

The Research Notebook

A Publication of the Office of Research

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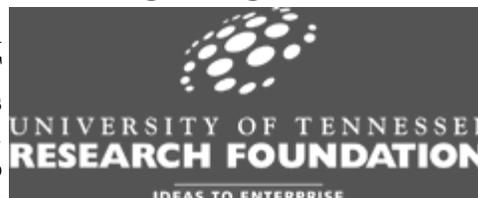
OCTOBER 2010

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2011 Technology Maturation Funding Program

UTRF announces the fourth annual maturation funding program to help UT researchers further develop technologies that have potential for commercial success. Grant funds will allow researchers to better position their technologies for licensing and commercialization. Up to \$15,000 (direct costs) will be awarded to the highest ranking proposals.



Researchers are invited to propose work on inventions and discoveries that either have been previously disclosed to UT and assigned to UTRF or to propose new disclosures with a development plan. Last year UTRF funded nine of forty-one UT system-wide submissions, four of which were from UTHSC researchers:

John Buolamwini, Pharmaceutical Sciences, for optimization of novel anti-cancer compounds with activity against multiple types of cancers

Michael Levin and Sangmin Lee, Neurology, for testing a serum biomarker for Alzheimer’s disease

Jenna Steinle, Ophthalmology, for eye drops that prevent diabetic retinopathy
Emma Tillman, Richard Helms, and Michael Storm, Clinical Pharmacy, for a new treatment for parenteral nutrition associated liver disease

UTRF used a panel of subject matter and technology commercialization experts from across the state to evaluate both the technology and the development plan proposed by each researcher. UTRF also solicited advice from Technology 2020 and Memphis Bioworks Foundation, economic development organizations engaged by UTRF to assist with technology commercialization.

The maturation program has already shown how modest amounts of funding can significantly impact the potential success of an invention. Of 20 projects funded for the prior two years, 12 have either resulted in obtaining additional research funds, executing a license, or the technologies are in discussions with potential licensees.

Submission Rules

- Open to all UT researchers (faculty, staff and students) at all campuses and institutes.
- Projects must be related to an existing UT invention/creation disclosure OR a proposal can be accompanied by a new UT invention/creation disclosure.
- Projects should provide new data or further demonstrate the technology to increase its commercial readiness.
- Funds should be directed to labor, materials, and services necessary to achieve the proposed deliverable(s).
- Proposal should not exceed 3 pages and should describe the technology, the plan of work, the expected results, a budget (direct expenses only), and your assessment of the commercial opportunities for the technology.

(Continued on page 2)

2011 Technology Maturation Funding Program (cntd.)

(Continued from page 1)

- Proposal should be submitted to your campus research office by November 12, 2010.

Judging Criteria

- Demonstration of a path for commercial development (45%)
- Market potential (40%)
- Stage of development (15%)

Deadlines & Schedule

Deadline for proposal submission	November 12, 2010
Awards announced	December 17, 2010
Project start date	January 17, 2011
Project completion date	October 14, 2011
Final report due	November 18, 2011

For more information, visit http://utr.f.tennessee.edu/faculty/funding_programs.php

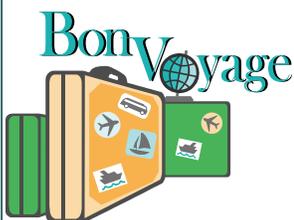
or contact: Dr. Richard Magid
Vice President, UT Research Foundation
rmagid1@uthsc.edu
901-448-1562
<http://utr.f.tennessee.edu>

RBL Goes Live

The Regional Biocontainment Laboratory (RBL) officially began operations the week of September 27, when two investigators relocated their research efforts into the lab. This building, funded largely from a grant from the NIAID, is the culmination of years of planning, building, commissioning and certifications to commence operations. The primary purpose of the RBL is to provide a safe, state-of-the-art facility for research requiring Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) containment. Research conducted at the RBL will focus on the development of new drugs, vaccines, and diagnostics to protect the general population from emerging infectious diseases and the intentional nefarious use of biological agents. The RBL is fully equipped to provide investigators with advanced imaging and immunology capabilities to support and enhance their research projects. Prior to going "hot", RBL leaders provided tours of the facilities so that interested UT and community leaders would be able to experience first-hand the innovative facilities and infrastructure required to maintain operations. Now that research is ongoing, building access will be restricted to authorized research personnel. For additional information, please visit the RBL website at <http://www.uthsc.edu/research/RBL/>.



