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UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

Presented by: Office of the Vice Chancellor for Research

Date: November 4, 2014

Agenda

- **Updates & Timely Information from Research Support:**
  - Office of the VCR
    - RSC
    - IRB
  - IACUC
    - HIPAA
    - UAMS Library
    - BioVentures
  - TRI
    - COI
  - ORSP
  - ORRA
    - DLAM
    - OGSP
    - CCTR/Core Facilities
    - Medical Informatics

Upcoming Changes in Biosafety Protocol Submission and Renewal

Daniel E. Voth, Ph.D.
Chair, Institutional Biosafety Committee

- **New Biosafety Protocol Form**
  - In effect since April 2014
    - New information required
    - Combine multiple protocols into one
  - Protocols will be reviewed by the IBC every 3 yrs
  - Protocols will be updated annually
  - All protocols must be converted to new form
    - Changeover will begin January 1
      - PI must submit new protocol at time of annual renewal

Upcoming Changes in Biosafety Protocol Submission and Renewal

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Chair, Institutional Biosafety Committee

Biosafety Protocol

Infectious Agents, Recombinant DNA, and Highly Toxic Materials Protocol

University of Arkansas for Medical Sciences
Institutional Biosafety Committee/Occupational Health & Safety (OH&S)/Biosafety Division
Return completed form to OH&S/Biosafety Division as an email attachment to: Carol Price

I. CORE REGISTRATION INFORMATION

Principal Investigator (PI): _____

Office Phone: _____ **Lab Phone:** _____

Department: _____

Email Address: _____

Protocol Type: Check which applies	
New	☐
Amendment	☐

General Protocol Title: _____

_____

_____

Signature of Principal Investigator _____ **Date** _____ **Chair, Institutional Biosafety Committee** _____ **Date** _____

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IV. LABORATORY/ADMINISTRATIVE PERSONNEL

List laboratory personnel involved with work covered under this research registration. Include investigators, students, and research staff. Mark (bold or asterisk) the lab supervisor or administrative coordinator whom you would like OH&S to contact for information about this protocol. The Biosafety Committee should be updated when personnel changes occur.

Last name, First name	Job Title	Phone number

V. RESEARCH ELEMENTS (Choose only sections that apply.)

- **Complete Section A if you are working with rDNA.**
- **Complete Section B if you are working with Infectious Agent(s) (non-rDNA materials).**
- **Complete Section C if you are working with highly toxic chemicals used to elicit a biological response.**

Typically animal research

Upcoming Changes in Biosafety Protocol Submission and Renewal

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Chair, Institutional Biosafety Committee

- **Questions?**
  - A new protocol example will be available Dec. 1
  - Contact Dan Voth or Carol Price

IACUC Addendum Policy

Kerrey Roberto, IACUC Administrator

- Minor change in deadline
- Applies only to Addendum Requests
- Does not apply to new AUP submissions
  - Still due the first Friday of each month!

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IACUC Addendum Policy

Kerrey Roberto, IACUC Administrator

- **Addendum requests (changes to approved protocols)** are due by noon on Wednesday for review on Friday the same week
- **Requests submitted after noon on Wednesday will be reviewed on Friday the following week**

IACUC Addendum Policy

Kerrey Roberto, IACUC Administrator

- **Review day may be adjusted due to holidays**
  - 2014: November 28, (December 26)
  - 2015: (January 2), July 3, December 25
  - 2016: January 1, …

IACUC Addendum Policy

Kerrey Roberto, IACUC Administrator

- **Questions?**

- http://iacuc.ad.uams.edu/

In Vitro Device Companion Diagnostic Device

Carole Hamon, Assoc. Director, Regulatory Affairs Mgr., Office of Research Regulatory Affairs

- **FDA Final Guidance, August 6, 2014**
  - Purpose
- Definitions
  - In vitro device (IVD)
  - In vitro device companion diagnostic device (CoDx)
- Examples
- Questions – Contacts – Links

In Vitro Device Companion Diagnostic Device

Carole Hamon, Assoc. Director, Regulatory Affairs Mgr., Office of Research Regulatory Affairs

Guidance Purpose:

1) Assist in developing a therapeutic product (novel or existing product/new indication) for which an *in vitro* companion diagnostic device (or test) is essential for the therapeutic product's safe and effective use.

2) Assist sponsors planning to develop an *in vitro* companion diagnostic device intending to be used with a corresponding therapeutic product.

