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UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

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

**Date: October 7, 2014**

# Agenda

- **Updates & Timely Information from Research Support:**

Office of the VCR
RSC
IRB
- IACUC
HIPAA
- UAMS Library
BioVentures
Occupational Health & Safety
COI
- ORSP
- ORRA
DLAM
OGSP
CCTR/Core Facilities
Medical Informatics

# CITI Training for Animal Users

**Bill Gurley, Ph.D., IACUC Chairman, and**
**Darri Scalzo, Research Compliance Officer**

- The Animal Welfare Regulations (AWR) Section 2.32(a) and (b) require the institution to ensure that faculty, staff, and students conducting research, teaching, or testing involving animals are qualified to perform their duties.

- The PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) Section IV.C.1.f. clarifies this requirement and places the responsibility for review of appropriate qualifications and training of personnel with the Institutional Animal Care and Use Committee (IACUC).

# CITI Training for Animal Users

**Bill Gurley, Ph.D., IACUC Chairman, and**
**Darri Scalzo, Research Compliance Officer**

- All staff working with laboratory animals must be appropriately qualified to do so in order to ensure the humane treatment of animals.

# CITI Training for Animal Users

**Bill Gurley, Ph.D., IACUC Chairman, and**
**Darri Scalzo, Research Compliance Officer**

## Current Requirements for All Animal Users:

- Participation in Occupational Health Program
- Attend the Certification Class/Presentation

# CITI Training for Animal Users

**Bill Gurley, Ph.D., IACUC Chairman, and**
**Darri Scalzo, Research Compliance Officer**

## New Requirements for All Animal Users:

- Participation in Occupational Health Program
- Attend the Certification Class/Presentation
- Completion of the designated CITI training modules
- Follow up with refresher module every 3 years

# CITI Training for Animal Users

**Bill Gurley, Ph.D., IACUC Chairman, and**
**Darri Scalzo, Research Compliance Officer**

## How will this requirement be implemented?

- Principle Investigators with active protocols will be notified of the new training requirement.
  - Initial deadline for CITI Training of PIs and staff (post docs, technicians, etc.) is January 15, 2015.
  - Takes about 1 hour to complete
- Notification will include instructions for CITI
- Notification will include a timeline for required completion
- Refresher course must be completed every 3 years
  - Takes about 30 minutes to complete



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# CITI Training for Animal Users

Bill Gurley, Ph.D., IACUC Chairman, and
Darri Scalzo, Research Compliance Officer

## Initial CITI Training Deadline:

**January 15, 2015**

**All UAMS and ACHRI PIs that utilize animals in their research as well as post-docs, technicians, graduate students, etc.**

# CITI Training for Animal Users

**Bill Gurley, Ph.D., IACUC Chairman, and**
**Darri Scalzo, Research Compliance Officer**

## How will this requirement be implemented?

- No new protocols or annual reviews will be approved if training requirements are not met by the deadline as set by the IACUC for initial CITI training completion
- VA animal users are already required to complete the CITI training modules.
- VA Personnel will not have to repeat the CITI training for UAMS. They can provide a transcript from CITI or affiliate with UAMS as an additional institution in CITI.

# CITI Training for Animal Users

**Bill Gurley, Ph.D., IACUC Chairman, and**
**Darri Scalzo, Research Compliance Officer**

Collaborative Institutional Training Initiative (CITI)

https://www.citiprogram.org/

# CITI Training for Animal Users

**Bill Gurley, Ph.D., IACUC Chairman, and**
**Darri Scalzo, Research Compliance Officer**

## Questions or Comments?


# NIH Policy on Genomic Data Sharing

Joe Underwood, J.D., Ph.D.,
Sr. Contracts Attorney, ORRA

On August 27, 2014, the NIH issued its final Genomic Data Sharing (GDS) Policy. The GDS Policy broadens the Genome Wide Association Studies (GWAS) Policy from 2007.

