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FOR MEDICAL SCIENCES

Research Support Information Network (RESIN)

Presented by: Office of the Vice Chancellor for Research

Date: February 2, 2016

Agenda

- **Updates & Timely Information from Research Support:**
  - Office of the VCR
    - URC
    - IRB
    - Contract Administration
    - IACUC
  - ORRA
    - Procurement Services
    - BioVentures
    - Travel
  - ORSP
    - Research Compliance
    - Office of Finance
  - DLAM
  - COI
  - TRI
    - COP - COBRE

- **Update on TRI Project Support Unit**
  - Organizational Structure
  - Staff
  - New Services

TRI Clinical Trials Support: From Soup to Nuts

Alison Oliveto, Ph.D.
Director, TRI Project Support Unit

Jonathan Young
Senior Program Manager

Kennetha Newman
Program Coordinator

Cynthia Spinks
Research Finance Team Manager

Mtonya Hunter-Lewis
Regulatory Management Services Supervisor

Shawna Owens
Research Coordinator Services Manager

Mtonya Hunter-Lewis
Angela Garland
Suzannah Kirby
Lisa Richardson
Sharon Sandria
Tracy Thurman

Charles Michael Bailey
Charity Washam

Suzan Blair
Ashley Sides
Rita Vaughn

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Clinical Trials Support: From Soup to Nuts

Alison Oliveto, Ph.D.
Director, TRI Project Support Unit

Continuing Services/Support	New Services
CLARA Routing	Liaison with Industry/PI
Protocol Development	Feasibility Tools
Regulatory Management*	Medicare Coverage Analysis
Medicare Coverage Review	Budget Development
Budget Review	Budget Negotiations
Research Coordinator Support*	

* - *fee for service*

For more information: http://tri.uams.edu/clinical-research-facilities-support/
To request services: TRIServices@uams.edu

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Profiles Training

Alison Oliveto, Ph.D.
Director, TRI Project Support Unit

- **Profiles** is now live and accessible: http://tri.uams.edu/profiles
- Upcoming Trainings are scheduled:

  February 23rd
  12:00 p.m. - 1:00 p.m.
  4:00 p.m. - 5:00 p.m.

  March 2nd
  12:00 p.m. - 1:00 p.m.

  March 8th
  4:00 p.m. - 5:00 p.m.

- **All Trainings held in EDII 8/105 A/B**
- Sign up in Training Tracker
- Class size is limited to 30

Office of the General Counsel

Dori Wong Scoggins, J.D.
Sr. Contracts Attorney

- **Research Contracts Review and Negotiation**
  - Confidentiality Agreements
  - Material Transfer Agreements (Addgene, UBMTA)
  - Clinical Trial Agreements
    - PI Initiated and Industry Sponsored
    - Contract, Consent, Payment Terms
  - Research Agreements
  - HIPAA Data Use Agreements
  - Memorandum of Understanding
  - Grant Agreements
  - Licensing Agreements

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Office of the General Counsel

Dori Wong Scoggins, J.D.
Sr. Contract Attorney

- **Contact Information**

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New OLAW Mechanism for Changes to Animal Use Protocols

John Lowery, DVM, DLAM

- **Veterinary Verification and Consultation (VVC)**
  - In an effort to reduce regulatory burden for Investigators, OLAW recently issued new guidance regarding the review process required for significant changes (Amendments) to approved Animal Use protocols. This new VVC process will allow Amendment approval without the typical IACUC review. Recognizing performance standards and professional judgment, OLAW will allow the following types of amendments to be implemented simply following consultation and verification by an authorized veterinarian.