Personnel Changes at UT Research Foundation



The UT Research Foundation wishes Marcia Phillips a happy retirement and welcomes Tinieka Triplett as our new Senior Administrative Services Assistant. Marcia worked at UTRF from 2001 to 2010, keeping the technology transfer office running as UTRF expanded from two to four people and moved several times. Tinieka is moving to UTRF from the Office of Research Compliance and will be located at our office in the 910 Madison Building, Suite 827. You may also contact Tinieka at ttriple2@uthsc.edu or 448-7827.



Office of Research Administration

Reminder from NIH: Last Chance to Submit Second Resubmissions

As we near the end of A2s (second resubmissions), take the opportunity to revise and resubmit before the [final deadlines](#). You can determine your eligibility by checking the status screen of your eRA Commons account. Applications with Council meeting dates through 2009/08 are eligible for two resubmissions.

If you are eligible to submit a second resubmission, it must be submitted no later than the appropriate upcoming due dates for [Cycle III](#). Remember, even if your original competing application was submitted when longer page limits were in effect, [the resubmission has to conform to the new format and shorter page limits](#).



NIH Podcasts Available

NIH has a number of podcasts available for investigators, including a recent podcast on "Using Plain Language in NIH Applications."

Dr. Sally Rockey, Director for Extramural Research, describes which parts of the application are made public via the RePORTER website and why using plain language in these sections can help express the value of your research to the public in "[Using Plain Language for Application Titles, Abstracts and Public Health Relevance Statements](#)."

A list of podcasts with links and transcripts is available here: http://grants.nih.gov/podcasts/All_About_Grants/index.htm



Welcome Monica Orange

The Office of Research Administration welcomes Monica Orange, our new Grants and Contracts Specialist. Monica began her career with UTHSC in December, 2007, in the Department of Telehealth as an Administrative Assistant working with various projects, including ADT (Addressing Diabetes in Tennessee), Rural Pharmacy Program, and Kids in Custody. Monica prides herself in being helpful and always a team player. Please help us welcome Monica when you visit our office; you will see her smiling face at the front desk. You may contact her at morange@uthsc.edu or 448-5587.



Reminder to Send ORA the Final Version of the Grant

Once your grant is submitted to Research Administration and errors noted by ORA have been corrected, the application package will be submitted to the NIH. Once the grant has been submitted via grants.gov, we cannot resubmit to correct typos, etc. If an error is noted due to a problem that occurred during transmission, we can reject the application and resubmit with a cover letter explaining the problem.

NIH, AHRQ, and NIOSH to Eliminate Error Correction Window for Due Dates on or after January 25, 2011

(excerpted from <http://grants.nih.gov/grants/guide/notice-files/not-od-10-123.html>)

Beginning with due dates on or after January 25, 2011, NIH, AHRQ, and NIOSH will eliminate the [error correction window](#) from the application submission process. The agencies have made this decision after carefully evaluating the comments received from the public in response to the [RFI \(Request for Information\)](#) released on March 12, 2010. Eliminating the error correction window will ensure consistent and fair deadlines for all applicants and better align these agencies' application submission processes with the submission processes of other federal agencies.

The error correction window originally was implemented in December, 2005, as a temporary measure to facilitate the transition from paper to electronic submission of grant applications. The window allowed applicants an opportunity after the deadline to correct missing or incorrect aspects of their applications, identified by NIH system-generated errors and warnings displayed to the applicant after submission.

Beginning on January 25, 2011, all applications submitted after 5 p.m. local time of the applicant organization on the due date will be subject to the [NIH late policy](#) and may not be accepted for review. In addition, any post-submission application materials will be subject to the new policy detailed in the NIH Guide Notice [NOT-OD-10-115](#).

Please note that NIH will continue to make accommodations for Federal [system issues](#) that threaten or prevent on-time submission of an individual application, [if appropriately documented and verified by NIH support staff](#). Moreover, NIH still will determine and implement contingency plans on an as-needed basis for widespread system issues and natural disasters. The agencies remain committed to assisting all grant applicants through the electronic submission process. To this end, NIH conducts periodic reviews of its system [validations](#) and has made many changes over the years to relax enforcement of business rules that may not be necessary to perform a thorough scientific review of each application. NIH will continue to reevaluate its validations to determine the necessity of each.

