

**UAMS**

UNIVERSITY OF ARKANSAS  
FOR MEDICAL SCIENCES



# **Research Support Information Network (RESIN)**

**Presented by: Office of the Vice Chancellor for Research**

**Date: January 5, 2016**



# Agenda

## ■ Updates & Timely Information from Research Support:

- ✦ Office of the VCR
- URC
- IRB
- Contract Administration
- IACUC
- Library
- Procurement Services
- BioVentures

- Travel
- ORSP
- ✦ Research Compliance
- ✦ Office of Finance
- DLAM
- ✦ OGSP
- ✦ TRI
- COP - COBRE



# Rigor and Transparency in NIH

**Proposals** DeAnn Hubberd, Associate  
Director, OGSP

- **NOT-OD-16-011: Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications**
  - Revisions to application guidelines for Significance and Approach sections in Research Strategy and to review criteria
  - Consideration of relevant biological variables
  - New "Authentication of Key Biological and/or Chemical Resources" attachment



# Rigor and Transparency in NIH

**Proposals** DeAnn Hubberd, Associate  
Director, OGSP

- **Revisions to Significance Guideline and Review Criterion**
  - In Significance section
    - Describe the scientific premise, including consideration of the strengths and weaknesses of published research or preliminary data crucial to support the application.
  - Significance review criterion
    - Is there a strong scientific premise for the project?



# Rigor and Transparency in NIH

**Proposals** DeAnn Hubberd, Associate  
Director, OGSP

## ■ Revisions to Approach Guideline and Review Criterion

### ■ In Approach section

- Describe the experimental design and methods and how they will achieve robust and unbiased results.
  - Have the investigators presented strategies to ensure this goal?
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans.
  - Have the investigators presented adequate plans to address these?



# Rigor and Transparency in NIH

**Proposals** DeAnn Hubberd, Associate  
Director, OGSP

- **For Applications Proposing to Study Only One Sex:**
  - Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided.
  - See [NOT-OD-15-102: Consideration of Sex as a Biological Variable in NIH-funded Research](#)



# Rigor and Transparency in NIH

**Proposals** DeAnn Hubberd, Associate  
Director, OGSP

- **Authentication of Key Biological and/or Chemical Resources**
  - New PDF attachment
  - Describe methods to ensure the identity and validity of key biological and/or chemical resources used, e.g., cell lines, specialty chemicals, antibodies, and other biologics
  - Reviewers will comment on the plans



# Rigor and Transparency in NIH

**Proposals** DeAnn Hubberd, Associate  
Director, OGSP

## ■ Implementation Dates

- [November 25, 2015](#): updated application guide was released including instructions for:
  - Changes to Research Strategy sections
  - Preparing and uploading the "Authentication of Key Resources Plan"
  - Addressing rigor to ensure robust and unbiased results in RPPRs for research or training grants
- Due dates on or after [January 25, 2016](#)
  - Updates take effect for most research grant applications and RPPRs





# Rigor and Transparency in NIH Proposals

DeAnn Hubberd, Associate Director, OGSP

- **Helpful Links on Rigor and Reproducibility**
  - [NOT-OD-16-011](#)
  - [NIH Website](#)
  - [Frequently Asked Questions](#)



# Noncompliance Reporting

Darri Scalzo, CHRC, Research Compliance Officer

- **Request from Campus Leadership to report all potential noncompliance to Department Chairs and/or Service Line Directors**
- **Reviewed and approved by CCR and IACUC**
  - Goal is to correct noncompliance before it becomes serious or continuing, and thus requires reporting to outside agencies such as OHRP, FDA, or OLAW.



# Noncompliance Reporting

Darri Scalzo, CHRC, Research Compliance Officer

- **The following situations are examples of reportable noncompliance or noncompliance which could place the institution at risk:**
  - Determinations of serious or continuing noncompliance or of Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs) must be reported to OHRP by the IRB.
  - Suspension or termination of a study must be reported to OHRP by the IRB.
  - IND or IDE noncompliance issues must be reported to the FDA by the sponsor



# Noncompliance Reporting

Darri Scalzo, CHRC, Research Compliance Officer

- **Examples of Reportable Noncompliance** (cont.)
  - Serious or continuing noncompliance found in an FDA-regulated trial by the monitors must be reported to the FDA by the sponsor.
  - Suspension or termination of an FDA-regulated trial must be reported to the FDA.
  - Clinicaltrials.gov registration issues, particularly late reporting of results which could result in significant monetary fines.
  - Determinations of animal welfare issues must be reported to OLAW by the IACUC.
  - Determinations of serious or continuing noncompliance must be reported to OLAW (and USDA if it involves USDA-regulated species) by the IACUC.



