

# The Research Notebook

*A Publication of the Office of Research*

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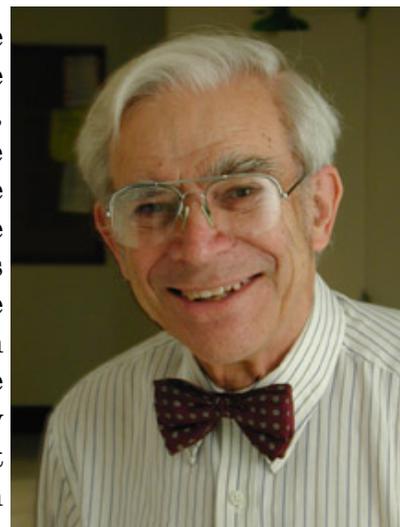
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**Special points of interest:**

- NIH Medical Student Fellows
- Translational Research Informatics

## ***VanMiddlesworth Nominated for the Prince Mahidol Award***

The Research Committee of the Faculty Senate has voted to nominate Lester VanMiddlesworth, Ph.D., M.D., Emeritus Professor of Physiology, for the prestigious Prince Mahidol Award. The award is presented annually by the government of Thailand to individuals who have contributed to “the advancement of medical and public health services for humanity throughout the world.” Dr. Van, as he is affectionately known on campus, has been a professor at UTHSC since 1959 and associated with the College of Medicine since 1946, when he joined as both an instructor and a medical student.



Dr. Van is one of the world’s leading experts on the physiology of the thyroid gland. In 1954, he discovered that bovine thyroid glands from a Memphis slaughterhouse were contaminated with Iodine-131. Finding the same contamination in thyroid glands from other U.S. cities, he linked the I-131, a breakdown product of plutonium, with fallout from atmospheric nuclear tests. By 1960 he had made 14,000 analyses of I-131 in animal thyroids from around the world and was able to predict where nuclear tests had occurred. His work has been published in numerous scientific journals, primarily in *Nature* and *Science*.

This work was instrumental in the development and subsequent signing in 1963 of the “International Limited Test Ban Treaty,” which banned atmospheric testing of nuclear weapons. In 1994, the National Smithsonian Institute placed some of Dr. Van’s records from the 1950’s on permanent display. The display includes a photograph of the signing of the test ban treaty and an explanation of the essential role played by these data. One can safely say that Dr. Van has contributed to the medical and public health of everyone in the world.

## ***O’Nuallain and Zite Recognized for Excellence in Research***

Annually, the UT Graduate School of Medicine, Knoxville, hosts a reception to welcome new resident physicians and fellows and to honor its teaching physicians, dentists, volunteer faculty physicians, and researchers. Five physicians and researchers are honored with awards for excellence in research, teaching and other areas of medical academia.

At this year’s event, the Excellence and Leadership in Basic Science Research award was given to Brian O’Nuallain, PhD, Assistant Professor, Department of Medicine, Human Immunology and Cancer Program. This award recognizes an outstanding principal investigator for excellence in basic science research. In nominating Dr. O’Nuallain, James Neutens, PhD, Dean of the UT Graduate School of Medicine, said, “Dr. O’Nuallain is responsible for some of the best research of any young investigator in the United States.” Dr. O’Nuallain also received a 2006 Brian D. Novis Junior Research Grant from the International

Myeloma Foundation. The grant supports investigators searching for better treatment, management, prevention and ultimately a cure for myeloma.

Nikki Zite, MD, PhD, Assistant Professor and Associate Residency Director for the UT Graduate School of Medicine Department of OB/GYN, received the Excellence in Leadership in Clinical Research award. This award is offered to recognize, reward, and reinforce outstanding investigators and to promote excellence in clinical research. Dr. Zite was nominated by Robert Elder, MD, Interim Chair of the Department of OB/GYN. “Dr. Zite has expanded the educational experience for our residents immensely by virtue of her clinical expertise, teaching techniques and interest in clinical research,” said Dr. Elder. “Through her guidance, a number of research projects have been accepted for presentation at a national level, several of them garnering recognition and awards.”

