

# The Research Notebook

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#### Congratulations to UTHSC's "Most Influential Scientists"!

Dr. Karen Johnson, Professor, Preventive Medicine, was one of two UTHSC faculty recently named among the world's most influential scientists by Thomson Reuters. Researchers earn this distinction by "ranking among the top 1% most cited for their subject field and year of publication—between 2002 and 2012." The work of Dr. David Nelson, the other UTHSC recipient, was summarized in the October issue of The Research Notebook. We have invited Dr. Johnson to summarize her work below.

#### Dr. Karen Johnson on Work in Preventive Medicine

I have always loved asking new questions, being creative and trying to figure out how to help people be healthier and live better-quality lives.

I received my medical degree from the UTHSC College of Medicine, where I also completed an internal medicine residency. During this residency, I became very interested in prevention and decided to complete a second residency in preventive medicine at Johns Hopkins in Baltimore and get a master's degree in public health. I really learned how to do research during my preventive medicine residency program at Hopkins.

The Reuters honor may be due in large part to one of my most influential research studies, the Women's Health Initiative (WHI), a large multi-



Karen C. Johnson, M.D., M.P.H.

center clinical trial and cohort study of more than 161,000 women that began in 1993 to look at diseases that affect women and how to help them stay healthier. Our WHI site enrolled more than 4,200 women in the study from Memphis and the surrounding area. The study, funded by the National Heart, Lung, and Blood Institute (NHLBI) through at least 2015 and expected to continue to 2020, is best known for its recommendation that menopausal hormone therapy should not be started or continued for the purpose of preventing cardiovascular disease. This finding from the WHI Hormone Trial influenced how physicians treat postmenopausal women and resulted in a large reduction in use of estrogen with or without a progestin after menopause worldwide.

I am currently the principal investigator on five NIH funded grants or contracts being conducted in Preventive Medicine including TARGIT,

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SPRINT, Look AHEAD, D2d, and the WHI. Throughout my research career I have brought more than \$40 million to The University of Tennessee Health Science Center (UTHSC) to conduct research on health promotion and disease prevention topics.

Dr. Johnson recently was awarded the first UTHSC College of Medicine Endowed Professorship in Women's Health. The professorship, conferred because of excellence in research, is supported by the Kathryn Sullivan Bowld Endowment Fund.

Dr. Johnson says, "It is a great honor to be recognized for my work in the area of clinical preventive medicine research."

## UTRF Congratulates Maturation Grant Recipients

The University of Tennessee Research Foundation (UTRF) has selected four projects to receive technology-development grants. Each project will receive \$15,000 to assist in further developing the technology, and better positioning it for licensing and commercialization.

The four projects funded by the UTRF Health Science Center office are:

Monica Jablonski, "Biodistribution, Pharmacokinetic Assessment and Long-Term Safety of a Novel Treatment for Age-Related Macular Degeneration"

Wei Li, "Stability and in vivo pharmacokinetic evaluation of selective survivin inhibitors in rats"

Larry Reiter, "Blood Test for Familial Autoimmune Positive Autism Spectrum Disorder"

Ryan Yates, "Pre-clinical ADMET of JP-153: A Treatment for Retinal Neovascularization"

Fourty proposals were submitted from the various campuses and institutes of the UT system, including 17 from UTHSC. Since the Maturation Funding Program was initiated in 2007, over \$1,000,000 has been awarded for more than 60 projects.

#### UTRF 2014 Innovation Ceremony

Over fifty researchers at The University of Tennessee Health Science Center were celebrated on Tuesday, December 9th at the 2014 Innovation Awards ceremony. These individuals were acknowledged for their contributions in both the development and commercialization of discoveries with the capacity to change and improve lives. The University of Tennessee Research Foundation (UTRF) hosted the ceremony, and speakers included UTHSC's Executive Vice Chancellor Kennard Brown and UTRF's Vice President, Richard Magid. The ceremony serves to recognize and honor noted researchers and the innovations they have made at the University. Individuals who were granted a US Patent in 2014 were presented with plaques in tribute of the accomplishment. The recipients of UTRF Maturation Grants were also recognized at the ceremony.



From left: Dr. Kennard Brown, Dr. Duane Miller, Dr. Richard Magid, and Dr. David Millhorn assist Dr. Miller display plaques representing his seven patents.

