

UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES



RESIN (Research Support Information Network)

Presented by: Office of the Vice Chancellor for Research

Date: August 7, 2012



Agenda

■ Research Updates & Timely Information:

- ⊕ Office of the VCR
- RSC
- ⊕ IRB
- ⊕ IACUC
- COM Finance & Admin
- UAMS Library
- BioVentures
- ⊕ Occupational Health & Safety
- ⊕ COI
- ORSP
- ORC
- DLAM
- OGSP
- TRI/Core Facilities
- ⊕ UAMS Library



Basics of Biosafety

Carol Price, Director, OH&S

■ History

- No formal program available in the past
- NIH guidelines - “ensure appropriate training”
- OSHA Bloodborne Pathogens Standard



Basics of Biosafety

Carol Price, Director, OH&S

- **Proposed- for all laboratory staff**
 - On-line = access through OH&S website
 - Test to follow training module
 - Annual reminder
 - [UAMS OH&S - Biological Safety Division](#)



Basics of Biosafety

Carol Price, Director, OH&S

■ Benefits

- All employees have basic knowledge
- Understanding of biosafety levels and risks
- Ensure employees are offered appropriate care-
 - HBV vaccine - if working with human blood/body fluids
 - Regulatory compliance



Basics of Biosafety

Carol Price, Director, OH&S

- **Contact Information!**
 - **Carol Price, Director**
 - 686-5536
 - CJPrice@uams.edu
 - Central Building, G-154



Revised Federal Conflict of Interest Regulations

Jennifer Smith, JD, RN, Conflict of Interest Director

Revised Conflict of Interest Regulations

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Investigator Responsibilities

Compliance Deadline: **August 24, 2012**



Revised Federal Conflict of Interest Regulations

Jennifer Smith, JD, RN, Conflict of Interest Director

- **Academic Staff (Faculty & Key Research Personnel) must complete a COI disclosure at least annually and within 30 days of a change.**
- **Disclosures must be current at the time a grant application is submitted.**
- **Investigators whose disclosure has expired (>365 days since last disclosure) may not participate in research until the deficiency is cured.**



Revised Federal Conflict of Interest Regulations

Jennifer Smith, JD, RN, Conflict of Interest Director

All Investigators involved in federally - funded research must receive COI training **prior to engaging in the research and at least every 4 years thereafter.**



Revised Federal Conflict of Interest Regulations

Jennifer Smith, JD, RN, Conflict of Interest Director

For current projects, COI Training must be completed by **August 24, 2012.**

Training Schedule:

August 10, 2012, 10am, ACHRI, Brandon

Auditorium

August 23, 2012, 2pm, COPH 8240

Intranet:

http://intranet.uams.edu/staffeducation/E_Learning/PublishedFiles/FCOI/FCOI fs.htm



Revised Federal Conflict of Interest Regulations

Jennifer Smith, JD, RN, Conflict of Interest Director

Conflicts of interest related to federally-funded research must be identified and managed **prior to fund expenditure** or within 60 days (for any COIs that arise after the research project begins).



Revised Federal Conflict of Interest Regulations

Jennifer Smith, JD, RN, Conflict of Interest Director

■ Non-Compliance

Retrospective Reviews must be conducted in cases where a COI is not identified and managed in a timely manner, either because an investigator failed to disclose the conflict within the required time frame or UAMS failed to identify and manage the conflict within the required time frame.

Non-compliance with the COI policy may result in removal from research projects or other sanctions.



Revised Federal Conflict of Interest Regulations

Jennifer Smith, JD, RN, Conflict of Interest Director

QUESTIONS?

Jennifer Smith, JD, RN

Director of Conflict of Interest Office

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Post Approval Monitoring

Bill Gurley, Ph.D., IACUC Chair, and

Nancy Rhea, MS, Research Compliance Analyst

- **What is Post Approval Monitoring (PAM) for Animal Research at UAMS?**
 - A program designed to assist the research community with animal based compliance, regulatory standards and UAMS policies
 - PAM audits all aspects of the animal care program by
 - Providing a deeper look into animal activities
 - Suggesting training opportunities to the IACUC



Post Approval Monitoring

Bill Gurley, Ph.D., IACUC Chair, and

Nancy Rhea, MS, Research Compliance Analyst

■ What PAM is not

- PAM is not intended to be the “animal cops”
- PAM is not a replacement for the IACUC semi-annual site visits
- PAM is not required by regulation (but is a “should” in the new Guide)



Post Approval Monitoring

Bill Gurley, Ph.D., IACUC Chair, and

Nancy Rhea, MS, Research Compliance Analyst

■ Goals and Benefits of PAM

- Ensure animal well-being
- Support science
- Protect the institution
- Facilitate communication between research staff and IACUC/Compliance staff
- Ensure regulatory compliance
- Provide a paper trail documenting compliance



Post Approval Monitoring

Bill Gurley, Ph.D., IACUC Chair, and

Nancy Rhea, MS, Research Compliance Analyst

■ What Happens During a PAM Visit?

