

The Research Notebook

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Inside this issue:

<i>Welcome</i>	1
<i>New Assistant Vice Chancellor for Research</i>	1
<i>Research Administration</i>	2
<i>Research Compliance</i>	3
<i>FAQ</i>	4
<i>Human Subject Protections</i>	5
<i>Contact List</i>	6

Special points of interest:

- Randall Nelson, Ph.D., named Assistant Vice Chancellor for Research
- Task Forces formed to evaluate F&A recoveries, clinical trial processes, and electronic grant proposal submissions
- New chairs named for IACUC and rDNA committees

Welcome from Interim Vice Chancellor

Welcome to the inaugural edition of the Office of Research Newsletter. We will use the newsletter to keep the campus apprised of local, national, and international developments in the research arena. My first project as Interim Vice Chancellor will be to consolidate and formalize our efforts in research compliance. We have named Dr. Randall J. Nelson as Assistant Vice Chancellor for Research to head a campus research compliance reorganization. We have also organized three task forces to make recommendations for



improvements regarding processes for F&A recoveries, clinical trials administration, and electronic grant submissions. We welcome your comments and suggestions to improve campus communication regarding research issues.

Assistant Vice Chancellor for Research Named

Dr. Randall J. (Randy) Nelson, Professor of Anatomy and Neurobiology, has been named Assistant Vice Chancellor for Research. Dr. Nelson will coordinate research compliance activities related to human subjects protection, animal care and use, recombinant DNA, biosafety, and environmental and workplace safety. Dr. Nelson recently completed his term as a council member of the Institute for Laboratory Animal Research (ILAR), which is part of the National Research Council of the National Academies of Science. He is a member of the Committee on

Animal Research of the Society for Neuroscience and has recently been appointed as an *Ad Hoc* Consultant for the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). He also served as a scientific delegate to an international harmonization workshop held in conjunction with the 5th World Congress on Alternatives and Animal Use in the Life Sciences. With this new position, he steps down from the Institutional Animal Care and Use Committee (IACUC), of which he has been a member for twelve years and chair for the last three.

Office of Research Administration

Electronic Proposal Submission

A working group has been formed to plan and test an electronic proposal development and submission system.

The planned system would allow principal investigators to develop their entire proposal electronically. The PIs could then electronically submit their proposal for departmental and campus

Working group set to evaluate online proposal development system.

approvals. The planned system has been approved for system-to-system online proposal submissions to meet the

requirements of federal granting agencies.

This initial small task force is composed of representatives of departmental, college, and institutional personnel involved in grant preparation and submission and is chaired by Dr. Deborah L. Smith, Director of Research Administration.



Clinical Trials Task Force

A Clinical Trials Task Force has been formed to discuss, review, and make recommendations for expediting the campus clinical trials review and approval process. Dr. Grant Some, chair of Preventive Medicine, is chairing the task force.

The Clinical Trials Task Force is composed of 25

members representing the colleges of UTHSC, Methodist University Hospital, UTRF, The MED, and UT Medical Group.

The group will conduct several fact-finding meetings prior to making recommendations for process improvement to Dr. Rusty Johnson.

Clinical Research Listserv

The Clnresearch Listserv is a mailing list that was created to provide a forum for research professionals to discuss issues in support of clinical trials at the UT Health Science Center. Members of the listserv may include investigators, clinical coordinators, trial managers, site managers, and research professionals from the committees, boards, offices and departments that support clinical trials at UTHSC.

Members may use the listserv to ask questions of their peers and to clarify the process at UTHSC for participating in clinical trials. The Clnresearch Listserv sends out e-mails about Internet and software technology being pursued at the UT Health Science Center in support of clinical trials. Administrative and compliance issues are also discussed on the Clnresearch listserv.

Two ways to join the clnresearch listserv:

1. Send an e-mail to Anne Laulederkind at alauled@utmem.edu with your name and the e-mail address you wish to have added to the listserv.
2. Send an email to clnresearch-request@listserv.utmem.edu with SUBSCRIBE as the subject line.

Office of Research Compliance

The newly-formed Office of Research Compliance will serve as a nexus for compliance-related education, training, and monitoring, as well as assuring that there is quality control of UTHSC research endeavors. This office will provide centralized administration and serve as the primary point of contact for research compliance issues. As such, the function of this office is to provide an interface between faculty, staff, students, and campus compliance committees. It will foster and safeguard the



institution's culture of compliance. This office will coordinate many research-related aspects of human subjects protection, animal welfare, biosafety, and safety in the research workplace. By centralizing administrative functions of the institution's compliance committees, it will be possible to shorten the time between protocol submission and approval, increase interactions between committees, and provide the research stakeholders with a primary point of contact for compliance-related activities and issues.