2014 Patent plaque recipients: Edward Chaum, James Dale, Charles Duke (2 patents), Timothy Fabian, Lisa Jennings, Richard Lee, Wei Li (3 patents), Jiuyu Liu, Tao Lowe, Bernd Meibohm, Duane Miller (7 patents), Bob Moore, Rakesh, Gabor Tigyi, and C. Ryan Yates

2014 Research Award recipients: Monica Jablonski, Wei Li, Larry Reiter, Ryan Yates

## 2014 Pediatric Research Day

The seventh annual Pediatric Research Day, held November 19th, 2014, was very well attended and again deemed a success. This year's morning session focused on pediatric nephrology. The 2014 James Hunt Distinguished Visiting Professorship Lecturer, Dr. Carlton Bates from the Children's Hospital of Pittsburgh, gave a presentation of his current research on the genetics of kidney disease in children. His talk was followed by several presentations by faculty, most of whom were from the nephrology division of Pediatrics: Drs. John Bissler, David Hains, Russell Chesney and Robert Wyatt. Dr. Adebowale Adebiyi of the Department of Physiology also gave a talk. This year there were more than 90 poster presentations of the basic science, clinical, and translational research being conducted at UTHSC, Le Bonheur Children's Hospital and St. Jude Children's Research Hospital. Congratulations to the winners of the outstanding poster awards selected by a panel of 25 judges from among many very good presentations.



Dr. McCullers presenting the Hunt Distinguished Visiting Professorship Award to Dr. Bates

#### General poster competition winners

Cecilia Scaglioni-Weinlich: Activity of oral AL-8176 in a respiratory syncytial virus challenge study

Viraj Ichhaporia: Characterizing the myopathy in a mouse model of Marinesco-Sjögren syndrome

Sridhar Jaligama: Exposure to combustion derived particulate matter suppresses pulmonary host defense

Amali Samarasinghe: Resistin-like molecules reduce influenza morbidity in mice

Carol O'Hear: Anti-CD33 chimeric antigen receptor therapy for acute myeloid leukemia

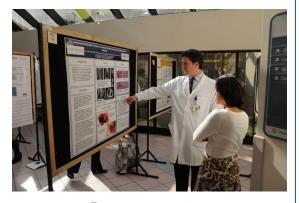
Tae Won Yoon: Contribution of protein kinase D1 and a pharmacological protein kinase D inhibitor Gö6976 on development and progression of experimental arthritis

#### Medical student winners

Heather A. Cole: Prevalence of hypertension in pediatric tibia vara and slipped capital femoral epiphysis

Katherine M. DiGiovanni: Permissive role of nitric oxide in cerebral vasodilation to H<sub>2</sub>S in newborn pigs

Aaron J. Shaw: Age-dependent differences in naïve CD4 T cell polarization



Poster presentation

#### Welcome Rene' Smira

The Office of Research is happy to welcome Rene' Smira as the Business Manager for the Molecular Resource Center (MRC), the Cancer Research Building (CRB) and various self-funded core labs. Mrs. Smira is a former UTHSC employee who left us for a while, but has returned to merge her business knowledge with the Research team. She has 13 years' experience with UTHSC and 12 years with other endeavors, including Administrator for Mississippi Department of Healthy District VII, and Assistant Project Director for the federal grants-Safe Schools/Health Students. Please stop by the Cancer Research Building to welcome Rene'!



## 20th Annual Hinman Student Research Symposium

This fall the College of Dentistry was honored to host the largest-ever Hinman Student Research Symposium at the famous Peabody Hotel. The 20<sup>th</sup> annual symposium included representatives from 47 dental schools from across the U.S. and Canada, with six UTHSC dental students participating.

The Symposium was sponsored by the University of Tennessee, College of Dentistry and co-sponsored by the Hinman Dental Society, which holds one of the nation's largest continuing dental education meetings each March in Atlanta. The Symposium was also supported in part by grants from the National Institute for Dental and Craniofacial Research (NIDCR), the ADEAGies Foundation, the Procter & Gamble Company, The University of Tennessee College of Dentistry Alumni Association, the Tennessee Dental Association Foundation, and the Colgate-Palmolive Company.

Dr. Patrick H. Yancey, III, President of the Hinman Dental Society, welcomed the participants, praised the



Dr. Franklin Garcia-Godoy offers keynote speaker Dr. Lawrence Tabak, Principal Deputy Director and Senior Investigator of the NIH, recognition for his contributions in science, health care, as an educator, researcher and administrator.