In Vitro Device Companion Diagnostic Device

Carole Hamon, Assoc. Director, Regulatory Affairs Mgr., Office of Research Regulatory Affairs

Definitions:

- **An *in vitro* device (IVD)** is one used in the analysis of human samples including commercial test products and instruments used in testing, among other things. Not essential to the safe and effective use of a therapeutic product.
- **An IVD companion device (CoDx)** is an *in vitro* diagnostic device that provides information essential for safe and effective use of a corresponding therapeutic product whose use must be stipulated in the instructions for use as well as in labeling of both the IVD and the corresponding therapeutic product.

In Vitro Device Companion Diagnostic Device

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Additional CoDx Definition:

CoDx tests “identify patients who are most likely to benefit from a particular therapeutic product” or are “likely to be at increased risk for serious adverse reactions as a result of treatment with a particular therapeutic product.”

Draft Guidance issued July 14, 2011/Congressional Research Service

In Vitro Device Companion Diagnostic Device

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IVD Examples:

- Pregnancy test kits for home use
- Blood glucose tests for home use
- Laboratory tests for infectious diseases (i.e., HIV or hepatitis)
- Tests for various genetic diseases or conditions

In Vitro Device Companion Diagnostic Device

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IVD Companion Diagnostic Device Examples:

- HER2 breast cancer test as a predictor of success of Herceptin
- KRAS RGQ PCR kit to identify patients with metastatic colorectal cancer most likely to respond to Erbitux
- DAKO C-KIT to identify patients with GI stromal tumors likely to respond to Gleevec

In Vitro Device Companion Diagnostic Device

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Links 1) Guidance 2) Approved/Cleared IVD Companion Devices:

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM262327.pdf

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm

In Vitro Device Companion Diagnostic Device

Carole Hamon, Assoc. Director, Regulatory Affairs Mgr., Office of Research Regulatory Affairs

Contacts:

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MGClark@uams.edu; 686-8098

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LDParker@uams.edu; 686-6284

In Vitro Device Companion Diagnostic Device

Carole Hamon, Assoc. Director, Regulatory Affairs Mgr., Office of Research Regulatory Affairs

- **Questions?**

New TRI Protocol Development and Review Process

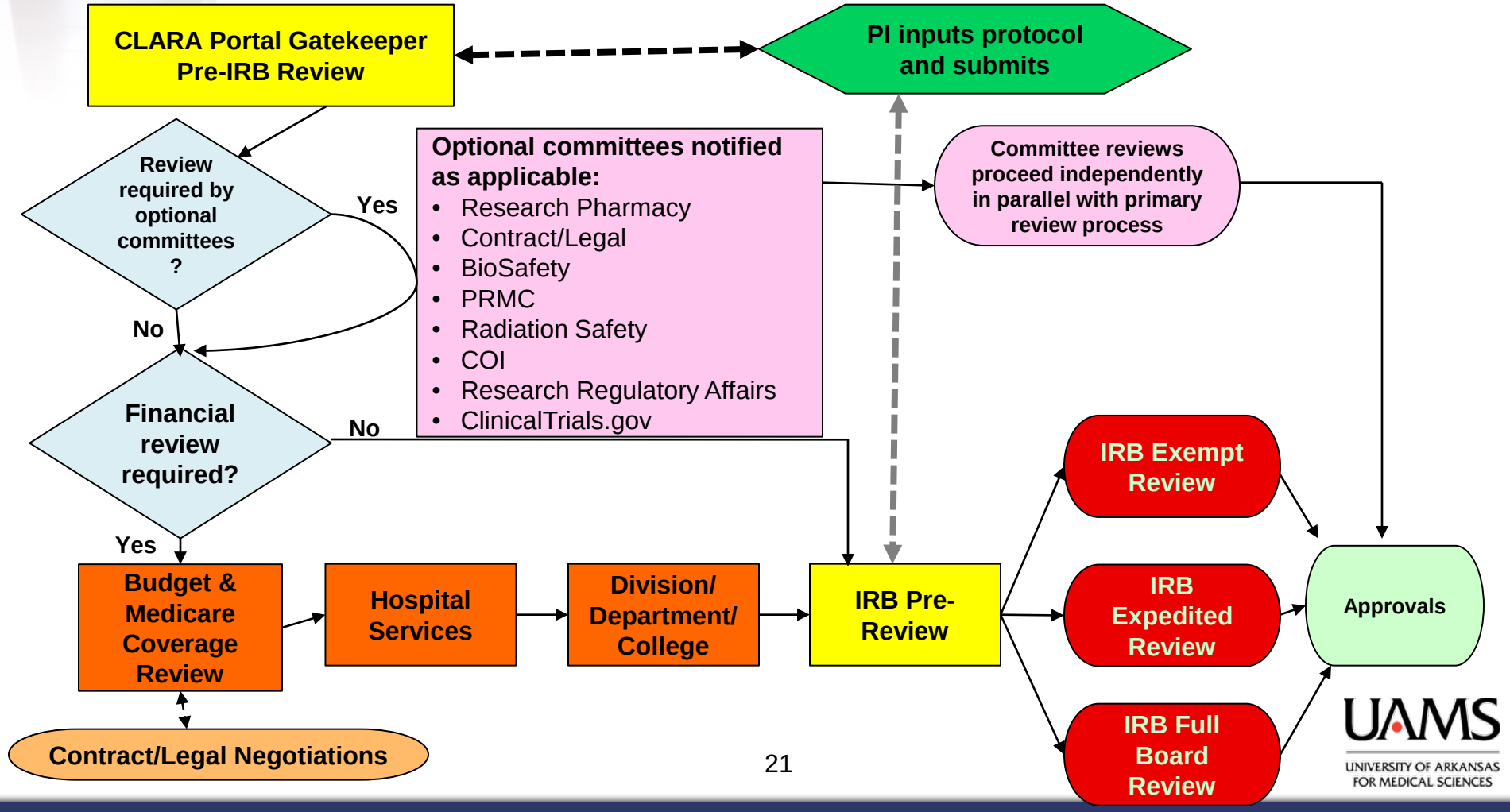
Alison Oliveto, Ph.D.,
Director, Translational Research Services Center, TRI