Winners of the awards are nominated by their colleagues,



**Brian O’Nuallain, Ph.D.**



**Nikki Zite, M.D., M.P.H.**

and each year’s honorees join a list of others who have graciously given their time and talents to the betterment of medical education.

## ***Congratulations to Dr. Stuart, VA Memphis ACOS Research***

Congratulations to Dr. John M. Stuart, Associate Chief of Staff for Research and Development, Memphis VA Medical Center. Dr. Stuart was elected by his peers, VA Associate Chiefs of Staff for Research nation-wide, to represent the Mid-Atlantic region’s research interests to the Veterans Affairs Central Office Field Research Advisory Committee. As the newly elected representative for the Mid-Atlantic Region, Dr. Stuart will have direct input into the policies and procedures that govern medical research throughout the Department of Veterans Affairs and their academic partners at universities across the United States.

## *NIH Medical Student Research Fellowship Students for 2007*

The UTHSC NIH Medical Student Research Fellowship Program has accepted 26 students in its 28th year. The MSRF Program introduces students to biomedical research, careers in academic medicine, and provides an excellent opportunity for professional and academic growth. Students are accepted after a competitive review of their project proposals. Proposed projects are very focused and expected to be completed within three to four months. This year's scholars, their preceptors, and project titles are listed below.



2007 Student Research Fellows Left to right, Row 1: Peter Riedell, Brooke Warren, John Stanifer, Emily Joyce, Katherine Frederick, Doug Campbell, Bryan Payne, Juliette Sandifer, Row 2: Benton Pitkanen, Joshua French, Daniel Doty, Vikram Saini, Row 3: Alkesh Amin, David McNeely, David Lazarus, Michael Baddour, Brian Bogdanowicz, Scott Castle Not Pictured: Jonathon Boone, Damon DeLeon, Arjun Dirghangi, Amy Mauritsen, Ashley Roberson, Christina Simpson, Natalie Young, and Sarah Williamson

<b>Student</b>	<b>Preceptor, Department</b>	<b>Project Title</b>
Amin, Alkesh	Ahokas, Robert, Ph.D. Associate Professor Obstetrics and Gynecology	Amlodipine treatment in recovery from cachexia in rats with aldosteronism
Baddour, Michael	Sun, Yao, M.D., Ph.D. Professor, Medicine-Cardiology	Natural recovery from cachexia associated with aldosteronism
Bogdanowicz, Brian	Alpert, Bruce, M.D. Professor, Pediatrics	Non-invasive assessment of arterial compliance in rheumatologic arthritic pediatric patients at risk for cardiovascular disease
Boone, Jonathan	Hofmann, Polly, Ph.D. Professor, Physiology	$\beta$ -adrenergic activation of protein phosphatase A in ventricular myocytes
Campbell, Douglas	Pfeffer, Lawrence M., Ph.D. Professor, Pathology	NF- $\kappa$ B inhibitor velcade potentiates the anti-tumor action of interferon on neuroblastoma cells
Castle, Scott	Hasty, Karen, Ph.D. Professor, Orthopaedic Surgery	Immunofluorescent detection of artificially and naturally induced osteoarthritis in porcine hip and knee joints
Joyce, Emily	Leffler, Charles W., Ph.D. Professor, Physiology	Contribution of astrocytes to autoregulatory cerebral vasodilatation in newborns
DeLeon, Damon	Slominski, Andrzej, M.D., Ph.D. Professor, Pathology	Activity of novel derivatives of vitamin D on the growth and tumorigenicity of melanoma cells