Symposium organizers and the student participants, and presented an overview of the upcoming Hinman Meeting to be held in Atlanta on March 26-28, 2015. The keynote speaker at the Welcoming Banquet was Dr. Lawrence A. Tabak, Principal Deputy Director and Senior Investigator of the National Institutes of Health and former Director of the NIDCR. Dr. Tabak spoke on "The Top 10 Things I Have Learned," which included valuable insights on working with others, benefiting from the mentor-mentee relationship, and being guided by your data even when the results conflict with your understanding of how things work.

#### **Award Winners**

#### Most Outstanding Presentations in Clinical Research

Kevin Carey, K Markowitz - An In Vitro Study Assessing the Treatment of Artificial White Spots with Resin Infiltrant, Rutgers University, Newark, New Jersey

Sarah Kaplan, R Ohrbach - Comparison of Modes of Self-Report of Waking-State Oral Parafunctional Behaviors, University at Buffalo, New York

Sawan V Prabhu, KJ Zullig - The Association between Dental Visits and Selected Oral Risk and Protective Factors among College Students, West Virginia University, Morgantown

Cassandra R Stewart, N Obi, E Epane, A Akbari, K Ravella, L Halpern, JH Southerland, PR Gangula - Effect of Diabetes on Salivary Gland Protein Expression of Tetrahydrobiopterin and Nitric Oxide Synthesis and Function, Meharry Medical College, Nashville, Tennessee

#### Most Outstanding Presentations in Basic Science Research

Nicolas Branshaw, D Serge, E Salih - Topographical Distribution of Phosphorylation and Hydroxyproline Sites in Dentin Collagen Type I by Mass Spectrometry Boston University, Massachusetts, Harvard University, Boston, Massachusetts

## Hinman Symposium (cntd.)

(Continued from page 4)

Jeffrey Dyke, L Mailli, R Plant, A Letra, S Blanton, JT Hecht, B Chiquet - Genetic Variations Associated with the Etiology of Non-syndromic Cleft Lip with or without Cleft PalateFollowing Knockdown of CRISPLD2, The University of Texas Health Science Center at Houston

Adiha Khan, I El-Ayachi, G T-J Huang - Odontoblastic Differentiation of iPS Derived from Dental Stem Cells versus HeSC, The University of Tennessee Health Science Center, Memphis

Alexandria Hawkins, NB Swaar, JF Hatton, C Poeschl, A Marcuzzi, MJ Gillespie - Comparative Disinfection of Enterococcus faecalis Loaded Root Canals, Southern Illinois University, Alton Saint Louis University, Missouri

#### 2014 President's Award for Excellence in Dental Research from the National Students Research Group of the American Association for Dental Research

Amanda Francis, H Huang, S Wallet, T Langaee, I Aukhil, L Shaddox - Epigenetic Regulation of the Inflammatory Response in Localized Aggressive Periodontitis, University of Florida, Gainesville



Adiha Khan, UTHSC D-2, won an award for Most Outstanding Presentations in Basic Research.

## Major Revision/3rd Annual Renewal Animal Census

Major revisions and 3rd annual renewals are essentially treated as a new protocol submission through the ACAP system. The Principal Investigator (PI) is required to submit the new protocol prior to the 1st of the month for review by the IACUC at the next regularly scheduled monthly meeting (see IACUC Calendar on website for deadlines). If there are animals on census under the expiring protocol number, those animals will be transferred to the new protocol. Therefore, based on study needs, the number of animals on inventory (individual animals, not boxes) must be included in the new protocol submission in addition to other animal numbers requested for the next 3 years. The PI is responsible for obtaining an accurate census of animals (individual animals, no boxes) by completing the "Animal Census Worksheet." The census must be performed within 10 business days of the protocol submission to be considered valid. If no animals are currently being housed, this requirement can be entered as zero in the table.

Please note that for all USDA species: PIs must meet with LACU building supervisor to complete the census.

Once approved, the animals on the expiring protocol must be transferred to the new protocol by the PI or Lab members with animal ordering rights through ACAP. In order to transfer the animals, the numbers/categories from the table on the "Animal Census Worksheet" submitted with the new protocol should be used.

After transfer of the animals from the old protocol to the newly approved protocol, there is no need to reprint cage cards. The barcode number will remain the same, the only thing that will change is the protocol number located in the upper lefthand corner of the cage cards which can be manually corrected if needed. All LACU tracking is done with the barcode number, which will link with the new protocol number despite the card's reflecting the old protocol number.