New OLAW Mechanism for Changes to Animal Use Protocols

John Lowery, DVM, DLAM

- **Amendments Approved for VVC**
  - 1) Changes in anesthesia, analgesia, sedation or experimental substances
  - 2) Changes from one AVMA-approved method of euthanasia to another
  - 3) Changes in the duration, frequency, number or variation of non-surgical procedures performed

New OLAW Mechanism for Changes to Animal Use Protocols

John Lowery, DVM, DLAM

- **Changes That Cannot Be Used by VVC**
  - 1) Change from nonsurvival to survival surgery
  - 2) Changes that result in greater pain, distress, or invasiveness
  - 3) Change in species
  - 4) Change in study objective
  - 5) Change in P.I.
  - 6) Change that impacts personnel safety
  - 7) Change in housing or use of animals in a location that is not part of the animal program overseen by the IACUC

New OLAW Mechanism for Changes to Animal Use Protocols

John Lowery, DVM, DLAM

- **IACUC Addendum Form**

UAMS/ACHRI
Institutional Animal Care and Use Committee
Request for Veterinary Verification and Consultation (VVC) or Protocol Addendum

This form should only be used to make a change to an **approved** animal protocol. VVC cannot be used to add a new procedure or to make a change that would significantly increase animal pain or distress. Only changes in a-c, below, are eligible for VVC. All other changes require a Protocol Addendum. If changes are substantial, e.g. change of or additional animal species, additional animals in excess of 10% of the originally approved number, survival surgery, or the proposed change increases the potential for pain or distress in an animal, or involves a significant procedure not previously approved for these particular animals, a new AUP may be required.

1. Protocol Information

Principal Investigator Click here to enter text.
AUP # Click here to enter text.
AUP Title Click here to enter text.
Species Approved Click here to enter text.

2. Change(s) Requested

Eligible for VVC:
a. ☐Anesthesia, ☐analgesia, ☐sedation, ☐experimental substances
b. ☐Euthanasia (in accordance with current AVMA Guidelines)
c. ☐Duration, ☐frequency, ☐number, ☐variation of non-surgical procedures performed

Protocol Addendum Required:
d. ☐Add Experimental Procedure
e. ☐Imaging (ultrasound, MRI, PET, etc.)
f. ☐Animal Strain
g. ☐Animal Number
h. ☐Personnel
i. ☐Other (specify) Click here to enter text.

3. Detailed description of changes
(FOR IMAGING: Include anesthetics used, as well as post-procedural care or euthanization.)

4. Justification for changes

Click here to enter text.

5. For new procedures:
Who will perform the procedure(s)? Click here to enter text.
What are their qualifications (training and/or experience) to perform the procedure(s) on this species?
Click here to enter text.

6. For new personnel:
DLAM Certification Number: Click here to enter text.
Has CITI Training for Animal Users been completed?
☐**Yes** ☐**No**
Which procedures will this person be performing?
Click here to enter text.
What are their qualifications (training and/or experience) to perform the procedure(s) on this species?
Click here to enter text.

7. Additional animals:

Will the proposed changes increase the total number of animals used in this protocol?

☐**NO**
☐**YES (provide information below)**
Total number of additional animals: Click here to enter text.
Number per USDA Category (B, C, D, E): Click here to enter text.

INVESTIGATOR ASSURANCE: I have determined that the research proposed in this addendum is not unnecessarily duplicative of previously reported research and that the use of animals is necessary. I agree to conduct this project in accordance with applicable provisions of the Animal Welfare Act, the Public Health Service Policy and the 8th edition of the Guide for the Care and Use of Laboratory Animals.

CT.Gov: Status of Compliance

Tracy Gatlin, CT.Gov Administrator

- **Trials Required to Register**
  - Applicable Clinical Trials
    - Drugs
    - Devices
  - Qualifying Medicare Studies
    - Are you billing Medicare?
  - ICMJE
    - Do you want to publish?

CT.Gov: Status of Compliance

Tracy Gatlin, CT.Gov Administrator

What happens if I don't register or maintain my study?

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CT.Gov: Status of Compliance

Tracy Gatlin, CT.Gov Administrator

FDAAA

- Public notices of noncompliance and violations
- Withholding of NIH funds
- FDA sanctions
- Civil monetary penalties (up to $10,000/day)

CMS

- Bills will be affected: Bills may need to be held for NCT # to be added or CMS claims may be denied.