Student	Preceptor, Department	Project Title
Dirghangi, Arjun	Dale, James B., M.D. Professor, Medicine-Infectious Disease	Identification of new protective antigens of Group A Streptococci
Doty, Daniel	Croce, Martin A., M.D. Professor, Surgery	Efficacy of antibiotic coating of central venous catheters in preventing infection with <i>staphylococcus aureus</i>
Frederick, Katherine	Bahouth, Suleiman, Ph.D. Associate Professor, Pharmacology	Characterization of the role of Rab11 in the recycling of the human $\beta_1$ adrenergic receptor
French, Joshua	Bhattacharya, Syamal, Ph.D. Professor, Surgery	Role of N-acetylcysteine in the recovery of heart and skeletal muscle wasting due to the oxidative stress associated with aldosteronism in rats
Lazarus, David	Gerling, Ivan, Ph.D. Professor, Medicine-Endocrinology	Biochemical and gene expression abnormalities of chronic aldosteronism in cardiac and skeletal muscle together with their potential for assisted recovery using spironolactone
Mauritson, Amy E.	Helton, Kathleen, J., M.D. Assistant Professor Radiology	Correlation of arterial spin labeling perfusion and diffusion tensor imaging with neurocognitive testing in children with sickle cell anemia
McNeely, David	Chaum, Edward, M.D., Ph.D. Professor, Ophthalmology	A novel microfabricated, disposable instrument to treat recurrent corneal erosions and deliver drugs to the cornea
Payne, Bryan K.	Dyer, Michael A., Ph.D. Assistant Professor Ophthalmology	Targeted chemotherapy in pre-clinical mouse models of retinoblastoma
Pitkanen, Benton	Alpert, Bruce, M.D. Professor, Pediatrics	Arterial stiffness in children with sickle-cell disease
Riedell, Peter	Nienhuis, Arthur, M.D. Professor, Pediatrics	Evaluation of the safety of globin lentiviral vector integration
Roberson, Ashley	Lew, Betty D., M.D. Professor, Pediatrics	Identification of optimal dose and dose timing of intranasal mannan treatment in allergic mice
Sandifer, Juliette	Russell, Charles J., Ph.D. Assistant Professor Molecular Sciences	Real-time imaging of parainfluenza virus infection in a natural host
Saini, Vikram	Edward Chaum, M.D., Ph.D. Professor, Ophthalmology	The Use of Content-Based Image Retrieval in the Diagnosis of Retinal Disease
Simpson, Christina	Samant, Sandeep, M.D. Associate Professor, Otolaryngology	Retrospective study examining integration of human papilloma virus in head and neck cancer
	Albritton, Lorraine M., Ph.D. Professor, Molecular Sciences	
Stanifer, John	Geiger, Terrence, M.D., Ph.D. Associate Professor, Pathology	Creation of a functional single-chain T-cell receptor specific for the myelin oligodendroglial glycoprotein receptor MOG9
Young, Natalie	Dalton, James T., Ph.D. Adjunct Associate Professor Pharmaceutical Sciences	Role of co-regulators in the tissue selectivity of selective androgen receptor modulators
Warren, Brooke	Stentz, Frankie, Ph.D. Associate Professor Medicine-Endocrinology	Stimulatory and inhibitory effects of fatty acids on glucose-induced activation of human T-lymphocytes
	Kitabchi, Abbas, M.D., Ph.D. Professor, Medicine-Endocrinology	
Williamson, Sarah	Waters, Bradford, M.D. Associate Professor, Medicine	Metabolic syndrome and non-alcoholic fatty liver disease in patients with hypopituitarism
	Solomon, Solomon S., M.D. Professor, Medicine-Endocrinology	
	Nynewe, Ebenezer, M.D., GME Resident	

# Office of Research Administration

## Electronic Submission of Grants—5-Working-Day Deadline

Last year, the UTHSC Faculty Senate approved a 5-working-day deadline for grant applications to allow adequate time for review, approval, and submission of grant applications and any necessary corrections prior to the agency deadlines. Compliance with the 5-working-day deadline has been mediocre. Faculty are reminded that the Faculty Senate also approved a "first

in/first out" approach for review and submission of grants; so grants that arrive after the deadline go to the bottom of the queue. ORA staff are working to ensure that grants meet the agency deadlines. Please remember that the FINAL electronic version (with routing documents and one paper copy) are due in ORA five (5) working days in advance of the agency

deadline. This allows time for the correction of errors prior to submission and time for resubmission if necessary. Additionally, the Grants.gov servers have a significantly longer response time as the deadline approaches. If a proposal is rejected due to errors we may not receive the notice until after the deadline.

