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UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

Research Support Information Network (RESIN)

Presented by: Office of the Vice Chancellor for Research

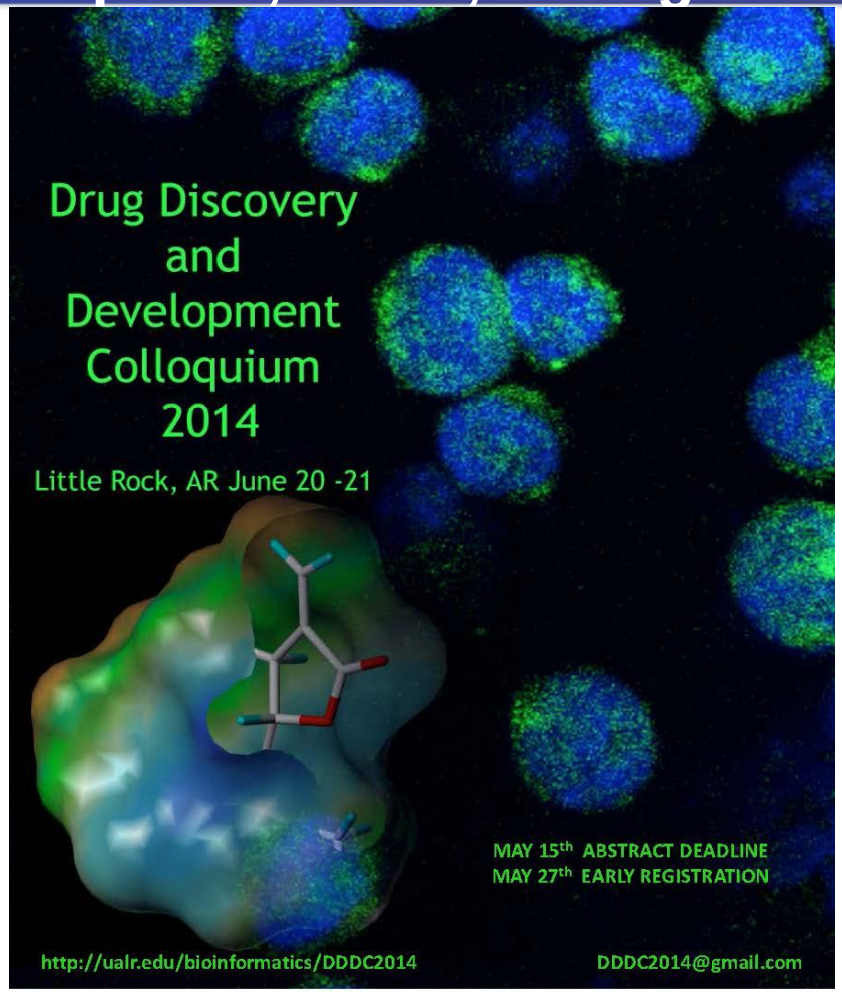
Date: June 3, 2014

Agenda

- **Updates & Timely Information from Research Support:**
  - Office of the VCR
    - RSC
  - IRB
  - IACUC
    - HIPAA
    - UAMS Library
  - Campus Operations
    - Cost/Grants Accounting
    - COI
    - ORSP
    - ORC
    - DLAM
    - OGSP
    - TRI
    - Medical Informatics
  - College of Pharmacy

Drug Discovery & Development Colloquium 2014

Cesar Compadre, Ph.D., College of Pharmacy



Equipment Monitoring

William Johnson, Campus Operations Analytics and Support

- **CO Call Center -- What We Do**
- **Associated Costs for Monitoring**
- **When We Receive an Alarm**

Equipment Monitoring

William Johnson, Campus Operations Analytics and Support

- Users Responsibilities
- What's Next
- Questions?

- 526-0000 Call Center Number

KEEP CALM AND DON'T SHOOT THE MESSENGER

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NIH to Balance Sex in Cell and Animal Studies

Kerrey Roberto, IACUC Administrator

- Policies are still under development
- Appears to apply only to new studies
- "Phased" roll-out to begin in October 2014
  - "Phases" as yet unknown
- Training modules will be posted on NIH website by the end of 2014
- Journals will be encouraged to require information on cells and animals
- Ongoing initiative…will need to keep up with changes

NIH to Balance Sex in Cell and Animal Studies

Kerrey Roberto, IACUC Administrator

- Lack of reproducibility
- One element of experimental design
- Translation from animals to humans
- Clinical trials require inclusion of women
- Reduce wasted time, animals and $$$

NIH to Balance Sex in Cell and Animal Studies

Kerrey Roberto, IACUC Administrator

How can you use the ARRIVE guidelines?