Nowak Named Chair of IACUC

Interim Vice Chancellor Johnson has appointed Dr. Thaddeus S. Nowak, Jr. to chair the IACUC. His term as chair began on November 1.

Dr. Nowak, Professor of Neurology, has been on the

faculty of UTHSC for 13 years, having arrived here in 1992 following 12 years at NIH. Dr. Nowak has gained expertise in all aspects of animal care and use regulations through his IACUC membership. His

research involves experimental models of stroke and recovery.



Albritton Named Chair of rDNA Committee

This summer, Dr. Lorraine Albritton, Professor, Department of Molecular Sciences, joined as chair, the committee reviewing rDNA applications. Dr. Albritton assumed the responsibilities of the Chair from Dr. Pat Ryan, Associate Professor, Department of Molecular Sciences, who served the University in that capacity for over 15 years.

Chancellor Owen approved a staff support person for the rDNA committee, and Ms. Deborah James assumed the position in mid-July.



In addition to her administrative duties in maintaining the records of rDNA protocols and organizing committee meetings, Ms. James can assist faculty in locating safety regulations and Standard Operating Procedures for new and revised protocol submissions. She has made available a new online rDNA form on the Compliance page of the Office of Research website at http://www.utm.edu/research/research_admin/index.php?doc=compliance.htm. You can reach Deborah James by phone at 448-4286 or via email at DJames8@utm.edu.

Licensing for the Use of Controlled Substances

It is imperative that all researchers using controlled substances and/or legend drugs obtain an individual license from the Tennessee State Board of Pharmacy (TSBP) for the use of these substances in addition to obtaining a license from the DEA. On July 6, 2005 all researchers received a memorandum indicating that soon it will no longer be appropriate to reference the university's TSBP license number (R00019) when submitting applications to the DEA. That license will expire on December 31,



2005. The process for obtaining a TSBP Researcher License is relatively simple. Several researchers on campus have obtained their own license already. Application forms and instructions for completing these forms may be obtained by contacting Mary Frances Braslow (448-3904). The cost of the application is \$60.00 and the license is issued for two years. Please apply for your Tennessee State Board of Pharmacy Researcher License at your earliest convenience.

New Human Subject Training Program Launched

A new human subject training program has been approved by the Chancellor and the Interim Vice Chancellor for Research. The Office of Human Subject Protections is offering this mandatory program for investigators and all personnel involved in human research at the Health Science Center. The Blackboard module will no longer be used. Because this requirement

will affect many individuals, it was felt that it would be helpful to have Registration Guide readily accessible on-line prior to implementation. You can access the Registration Guide on the web at the following URL:

http://www.utmem.edu/research/compliance/OHSP/index.php?doc=CITI/citi_reg.htm

Did You Know?



Q: I am planning a research project using purchased human cell lines in an animal model. Do I need IRB approval?

A: Yes, Cell research involving human subjects or information, or products derived from human subjects must be submitted to the IRB for approval.

Q: I am submitting a grant which requires electronic submission by the PI. Do I have to let anyone know?

A: Yes, All grant proposals should be submitted for review and approval by department, college, and institutional offices prior to submission to the funding agency.

Q: Is it permissible to grant an administrative extension of IACUC approval so as to avoid expiration?

A: No. For PHS purposes, IACUC review following the provisions at IV.C.2. of the PHS Policy must be accomplished at least once every three years. The IACUC may not extend the three-year approval by any means other than IACUC review and approval using the procedures of IV.C.2. When IACUC approval expires, it is no longer valid. Continuation of animal activities beyond the expiration is a serious and reportable violation of PHS Policy. ***In all issues involving animal care and use, it is wise to first consult the IACUC before proceeding with the activity.***

Office of Human Subject Protections

With offices and personnel at Memphis, and the Graduate School of Medicine in Chattanooga and Knoxville, the Office of Human Subject Protections provides oversight to all activities that pertain to the inclusion of humans as research participants. Its mission is to create an environment that fosters the ethical conduct of human subjects' research through quality assurance and education.

Compliance Officers:

- Sherry Brewer, JD
OHSP, Knoxville
- Sylvia Freidl, BS
OHSP, Chattanooga
- Janie Gardner, MS, CCRP
OHSP Memphis



Monthly OHSP Research Forum



The monthly research forum will resume in January 2006. OHSP forums are held on the second Tuesday of each month (except July and December) at noon in the 1st floor conference room of the 66 Pauline Building. All research staff are invited to attend. Contact Janie Gardner at jjgardner@utmem.edu with suggestions for topics and/or speakers for the upcoming year.

OHSP monthly research forums meet the criteria for professional development credit, and attendance is documented in the Human Resources Training Database. Letters will be distributed to each participant each December documenting total earned hours of credit. Forums are also approved for continuing education credit.