## Office of Research Web Page Redesign



The campus web site is being re-developed and the Office of Research areas, like all departments on campus, will soon be transitioning to the new format. The Office of Research is taking this opportunity to review the content of all our pages. We welcome suggestions from the campus community about

additional content items that should be included and, as always, we encourage the campus community to let us know of pages that need to be updated. Please send suggestions either to the contact address on the pages or to Jeanne Hermann [jhermann@utmem.edu](mailto:jhermann@utmem.edu).

## Grants.gov Adobe Implementation Anticipated Soon

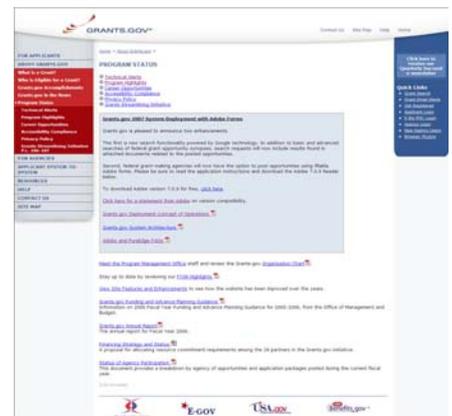
The Grants.gov electronic grant submission system has announced plans to switch from PureEdge software to an Adobe fillable form format to facilitate submissions from both Macintosh and Windows systems. After a delay from the originally planned April 2007 release, another nation-wide web cast seminar has been scheduled for Thursday, July 19th at 12 noon CDT. ORA has reserved GEB A303 for those

who would like to attend, HR128 credit will be offered.

The Office of Research Administration will post additional information on its web site and send email notices to the campus as more information and a definitive timeline for transition to Adobe from PureEdge and Citrix is announced by Grants.gov

You may read more about the transition including required versions of Adobe

Reader at <http://www.grants.gov/aboutgrants/>



## Office of Research Compliance

### *Soon Available! Good Clinical Practices Training*

The Collaborative Institutional Training Initiative (CITI) has added a twelve module course in FDA and ICH Good Clinical Practices (GCP's) to their Human Subjects Protections program. This training will soon be available to investigators and research staff at the Health Science Center.

The twelve modules cover topics ranging from an overview of the process of the development of a new drug, through study conduct, to monitoring, and audits in clinical trials. A certificate of completion is available at the completion of all twelve modules.

Though not mandatory at this time, clinical researchers and staff are encouraged to complete this training ensuring a minimum standard of education in GCP's for clinical trials. Access to training should be available in early August 2007.

### *Federal Appeals Court Rules on Biological Specimen Ownership*

A decision from a federal appeals court last month has bolstered support for university ownership of donated biologic specimens and reaffirmed the currently prevailing view that research participants' ability to control those specimens after donation is profoundly limited. The significance of the decision was underscored by the fact that major research institutions—including Duke, Johns Hopkins and Cornell—along with the American College of Medical Schools, had filed friend of the court briefs in support of the university's ownership of the specimens.

The particular question posed by the lawsuit in *Washington University v. Catalona* was whether 6,000 individuals who had donated tissue to a university biorepository for research reserved sufficient ownership interest in the donated material to dictate that it should be transferred to another institution or individual. In that case donors wanted their specimens to follow their physician/

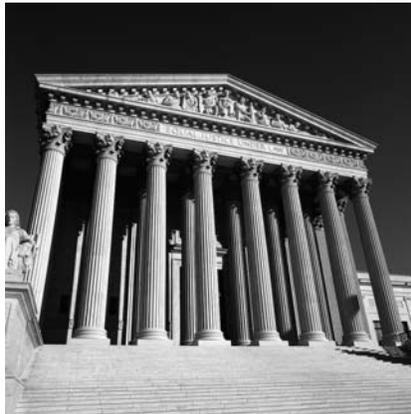
investigator to another university after he left Washington University. The University asserted ownership of the specimens and refused to transfer them as directed by some of the donors.

In granting summary judgment for the university, a federal district court ruled last summer that the donation of biologic materials met all the requirements of an *inter vivos* gift from the research participants to the university, rather than the individual investigator.

On appeal the 8<sup>th</sup> Circuit Court of Appeals last month affirmed the lower court decision and found that even though the consent form signed by most of the participants acknowledged a right to withdraw from the research, participants did not "retain the right to revoke or physically repossess the donated biological materials."