The guidelines can be used when reporting research. In brief, the ARRIVE guidelines include the following:

Title

1. Accurate & concise description

Abstract

2. Background, objectives, methods, key findings and conclusions

Introduction

3. Background

4. Objectives

Methods

5. Ethical statement

6. Study design (blinding/randomisation)

7. Experimental procedures (How? When? Where? Why?)

8. Experimental animals (species, sex, weight)

9. Housing and husbandry

10. Sample size

11. Allocation experimental groups

12. Experimental outcomes

13. Statistical methods

Results

14. Baseline Data

15. Numbers Analysed

16. Outcomes & estimation

17. Adverse events

Discussion

18. Interpretation & implications

19. Generalisability and translation

20. Funding

NC 3Rs

For a full description, see the 20-point check list at www.nc3rs.org.uk/ARRIVE

ARRIVE

NIH to Balance Sex in Cell and Animal Studies

Kerrey Roberto, IACUC Administrator

- **LINKS**
  - NIH
    - http://www.nih.gov/
  - Nature Article
    - http://www.nature.com/news/policy-nih-to-balance-sex-in-cell-and-animal-studies-1.15195

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- NSB Report evolved out of previous Federal Demonstration Project (FDP) reports
- NSB sought information and suggestions from research faculty and administration
- The full report can be found at:
  - http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Most Frequently Reported Areas with a High Administrative Workload**
  - Financial Management
  - Grant Proposal Process
  - Progress and Other Outcome Reporting
  - Human Subject Research/IRB
  - Time and Effort Reporting

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Most Frequently Reported Areas with a High Administrative Workload** (cont.)
  - Animal Research/IACUC
  - Personnel Management
  - Subcontracts
  - Financial COI
  - Training
  - Laboratory Safety
  - Security

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Recommendation Area: Focus on the Science**
  - Agencies should modify proposal requirements to focus only on items essential to evaluating the merit of the proposed research and making a funding determination. Suggested ideas:
    - Preliminary proposals
    - Broadening just-in-time submission options
    - Simplifying budget requirements

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Recommendation Area: Focus on the Science** (cont.)
  - Limit biannual progress reports to include only research outcomes, simplify formats, and allow variation in requirements based on size of the award. Limit additional data requests to items essential for assessment of performance and compliance
  - NSF specific – Request the NSF Director to fully review and consider the agency-specific comments received and to report to NSB on review and progress within six months of this report

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Recommendation Area: Eliminate or Modify Ineffective Regulations**
  - Office of Management and Budget (OMB) should identify appropriate means by which the piloted payroll certification approach for time and effort reporting can be used by universities
    - Auditors and Inspectors General (IGs) should not go beyond the regulations and guidance. A Memo of Clarification should be issued indicating that the payroll certification method is acceptable to the Federal Government

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Recommendation Area: Eliminate or Modify Ineffective Regulations** (cont.)
  - Many recently proposed reforms to regulations governing human subjects research should be adopted, including:
    - Encouraging the use of a single IRB for multi-site studies
    - Eliminating continuing review for all expedited/minimal-risk protocols
    - Expansion and clarification of current exemption categories.
    - Endorsement of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) recommendation to allow all minimal risk research as eligible for expedited review
    - Eliminate requirement that IRBs review grant proposals and the requirement to submit IRB approved research protocols for review by agency IRB or peer review panel

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Recommendation Area: Eliminate or Modify Ineffective Regulations** (cont.)
  - Evaluate all regulations, policies, guidance, best practices and FAQs from all regulatory and accreditation sources , and other bodies governing animal research to identify requirements that increase investigators' administrative workload without improving care and use of animals

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Recommendation Area: Eliminate or Modify Ineffective Regulations (cont.)**
  - Evaluate all regulations, policies, guidance, best practices and FAQs from all regulatory and accreditation sources , and other bodies governing animal research to identify requirements that increase investigators' administrative workload without improving care and use of animals

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

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- **Recommendation Area: Eliminate or Modify Ineffective Regulations (cont.)**
  - Balance needed COI protections yet still encourage university/industry partnership to facilitate sound investment of federal funding in innovative activities
    - Evaluate recent changes to PHS COI regulations for cost and effectiveness and its impact on entrepreneurial activities
    - Other federal agencies should not adopt the PHS COI regulations
  - Re-examine current safety and security requirements that target industry but are applied to academic research. Identify and implement appropriate alternatives