The elimination of the error correction window does not affect the two-business-day [application viewing window](#) (i.e. the time an applicant has to view the electronic application image in eRA Commons upon NIH's receipt of an error-free application). Applicants still will be able to view their application and reject and submit a corrected application prior to the submission deadline. NIH, AHRQ and NIOSH encourage applicants to submit in advance of the due date to take advantage of the opportunity to correct errors and warnings and to review the application in the eRA Commons before the deadline.

NIH's [Applying Electronically website](#) includes a section on [avoiding common errors](#), [annotated application "cheat sheets"](#), and a detailed list of the [error and warning messages](#) an applicant may encounter, among other resources that may be of interest.

Questions about this notice should be directed to:

NIH Grants Info
Phone: 301-435-0714
TTY: 301-451-5936
E-mail: GrantsInfo@nih.gov



Office of Research Compliance

OHSP Training Opportunities



Chattanooga OHSP Monthly Forum

The Research Coordinator Forum is a monthly “brown-bag lunch” series that is open to all research coordinators and key personnel involved with and interested in research. Classes are held the fourth Tuesday of the month in the UTCOMC Suite 100 Conference Room. For more information, contact Sylvia.Friedl@erlangers.org.

October 26, 2010

Standard Operating Procedures:

Yours, Mine and Ours

Sylvia Friedl, CIP, CCRP

November 23, 2010

Research Risk Management

Jeffrey Woodard, Manager/Attorney

EHS Office of Risk Management

December 28, 2010

No program this month

January 25, 2011

Electronic Records and Signatures

(21 CFR Part 11 and Other Useful Info)

Steve Winter, EHS Security Analyst

Thursday, February 15, 2011

Research Symposium

Probasco Auditorium

March 22, 2011

Research Drug Accountability

Dennis Buckelew, D.Ph.

EHS Investigational Drug Services

April 26, 2011

How do YOU Do It?

A review of coordinators’ best loved templates and practices

May 24, 2011

SRC, IRB, and Contracting Update

Stacey Hendricks, CIM

UTCOMC/EHS IRB and SRC Administrator

Memphis Fall OHSP Conference

The UTHSC Office of Human Subjects Protection (OHSP) will be hosting its Fall Conference entitled “***Medical Device Clinical Trials: Regulatory Issues and Challenges***” on Thursday, October 21st from 8 AM -12 PM. The event will be held in room 305 of the UTHSC Student Alumni Center. This seminar will provide insight into a device trial from the perspective of the IRB, sponsor, and the law. You may register by visiting the OHSP upcoming events page at http://uthsc.edu/research/research_compliance/OHSP/events.php Please contact Patricia Kerby at 448-1869 with questions.

Speaker/Topics:

Review of Medical Device Studies - Terrence Ackerman, PhD

Regulatory Issues and Challenges: Perspective from the Medical Device Industry - Jason Jones, MS, CCRP

Device Clinical Trial Considerations from the Perspective of FDA’s Design Control Requirements - Susan Fentress, JD

Upcoming AAALAC Site Visit and Laboratory Preparations

On November 2nd and 3rd, 2010, the UTHSC animal care and use program will be visited by representatives from the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC), International. This is a re-accreditation site visit. All core animal facilities will be inspected thoroughly. In addition, the visitors will choose which animal research laboratories they wish to inspect. During these tours the visitors will likely ask to see locations, equipment, and records related to animal use. They may wish to ask questions of any and/or all individuals associated with experiments involving animals. Note that the site visitors will rely on adherence to the ILAR Guide for the Care and Use of Laboratory Animals, the Federal Animal Welfare Act and Regulations, and other key guidance documents as the basis for their assessment. Below, please find a series of suggestions for how you may prepare your research program for such a laboratory visit.