If you have any questions, please contact the IACUC office (448-3904) for assistance.

#### Mission, Vision, Action (Plan)!

What makes private grant seeking different from working on a government submission? It is all about relationship building, the "R" in corporate and foundation relations. It's all about understanding a prospect or sponsor's mindset via doing your "analytics homework." How does this happen? It's all in scoping out the prospect or sponsor *before* you actually complete the proposal. That is the plan. Doing so may save you from completing a proposal that does not fit with the grantmaker's capacity, inclination, or affinity to possibly fund your submission.

Most grant application forms from non-governmental organizations (e.g. associations, disease specific entities, etc.), corporations, and private or corporate-sponsored foundations have sections similar to government grants. So what is different? The key is to read *everything* on the website, before you dive into the actual application. The most important sections to check out on a private grantmaker's website are its mission, vision, if provided, and the action plan or strategic direction document and/or values.

Next, read the introduction from the leader – president, chairperson, etc. Follow up with skimming through the annual report if one is provided. Then, check out past awardees, if listed, and read through their information. Follow up with reviewing the members of the scientific advisory committee, board of trustees, and staff by reading any information provided. You may learn more about their history or pland of funding in a particular research area.

Pay significant attention to the criteria for selection of awarded proposals. When completing your proposal, keep the criteria visible along with the mission, vision, and other information handy to review, review! Private grantmaker reviewers actually read through your submission looking for that relationship building piece or how you "translated" the above information into your grant. So how do you do that?

If you have done your "homework" you are over 50% ready to "\match up your research with the sponsor's or prospect's priorities. Next, embed the information you learned into appropriate and relevant sections of your actual proposal. It is especially important to do this step with the criteria for award selection to demonstrate that you addressed all the points that will concern the reviewers (hint: they will have the criteria with them and be looking at your proposal to see if you have indeed done your "homework"). Your proposed project or research plus the embedding of the information learned will place your submission in a better position for a possible grant award.

Should you want to learn more about corporate and foundation relations analytics, contact Denise Rivers, Director of Corporate and Foundation Relations at drivers3@uthsc.edu.

#### Save the Date for Grant Consultant Dr. Israel Goldberg

Dr. Israel Goldberg, President of Health Research Associates, will visit the UTHSC Memphis campus **February 24 and 25, 2015**. Dr. Goldberg is under contract with the UTHSC Office of Research and has provided consultation that proved invaluable for the successful awarding of a number of NIH grants to faculty. Dr. Goldberg is available to assist faculty with individual grants, as well as with training grants and other programmatic funding. More details will follow in future campus announcements.

Faculty members may request one-on-one or small group consultation meetings with Dr. Goldberg during his visit. Long-distance consultation can also be arranged. Please contact Lisa Bronte ( <a href="mailto:lbronte@uthsc.edu">lbronte@uthsc.edu</a> ) for scheduling.



#### UTCOMC's Research Week

Information about the 2015 Research Week, occurring Monday, April 13, through Friday, April 17, has been posted at <a href="www.utcomchatt.org/researchweek">www.utcomchatt.org/researchweek</a>. Please see the "2014-2015 Timeline" link for important information about Fall, 2014 deadlines. There are also links to suggestions on how to create a poster, as well as presentation tips.

# UTHSC Center for Cancer Research Establishes Cell Line Xenograft Core (CLXC) Facility

The Center for Cancer Research's Cell Line Xenograft Core (CLXC) facility is now open to all UTHSC investigators interested in performing *in vivo* tumor studies. The CLXC core facility provides services ranging from preclinical oncology therapeutics/drug screening using xenograft models developed with over 200 cancer cell lines in immunocompromised NSG mice, Xenogen imaging to monitor tumor growth and metastasis, mechanistic studies (gene expression studies in tumor tissues using



NanoString, microarray, RNA-Seq, and others), immunohistochemistry, and measurement of tumor and serum drug concentrations using LC/MS-MS. UTHSC investigators and their personnel can also obtain insight into experimental design and data analysis from CLXC's scientific team. The CLXC is located in the Cancer Research Building (CRB) laboratories and vivarium, and two Research Specialists currently support research. To take advantage of the CLXC, please contact Dr. Lawrence M. Pfeffer at <a href="mailto:lpfeffer@uthsc.edu">lpfeffer@uthsc.edu</a> or 901-448-7855.