The decision of the 8<sup>th</sup> Circuit Court of Appeals is available at

<http://www.ca8.uscourts.gov/opndir/07/06/062286P.pdf>.



### *Memphis OHSP Monthly Forum*



OHSP monthly forum will not be held in the month of July but will resume on August 21, 2007. If you have suggestions for topics or would like to present your experiences in clinical trials, please contact Janie Gardner at [jgardner@utmem.edu](mailto:jgardner@utmem.edu) or 901 - 448 - 1869.

## ***OHSP Update: The Feds Target Fraud in Clinical Trials***

James Sheehan, Associate US Attorney predicted “a coming storm “ of enforcement focusing on fraud in clinical trials and research at the March 2005 International Pharmaceutical Compliance Summit on Medical Affairs, Clinical Trials, Safety and Publication meeting sponsored by Health Care Conference Administrators L.L.C.

Again in a 2006 speech, Mr. Sheehan noted that the “groundwork” for greater enforcement cooperation between federal regulators and prosecutors is being put in place. In fact, he noted that there will most likely be an upsurge in prosecutions as the HHS Office of Research Integrity (ORI) gets more and more misconduct allegations and establishes the basis for going forward with these cases. In addition, federal investigators and prosecutors are learning how to successfully pull these cases together to achieve a positive result for the plaintiffs.

In the past research misconduct has been viewed as an administrative issue but the move now is to prosecute these as cases of civil and criminal fraud. There are six major areas that engage a federal prosecutor’s interest in considering criminal action in a research misconduct case. These include:

- Cover-ups and Record Alteration or Destruction
- Obstruction During an Investigation
- Misleading, Mistreating or Harming Research Subjects
- Misleading and/or Cheating Sponsors and/or Payors
- Fraud Linked to the Approval of a Drug or Device, and
- Undisclosed Conflicts of Interest

Who is responsible for the mandatory reporting of misconduct? This is another issue that is receiving a lot more attention by prosecutors. Usually there are statutes, regulations and guidance that tell individuals and organizations what they can and cannot do. In research, that is not the case. Research rules mandate processes that rely on informed and independent judgment about whether what should be done is being done. In many institutions it is difficult to identify who “owns” research compliance. IRB’s, offices of research, institutional conflicts of interest committees, etc, all have some piece of the compliance and oversight effort. When prosecutors look at cases, they ask: “Who is in charge? The wrong answer is 20 people.

What can institutions do to avoid a government investigation of its clinical research? Probably the top of the list is for the institution to identify one individual who has the responsibility for the federal assurances and the institutional policies, procedures and guidances regarding research. Other strategies include:

**Establish an effective compliance program** that has written policies and procedures reflecting the institution’s commitment to compliance; designate a compliance officer and a compliance committee; provide education and training for all involved employees, create and maintain an internal monitoring and auditing program to identify problem areas and clearly define roles and responsibilities and assignment of oversight responsibilities.

**Establish a Data and Safety Monitoring plan** that includes a mechanism for monitoring the progress of trials and participant safety; that provides procedures for reporting adverse events; a plan to ensure data accuracy and protocol adherence and an audit program to make sure the data and safety monitoring plan is followed.

**Establish a conflict of interest policy** that designates an official that solicits and reviews financial disclosure statements from each investigator who participates in research; that requires investigators to update financial disclosures during the grant or contract period; that provides guidelines to identify conflicts and a plan to manage, reduce or eliminate conflicting interests; provides a mechanism for maintaining all financial disclosure records and records of any actions taken by the institution in response to an identified conflict as well as conditions imposed on investigators who have conflicts of interest and a policy making available to the appropriate government agency any records regarding all conflicts of interest identified by the institution and the manner in which these conflicts were managed, reduced or eliminated.