ICMJE

- Cannot publish in journals following ICMJE policy, and other select journals

CT.Gov: Status of Compliance

Tracy Gatlin, CT.Gov Administrator

- **December 2015; Charles Piller at STAT News publishes "A Failure to Report: A STAT Investigation" on ClinicalTrials.Gov**
  - Showed "routine and flagrant violations of the law.
    - Sloan Kettering: 100% Late/No Results
    - Stanford: 95% Late/No Results
    - NIH: 75% Late/No Results
  - Industry is doing slightly better than academia.

CT.Gov: Status of Compliance

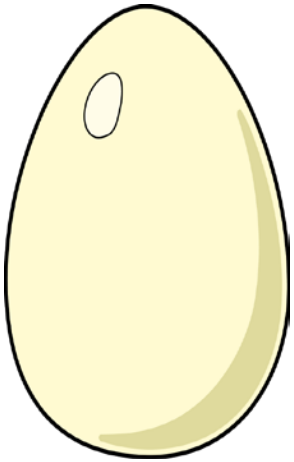
Tracy Gatlin, CT.Gov Administrator

- **How did University of Arkansas do?**
  - 216 trials currently registered in the CT.Gov database
    - 21 trials required to register results
      - 95% had results
      - 5% had no results or late results
      - Average days late for results reporting: 98

CT.Gov: Status of Compliance

Tracy Gatlin, CT.Gov Administrator

- **How many fines have been leveled for non-compliance?**



CT.Gov: Status of Compliance

Tracy Gatlin, CT.Gov Administrator

- **Steps being taken at UAMS to ensure compliance:**
  - Early notification whenever possible by administrator
    - Emails: Coordinator/PI/Division Chairman
  - Encourage use of available resources for results reporting.
  - Monthly reports to V.C. of Research

CT.Gov: Status of Compliance

Tracy Gatlin, CT.Gov Administrator

- **Status of Final Rule/Revised NIH policy**
  - Comment period ended in mid 2015
  - Finalization expected sometime in 2016
- Strong enforcement expected after finalization of the rule/policy by FDA

UAMS ClinicalTrials.Gov Administrator

Tracy Gatlin

Ph: 501-686-6803

Email: tlgatlin@uams.edu

The Federal Demonstration Partnership Suzanne Alstadt, ORSP Director Steve Post, PhD

- **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

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The Federal Demonstration Partnership

Suzanne Alstadt, ORSP Director
Steve Post, PhD

- **History of FDP**
  - **1986 – Florida Demonstration Project**
  - **1988 – Federal Demonstration Project, Phase II**
  - **1996 – FDP, Phase III**

    Expansion
  - **2002 – FDP IV**
  - **2008 – FDP V**

    Emerging Research Institutions
    Workload Surveys
  - **2014 – FDP VI**
    - 155 institutions, 10 fed agencies

