UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

# RESIN (Research Support Information Network)

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

**Date**: January 28, 2011

# Agenda

- Intros
- Updates & timely information from research support:
  - Office of the VCR
  - RSC
  - IRB
  - IACUC
  - HIPAA
  - UAMS Library BioVentures
  - COI
  - ORSP
  - ORC
  - DLAM
  - OGSP
  - Medical Informatics

# Office of the VCR

- Vice Chancellor for Research
  - Office of the Vice Chancellor for Research
  - Introduction to Resin
  - Research support units

# ORSP

**Suzanne Alstadt, Director**

- NIH Policy Changes
  - End of the “grandparent” period for A2 submissions (NIH NOT-OD-10-135)
  - Time limit for resubmissions – 37 months (NIH NOT-OD-10-140)
  - Post-Submission Materials Restrictions (NIH NOT-10-091)
  - New Forms – Adobe B1
  - Error correction window eliminated (NIH NOT-OD-10-123)

# ORSP

## Suzanne Alstadt, Director

## Timeline for Friday Deadline

| Proposal Entered in ARIA and Signed by PI | Department Approval | ORSP Provides Review of Draft Proposal | Final Due to ORSP | Proposal Due Date |
|---|---|---|---|---|
| Wednesday – 5 pm | Friday– 5 pm | Tuesday – 5 pm | Wednesday – 5 pm | Friday – 5 pm |

## Timeline for Monday Deadline

| Proposal Entered in ARIA and Signed by PI | Department Approval | ORSP Provides Review of Draft Proposal | Final Due to ORSP | Proposal Due Date |
|---|---|---|---|---|
| Thursday – 5 pm | Monday – 5 pm | Wednesday – 5 pm | Thursday – 5 pm | Monday – 5 pm |

# ORC

**Darri Scalzo, Research Compliance Officer**

- Export Control Regulations
  - Export Administration Regulations (EAR, 15 CFR 730, U.S. Department of Commerce)
  - International Traffic in Arms Regulations (ITAR, 22 CFR 120-130, U.S. Department of State)
  - Does not apply to the conduct of *fundamental research* within the United States

- **Form I-129 Petition for a Nonimmigrant Worker – New Federal Requirements**
  - "Certification Regarding the Release of Controlled Technology Data to Foreign Persons in the United States" for all workers on an H-1B, L-1 or O-1A visa
  - Any data or technology to which the foreign national will have access must be reviewed against the EAR and the ITAR to determine whether the data or technology is covered by the regulations

- **NIH's Public Access Policy: How the Library Can Help**
- **The Law**
  - All articles resulting from any NIH funded (directly or indirectly) projects (in part or whole) must be made available in PMC within 12 months of publication in a peer-reviewed journal

# UAMS Library

**Susan Steelman, MLIS**
**Coordinator, Research & Clinical Search Services**

- **Important Dates:**
  - NIH funded grants active
    Oct. 2007 – to date
  - NIH contracts signed
    April 7, 2008 - to date

# Why Care? Enforcement Possibilities

- Place special conditions on awards, such as closer monitoring
- Switch from advance payment to cost reimbursement
- Suspend, terminate or withhold support
- Seek recovery of funds
- Prevent grantee from receiving future NIH funding.

# UAMS Library

**Susan Steelman, MLIS**
**Coordinator, Research & Clinical Search Services**

## NIH's Library Pilot Project

- Website Create, Updated, Revised
- Fact Sheet Compiled
- Presentations & Newsletter Articles
- Individual Consultations & Questions
- Building Contact Points in Departments
- Customized Reports
- Providing Feedback to NLM

## Compliance Rates: Summary

**Summary**

Status as of 01/07/2011 for articles published between 07/01/2008 and 01/07/2011 GO

| University of Arkansas | | | | | |
|---|---|---|---|---|---|
| Affiliation | Compliant | Non-Compliant | In Process | Total | Compliance Rate |
| ARKANSAS CHILDREN'S HOSPITAL RESEARCH INSTITUTE | 40 | 4 | 0 | 44 | 90.9% |
| UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES | 359 | 108 | 5 | 472 | 76.1% |

# Important Tips

- Authors must retain right to submit to PMC when signing copyright agreement
- Authors should start submission process upon acceptance for publication
- 3 months after publication date – shows up on non-compliant list
- Embargo date can be set by author