# NIH Policy on Genomic Data Sharing

Joe Underwood, J.D., Ph.D.,
Sr. Contracts Attorney, ORRA

- **Effective Date of the GDS Policy**
  - January 25, 2015
- **Applicability**
  - Competing grant applications
  - Proposals for contracts with NIH
  - NIH intramural projects

# NIH Policy on Genomic Data Sharing

Joe Underwood, J.D., Ph.D.,
Sr. Contracts Attorney, ORRA

- **Investigator submission responsibilities**
  - GDS Sharing Plans
  - Non-human genomic data
    - Data submission timeline
    - May be submitted to various NIH or non-NIH repositories

# NIH Policy on Genomic Data Sharing

Joe Underwood, J.D., Ph.D.,
Sr. Contracts Attorney, ORRA

- **Investigator submission responsibilities**
  - GDS Sharing Plans
  - Non-human genomic data
  - Human Genomic Data
    - Data submission timeline
    - Register study with dbGaP
    - Submit data to proper NIH-designated data repository
    - Informed consent will determine tier of distribution for the data (controlled vs. unrestricted)

# NIH Policy on Genomic Data Sharing

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- **Investigator submission responsibilities**
  - GDS Sharing Plans
  - Non-human genomic data
  - Human Genomic Data
    - Data submission timeline
    - Register study with dbGaP
    - Submit data to proper NIH-designated data repository
    - Informed consent will determine tier of distribution for the data (controlled vs. unrestricted)
  - Institutional Certification regarding data, sharing plan and submission
  - Justification for exceptions to data submission
  - Can request removal of data if a patient withdraws consent

# NIH Policy on Genomic Data Sharing

Joe Underwood, J.D., Ph.D.,
Sr. Contracts Attorney, ORRA

- **Investigator Usage Responsibilities**
  - Stringent conditions for use of controlled-access data
  - Less stringent conditions for use of unrestricted-access data
- **Intellectual Property**
  - Data made available through this process should remain freely available and discourages the use of patents to block access to genomic data developed with NIH support

# NIH Policy on Genomic Data Sharing

Joe Underwood, J.D., Ph.D.,
Sr. Contracts Attorney, ORRA

**Resources**:

http://gds.nih.gov/

**Questions?**

Joe Underwood, J.D., Ph.D.