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Recommendation Area: Harmonize and Streamline Requirements**
  - Federal agencies should accelerate efforts to harmonize and streamline the grant proposal and submission processes and post-award requirements
  - Agencies should establish uniform and consistent audit practices based clearly and directly on regulatory requirements
  - Agencies and institutions should consider requiring receipts and justifications only for larger purchases
  - Audits should focus on larger expenditures, outcomes, and infrastructure for compliance and risk management

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Recommendation Area: Increase University Efficiency and Effectiveness**
  - Communicate the origin of compliance requirements to researchers.
  - Avoid adding unnecessary requirements to those already mandated unless compelling reasons exist to do so.
  - Federal agencies should collaborate with research institutions, and organizations representing investigators and institutions to identify and disseminate model programs and best practices.
  - Protocol preparation, revision, and review could likely be reduced if IRB and IACUC staff provided researchers with knowledgeable assistance in the preparation and modification of these protocols.
  - Review their IRB and IACUC processes and staff organization with the goal of achieving rapid approval of high-quality protocols that protect research subjects.

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Review of NSB IRB Specific Recommendations**
  - Encourages the use of a single IRB for multi-site studies
    - UAMS has approved the use of a single IRB for ACH based studies. UAMS is developing processes and procedures to address the institution specific requirements to allow the use of outside IRBs for UAMS based studies.
- Endorsement of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) recommendation to allow all minimal risk research as eligible for expedited review.
  - Currently regulations only allow newly submitted research that falls into one of 7categories to be expedited
  - AAHRPP accreditation prompted complete overhaul of IRB approach to reviews

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Review of NSB IRB Specific Recommendations** (cont.)
  - Eliminate continuing review for all expedited/minimal-risk protocols
    - Agency recommendation, however, UAMS has already began using the regulatory flexibility to review many continuing reviews via the expedited process
  - Expansion and clarification of current exemption categories
    - The IRB revised its practices to first determine if submitted projects meet the definition of Human Subject Research

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Review of NSB IRB Specific Recommendations** (cont.)
  - Eliminate requirement that IRBs review grant proposals and requirement to submit IRB approved research protocols for review by agency IRB or peer review panel
    - IRBs and funding agencies review for very different purposes. Agencies do not know the IRB regulatory requirements
  - Communicate the origin of compliance requirements to researchers
    - Research newsletters, policies and blogs are used to improve communication between the IRB and research community
  - Avoid adding unnecessary requirements to those already mandated unless compelling reasons exist to do so
    - IRB has eliminated policy and system requirements that are redundant or unnecessary

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

Jennifer Holland, JD, IRB Director

- **Review of NSB IRB Specific Recommendations** (cont.)
  - Federal agencies should collaborate with research institutions, and organizations representing investigators and institutions to identify and disseminate model programs and best practices
    - UAMS has developed templates and checklists for use as appropriate
    - Be careful what you ask for
  - Protocol preparation, revision, and review could likely be reduced if IRB and IACUC staff provided researchers with knowledgeable assistance in the preparation and modification of these protocols
    - RSC and IRB provide assistance with preparation and modification of protocols through pre-review processes

"Reducing Investigators' Administrative Workload for Federally Funded Research" Report by National Science Board (NSB)