- An analyst from the Office of Research Compliance along with a veterinarian from DLAM will visit the animal research lab and:
 - Compare protocols to lab activities
 - Communicate changes in regulations or policies
 - Provide education and support to animal research staff
 - Identify problems and determine action plan
 - Communicate any ongoing compliance concerns to the IACUC
 - Take feedback to the IACUC and DLAM



Post Approval Monitoring

Bill Gurley, Ph.D., IACUC Chair, and
Nancy Rhea, MS, Research Compliance Analyst

- **Who Will Be Selected for a PAM visit?**
 - All active IACUC protocols will be eligible
 - Selection will usually be random
 - IACUC may request a *Directed* visit
 - Investigators may request a visit



Post Approval Monitoring

Bill Gurley, Ph.D., IACUC Chair, and
Nancy Rhea, MS, Research Compliance Analyst

- **Common Areas of Noncompliance**
 - Changes in procedures without a protocol amendment
 - Problems with recordkeeping
 - Lack of proper training
 - Unexpected mortality or morbidity rates



Post Approval Monitoring

Bill Gurley, Ph.D., IACUC Chair, and
Nancy Rhea, MS, Research Compliance Analyst

Office of Research Compliance

Nancy Rhea, MS

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IRB Updates

Jennifer Sharp, J.D., IRB Director

- **New Faces**
 - IRB Chair
 - IRB Office
- **New System**
 - CLARA
- **Newly Re-accredited**
- **IRB by the Numbers**



Predatory Open Access Publishers

Mary L. Ryan, UAMS Library Director

- **Legitimate Open Access Publishing**
 - Articles freely available
 - Author usually pays publication fee
 - Author retains copyright
 - PLoS, Biomed Central, etc.



Predatory Open Access Publishers

Mary L. Ryan, Library Director

■ Predatory OA Publishers

- Main goal is profit, not promoting scholarship
- Indicators
 - Not indexed in PubMed
 - Mass email solicitations for articles and editors
 - No editor-in-chief and/or very large editorial board
 - Very short turnaround on peer review
 - No publication fee indicated on web site



Predatory Open Access Publishing

Mary L. Ryan, Library Director

■ Beall's List of Predatory OA Publishers

<http://carbon.ucdenver.edu/~jbeall/Beall's%20List%20of%20Predatory,%20Open-Access%20Publishers%202012.pdf>
[PDF Version]



NIH Update - What to Expect in FY13

Larry Cornett, Vice Chancellor for Research





NIH Update - What to Expect in FY13

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Agency	FY12 (Actual) (\$, billions)	FY13 (President's) (\$, billions)
NIH	30.7	30.7
AHRQ	0.405	0.409
NSF	7.03	7.34
VA Medical Research	0.581	
PCORI	0.160	
CDC	11.20	





NIH Update - What to Expect in FY13

Larry Cornett, Vice Chancellor for Research

Senate Labor-HHS Bill

\$30.723 b for NIH

\$276 m for IDeA

Salary cap at \$179,700

House Labor-HHS Bill

\$30.6 b for NIH

\$376 m for IDeA

Salary cap at \$165,300

No funding for PCOR

Kills AHRQ



NIH Update - What to Expect in FY13

Larry Cornett, Vice Chancellor for Research

- **Date of Signing of Labor-HHS Appropriation Bill** (Fiscal years 2002-2011)
 - mean = 117 ± 41 days
 - range = 68-197 days
- **Reid/Boehner Announce on 7/31/12 agreement on 6 month Continuing Resolution**
- **Sequestration (1/1/13) still looming**



NIH Update - What to Expect in FY13

Larry Cornett, Vice Chancellor for Research

- NIH and other federal agencies will be conservative in making awards during the C.R.
- For new grants, awards likely to be 90% (maybe less) of approved award amount
- For non-competing renewals, budget reductions likely
- Federal agencies are being asked by OMB to prepare plans for sequestration



NIH Update - What to Expect in FY13

Larry Cornett, Vice Chancellor for Research





Next RESIN

Next RESIN

- **September 4, 2012 @ 12:00p.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