501-686-8846

junderwood@uams.edu

Office of Research and Regulatory Affairs

# Librarians' Support of Medical School IACUCs: Survey Says…

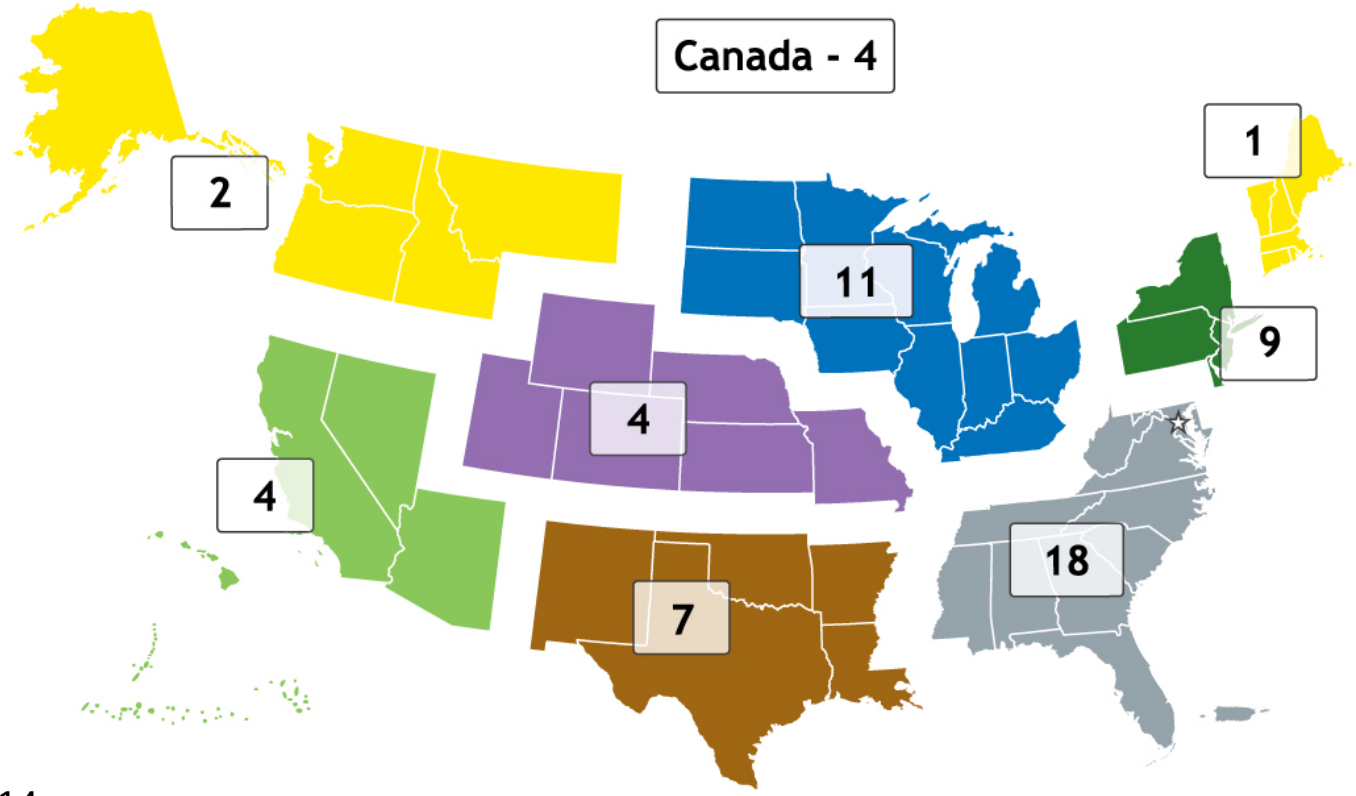
Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

- **Librarians @ UAMS & the IACUC**
  - Overarching Inquiries
    - How do librarians support IACUCs?
    - How do librarians support researchers & AUPs?
  - Study Design & Timing

# Librarians' Support of Medical School IACUCs: Survey Says…

Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

- **Distribution of the 60 (39%) responses by NN/LM Region**





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# Librarians' Support of Medical School IACUCs: Survey Says…