*This update is a summary of a report in Drug and Device Litigation: Impact of 2007 and Beyond, Chapter 4, Fraud in Clinical Trials: The Widening Reach of Liability, Enforcement. Dennis A Tosh, Esq. Ed., Thompson Publishing Group, Inc., 2007*

## Research Support Services

### *Dr. Dumas joins LACU*

Effective July 1, Dr. Lynn Dumas began work at UT as the newest resident in laboratory animal medicine. A graduate of Auburn University College of Veterinary Medicine, her special interests are soft tissue surgery, internal and behavioral medicine. Her eight years in private practice will be an asset to the animal care program. Dr. Dumas joins fellow residents Drs. David Hamilton (3<sup>rd</sup> year resident) and Jeetendra Eswaraka (2<sup>nd</sup> year resident) in the 3-year training program that is recognized by the American College of Laboratory Animal Medicine.

### *LACU Per Diem Rates Unchanged for FY08*

The Lab Animal Care Unit (LACU) is pleased to announce that per diem and service rates will remain the same for Fiscal Year 2008. The LACU has implemented a number of measures to reduce overall operating expenses through changes in staffing and operating procedures that have helped to curtail costs through improvements in efficiency. These changes, along with the per diem increase that became effective in October 2006, support keeping the FY08 per diem rates unchanged. Investigators should note, however, that the LACU budget is subject to changes from year to year based on census, species, staffing, supplies and equipment. The FY09 and FY10 projected per diem rates are to be increased based on inflation and adjustment of large animal rates.

With the FY07 budget, the LACU received funding from the State for a capital improvement project that includes replacement of critical major equipment, certain renovations, new automated watering systems, and ventilated caging. The net result of these enhancements will be increased efficiency in husbandry and cagewash operations through labor savings. Project work will be started in late 2007 and completed in early 2008.

The continued concern and support from administration and faculty for the animal resource program has enabled the unit to move forward to accommodate the increased complexity of research at UTHSC while maintaining full compliance with Federal regulations and accrediting agency standards. These resulting changes increase demand for qualified personnel and resources as well as challenge efforts to maintain an AAALAC accredited program. Future goals for LACU will be to continue to implement procedural changes to protect the health of valuable animal subjects, to improve the effectiveness of the overall operations, and to promote the highest level of animal care. Per diem rates can be reviewed on the Lab Animal Care website at <http://www.utmem.edu/research/LACU/index.php>

### *Biomedical Instrumentation Provides Steris Contract Service*

July 1, 2007, marked the beginning of a new service provided to UTHSC by Biomedical Instrumentation (BMI). The contract with Steris Corporation for preventive and corrective maintenance on Steris sterilizers, glassware washers and glassware dryers expired June 30<sup>th</sup> and BMI assumed the role as provider of those services July 1<sup>st</sup>. Three BMI employees have been trained at the Steris Training Center to ensure the same high level of service now received from Steris's own technicians.

BMI will provide four (4) preventive maintenance (PM) inspections per year on each piece of equipment and 24/7 corrective maintenance support in accordance with the FY08 contract proposal. The equipment will be maintained in conformance with the manufacturers' performance standards. PM inspections will be performed during normal working hours and approximately 90 days apart. BMI will maintain detailed documentation on all work performed.

The Biomedical Instrumentation Division has served the extended UT Health Science Center campus since 1948. It offers a broad range of specialized services including computer repair, electronic fabrication, equipment design and repair, mechanical design and fabrication, microscope repair, and rehabilitation engineering services. Visit the web site at <http://www.utmem.edu/research/BMI/> or call 448-5652 for more information.

# Frequently Asked Questions

## *Did You Know?*

### *Research Administration*

**Q: For electronic submissions, what should I list as the site of my NIH grant?**

**A:** The site should be the PI's lab or other location where the work will actually be completed. More than one location can be listed, in cases where co-investigators are working in different labs, either on this campus or at other institutions.

**Q: If I have no human subjects, animals, select agents, consortium agreements, or multiple PI leadership plan, what should I do about those sections on the Research Plan section on an electronic submission?**

**A:** The best thing to do is to skip those sections that are not applicable to your grant on the PHS 398 Research Plan section of the PureEdge form. If you upload a document indicating "Not Applicable," it will take up space and reduce the amount of available space for the actual relevant portions of the grant (please bear in mind the page limitations).

**Q: When I complete my NIH Progress Report (e-SNAP) on Commons, to whom should I route it?**

**A:** Route it to Virginia Geer or Connie Bozant, who will review it and route it to Debbie Smith for final submission. Ginny or Connie will contact the PI if there are any corrections that need to be made.