# Questions?

UAMS Library – NIH PA Policy Site
http://www.library.uams.edu/schpub/nihpolicy.aspx

Susan Steelman, 686-6737

# RSC

**Tom Wells, Director**

- **Budgeting for Clinical Trials Not Sponsored by Industry**
  - Problem: grant awarded with insufficient funds to do clinical procedures
  - Funding sources:
    - Grant or foundation money from any source
    - Industry supported (not sponsored)
  - Proposals that include procedures performed by:
    - UAMS Clinical Laboratory, Pathology, Radiology, etc.
    - UAMS Research Pharmacy
  - Solution:
    - Call RSC; we will help you find the correct prices for UAMS services and lock them in for the duration of your study

# RSC

Amy Jo Jenkins, Monitoring Manager

- **New Safety Reporting Requirements for INDs and BA/BE Studies:** Effective March 28, 2011
  - ***Overview of changes:***
    - New definitions for adverse event, suspected adverse reaction, unexpected, serious, and life threatening
    - Rapid reporting (within 7-15 days) – only when a reasonable possibility investigational drug caused the AE
    - Report only info that will help FDA assess the safety of the drug being studied.
    - Some AEs now reported in aggregate
    - SAEs from bioavailability/bioequivalence studies required to be reported rapidly
    - Seriousness and Causality: Sponsor and/or PI decide
  - ***Links to more information:***
    - http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2010_register&docid=fr29se10-3.pdf
    - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf

# Comment

- Often multiple experiments in a protocol
- May differ in:
  - Design
  - Size
  - Outcomes
- Usually answers are needed for each unique design-size-outcome combination

# IACUC

**Reid Landes, Ph.D.**

## 1. What are you measuring?

- Define your outcome measures
- Give their units
- Several outcomes in one experiment?
  - Which is most important?
  - Which is most variable?
  - On what outcome is the power analysis based?



# Non-statistical Justifications

*Reviewer*: Measuring what?

*PI*: Nothing from the animals or their parts.

- Typical protocols with this answer
  - Breeding protocols
  - Materials protocols
- Pilot studies? Not in this category

# IACUC

**Reid Landes, Ph.D.**

## 2. What are the groups?

- Describe the “experiment design”
- List the groups (and how they are formed)
- The Methods section contains what happens to animals in the various groups

# Experiment Design Example

| **Strain** | WT | | | | | KO | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Drug** | -- | A | | B | | -- | A | | B | |
| **Dose** | 0 | Lo | Hi | Lo | Hi | 0 | Lo | Hi | Lo | Hi |

- "Mice within a strain equally randomized among the 5 drug-dose combinations"
- 6 mice / strain-drug-dose combo X 10 strain-drug-dose combos = 60 mice



# 3. What do you want to learn?

- "What are your **research hypotheses**?"
- Identify **comparisons are of interest**
- Sometimes comparisons are ordered
  - Primary, secondary, tertiary
  - Base power analyses on primary ones
- Often possible comparisons exceed comparisons of interest

# 4. Do the animal numbers match your *need*?

- Provide a well-described **power analysis**
- Attributes of "well-described"
  1. Describes statistical analyses that are consistent with experiment design
  2. Describes a power analysis that *can be reproduced*
  3. Presents and justifies the parameters and assumptions required in the power analysis

# Example Write Up

"With 6 mice per strain-drug-dose combination, we can detect a difference of 1.3 SDs for the primary comparisons of interest with at least .80 power using a .05 level two-sided *t*-test, adjusted for 2 tests with Bonferroni's method and conducted within an one-way ANOVA context.

"SDs of survival times have been estimated to be as high as 10 days [refs]. A difference of 2 weeks was found between Drug A and a control in [ref]; hence, providing evidence that a difference of 13 days is not unreasonable to expect."

# IACUC

**Reid Landes, Ph.D.**

## Contact Information


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# Next RESIN

- **Next RESIN**
  - February 25, 2011 @ 1:30p.m.
- **February RESIN** event will move to the centrally located Walton Auditorium in the Winthrop P. Rockefeller Cancer Institute to facilitate attendance
- All RESIN presentations will be archived on the UAMS Research website