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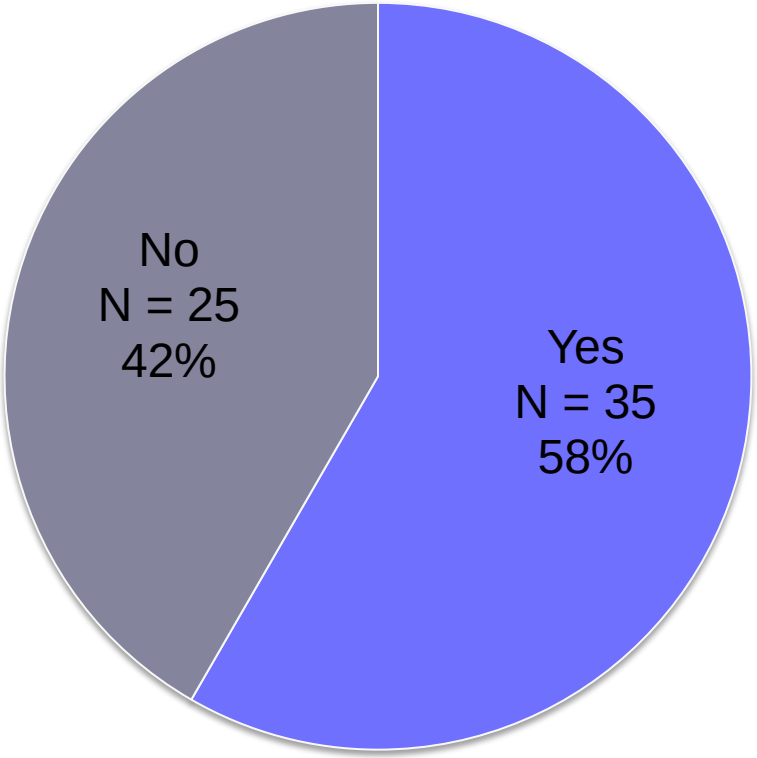
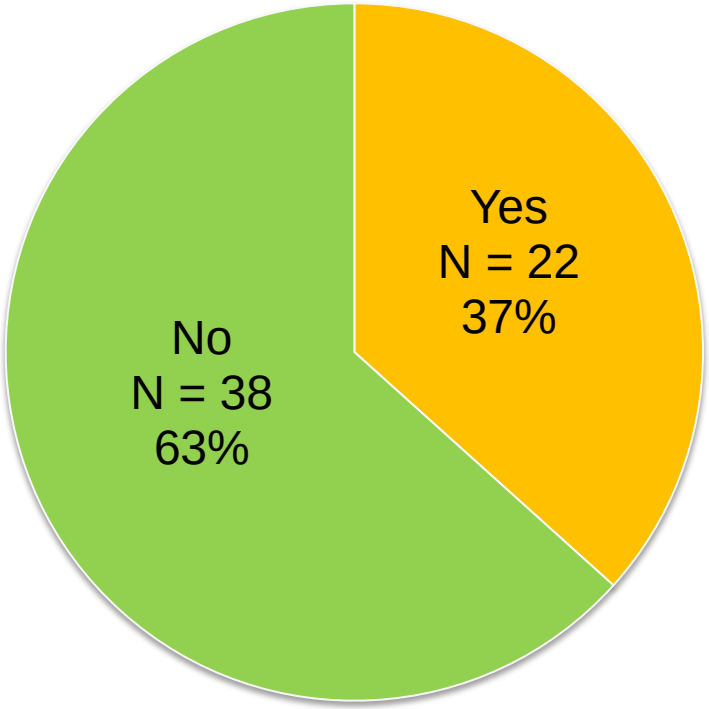
- **Does a librarian provide literature searches or search consultations for AUPs?**



# Librarians' Support of Medical School IACUCs: Survey Says…

Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

- **Does a librarian currently serve on your campus IACUC?**



# Librarians' Support of Medical School IACUCs: Survey Says…

Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

- **IACUC Participation**
  - Does IACUC-member librarian review protocols?
    - Yes – 21, No – 1
  - Does IACUC-member librarian vote on AUPs?
    - Yes – 16, No – 7

# Librarians' Support of Medical School IACUCs: Survey Says…

Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

- **Librarians received positive feedback from:**
  - Researchers / PIs
  - IACUC chair, members and staff
  - Dean / Vice Chancellor
  - Auditors

# Librarians' Support of Medical School IACUCs: Survey Says…

Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

## Pros

- Better understanding of research activities and areas [15]
- Improved working relationships with researchers [12]
- Increased library/librarian profile, opportunities for marketing services [7]
- Interesting work [6]
- Enhanced searching skills [3]

## Cons

- Heavy workload; major time commitment [13]
- Frustration/resentment displayed by researchers to librarian [3]
- Ethical/emotional issues around animal research [3]
- Confidentiality [2]

# Librarians' Support of Medical School IACUCs: Survey Says…

Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

- **Wish List**
  - Require librarian review of literature searches as part of the approval process (3)
  - More librarians involved (2)
  - More contact with librarians in other institutions doing this work (2)
  - Encourage researchers to involve the librarian (i.e., literature reviews) earlier in the research design process
  - Release time from other work
  - More science training

# Librarians' Support of Medical School IACUCs: Survey Says…

Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

## Comments of Interest

- It is unclear if the researchers or IACUC members really look closely at the results of the literature searches.
- I have not seen good evidence that the literature searches (often after the rest of the protocol is written) have any impact on the research.
- IACUC-member librarian will chair the IACUC next year.
- Librarian received positive feedback from the auditors about the quality and completeness of the animal alternative literature searches.