# Noncompliance Reporting

Darri Scalzo, CHRC, Research Compliance Officer

- **New Noncompliance Reporting Procedures:**
  - Monitoring reports for IND/IDE studies in which UAMS is the Sponsor (and which revealed issues that are not being addressed) will be shared with the Dept. Chair and/or Service Line Director.
  - Office of Research Compliance (ORC) human subjects research audit reports will be shared with the Department Chair and/or Service Line Director.
  - ORC Post-Approval Monitoring reports of animal research protocols will be shared with the Chair.



# Noncompliance Reporting

Darri Scalzo, CHRC, Research Compliance Officer

- **New Noncompliance Reporting Procedures** (cont.)
  - In each of the above mentioned cases, the reports will first be discussed with the Principal Investigator before they are shared with the Department Chair and/or Service Line Director.
  - The Principal Investigator should copy the Department Chair and/or Service Line Director on their response to the audit report.



# Noncompliance Reporting

Darri Scalzo, CHRC, Research Compliance Officer

- **For any questions, please contact:**
  - **Darri Scalzo**, Research Compliance Officer
    - 501-686-8062
    - [dlscalzo@uams.edu](mailto:dlscalzo@uams.edu)



# Research Means Hope

David Robinson, Communications Mgr, TRI; Senior Writer, UAMS Communications & Marketing

## ■ A National Platform for UAMS Research Success Stories

- Association of American Medical Colleges (AAMC) introduced Research Means Hope in July 2013
- Campaign using Tumblr site to raise public awareness of the critical need for sustained federal funding for medical research
- Highlights federally funded medical research advances at the nation's medical schools and teaching hospitals
- Includes stories of patients who have benefited from advances in medical research





# Research Means Hope

David Robinson, Communications Mgr, TRI; Senior Writer, UAMS Communications & Marketing

- 43,846 subscribers
- 1,297 story posts
- ~300 notes (engagements) per week

RESEARCH MEANS HOPE

Home About Medical Research in Your State Contact Us Share Your Story

## RESEARCH MEANS HOPE

Research advances from our nation's medical schools and teaching hospitals.

### Smartphones Can Track Your Health

The MoveSense app, powered by GaitTrack technology developed by researchers at the University of Illinois at Urbana-Champaign and the U. of I. at Chicago, uses eight motion parameters to perform a detailed analysis of a person's gait, or walking pattern, which can tell physicians much about a patient's cardiopulmonary, muscular and neurological health.

Researchers envision the GaitTrack app running constantly in the

RESEARCH MEANS HOPE

Research Means Hope is a campaign of the Association of American Medical Colleges and its member-medical schools and teaching hospitals to raise public awareness of the critical need for sustained federal investment in medical research conducted through...

Looking For Something?

Try searching by topics, including disease or institution.

Search the RMH Tumblr...

More information



# Research Means Hope

David Robinson, Communications Mgr, TRI; Senior Writer, UAMS Communications & Marketing

## UAMS Stories Posted by Research Means Hope:

- New Drug Part of International Effort to Combat Castleman Disease (van Rhee)
- Laser Device Offers Hope for Cancer Detection, Treatment (Zharov)
- HPV Vaccine for Pre-Cancerous Lesions Shows Promise (Nakagawa)
- Breast Cancer Vaccine Shines in First Human Trial (Kieber-Emmons)
- An Rx to Beat Meth Addiction (Owens, et al)
- Using Telemedicine to Treat Depression (Fortney)

RESEARCH MEANS HOPE

Home About Medical Research in Your State Contact Us Share Your Story

7 results for "UAMS"

### New Drug Just Part of International Effort to Combat Castleman Disease

Probably few people would say Carl Guenther's diagnosis was lucky, although he says so, and he has agreement from the world's foremost expert on Castleman disease, Frits van Rhee, M.D., Ph.D., at the University of Arkansas for Medical Sciences (UAMS).

Guenther, a Wilmington, Ohio, father of two, was diagnosed with Castleman disease and given two years to live just months after his wife died of ovarian cancer. The lucky part? His doctor, who had recently completed medical training, remembered the disease from textbooks and correctly diagnosed it -- no easy feat for a rare disease with no formal diagnostic criteria, van Rhee said.

"The average oncology doctor may see one Castleman disease patient in their lifetime, so you cannot possibly expect them to be an expert on a really rare disease," van Rhee said. "In my opinion, people will die of this disease because they will not get the correct diagnosis, the diagnosis will be delayed, or they will receive inappropriate treatment."

READ MORE >>>

Funding: National Institutes of Health National Cancer Institute P01 CA020819-20 (NCI); American Society of Hematology Bridge Fund for Hematology Research; National Cancer Institute, 2014

18

0th Jul 2015

Research Means Hope is a campaign of the Association of American Medical Colleges and its member-medical schools and teaching hospitals to raise public awareness of the critical need for sustained federal investment in medical research conducted through...

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Search the RHM Tumblr...