Before the visit:

- Make sure that all personnel that have contact with animals or animal tissue are current with their registration in the UTHSC Occupational Health and Safety Program (OHSP). AAALAC will closely assess if we have a functional OHSP.
- Make sure that all personnel associated with animal protocols are aware of the goals and procedures used in the protocol, have been fully trained to do the work assigned to them, and follow the protocol as approved. There will be emphasis on animal studies that involve survival surgery, the use of hazardous agents, and experiments that may result in more than momentary or slight pain or distress. AAALAC may ask laboratory personnel about studies at random.
- Make sure that all experimental, animal, drug, and chemical documentation (including MSDS sheets) is up to date, organized, and readily accessible. AAALAC may ask to spot-check your records.
- Make sure that there is current TN State Board of Pharmacy Researcher and DEA licensure for all controlled substances used in animal experimentation. AAALAC may ask to see your drug records.
- Make sure that pharmaceutical-grade drugs are being used when they are available and that no drugs are used past their expiration date.
- Make sure that all equipment associated with animal experimentation is clean and in working order. AAALAC may ask to see this equipment.
- Make sure that all canisters used to scavenge expelled anesthetic gases have been weighed before the first use and that any that are overweight have been discarded.
- Make sure that appropriate Personal Protective Equipment (PPE) is available and that all personnel are using it in the correct manner.
- Make sure all animal protocols are up to date, that all animal activities are described in an approved protocol, and that a copy of all documentation is readily available and can be supplied upon requested.
- Make sure that each performance site has a copy of the page entitled "Have Concerns Regarding Animal Care or Treatment?" prominently posted. You may be asked what you would do to report animal care concerns. If you do not have this notice, please contact the IACUC office to obtain a fresh copy.

At the time of the site visit:

- Please try to be present in the laboratory (or accessible) if possible on the afternoon of November 2nd and the morning of November 3rd. If you cannot be present, please try to have an informed individual available to answer questions about your protocol(s) in case they should arise.
- Realize that the AAALAC site visitors may view any animal experiments being conducted on those days.
- If asked a question regarding your work, please try to answer it fully, realizing that the AAALAC site visitors are our advocates with AAALAC Council and are engaged in gathering information to support our case for continued full accreditation.

If you have questions or comments about this process, please do not hesitate to contact the Office of Research Compliance (448-3904), and we will be more than happy to assist you.

Frequently Asked Questions

Did You Know?

Research Administration

Q: I am submitting an NIH grant with a modular budget. Does ORA require a detailed budget?

A: No. ORA does not require detailed budgets for modular grants. However, if not enough information is provided for ORA staff to determine the calculation of F&A, they may ask for additional information. Some departments or colleges may require the detailed budget at the time of grant submission, and the Office of Sponsored Projects (accounting) will require one when the grant is funded.



Q: Must I include F&A costs when submitting a grant? Is it okay if I use a lower rate than that approved for the campus?

A: UTHSC requires that full F&A be included with all grant applications unless the sponsor has a written policy stipulating that F&A is not allowed or stipulating a rate lower than UTHSC's standard rates. Any exceptions must be approved by the Vice Chancellor for Finance and Operations. Information on UTHSC F&A rates is here: http://www.uthsc.edu/research/research_administration/docs/F&A%20info%20for%20web%207%2014%2008.pdf

Institutional Biosafety Committee

Q: My lab is using transgenic animals for studies that do not otherwise involve plasmids or viral vectors. Do I need to submit an IBC registration and get IBC approval for this work?

A: Yes. According to the *NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES* (Sept. 2009) work with transgenic animals is considered “recombinant DNA research.” There are three levels for work utilizing transgenic animals.

- If you are purchasing (or obtaining) transgenic animals and using them directly, or if you are maintaining a breeding colony where you are not cross-breeding two transgenic strains, then the work is classified as III-F (exempt). Note that exempt work still needs to be registered with the IBC.
- If you are cross-breeding two transgenic lines to generate a new strain the work is classified as III-E, which means you must submit an IBC registration at the time the work is initiated; e.g. you do not need prior approval from the IBC before the work begins, but a registration must be submitted.
- If you are generating transgenic animals de novo the work may be either III-D or III-E, depending on the transgene. Generally, you should submit a registration and obtain approval prior to initiating this type of work (e.g. III-D classification).

Q: I am interested in doing work in the Regional Biocontainment Laboratory. Where can I find information on the RBL and the procedures needed to initiate a project?