# Librarians' Support of Medical School IACUCs: Survey Says…

Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

- Librarians are under-utilized in this activity
- Librarians who do this work see many benefits

## CITATION…

Academic health sciences librarians' contributions to institutional animal care and use committees.
Steelman SC, Thomas SL.
J Med Libr Assoc. 2014 Jul;102(3):215-9. doi: 10.3163/1536-5050.102.3.014.
PMID: **25031565** Free PMC Article PMC4076133

# Librarians' Support of Medical School IACUCs: Survey Says…

Susan Steelman, MLIS / Sheila Thomas, MA(LS), MEd.

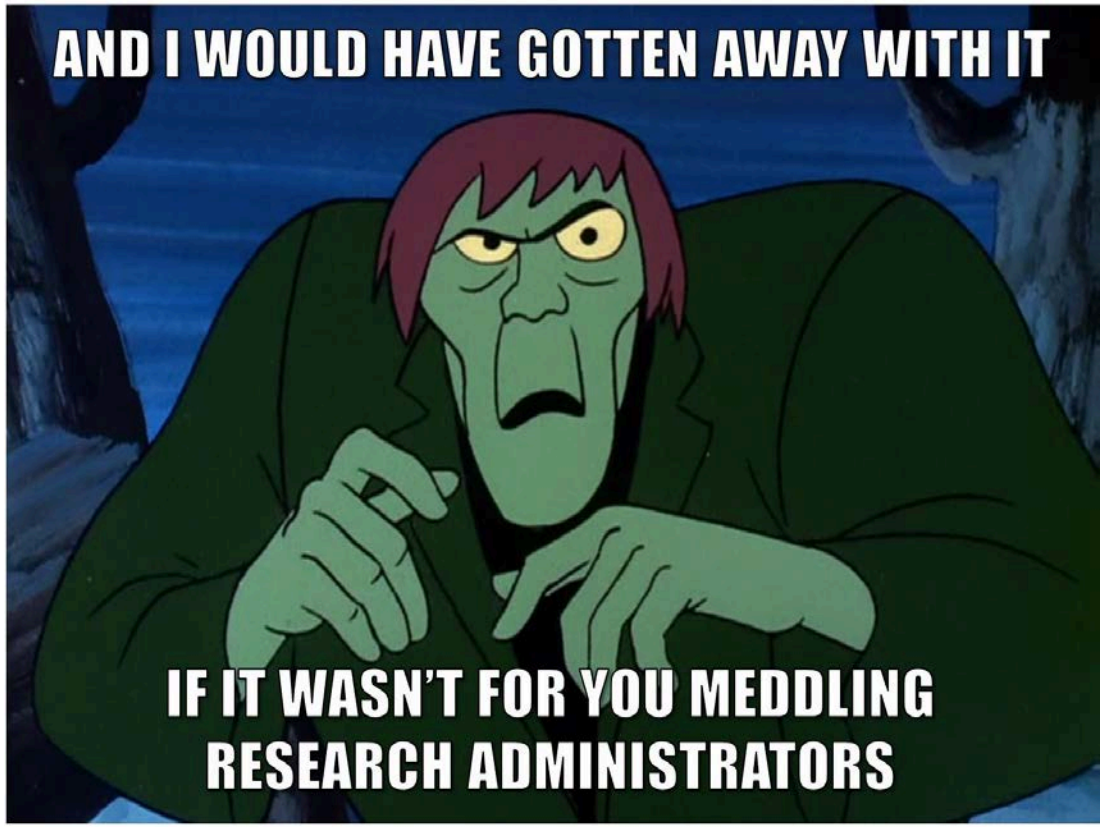
- *Thank you!*

UAMS Library

UAMS Biomedical Research

# The Federal Demonstration Partnership

## Suzanne Alstadt, Director, ORSP



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# The Federal Demonstration Partnership

## Suzanne Alstadt, Director, ORSP

- **Federal Demonstration Partnership (FDP)**
  - Cooperative initiative of federal granting agencies, institutional recipients of federal funds, and research policy organizations
  - Purpose is to work collectively to identify, test, and implement new and more effective ways of managing federal research grant.
  - Goal is to improve productivity of research and the national research enterprise
  - Pilot new ways of managing grants before introducing the initiatives to the wider research community