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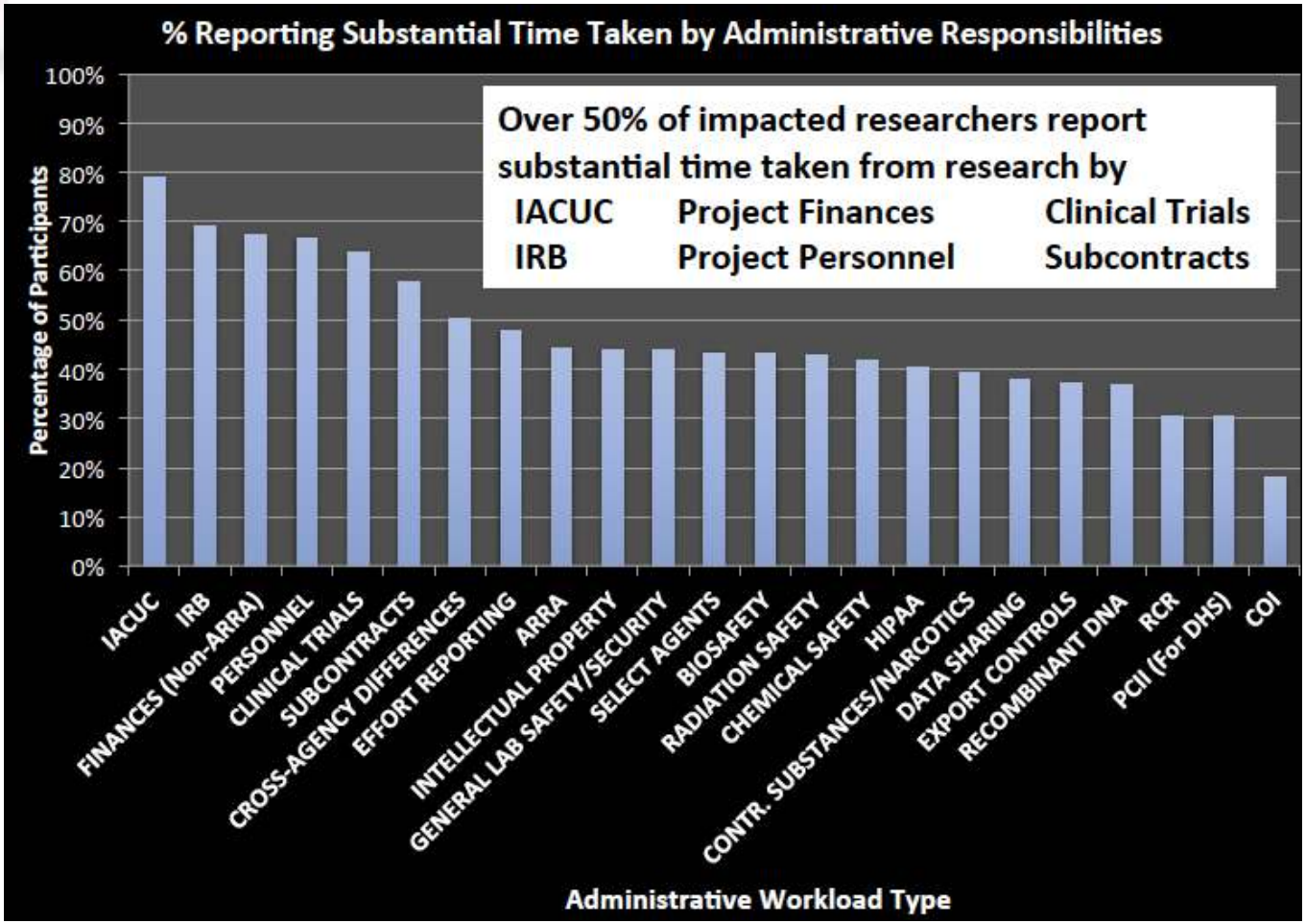
Suzanne Alstadt, ORSP Director