#### UTHSC investigators' pricing for services provided by CLXC:

Standard mouse dosing experiment \$250.00/mouse
Add-on for Xenogen imaging, 2x/week \$25/mouse
Add-on for bi-weekly blood collection \$10/mouse
Add-on for bi-weekly blood glucose monitoring \$10/mouse

## Sigma Xi Recognized Jessica Clower for Excellence in Student Research

Jessica Clower, a Master's student from the Department of Clinical Laboratory Sciences, College of Health Professions, was a winner of a Sigma Xi Excellence in Student Research Award for the outstanding project that she conducted with Dr. Yanhui Zhang and Dr. Franklin Garcia-Godoy last summer, in the Bioscience Research Center. The title of Jessica's research was: Real-time PCR analysis of differentially expressed genes involved in oral squamous cell carcinoma.

SCIENCEDOMAIN international Excellence Award

Last year, Robyn Bills, from the same Department of Clinical Laboratory Sciences and under Dr. Zhang and Dr. Garcia-Godoy's mentorship, also won the same award.

Dr. Linda L. Williford Pifer, from the Department of Clinical Laboratory Sciences, is the coordinator of the Master's program.

The certificate with the award is presented at the College of Health Professions Convocation. Sigma Xi, the Research Society, is the world's largest international society (by invitation) of professional scientists. It was founded in 1886 at Cornell University and has a worldwide membership of about 60,000 scientists and engineers. The Society's motto is "Companions in zealous research."

## New Biosketch Format for NIH and AHRQ Grants

The new biosketch format is strongly recommended for all NIH and AHRQ proposal for due dates on or after January 25, 2015, and will be required for due dates on or after May 25, 2015.

The revised forms and instructions are now available on the SF 424 (R&R) Forms and Applications page (<a href="http://grants.nih.gov/grants/funding/424/index.htm#format">http://grants.nih.gov/grants/funding/424/index.htm#format</a>). The new format extends the page limit from four to five pages, and allows researchers to describe up to five of their most significant contributions to science, along with the historical background that framed their research. Investigators can outline the central findings of prior work and the influence of those findings on the investigator's field. Investigators involved in Team Science are provided the opportunity to describe their specific role(s) in the work. Each description can be accompanied by a listing of up to four relevant peer-reviewed publications or other non-publication research products, including audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware that are relevant to the described contribution. In addition to the descriptions of specific contributions and documentation, researchers will be allowed to include a link to a full list of their published work as found in a publicly available digital database such as MyBibliography (<a href="http://www.ncbi.nlm.nih.gov/books/NBK53595/">http://www.ncbi.nlm.nih.gov/sciency/</a>).

#### Tool to Help Build the New Biosketch

The Science Experts Network (SciENcv), which serves as an interagency system designed to create biosketches for multiple federal agencies, will be updated and available within a few weeks to support the new biosketch format. SciENcv pulls information



from available resources, making it easy to develop a repository of information that can be readily updated and modified to prepare future biosketches. A YouTube video provides instructions for using SciENcy.

- See more at: <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-024.html#sthash.1lUrAUig.dpuf">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-024.html#sthash.1lUrAUig.dpuf</a>

From NIH Guide http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-024.html

## Uniform Guidance - New Regulations Affecting Grants and Subawards

The Office of Management and Budget circular that replaces eight previous circulars relevant to federal grants and contracts took effect December 26, 2014. This document is commonly called the "Uniform Guidance" and can be found in full text here:



(http://www.ecfr.gov/cgi-bin/text-idx?

<u>SID=ee873e1aa906cf3b0d7474d25be3b5a9&node=2:1.1.2.2.1&rgn=div5</u> ). A number of UT policies are being revised as a result of the implementation of the Uniform Guidance, and some new policies and helpful tools have been developed. All of the revised policies and tools will be posted on the ORA web page, and an announcement will be sent to the campus when it is finalized.

# A Proposed HHS Regulation and NIH Policy to Further the Impact of Clinical Trials Research

Posted on November 19, 2014, by Sally Rockey

# Clinical Trials.gov

Clinical trials play a vital role in transforming scientific research into medical interventions to improve human health. Transparency about the

A service of the U.S. National Institutes of Health

clinical trials underway and their subsequent results ensure potential participants can make informed decisions about enrolling in clinical trials, can make informed decisions about potential trial participation, and know how their participation may have helped others. Clinicians benefit by knowing about trials in which their patients might participate, having a more complete evidence base for decision-making, and seeing potential new treatments as they emerge. And for you, the research community, you can take timely information about clinical trial findings, be they positive or negative, to guide future research toward the next great innovation in health. We believe strongly that we have an obligation to share clinical trial information widely and in a way that both protects participant privacy and accelerates scientific discovery. Thus we are taking important steps to advance the sharing of clinical trial results.