# The Federal Demonstration Partnership

## Suzanne Alstadt, Director, ORSP

- **History of FDP**
  - **1986 – Florida Demonstration Project**
    - Created to develop and test new grants management procedures
    - DOE, NSF, NIH, ONR, USDA, FL State Univ. System & Univ. of Miami
    - No-cost extensions, pre-award costs, carry-forward across continuation years, streamlined research grants terms & conditions.
  - **1988 – Federal Demonstration Project, Phase II**
    - 45 institutions in 14 states & 10 Federal Agencies

# The Federal Demonstration Partnership

## Suzanne Alstadt, Director, ORSP

- **1996 – Federal Demonstration Partnership, Phase III**
  - 20 institutions, 1 federal agency, and 7 professional associations added
  - UAMS joined FDP
  - Added faculty members and program officers as members
  - Cost sharing, effort reporting, subawards
- **2002 – FDP IV**
  - Efforts made to increase participation of minority serving and emerging research institutions.
  - Increasing number of federal auditors and costing officials involved in task forces and committees

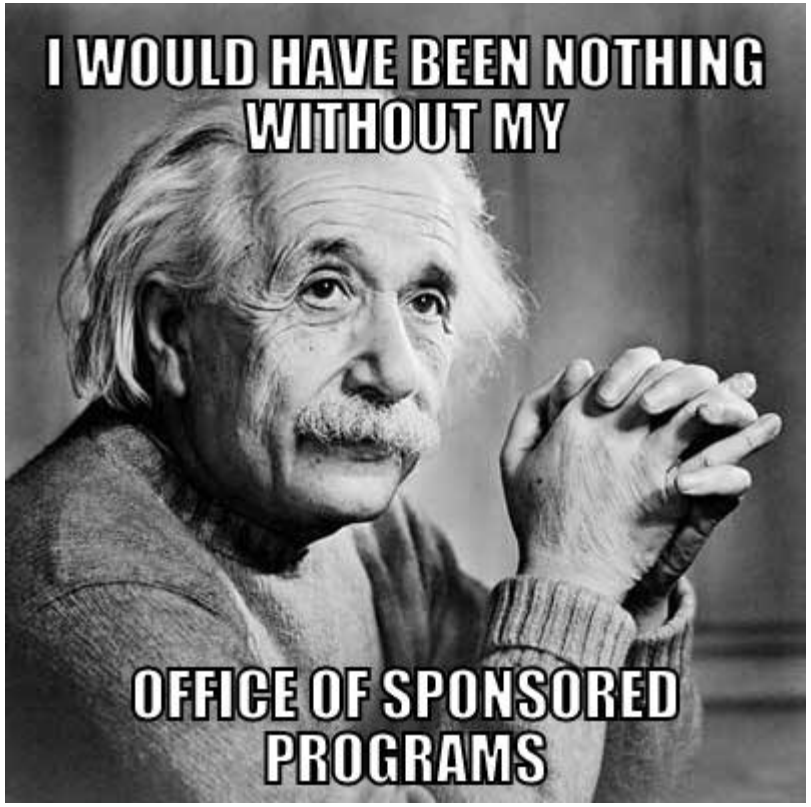
# The Federal Demonstration Partnership

## Suzanne Alstadt, Director, ORSP

- **2008 – FDP V**
  - A-133 Subrecipient monitoring
  - Electronic Research Administration/Grants.Gov
  - 2nd faculty workload survey
- **2014 – FDP VI**
  - Kick-off meeting in September
  - 155 institutions, 10 fed agencies
  - Welcome to our new Faculty Rep – Dr. Steven Post

# A Comedy of Errors: a Brief History of ORSP Proposal Review at UAMS

## Suzanne Alstadt, ORSP Director





# Recently NIH sent out

## "Systematic Application Compliance Checking – What It Is…"

- A strategy for providing users an opportunity to identify and fix many errors prior to submission deadlines.
- A mechanism to reduce the number of applications NIH staff have to turn back for noncompliance.
- An efficient method of ensuring large numbers of applications follow the same general rules and that the rules are enforced with consistency and fairness.
- A way to ensure application information is formatted appropriately for NIH systems and can be assembled into a consolidated application image for review.