More Information

AAMC  
Tomorrow's Doctors. Tomorrow's Cures®  
Learn more about the Association of American Medical Colleges and the nation's medical schools and teaching hospitals.

NIH  
National Institutes of Health  
Find out more about the National Institutes of Health and life-saving medical research.



# Research Means Hope

David Robinson, Communications Mgr, TRI; Senior Writer, UAMS Communications & Marketing

## Story Ideas?

Please contact me:

[davidr@uams.edu](mailto:davidr@uams.edu)

501-686-6270



[View Source](#)

*Image: UAMS' Thomas Kieber-Emmons, Ph.D., and Laura Hutchins, M.D., are collaborating on research of a promising breast cancer vaccine.*

**Breast Cancer Vaccine Shines in First Human Trial**



breast cancer

cancer

clinical research

submission

UAMS

research

health

women

funding

AR

team

medicine

46

16th Mar 2014

1/5/2016



# Sponsored Programs Administrative Network

Renee Raines, Project Leader

## ■ Project Team

- **William Bowes**, Chief Finance Officer, Project Sponsor
- **Renee Raines**, College of Medicine, Project Leader
- **Suzanne Alstadt**, Office of Research and Sponsored Programs
- **Suzy Sun**, Institute on Aging, Geriatrics
- **Lou Forst**, College of Pharmacy
- **Susan Leon**, College of Medicine
- **Darri Scalzo**, Office of Compliance
- **Rebecca Nickelson**, Director of Research Information Systems
- **Janet Hopper**, Grants Accounting
- **Mike Owens**, Department of Pharmacology
- **Michael Jennings**, Chair, Department of Physiology
- **Richard Morrison**, Department of Microbiology



# Sponsored Programs Administrative Network

Renee Raines, Project Leader

## ■ **Governance Committee**

- Geoffrey Curran, COP
- Jean McSweeney, CON
- Susan Long, COHP
- Lee Ann MacMillian-Crow, COM
- Alesia Ferguson, COHP
- Hari Eswaran, COM
- Kristie Hadden, Regional Programs
- Allison Oliveto, TRI
- Laura Hutchins, MD



# Sponsored Programs Administrative Network

Renee Raines, Project Leader

- Kick Off Meeting
  - **Thursday, January 14<sup>th</sup>, 2016**
  - 3:00 pm
  - Pauly Auditorium, COPH





# Sponsored Programs Administrative Network

Renee Raines, Project Leader

- Questions?
- [renee@uams.edu](mailto:renee@uams.edu)



# Community Engagement Services for Investigators

Kate Stewart, MD, MPH

- **Community Engagement Services**
  - Consultations and Technical Assistance
  - Community Review Boards
  - Equipment Library







# Community Engagement Services for Investigators

Kate Stewart, MD, MPH

## ■ Infrastructure Support

- Community Researchers Meetings
- Community Partner Database



# Community Engagement Services for Investigators

Kate Stewart, MD, MPH



**Kate Stewart**

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**Nicki Spencer**

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501-526-6629



# Up Close & Amazing –

## Research Support

Linda Williams, MS,

Research Liaison, Office of Research

- **Bimonthly Article Spotlighting a UAMS Research Staff Member**
  - **Purpose**
    - To gain insight into a research employee's job duties and associated skill set
    - Highlight those who have gone above and beyond to facilitate UAMS research
  - **Content**
    - Description of research clients' needs
    - Support activities and outlook
    - Posted on the Research website



# Up Close & Amazing –

## Research Support Linda Williams, MS, Research Liaison, Office of Research

### ■ Spotlight - Kerrey Roberto - IACUC Administrator



- At UAMS for 21 years → Current position, 2 years
- Day to Day
  - Handles ~300 active protocols from over 100 PIs from 24 depts/divisions.
  - Facilitates ~10 new protocols/month (120/yr) and performs annual reviews for ~15 protocols/month (180/yr)
  - Coordinates IACUC meetings (3<sup>rd</sup> Friday) and addendum request 25/month (300/yr) review subcommittee (every Friday)



# Up Close & Amazing –

**Research Support** Linda Williams, MS,  
Research Liaison, Office of Research

## ■ To Nominate an Exceptional Research Support Staff Person

### ■ Contact

- Linda Williams, 686-7418, [ldwilliams@uams.edu](mailto:ldwilliams@uams.edu)
- Office of Research, 686-5347

EXCELLENCE  
IS NOT A  
SKILL.  
IT IS AN  
ATTITUDE.

–RALPH MARSTON



# Next RESIN

## ■ Next RESIN

- **February 2, 2016 @ 12:00 p.m.**
- Location - **Walton Auditorium**, Winthrop P. Rockefeller Cancer Institute, 10<sup>th</sup> floor
- All RESIN presentations archived on the UAMS Research website
  - [http://www.uams.edu/research/RESIN\\_Archive.asp](http://www.uams.edu/research/RESIN_Archive.asp)