- **Change in CLARA workflow for new IRB protocol submissions**
  - Removed the first of 2 pre-IRB reviews of the protocol submission
    - Reduce redundancy of efforts and required PI responses during CLARA process
    - Track utilization of TRI protocol development services
    - Identify common issues for educational initiatives
    - Quantify demand for and satisfaction with this TRI service

New TRI Protocol Development and Review Process

Alison Oliveto, Ph.D.,
Director, Translational Research Services Center, TRI

Former CLARA Submission Process



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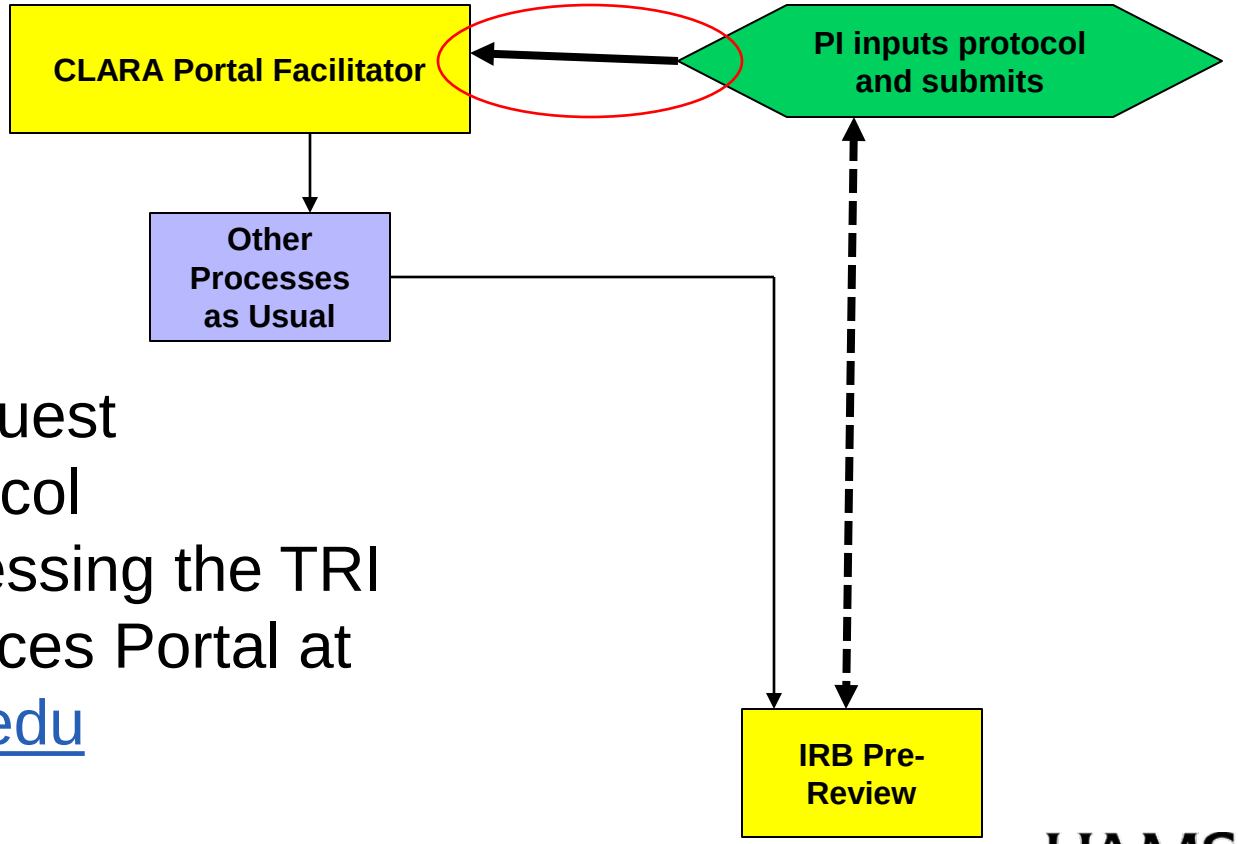
New TRI Protocol Development and Review Process