# "…and What It's Not"

- A way to reduce the number of applications received to bump up our success rates.
- A substitute for following the instructions provided in FOAs, application guides and notices in the NIH Guide for Grants and Contracts.
- Helpful, unless you submit early enough (as in days, not hours or minutes) to have time to fix identified errors.
- A guarantee your application will be accepted for review and funding consideration if you pass all system compliance checks.

# A Comedy of Errors: a Brief History of ORSP Proposal Review at UAMS
## Suzanne Alstadt, ORSP Director

## If NIH Checks all of these things, why does ORSP need to review my proposal?

- ORSP ensures that the proposal
  - Follows the instructions provided in FOAs, application guides and notices in the NIH Guide for Grants and Contracts. (Which change more than any of us like).
  - Complies with Federal, State, Local, and Institutional Regulations, Policies, and Procedures (Which also change more than any of us like).

- We have encountered almost every mistake that can be made on a proposal, and have had to figure out how to fix it.

- What follows are a few examples…



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# When Continuous Submission Does Not Apply

- Applications from Project Directors/Principal Investigators (PDs/PIs) or multiple PDs/PIs (MPI) who are eligible for continuous submission but wish to request an assignment to a specific study section.
- Applications from temporary or ad hoc members who have not contributed recent substantial review service.
- Applications for which the eligible members have roles other than PD/PI or MPI.
- **Applications submitted in response to Requests for Applications (RFAs).**
- Applications submitted in response to PARs with non-standard receipt dates.

# When the Latest Forms Are Not Used

- A PI completes an entire proposal packet and submits it to ORSP on 9/23/2014
- The due date is 10/05/2014
- The forms expired on 09/01/2014
- No one notices until the ORSP reviews it.
- The ORSP Grants Administrator gets to tell the PI that the entire proposal has to be redone on the new forms.
- Please don't make us have to tell you that.



# New Means New

- NIH and AHRQ will accept a new (A0) application following an unsuccessful resubmission (A1) application.
- The fine print that you have to actively seek
  - **You may not include previous scores, comments of the previous reviewers, your responses to those comments, or place marks in the text of the research strategy or any other section of the application to indicate changes from a previous submission. Remind collaborators providing letters of support not to refer to previous submissions or reviews, and for applications requiring reference letters, remind your referees that these letters should not include any references to a previous application or review.**
  - **Your application will be withdrawn from the review process if you include anywhere in the your application the kind of information that would be found in a previous summary statement (score, critique criterion scores, reviewers comments), information that would be appropriate for an Introduction (response to the previous review and information about how the application was changed), or marks in the text of the application to show how it has changed since the last submission.**



# Timelines and Deadlines and Commons PDFs

*When ORSP receives your final proposal 48 hours before the published deadline, you have plenty of time to view the PDF in NIH Commons and find errors.*

***Do not skip this step!  You as the PI are the one who can verify that everything looks exactly the way that you want the reviewers to see it.***

***Don't wait!  Act now! After the deadline has passed it is too late to correct the typo in your title, the illegible legend on your figures, the upside down Specific Aims page, or the **ADD VITAL DATA HERE** notation in your research strategy.***

# A Comedy of Errors: a Brief History of ORSP Proposal Review at UAMS

Suzanne Alstadt, ORSP Director

## Questions?

# Next RESIN

- **Next RESIN**
  - **November 4, 2014 @ 12:00 p.m.**
  - Location - **Walton Auditorium**, Winthrop P. Rockefeller Cancer Institute, 10th floor
  - All RESIN presentations archived on the UAMS Research website
    - http://www.uams.edu/research/RESIN_Achive.asp