Steve Post, PhD



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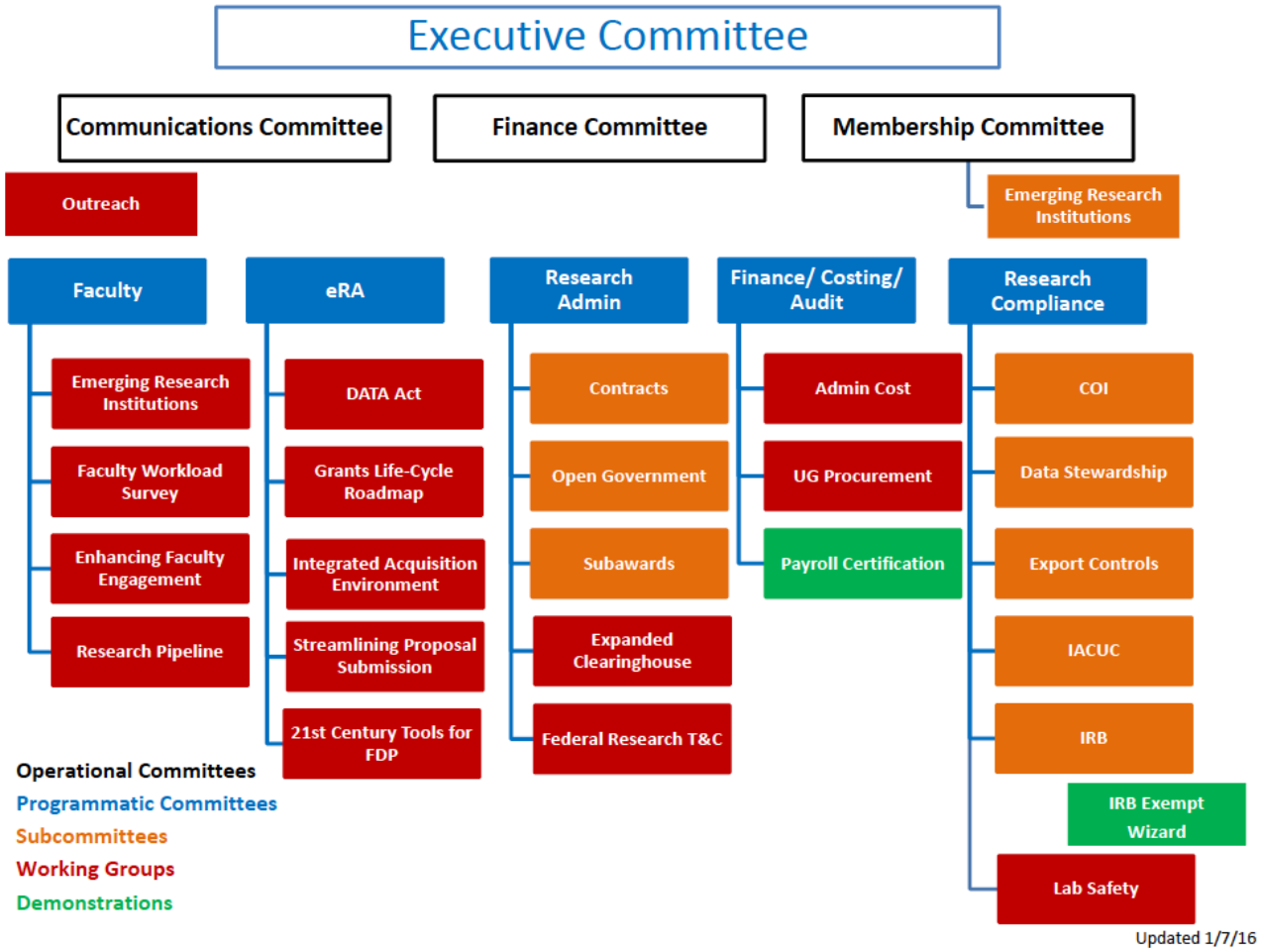

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The Federal Demonstration Partnership

Suzanne Alstadt, ORSP Director

Steve Post, PhD

The Federal Demonstration Partnership

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Steve Post, PhD

"Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century: Part 1" (2015)" *available on NAS website*

NEWS

The National Academies of
SCIENCES · ENGINEERING · MEDICINE

Sept. 22, 2015

Inconsistent, Duplicative Regulations Undercut Productivity of U.S. Research Enterprise; Actions Needed to Streamline and Harmonize Regulations, Reinvigorate Government-University Partnership

WASHINGTON -- Continuing expansion of federal research regulations and requirements is diminishing the effectiveness of the U.S. scientific enterprise and lowering the return on the federal investment in research by directing investigators' time away from research and toward administrative matters, says a new congressionally mandated report from the National Academies of Sciences, Engineering, and Medicine. The report identifies specific actions Congress, the White House, federal agencies, and research institutions should take to reduce the regulatory burden.