Alison Oliveto, Ph.D.,
Director, Translational Research Services Center, TRI

Current CLARA Submission Process (10/13/14)



Investigators can request assistance with protocol development by accessing the TRI Resources and Services Portal at TRIservices@uams.edu

Updates from SRA International Meeting Suzanne Alstadt, Director, ORSP

- Physician's Payments Sunshine Act
  - Established as part of the Affordable Care Act.
  - Requires pharmaceutical & medical device manufacturers to report annually to the DHHS payments and other transfers of value furnished to physicians and teaching hospitals.
  - Designed to encourage greater transparency in the relationships between manufacturers and physicians.
  - Information made available on a public website.

Updates from SRA International Meeting Suzanne Alstadt, Director, ORSP

- **Physician's Payments Sunshine Act**
  - What We All Need to Know
    - Sponsors (not covered entities or covered recipients) are responsible for reporting
    - Data currently available on website is incomplete
    - In theory, data reported should match data in our FCOI System TRACKS.
      - Because data reported was so incomplete and/or incorrect, it will not currently match.

Updates from SRA International Meeting Suzanne Alstadt, Director, ORSP

- **Physician's Payments Sunshine Act**
  - What PIs Need to Know
    - Research-Related Payments are Reportable if
      - Pursuant to any activity that meets the definition of research
      - Pursuant to written agreement, contract or protocol between sponsor and entity conducting research including agreements involving sponsor, CRO/SMO, and covered recipient
    - And even if PI receiving payment isn't a physician who regularly treats patients (includes Fellows/Excludes Residents)

Updates from SRA International Meeting Suzanne Alstadt, Director, ORSP

- **Physician's Payments Sunshine Act**
  - What PIs Need to Know
    - Create a login to the system so that you can verify that data is correct
    - The system is slow and creating an account may be frustrating
    - The data currently available may be incomplete or inaccurate
      - Your information may have been combined with another physician with the same name
      - Payments made through a contract to UAMS may be reflected as a personal payment
    - Disclose payments made to you by sponsors through our TRACKS FCOI system

Updates from SRA International Meeting Suzanne Alstadt, Director, ORSP

- **Physician's Payments Sunshine Act**
  - What Administrators Need to Know
    - Help educate the physicians in your department
      - To ensure that they are disclosing payments made to them by sponsors
      - That the data currently available may be incomplete or inaccurate
        - Their information may have been combined with another physician with the same name
        - Payments made through a contract to UAMS may be reflected as a personal payment

Updates from SRA International Meeting Suzanne Alstadt, Director, ORSP

Hyperlink to Slides from SRA Presentation

http://2014.srainternational.org/sites/default/files/pictures/W9_Physician%20Payments%20Sunshine%20Act%20v%20%205%20100914.pdf