Newly Certified Research Staff

To encourage certification of clinical research staff at UTHSC, OHSP hosted the Society of Clinical Research Associates (SoCRA) Certified Clinical Research Professionals examination on September 8, 2005. Newly certified as CCRPs are Linda Seely, Office of Research Administration Clinical Trials Unit, Mary Beth Murphy, RN, Department of Medicine-Endocrinology, and Janie Gardner, MS, Office of Human Subject Protections.

In addition, Neysa Rhoads, RN, Preventive Medicine and Dana Martin, RN, GYN Research received certification as Clinical Research Coordinators (CCRC) through the Association of Clinical Research Professionals in October.

Congratulations to all!

F & A Recovery Task Force



A Task Force on F&A Recovery, composed of faculty and staff, will review and make recommendations regarding distribution of F&A and salary recovery funds. Dr. David V. Smith, chair of Anatomy and Neurobiology, is chairing this Task Force.

New January Forum Date/Location

As a result of the combined efforts of the Office of Human Subject Protections, the Memphis VAMC, and the UTHSC Department of General Pediatrics, The Memphis Area Combined Ethics Conference will be held January 17, 2006. The OHSP January forum will be folded into this activity. Please come and listen to historian and author, James H. Jones, discuss the ethical issues revealed in his book, *Bad Blood: The Tuskegee Syphilis Experiment*, at noon in the Le Bonheur Auditorium. Lunch will be provided.

Contact List



<i>Name</i>	<i>Title</i>	<i>Office</i>	<i>Phone</i>	<i>Email</i>
Office of Research				
Leonard Johnson, Ph.D.	Interim Vice Chancellor		448-7125	ljohns28@utmem.edu
Jane Poulos	Senior Business Manager		448-3746	jpoulos@utmem.edu
Research Administration				
Deborah Smith, Ed.D.	Director		448-4823	dsmith@utmem.edu
Linda Seely	Associate Director	Clinical Trials	448-3303	lseely@utmem.edu
Lisa Bronte	Administrative Aide	Clinical Trials	448-3126	lbronte@utmem.edu
Vera Reeves-Hudson	Coordinator II	Research Admin	448-1668	vreeves@utmem.edu
Rosa Wilson	Specialist	Research Admin	448-5587	rwilso11@utmem.edu
Carol Baumgartner	Coordinator	Research Admin	448-5985	cbaumgar@utmem.edu
Wanda Donato	Coordinator	Research Admin	448-5587	wdonato@utmem.edu
Jewel Morgan	Specialist	Research Admin	448-5532	jmorgan6@utmem.edu
Chevella Oliver	Clerk	Research Admin	448-5985	coliver2@utmem.edu
Research Compliance				
Randall Nelson, Ph.D.	Assistant Vice Chancellor		448-3533	rnelson@utmem.edu
Mary Frances Braslow	Administrator	IACU	448-3904	mbraslow@utmem.edu
Thaddeus Nowak, Ph.D.	Chair	IACUC	448-7384	tnowak@utmem.edu
Robert Parker, Pharm.D.	Vice Chair	IACUC	448-7143	rparker@utmem.edu
Clair Cox, M.D.	Chair	IRB	448-5463	icox@utmem.edu
Terrence Ackerman, M.D.	Vice Chair	IRB	448-5686	tackerma@utmem.edu
Bridgette Bozicevich	Associate Director	IRB	448-5871	bbozicev@utmem.edu
Donna Hollaway	Compliance Specialist	IRB	448-2933	dhollawa@utmem.edu
Cameron Barclay	Administrator	IRB	448-4824	cbarclay@utmem.edu
Donna Stallings	Administrator	IRB	448-3805	dstallin@utmem.edu
Sharon Ellis	Administrative Asst.	IRB	448-4824	sellis3@utmem.edu
Sherry Brewer	Compliance Officer	OHSP-Knoxville	865-544-6192	sbrewer@mc.utmck.edu
Sylvia Friedl	Compliance Officer	OHSP-Chattanooga	423-778-3899	sfriedl@utmem.edu
Janie Gardner	Compliance Officer	OHSP-Memphis	448-1869	gardner@utmem.edu
Lorraine Albritton, Ph.D.	Chair	rDNA	448-5521	lalbritt@utmem.edu
Deborah James	Admin. Assistant	rDNA	448-4286	djames8@utmem.edu
Research Information Technology				
Jeanne Hermann	Director		448-5043	jhermann@utmem.edu
Bili Yang	IT Administrator		448-1183	byang2@utmem.edu

**UNIVERSITY OF TENNESSEE
HEALTH SCIENCE CENTER**

910 Madison Avenue
Suite 823
Memphis, TN 38163
Phone: 901-448-5587
Fax: 901-448-7600
E-mail: research@utmem.edu

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.