Today, the Department of Health and Human Services (HHS) <u>announced</u> proposed regulations to implement the clinical trial reporting requirements established by the Food and Drug Administration Amendments Act (FDAAA) of 2007. This <u>Notice of Proposed Rule Making</u> (NPRM) further clarifies clinical researchers' requirements under FDAAA for clinical trials that meet the legal definition of an "applicable clinical trial," including interventional studies of drugs, biological products, and devices that are regulated by the FDA, but excluding phase 1 and feasibility studies. Additionally, it proposes some changes to the information that must be submitted to the <u>ClinicalTrials.gov</u> database. As described in the proposed rule, clinical trials registration and results information would include additional data elements to more fully capture the information necessary to understand the results of a trial, and, most significantly, information would be required for the results of clinical trials of products not yet approved by FDA. NIH has developed a summary of the key proposals of the NPRM, and this can be found <u>on the NIH website</u>. To understand all the proposed changes to current practice and get prepared to submit public comments, NIH recommends that you review <u>the NPRM itself.</u>

Importantly, today NIH also <u>announced</u> a proposal to apply these same proposed requirements to all NIH-funded clinical trials, whether subject to FDAAA or not. <u>The proposed policy</u> would require that every <u>NIH-funded clinical trial</u> be registered in <u>ClinicalTrials.gov</u> and that summary results are posted to the database in a timely matter. This is important, since NIH funds trials beyond those that fall under the proposed regulation, and the inclusion of the other clinical trials as proposed in the new policy, will ensure that the results of all trials are widely disseminated and that this is done openly and promptly.

As described in the <u>NIH Guide</u> notice that came out this morning, we are encouraging the public to provide comments on any aspect of NIH's draft policy as well as the proposed regulations published today in the <u>Federal Register</u>. Both documents are open for a 90-day public comment period, and comments will be taken into consideration before final regulations and a final NIH Policy are issued. Remember that while your comments on this blog are welcome in line with our blog policies, only comments submitted according to the instructions described in the <u>Guide</u> and Federal Register can be considered in the development of the final policies.

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## Proposed HHS Regulation Proposal (cntd.)

(Continued from page 9)

You might also find it helpful to review NIH's recent guide notice on the revised definition of a clinical trial, to help ensure you are meeting your current obligations, and to help you understand what projects the proposed policy would affect. (Note that the revised clinical trial definition will apply to competing applications for the January 25, 2015, due date and subsequent due dates.)

Expanding the dissemination of NIH-funded clinical trial findings complements existing NIH policies to promote data sharing and public access to NIH-funded research results. Data sharing and transparency about publicly funded research protects the public's trust in research and maximizes the value of NIH's investment in research by allowing scientists to build upon existing results. And, <u>as the title of NIH's director's blog states</u>, it honors our promise to those who volunteer in clinical trials – that we are doing all that we can to further the impact of their valuable contribution to research to help others.

- See more at: http://nexus.od.nih.gov/all/2014/11/19/clinical-trials/#sthash.l1Dh536P.dpuf

# Why do I need to route a grant application if the sponsor doesn't require UT signature?

All grant applications, including requests for educational assistance to support conferences and symposia and on-line applications for small amounts (e.g., \$2,000), should be routed in PAMS before they are submitted to the sponsor. The purpose of routing these proposals is (1) to ensure departmental and college approvals, (2) to document the request, and (3) to ensure that the information



contained in the application is accurate. Many of these applications require submission by a 501(c)3 entity, which UT is not; however, we can apply through one of our foundations. While some faculty and departmental staff may not be aware of the distinction, ORA staff checks for that and other specifics to ensure that the information provided is accurate.

Letters of intent (LOIs), which are preliminary proposals that may not require a budget or institutional signature, do not need to be routed unless the sponsor requires a budget or institutional signature at the time of the LOI submission. LOIs are usually submitted as a preliminary draft of the project and are (hopefully) followed by an invitation from the sponsor to submit a full proposal. Also, when students submit applications for scholarships to be paid directly to the student (not the University), they do not need to be routed.

