate the terms of the MTA, based on information provided by the faculty member who plans to ship the material. The Biosafety Officer should also be aware of biological materials that are received by University personnel for use in University labs. If an MTA is required by the providing institution, it should be routed through the ORA; faculty are not authorized to sign MTAs. Questions about MTAs may be addressed to Dr. Lakita Cavin in UTRF at 901 448-7825. Questions about Biosafety should be addressed to Francine Rogers at 901 448-3537.

Office of Research Compliance

IRB Consolidation Imminent

The first meeting of the consolidated IRB joining the Methodist and UTHSC Boards is currently scheduled for January 28, 2009. The purpose of conjoining the IRBs is to simplify the approval process for UTHSC investigators who propose to conduct research with human subjects research in the facilities of Methodist Healthcare. Investigators were previously required to submit IRB applications to the committees of both institutions when proposing research at Methodist facilities other than Lebonheur Children's Medical Center. The new arrangement allows researchers to utilize the consolidated IRB and submit a single application using the electronic iMedRIS system.

The consolidated IRB will bring together members from the old Methodist and UTHSC IRBs. It will process new study applications from both UTHSC and Methodist personnel. The new IRB will consist in four panels, which will meet on the first four Wednesdays of each month. It is anticipated that the availability of four IRB sections, the utilization of the paperless IRB process, and the implementation of a three-week review cycle will greatly expedite the process of IRB approval.

The Methodist IRB will continue to provide oversight of studies that were previously approved under the auspices of its Board. Investigators with studies open under the Methodist IRB will continue to submit renewal applications, revisions of their research, and reports of adverse events to the Methodist IRB. The consolidated IRB will process all new study applications, as well as continuing to oversee studies previously approved by the UTHSC IRB.

Investigators should also be aware that, despite the consolidation of the IRBs, they must continue to secure approval to conduct their studies from the Research Administration at the various facilities in which research activities will occur, including Methodist University Hospital and Lebonheur Children's Medical Center. Approval from the relevant institutions is necessary if investigators intend to conduct any of the following activities in those facilities: identification of subjects through review of their medical records; recruitment of subjects; consent of subjects; performance of screening procedures; interventions or interactions with subjects; or collection of private information about subjects. Investigators must designate the relevant contact person at that institution as the Research Administrative Specialist on their IRB applications so that approval can be secured from the institution for the conduct of the study.

2009 in the Office of Human Subjects Protection

The Office of Human Subjects Protection is looking forward to a great and informative New Year. We had originally tried to change our Lunch and Learn meetings to the second Thursday of the month but we were unable to reserve room 304 in the GEB for this time slot. This room has the necessary equipment to capture presentations for later use. Due to the inability to secure this room for an alternate day, we will continue to have meetings on the second Wednesday of the month.

We have an interesting line-up of speakers for 2009:

On February 11th, we will have Susan Tobey C.H.C. A.A.D.P., speaking about the protection of human subjects and research from the perspective of an IRB community member.

Carol Schwab J.D., L.L.M will speak on legal issues related to research on April 8th.

Our May speaker will be Dr. Mona Wicks Ph.D., R.N., from the College of Nursing.

Please join us at noon each second Wednesday of the month for the latest information about research issues and human subjects protection.



Frequently Asked Questions

Did You Know?

Institutional Biosafety Committee

Q: Do I need to submit a new IBC registration if I have a change in personnel, or if I get a new plasmid or cDNA construct for my project?

A: No, all you need to do is to download the "Update Form" from the IBC website (http://www.utmem.edu/research/research_compliance/IBC/docs/rDNA_CF_Update_Form_82107.doc), complete the relevant information, and submit to the IBC office. The only exception is if the new cDNA clone or vector system increases the biosafety level from what you are already approved. This will be determined by the IBC and you will be contacted if there is a need to increase the containment level for your work.



Q: I want to "knock-down" expression of a gene using commercially available siRNA or shRNA constructs. Do I need to submit an rDNA registration for this work?

A: Yes, even though work with siRNA purchased from a company would likely be classified as Exempt under the NIH Guidelines, all research utilizing recombinant or synthetic nucleic acids must be registered with the IBC.

Q: Based on information in the NIH Guidelines, I believe my work is "exempt". Do I still need to submit an rDNA registration to the IBC?

A: Yes, you must submit a registration for any and all work utilizing rDNA. This includes the production of stable cell lines expressing a reporter such as green fluorescent protein (GFP). According to the NIH Office of Biotechnology Activities (OBA), which oversees and monitors rDNA work at institutions, it is the responsibility of the IBC to make the determination as to whether work can be considered exempt; therefore it is UTHSC policy that any research that utilizes rDNA must be submitted for review. All registrations are pre-reviewed by the Institutional Biosafety Officer (IBO) and Chair of the IBC and if the work falls under the exempt classification, the investigator will receive notification that the research described in the registration is exempt and that no other action is required.