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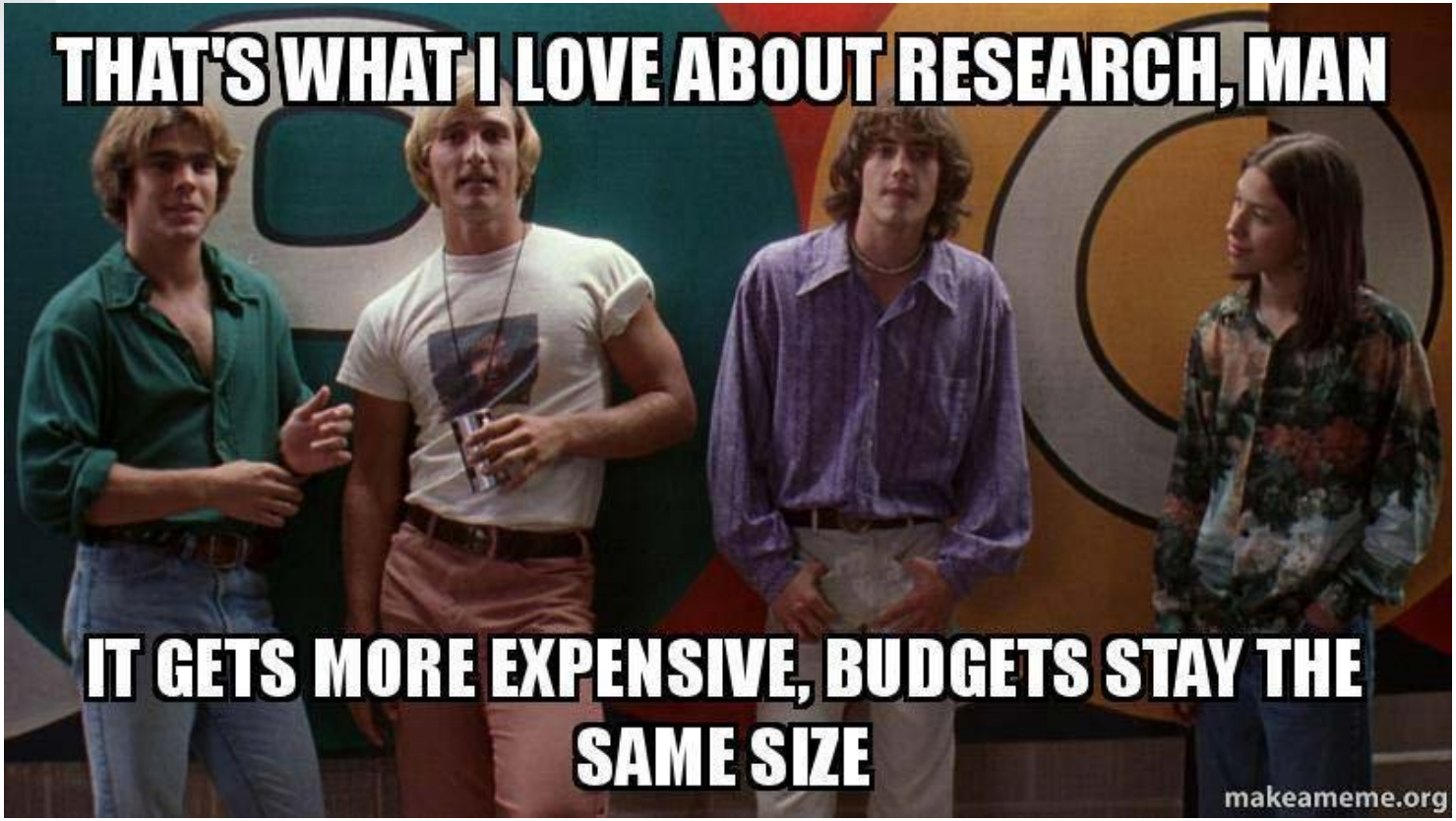
NIH Continuing Resolution

Suzanne Alstadt, Director, ORSP

- DHHS Continuing Appropriations Act, 2015
- Continues government operations through December 11, 2014 at 99.9% of FY 14 level
- NIH will issue non-competing grants in most cases at 90% of previously committed level.
- Adjustments may be made after FY 15 appropriations are enacted, but not guaranteed.

NIH Continuing Resolution

Suzanne Alstadt, Director, ORSP



Showcase of Medical Discoveries: Nutrition

Linda Williams, MS, Research Liaison

- **Nutrition Showcase next week!**
- **November 12, 2014**
  4:30 p.m. - 6:00 p.m.
  - 10th floor Cancer Institute
  - 12 UAMS research posters
  - Wine and hors d'oeuvres
  - Coffee and water

Next RESIN

- **Next RESIN**
  - **December 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