#### Abstracts in PAMS

Abstracts in PAMS are used by the Office of Research Administration when we review the proposal, as well as for various reports requested by the Chancellor and others, and to identify faculty working on specific disease areas. The abstract does not need to be lengthy, but should capture the essence of the project in lay language. For amendments, please be sure to use the actual project abstract. . . . including simplified information such as "amendment to previous agreement" is insufficient information.



#### Retention Rates for First-Time R01 Awardees

Reprinted from the Oct 28, 2014, post by Sally Rockey

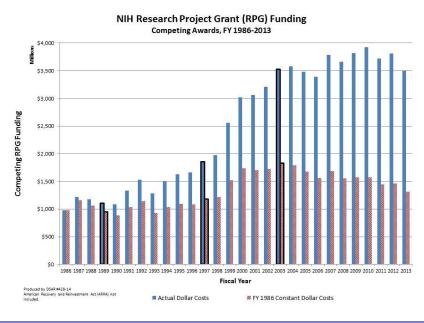
We have seen increased interest in the biomedical workforce by Congress and especially by our community. From our end we've in particular observed heightened attention to how the dynamics of the workforce impact researchers in the early stages of their careers. So the topic definitely deserves our continued attention and I thought in light of this it'd be a good time to share some of NIH's analyses on one specific aspect of this that my office has been closely examining.



We know that over time investigators are, on average, 42 years old when receiving their first R01, which is older than it was than before the doubling of the NIH began.

And, we know that funding rates for both first-time NIH investigators and experienced Salley Rockey, Ph.D. NIH investigators alike have declined. So we wondered, of those first-time recipients of NIH R01equivalent funding, how many years after their first year of R01 funding do they receive additional research grant funding? And furthermore, given the changes in NIH's budget over the years, does the year they received their first R01 – and the rise or fall of NIH funding – correlate with whether or not they remained an NIH-supported researcher in subsequent years?

Here is a graph of the amount of funding NIH had available for competing research project grant awards from 1986 through 2013. In blue are the actual dollar costs, and in red are constant dollars, normalized to the value of a dollar in 1986.



We chose three cohorts of first-time R01-equivalent awardees — those who received their first R01equivalent award in 1989, 1997, or 2003. We looked at these three time periods because of their relation to the NIH budget when their initial award was coming to end, i.e., what was the budget like when they would need to re-compete. For the cohort with an initial award in 1989, four years later (1993), the NIH budget took a dip with little to no growth for a few years. For the cohort with an initial award in 1997, four years later (2001) the NIH budget was in the midst of doubling. Finally, for the cohort with an initial award in 2003, four years later (2007) the NIH budget was not growing and was actually loosing purchasing power.

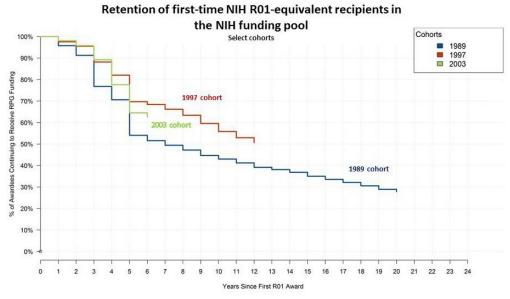
## Retention Rates (Cntd.)

(Continued from page 11)

First, let's look at how these cohorts compare:

	1989	1997	2003
Overall R01-equivalent success rate that year	27.9%	30.1%	30.2%
Number of first-time NIH R01-equivalent awardees	1,693	1,597	1,778
Average age of awardees	39.2	40.4	42.6
Average length of award	3.9	4.1	4.1
Average amount of first year award	\$137,670	\$179,880	\$318,285
Average amount of 1st year award in 1986 constant dollars	\$118,317	\$114,354	\$165,507

We used data on these three cohorts for a Kaplan-Meier analysis to look at rates of retention. Kaplan-Meier is a type of statistical analysis used to determine the likelihood that a specific event will occur (in this case, dropping out of the RPG funding pool) over the course of time. So we used this in analyzing the number of years between the first year of R01-equivalent funding, and the last time an individual receives any additional research project grant (RPG) funding – whether it be from the noncompeting continuation of their 1st R01 or another RPG award.