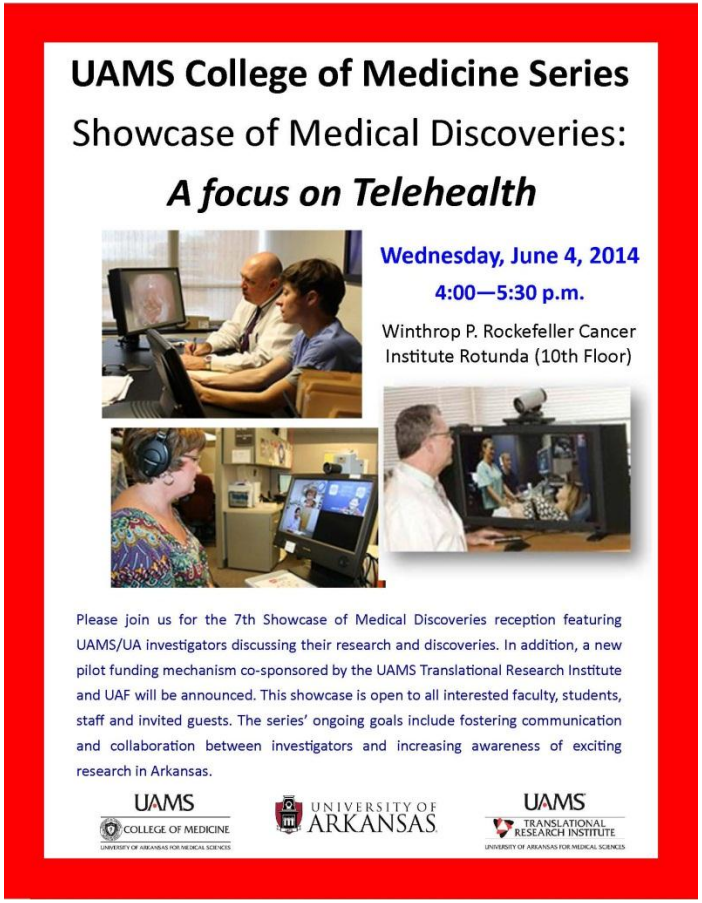
Jennifer Holland, JD, IRB Director

- **Review of NSB IRB Specific Recommendations** (cont.)
  - Review their IRB and IACUC processes and staff organization with the goal of achieving rapid approval of high-quality protocols that protect research subjects
    - Full board reviews are typically placed on agenda within two weeks of hitting the IRB queue. Letters are typically issued within three days of the meeting. Based on agenda queues, studies are often reviewed a week earlier than posted timeframes
    - Reviews that can be expedited are responded to within the same two week window. Average length of review is typically much shorter

Showcase of Medical Discoveries: Telehealth

Linda Williams, MS, Research Liaison

- **Showcase is TOMORROW**
  June 3, 2014, 4:00 p.m. - 5:30 p.m.
  - 10th floor Cancer Institute
  - 12 UAMS research posters
  - 3 UA research posters
  - 4 clinical operational posters
- Visitors from the Arkansas legislative offices, Medicare/Medicaid, Blue Cross/Blue Shield, and others will be attending.



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Medical Research Endowment Grants

Linda Williams, MS, Research Liaison

- **Medical Research Endowment Grants**
  - Granted by the UAMS Foundation Fund Board
  - ~$90,000 from the endowment income available for research projects in 2015
  - See guidelines and NIH biosketch format
    - http://research.uams.edu/files/2014/05/MRE-Guidelines-2015-lec-final.pdf
  - Application deadline is **July 16, 2014** at **5:00 p.m.**

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Medical Research Endowment Grants Linda Williams, MS, Research Liaison

- **Medical Research Endowment Grants (cont.)**
  - Applications to be turned into the Research Office (JarryJimieM@uams.edu; 501-686-5347)
  - Nonconforming applications will be returned without review
    - All applicable approvals (HRAC, biohazard, animal use, etc.) may be obtained after grant is approved, but must be obtained before funds are distributed

Medical Research Endowment Grants Linda Williams, MS, Research Liaison

- **Medical Research Endowment Grants (cont.)**
  - Submissions will be reviewed by faculty members from all colleges
  - The review process will be completed in the fall
  - The grant year begins January 1, 2015

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F&A Cost Sharing

Larry Cornett, Ph.D., Vice Chancellor for Research

Brief History

Pre-FY2000

--all F&A deposited into 111 fund

FY 2000-2014

--base amount of F&A established for each College
--above that amount, 30% to College and 70% to 111 fund

FY2014--

--F&A returned to Colleges*

F&A Cost Sharing

Larry Cornett, Ph.D., Vice Chancellor for Research

Effective July 1, 2014

--based on 2013 numbers, Colleges trade 111 fund dollars for F&A dollars**

--new formula for F&A:

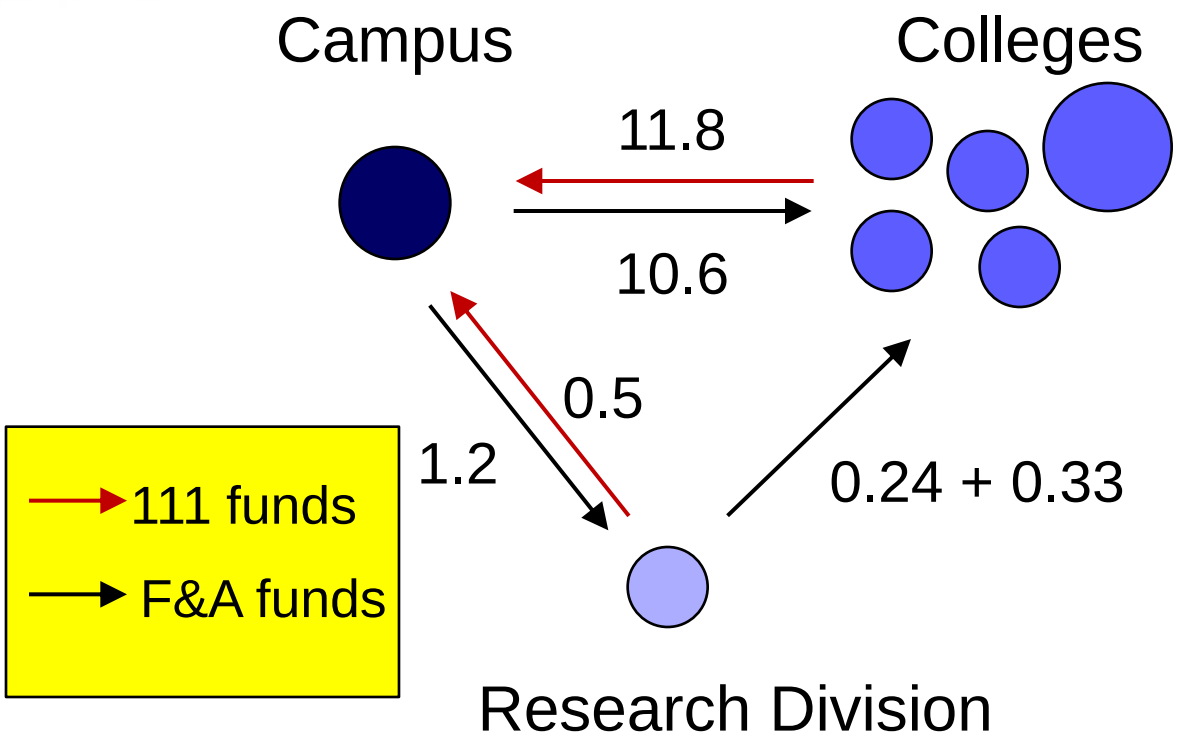
90% to PI's College
10% to Division of Research

**some exclusions, e.g., Headstart, TRI, BARDA grant, BTOP grant

F&A Cost Sharing

Larry Cornett, Ph.D., Vice Chancellor for Research

Transfers ($ in millions)



Budgets
($ in millions)

Campus	$102
Colleges	$560
Research Division	$6.8

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F&A Cost Sharing

Larry Cornett, Ph.D., Vice Chancellor for Research

3 Scenarios for FY15 and Beyond

Change	Total F&A ($ in millions)	Colleges' Share ($ in millions)	VCR Share ($ in millions)
10% increase	12.9	11.61 (↑$1.0 m)	1.29
No change	11.7	10.60	1.20
10% decrease	10.5	9.45 (↓$1.1 m)	1.05

F&A Cost Sharing

Larry Cornett, Ph.D., Vice Chancellor for Research

You've got to be very careful if you don't know where you are going because you might not get there.

Yogi Berra

An F&A cost recovery sharing plan would support inter-College collaboration.

Two plans under consideration:

Plan A—based on effort
Plan B—based on expenditures

F&A Cost Sharing

Larry Cornett, Ph.D., Vice Chancellor for Research

Plan A—Effort based

--PI's college receives 10% of F&A costs

--remainder allocated based on % effort of faculty in roles of PI, co-PI, co-investigator, etc.

--Deans can agree to alternate F&A recovery sharing plan

Example

NIH grant, PI and co-I in COP, efforts are 40% and 10%, co-I from CON with 20% effort, $120,000 in F&A received

10% to VCR	$12,000
10% to COP (PI College)	$12,000
80% left for sharing	
61.4% to COP (50/70 x $96k)	$68,544
28.6% to CON (20/70 x $96k)	$27,456

F&A Cost Sharing

Larry Cornett, Ph.D., Vice Chancellor for Research

Plan B—based on expenditures

--allocation based on amount of expenditures in each college
--separate WBS elements set up for respective budgets of each college's participation in the project
--Deans can agree to alternate F&A recovery sharing plan

Example

NIH grant, PI in COP & co-I in CON,
COP spends $140,000
CON spends $30,000
$83,300 in F&A received

10% to VCR	$8,330
90% left for sharing	
82% to COP (140/170 x $75k)	$68,544
18% to CON (30/170 x $75k)	$13,230

F&A Cost Sharing

Larry Cornett, Ph.D., Vice Chancellor for Research

UAMS Research Division
Office of the VCR

Larry Cornett, Ph.D.	Vice Chancellor
Caroline Miller-Robinson	Financial Officer
Jimie Jarry	Executive Assistant

Biomedical Research Building 2
Room 163-2
501.686.5347

Next RESIN

- **Next RESIN**
  - **September 2, 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