A: Information on the RBL, including currently approved SOPs, available resources, equipment, equipment usage charges, and project request forms can be found as sub-sections on the IBC home page (http://www.uthsc.edu/research/research_compliance/IBC/). The main RBL tab includes general information on the RBL as well as requirements for training and registration of personnel. The RBL Forms tab describes the procedure for submission and review of project requests. All projects must be vetted through the UT RBL Executive Committee (UTREC) and approved by the Committee on Biocontainment and Restricted Entities (COBRE), which is a sub-committee of the IBC. For additional information contact the RBL Director (Dr. Gerry Byrne – gbyrne@uthsc.edu) or the IBC chair (Dr. Michael Whitt – mwhitt@uthsc.edu).

Frequently Asked Questions

Did You Know?

Institutional Animal Care and Use Committee



Q. What approvals are necessary to make changes in animal activities supported by an NIH grant?

A. Changes in animal activities always require IACUC approval, but may also require independent review and approval by NIH. The terms “significant change” and “change in scope” define the distinctions to be made. A change in an animal activity can be both a significant change requiring IACUC review and a change in scope requiring notification to the NIH funding component.

A change in activities typically is not a change in scope. Most investigators should be familiar with the criteria for major and minor revisions in place at UTHSC, posted on the IACUC [forms](#) page. The investigator is responsible for submitting such revisions for IACUC review and approval by the appropriate mechanism before implementing any change.

In contrast, **change in scope**, according to [NIH Grants Policy Statement](#) (GPS), refers to a change in the direction, type of research or training from the aims, objectives, or purposes of the approved project. The GPS provides examples of potential "indicators" of changes in scope, and those relevant to animal activities include: change in specific aims, shift of research emphasis from one disease to another, substitution of one animal model for another, application of a new technology (e.g., changing assay methods), and "any change from the approved use of animals" (the latter seems more generally related to a change in protocol approval status, or to the addition or removal of animal studies under the project). Since not every change in animal model or animal use represents a change in scope, the interpretation of such "indicators" ultimately may require consultation with NIH grants management personnel.

The IACUC is not responsible for notifying the NIH of changes in scope; rather the Principal Investigator (PI) and the Authorized Organizational Official (AOO) are responsible for requesting such a change. The request must be made in writing to the Grants Management Officer (GMO) of the NIH Institute or Center (IC) that funds the grant (the funding component) no less than 30 days before the proposed change, and must be signed by both the PI and the AOO.

(Adapted from [FAQ B13](#) on the NIH Office of Laboratory Animal Welfare (OLAW) website.)

Institutional Review Board

Q: Are researchers required to maintain a subject eligibility checklist even if they are conducting an investigator initiated study?

A: The Guidance for Good Clinical Practice (GCP) recommends that researchers maintain certain essential documents for the conduct of a clinical trial. Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator with the standards of GCP and with all applicable regulatory requirements. In addition, these documents are also the ones that are usually audited to confirm the validity of the trial conduct and the integrity of data collected.

One example of an essential document is a Subject Screening Log or Eligibility Checklist. A screening log or eligibility checklist provides documentation of subjects who entered pretrial screening and whether or not the subjects met the study's inclusion/exclusion criteria. For more information regarding other essential documents for the conduct of a clinical trial, visit (<http://www.fda.gov/oc/gcp/default.htm>).