These retention curves tell us that for all three cohorts many PIs stop receiving NIH RPG funding about three to five years after they receive their first year of R01 funding. For the 1989 cohort, PIs drop out of the NIH RPG pool most markedly at years 3 and 5, with a sharp drop after year 5 followed by a steady slow subsequent decline. For the 1997 cohort, the drop between years 5 and 6 was much less precipitous, indicating that more PIs in this cohort were able to maintain competitive funding. This is not surprising given that they were re-competing during the NIH budget doubling. Indeed, 12 years later, over half of the PIs in the 1997 cohort still had RPG funding.

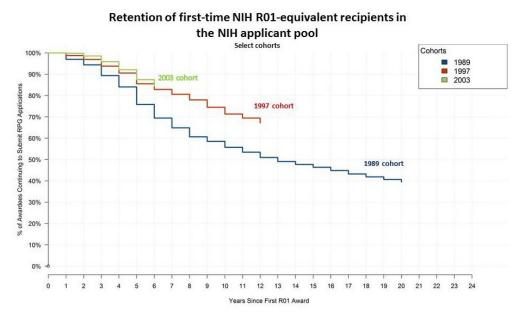
Now, let's look at the 2003 cohort. Again we see a drop between years 4 to 6, but it is not as severe as the 1989 cohort, yet not as buoyant as the 1997 cohort. As we complete the award data for FY 14, it will be interesting to see if the 2003 cohort continues to drop more sharply (because of the recent NIH budget) or if it moves into a more steady and slow decline similar to the earlier cohorts.

(Continued on page 13)

## Retention Rates (Cntd.)

(Continued from page 12)

This of course leads to the question – do these PIs disappear from NIH's pool of RPG awardees because they never came back to apply for another grant? So, we performed a similar analysis with these cohorts, following the individuals through FY2013 but this time looking at the last year they submitted an RPG and drop out of the RPG *applicant* pool.



Interestingly, the 1989 cohort didn't return for funding persistently after their first R01, but the 1997 and 2003 cohorts did continue to submit RPG applications. While we can't use this data alone to determine *why* the 1989 cohort dropped out of the applicant pool at a faster rate than the '97 and 2003 cohorts, it is interesting to note the difference between the 1989 and later cohorts.

Looking at these three cohorts, there are a couple of take-away messages. First, a significant number of first time PIs appear to drop out of RPG funding status following their initial award regardless of the economic times; all three cohorts had dropped between 30 to nearly 50% within 5 years of the initial award. For the 1989 cohort, the drop out closely tracked with their lack of persistence in submitting application whereas both the 1997 and 2003 cohorts showed a more gradual decline in submitting RPGs. Second, the rate of drop out corresponds to the NIH budget climate at the time of re-competition with more PIs staying in the system during the period of the doubling than the period of time prior to the doubling. Although it is too soon to see the longer term retention of the 2003 cohort, the data to-date suggest that their retention is worse than those who recompeted during the doubling, yet slightly better than those who were recompeting in the late 90's, before the NIH doubling. Time will tell if this "between the extremes" status continues into the future.

These data seem to support the concept that if there is an intervention needed in retaining scientists in research, it would need to come at the renewal stage of the first award, or as some call it the "second" award. Indeed, we are giving increased focus to this stage through some of our new award mechanisms, such as the National Cancer Institute's Outstanding Investigator award, and will continue to seek ways of keeping our talent from leaking out of the pipeline.

- See more at:  $\frac{http://nexus.od.nih.gov/all/2014/10/28/retention-of-first-time-r01-awardees/\#sthash.ctSeDgVd.dpuf}{awardees/\#sthash.ctSeDgVd.dpuf}$ 

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Cameron Barclay         Director         448-4824           Kim Prachniak         Sr. Regulatory Spec.         448-5060           Virginia Calvo-Torres         Compliance Advisor         448-2933           Margaret Sularin         Regulatory Specialist         448-4824           Elaine Todd         Regulatory Specialist         448-1343           Donna Stallings         Administrator         448-4824           Holly Herron         Administrator         448-4824           Melanie Saucier         Admin Research Asst.         448-4824           Office of Human Subject Protections           Vacant         C. Officer - Chattanooga         423-778-3899           Vacant         C. Officer - Memphis         448-1869           Vacant         C. Officer - Memphis         448-1869           Vacant         C. Officer - Knoxville         865-305-6192           Electronic Research Administration           Jeanne Hermann, Ph.D.         Director         448-5043           Lawson Culver         Administrator         448-183           Tricia Page         Program Manager         448-2389           Additional Research Related Contacts           University	Instit	utional Review Board			
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The Research Notebook Jeanne Hermann, Ph.D., 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.

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