Excerpt

- The report also recommends a number of specific action…
  - **Congress should**: work with OMB to conduct a review of agency research grant proposal documents for the purpose of developing…
  - **Federal agencies should:** limit research proposals to the minimum information necessary to permit peer evaluation of the merit of the scientific questions…
  - **Universities should:** conduct a review of institutional policies developed to comply with federal regulations of research…

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The Federal Demonstration Partnership

Suzanne Alstadt, ORSP Director
Steve Post, PhD

- **Compliance issues**
  - IRB—Upcoming changes to Common Rule, IRB exemption form, uniform modular consent form
  - IACUC—Institutional imposed policies
  - Data Stewardship—Massive undertaking
- **Faculty issues**
  - 3rd faculty workload survey—2017
  - Faculty engagement

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The Federal Demonstration Partnership

Suzanne Alstadt, ORSP Director
Steve Post, PhD

- **Administrative issues**
  - Subawards
  - COI Clearinghouse
  - Expanded Clearinghouse/Subrecipient Monitoring
  - Electronic Research Administration

Research Based Certifications

Lucie Ingram, JD
Director, Conflict of Interest

- **What?**
  - Research Based Certifications:
    - A study-specific disclosure in TRACKS-COI
      - Confirm the information on your current COI form is accurate and your Significant Interests (SI) are updated
      - Answer questions specific to the study to help the COI committee determine whether a SI is related to the study, and if related, whether the SI poses a conflict of interest

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Research Based Certifications

Lucie Ingram, JD
Director, Conflict of Interest

- **Why?**
  - Compliance with Federal Regulations and UAMS Policy
    - Federal regulations require UAMS to review, identify, manage, and report any financial conflict of interest prior to expenditure of award funds. 42 CFR § 50.605
  - Reduce risk of retrospective reviews
    - If an FCOI is not identified or managed in a timely manner, UAMS must complete a retrospective review of the investigator's activities/research project
  - Protect the integrity of research

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Research Based Certifications

Lucie Ingram, JD
Director, Conflict of Interest

- **Who?**
  - All individuals listed on the project as PI, KP, or Other Significant Contributor (any person involved in the design, conduct, or reporting of research) **must complete an RBC prior to the release of award funds**.

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Research Based Certifications

Lucie Ingram, JD
Director, Conflict of Interest

- **How?**
  - When ORSP receives award notice, those listed on the project will receive an email notification to complete the RBC
    - Complete the RBC as soon as possible, but no longer than 7 days of receipt of notice
  - COI office reviews RBCs and determines if an expedited review is required
    - If an expedited review is required, the COI committee will complete its review within 7 days of receipt of the RBC.
    - If an expedited review is *not* required, the RBC will be scheduled for review at the next COI committee meeting.
  - Once COI office receives all RBCs from those listed on the project and any required expedited reviews are completed, award is pushed to next step in Award Release process.

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Research Based Certifications

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Director, Conflict of Interest

- **When?**
  - Phase I **Mid-March 2016**: All projects initiated through TRACKS-Grants
  - Phase II **July 1, 2016**: All projects initiated through CLARA

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Questions?

UAMS Conflict of Interest Office

501-686-6447 or 501-686-6556

Lingram@uams.edu or MKSandlin@uams.edu

http://coi.uams.edu/

TRACKS-COI Disclosure System

http://coi.tracks.uams.edu/COI/

Showcase of Medical Discoveries – Training Grants

Linda Williams, MS, Research Liaison

- **Showcase – Training Grant Research**
- **February 10, 2016**
  - 4:30 p.m. - 6:00 p.m.
  - 10th floor Winthrop P. Rockefeller Cancer Institute
  - Wine & cheese research reception and 12 poster presentations

Next RESIN

- **Next RESIN**
  - **March 1, 2016 @ 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

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