Institutional Animal Care and Use Committee

The recent round of semi-annual laboratory inspections identified several instances of expired drugs and use of reagent grade chemicals rather than pharmaceutical preparations. Required practices are specifically addressed in the following, excerpted from a set of FAQs posted by the NIH Office of Laboratory Animal Welfare (<http://grants.nih.gov/grants/olaw/faqs.htm>), under the heading of Animal Use and Management:

Q: May investigators use non-pharmaceutical grade compounds in animals?

A: OLAW and USDA consider that the use of non-pharmaceutical grade compounds should be based on:

- * scientific necessity;
- * no availability of an acceptable veterinary or human pharmaceutical-grade compound; and
- * specific review and approval by the IACUC.

Investigators and IACUCs should consider relevant animal welfare and scientific issues including safety, efficacy, and the inadvertent introduction of new variables. Cost savings alone do not adequately justify the use of non-pharmaceutical-grade compounds in animals. Although the potential animal welfare consequences of complications are less evident in non-survival studies, the scientific issues remain the same and the principles and need for professional judgment outlined above still apply.

Frequently Asked Questions (cont.)

Did You Know?

Q: May investigators use expired pharmaceuticals, biologics, and supplies in animals?

A: The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. Euthanasia, anesthesia and analgesia agents should not be used beyond their expiration date, even if a procedure is terminal. Other expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document to the satisfaction of the IACUC that such use would not negatively impact animal welfare or compromise the validity of the study. The veterinarian and IACUC must maintain control over the use of expired medical materials in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals.



Q: Am I working under my PHS grant if I bought and cared for my animals using non-PHS funds?

A: Perhaps. The Office of Laboratory Animal Welfare has recent stated that investigators are considered to be working under the auspices of PHS grants if the ultimate goal is to publish the work and list the PHS grant as supporting any or all of the work described therein. Thus, regardless of the funds used to purchase and care for research animals, investigators are considered to be working under a PHS grant if the research is that described in the grant and is intended to be viewed by the public as being supported by such.

Q: May I use PHS funds to support animal work if my animal care and use protocol has lapsed or work has stopped because of possible non-compliance?

A: No. Please see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html> which details allowable costs when terms and conditions of PHS grants are not met. The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. Specific situations under which charges are not allowable are:

- The conduct of animal activities in the absence of a valid Assurance on file with OLAW.
- The conduct of animal activities in the absence of valid IACUC approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval. Suspension is described in the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) at section IV.C.6. (<http://grants.nih.gov/grants/olaw/references/phspol.htm>)

Institutions are required to report such situations to the Institute/Center (IC) supporting the award. NIH expects grantees to continue to maintain and care for animals during the periods described above. Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis.

Additionally, these situations constitute serious noncompliance with section IV.F.3. of the PHS Policy and as such must be promptly reported to OLAW in accord with the PHS Policy. See NOT OD-05-034, Guidance on Prompt Reporting to OLAW (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>)

Frequently Asked Questions (cont.)

Did You Know?

Research Administration

Q: Has the NIH page limit for the research plan portion of R01s changed?

A: Not yet. The page limit for the research plan portion of R01s is still 25 pages. NIH has indicated that the change to 12 pages is likely to be effective for the January 2010 deadlines. ORA will keep you posted.

Q: I'm getting ready to close out my NIH grant and can't remember if there were inventions or not; or I know there were inventions but I don't know when they were reported to NIH. How can I find out?

A: Contact the Office of Research Administration, and we will check our records and provide you with the information to complete the Final Invention Statement in Commons.

Q: I'm processing my e-SNAP (NIH progress report). To whom should I route it for final review and submission?

A: Route it to Virginia Geer or Connie Bozant; Ginny or Connie will check it and route it on to Debbie Smith for final submission.

Q: What version of Adobe do I need for Grants.gov?

A: Adobe version 8.1.3 or higher. Older versions WILL corrupt the package.

Q: I plan to submit an application to the National Science Foundation; should I use Grants.gov or FastLane?

A: Read the program announcement carefully. If it requires the use of Grants.gov, plan to submit via Grants.gov. Otherwise, plan to use FastLane.

Q: I am using de-identified human cell lines. How do I mark the human subjects question on the grant application and route sheet?

A: De-identified human cell lines are not considered human subjects; mark the application and route sheet as *No Human Subjects*. However, all research using human cell lines must be approved by the IRB and IBC, so be sure to submit the information to those compliance offices.