Contact List



<i>Name</i>	<i>Title</i>	<i>Phone</i>
Office of Research		
Leonard Johnson, Ph.D.	Vice Chancellor	448-7125
Jane Poulos	Sr. Business Manager	448-3746
Lisa Bronte	Sr. Admin Asst	448-7125
Connie Jackson	Accounting Asst	448-2734
Clinical and Translational Science Institute		
James Dale, M.D.	Assoc. Vice Chancellor	448-2101
Debbie Bueltemann	Exec Assistant	448-2101
CTSI Clinical Research Unit		
Sam Daggogo-Jack, M.D.	Director	448-2608
Risa Ramsey, Ph.D.	Admin. Director/RSA	516-2079
Kathy Pitts, R.N.	Nurse Director	516-2214
Cornelia Bobo, R.N.	Research Nurse	516-2212
Bridgette Cain	Administrative Assistant	516-2212
Ruben Cuervo, M.D.	Research Coordinator	516-2212
Turid Dulin, R.N.	Research Nurse	516-2212
Kristin McDaniel, R.D.	Nutritionist	516-2212
Alice Milem, R.N.	Research Nurse	516-2212
Mary Peterson, R.N.	Research Nurse	516-2212
Research Support Services		
Helen Parsons	Business Director	448-7101
Jayne Collins McKinnie	Budget Coordinator	448-5652
Lorraine Albritton, Ph.D.	Director - Viral Vector	448-2087
Dan Rosson, Ph.D.	Director - Flow Cyt	448-4279
Tiffany Seagroves, Ph.D.	Manager - Bio-Imaging	448-5018
Laboratory Animal Care Unit		
Tim Mandrell, D.V.M.	Director	448-5656
Andrea Briggs	Animal Procurement	448-5656
Joyce Jones	Business Manager	448-5453
Sherry Frazier	Facility Supervisor	448-7308
Barbara Blakely	Spvr - Nash/Wittenborg	448-1429
Brad Stevens	Spvr - Coleman, Mol. Sci.	448-5454
Leadra Williford	Lead Technician, CRB	448-5656
David Hamilton, D.V.M.	Asst Prof-Nash/CRB	448-7311
Scott Jackson, D.V.M.	Instr - Coleman/Mol. Sci.	448-7134
Molecular Resource Center		
Donald Thomason, Ph.D.	Executive Director	448-7224
William Taylor, Ph.D.	Director	448-6165
Tom Cunningham, Ph.D.	Associate Director	448-6191
Lorne Rose	Sr. Research Specialist	448-8229
Terry Mark-Major	Business Manager	448-2656
Felicia Waller	Specialist	448-8746
Jian Yan	Research Associate	448-2730
Cancer Research Building		
Lawrence Pfeffer, Ph.D.	Director	448-7855
Regional Biocontainment Laboratory		
Gerald Byrne, Ph.D.	Director	448-6060
Jennifer Stabenow	Facility Manager	448-6649
Lillian Zalduondo	Supervisor	448-6408

<i>Name</i>	<i>Title</i>	<i>Phone</i>
Research Administration		
Deborah Smith, Ed.D.	Asst Vice Chancellor	448-4823
Clinical Trials Unit		
Melanie Luchs	Associate Director	448-3303
Ruthie Ruston	Specialist	448-3126
Grants and Contracts Unit		
Ginny Geer	Program Admin	448-1668
Connie Bozant	Coordinator II	448-4188
Monica Orange	Specialist	448-5587
Carlisa Jackson	Data Control Spec.	448-5532
Vacant	Sr. Coordinator	448-3046
Wanda Donato	Sr. Coordinator	448-2037
Research Compliance		
Randall Nelson, Ph.D.	Assoc Vice Chancellor	448-3533
Vacant	Admin Svcs Asst	448-2164
Vicki Baselski	Infection Control Chair	448-6329
Michael Whitt, Ph.D.	IBC Chair	448-4634
Deborah James	IBC Admin Res Asst	448-2871
Vivian Loveless, Pharm.D.	Radiation Safety Chair	448-6931
Institutional Animal Care and Use		
Mary Frances Braslow	Administrator	448-3904
Thaddeus Nowak, Ph.D.	Chair	448-7384
Treavor Sweatman, Ph.D.	Vice Chair	448-3904
Institutional Review Board		
Terrence Ackerman, Ph.D.	Chair	448-4824
Cameron Barclay	Associate Director	448-4824
Donna Hollaway	Compliance Specialist	448-2933
Bonnie Binkley	Administrator	448-1343
Kim Prachniak	Administrator	448-5060
Donna Stallings	Administrator	448-4824
Holly Herron	Admin Research Asst	448-4824
Office of Human Subject Protections		
Sylvia Friedl	C. Officer - Chattanooga	
Patricia Kerby	C. Officer - Memphis	448-1869
Will Wallace, J.D.	C. Officer - Knoxville	865-305-6192
Research Informatics		
Jeanne Hermann	Director	448-5043
Lawson Culver	Administrator	448-1183
Tricia Page	Program Manager	448-2753
Steve Wills	Program Manager	448-2389
Additional Research Related Contacts		
University of Tennessee Research Foundation		
Richard Magid, Ph.D.	Vice President	448-1562
Lakita Cavin, J.D., Ph.D.	Staff Attorney	448-7827
Janet Ralbovsky, M.D.	Licensing Associate	448-1146
Tinieka Triplett	Office Manager	448-7827

The Research Notebook
Jeanne Hermann, Editor
jhermann@uthsc.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@uthsc.edu