**Q: When will the Adobe forms be ready for Grants.gov submission?**

**A:** That information is not available. PureEdge for PCs and Citrix for Macs will continue to be used until the Adobe package is ready. ORA will keep the campus informed about the status of the Adobe package as we receive information. It is expected that the package will look similar to the PureEdge package, but will operate on the Adobe software and will, therefore, be platform independent.

**Q: I am trying to meet the 5-working-day advance deadline for an electronic grant submission, but I am not finished with the science. Is it okay to send the package over for the 5-day-advance deadline, continue working on it, and then send a revised package later?**

**A:** No. Unfortunately about 90-95% of the applications received in ORA have SOME errors. The ORA staff needs this time to correct the errors and submit the packages before the agency deadline. If a new package is sent over, the entire package must be reviewed again, increasing the opportunity for errors to be overlooked. If errors are noted by the PI on a specific section after submission to ORA, please contact [egrants@utm.edu](mailto:egrants@utm.edu) for guidance.

**Q: I have not had an opportunity to attend a training session on electronic grant submission. Will the ORA prepare the grant package for me if I send the scientific portion over electronically?**

**A:** No. Unfortunately, ORA does not have the staff time to prepare grant applications for faculty. Departments should be working with faculty to be sure that everyone has the proper training and/or staff support to manage the electronic grant preparation process. Preparing the electronic package is no more difficult than filling out the paper forms; although some of the forms are different, and it requires careful attention to detail since the arrangement of data has been changed (at least for NIH applications). Trainings sessions have been provided and will continue to be provided so that everyone has an opportunity to attend a session. Individual training sessions for departments may be arranged upon request during non-deadline periods.



# Frequently Asked Questions (cont.)

## *Clinical Trials Unit*

**Q: If a study is terminated early, what are the Sponsor's obligations:**

**A:** Both parties are obligated to follow the terms of the agreement, and the agreement generally stipulates each party's obligations in case of early termination. Generally, the sponsor must pay for (1) any amounts earned prior to termination; (2) any nonrefundable costs already incurred (consistent with contract language); and (3) any required amounts negotiated between the parties in order to manage study subject withdrawal from the Study, if applicable. The sponsor's other obligations for indemnification, etc. will survive the early termination in accordance with the contract's terms.

**Q: With whom may confidential information of a sponsor be shared? If I'm working with a hospital or practice group, is it okay to share information with that entity?**

**A:** The Investigator is responsible for carefully reading the agreement and complying with all of its terms, including the confidentiality section (which may be in a confidentiality agreement and/or in a clinical study agreement).

The University is the contracting party and generally agrees to keep certain information (identified in the agreement) confidential and to disclose it only to its employees who have a need to know for the purposes of the agreement/study and to designated third parties ONLY with the sponsor's prior written permission.

So, confidential information provided to the University by the sponsor or as otherwise defined in the agreement cannot be shared with third parties (including hospitals, practice groups, or other non-UT personnel) unless the specific permission is granted by the sponsor.

**Q: If e-transmission of study data is a component of the research study, what issues need to be addressed prior to study commencement?**

**A:** (1) Confirmation, in writing, from the IT area at the site that the site's data transmission lines meet the specifications required by the protocol and the contract's e-transmission section and have been approved by both UT and the Sponsor. The Sponsor/CRO should also be able to provide documentation that they certify or represent that the system of encryption and e-transmission utilized in the research study meet regulatory requirements for such data transmission.

(2) Documentation that all study personnel are trained in e-transmission requirements.

(3) Documentation of system and software training and validation if computer equipment provided by Sponsor/CRO is to be utilized in the Study.

## *Institutional Review Board*

**Q: I am interested in conducting a research study using a commercially available drug for the approved purpose. Does the UTHSC IRB need to review this research before my study is initiated?**

**A:** Yes. All clinical investigations (which means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA), or is not subject to requirements for prior submission to the FDA, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit) require UTHSC IRB review and approval.

# Contact List



Name	Title	Office	Phone	Email
<b>Office of Research</b>				
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