Contact List



Name	Title	Phone
Office of Research		
Leonard Johnson, Ph.D.	Vice Chancellor	901-448-7125
Jane Poulos	Sr. Business Manager	901-448-3746
Lisa Bronte	Sr. Admin. Asst	901-448-7125
Connie Jackson	Accounting Asst	901-448-2734
Research Support Services		
Helen Parsons	Business Director	901-448-7101
Dan Rosson, Ph.D.	Director - Flow Cytometry	901-448-4279
Jinsong Huang	Director - Micro CT Lab	901-647-7909
Haibao Wan	Director - Mass Spectrometry	901-448-3414
Biomedical Instrumentation		
Jayne Collins	Budget Coordinator	901-448-5652
David Eppes	Computer Programmer	901-448-5302
Cheryl Gaul	Sr. Bioengr Tech - Comp	901-448-5339
Susan Ledbetter	Sr. Bioengr Tech - Comp	901-448-5652
Dennis Martin	Sr. Design Tech. - Instruments	901-448-5093
Bob Gallik	Sr. Design Tech. - Mechanical	901-448-2121
Don Martz	Sr. Design Tech. - Mechanical	901-448-2122
Micheal Nguyen	Sr. Design Tech. - Mechanical	901-448-2123
Glen Dawkins	Sr. Design Tech. - Microscopes	901-448-5267
Laboratory Animal Care Unit		
Tim Mandrell, D.V.M.	Director	901-448-5656
Andrea Briggs	Animal Procurement	901-448-5656
Joyce Jones	Business Manager	901-448-5453
Sherry Frazier	Facility Manager	901-448-7308
Barbara Blakely	Supervisor - Nash/Wittenborg	901-448-1429
Brad Stevens	Supervisor - Coleman, Mol. Sci.	901-448-5454
Courtney Yates	Lead Technician	901-448-5656
David Hamilton, D.V.M.	Asst Professor - Nash/Witt./Cancer Ctr	901-448-7311
Scott Jackson, D.V.M.	Instructor - Coleman/Mol. Sci.	901-448-7134
Molecular Resource Center		
Donald Thomason	Executive Director	901-448-7224
William Taylor	Director	901-448-6165
Tom Cunningham	Associate Director	901-448-6191
Terry Mark-Major	Business Manager	901-448-2656
Vivian Simon	Accounting Asst	901-448-6194
Felicia Waller	Specialist	901-448-7248
Jian Yan	Research Associate	901-448-7828
Research Informatics		
Jeanne Hermann	Director	901-448-5043
Bili Yang	Administrator	901-448-1183
Tricia Page	iMedRIS Program Manager	901-448-2753
Steve Wills	Coelus Program Manager	901-448-2389

Name	Title	Phone
Research Administration		
Deborah Smith, Ed.D.	Asst Vice Chancellor	901-448-4823
Clinical Trials Unit		
Melanie Luchs	Associate Director	901-448-3303
Ruthie Ruston	Specialist	901-448-3126
Grants and Contracts Unit		
Ginny Geer	Program Administrator	901-448-1668
Connie Bozant	Coordinator II	901-448-4188
Rosa Wilson	Specialist	901-448-5587
Carlisa Jackson	Data Control Specialist	901-448-5532
Nonie Simard	Principal Secretary	901-448-5985
Carol Baumgartner	Sr. Coordinator	901-448-3046
Wanda Donato	Sr. Coordinator	901-448-2037
Research Compliance		
Randall Nelson, Ph.D.	Assoc Vice Chancellor	901-448-3533
Tinieka Triplett	Admin Svcs Asst	901-448-2164
Francine Rogers	Institutional Biosafety Officer	901-448-2871
Vicki Baselski	Infection Control Chair	901-448-6329
Michael Whitt, Ph.D.	IBC Chair	901-448-4634
Deborah James	IBC Admin Research Asst	901-448-2871
Vivian Loveless, Pharm.D.	Radiation Safety Chair	901-448-6931
Institutional Animal Care and Use		
Mary Frances Braslow	Administrator	901-448-3904
Thaddeus Nowak, Ph.D.	Chair	901-448-7384
Robert Parker, Pharm.D.	Vice Chair	901-448-7143
Institutional Review Board		
Terrence Ackerman, Ph.D.	Chair	901-448-4824
Clair Cox, M.D.	Chair Emeritus	901-448-5463
Cameron Barclay	Associate Director	901-448-4824
Donna Hollaway	Compliance Specialist	901-448-2933
Bonnie Binkley	Administrator	901-448-1343
Kim Prachniak	Administrator	901-448-5060
Nanette Graddy	Administrator	901-448-4824
Donna Stallings	Administrator	901-448-4824
Holly Herron	Admin Research Asst	901-448-4824
Office of Human Subject Protections		
Sylvia Friedl	Compliance Officer - Chatt.	423-778-3899
Patricia Kerby	Compliance Officer - Memphis	901-448-1869
Will Wallace, J.D.	Compliance Officer - Knoxville	865-305-6192
24 Hour Reporting Line	Toll Free	800-216-1704
24 Hour Reporting Line	Memphis local	901-448-1771

Additional Research Related Contacts		
University of Tennessee Research Foundation		
Richard Magid	Technology Transfer	901-448-1562
Lakita Cavin	Material Transfer Aggements	901-448-7827
Marcia Phillips	Office Manager	901-448-7827

The Research Notebook
 Jeanne Hermann, Editor
 jhermann@utm.edu
 901-448-5043

The Office of Research provides support for the faculty and staff of the Health Science Center in their efforts to obtain external funding for research and other sponsored projects, while ensuring compliance with UT policy, sponsor policy, and applicable law.

UTHSC Office of Research
 62 S. Dunlap, Suite 400
 Memphis, TN 38163
 Phone: 901-448-7125
 Fax: 901-448-7133
 E-mail: research@utm.edu