

UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES



RESIN (Research Support Information Network)

Presented by: Office of the Vice Chancellor for Research

Date: February 25, 2011



Agenda

■ Updates & Timely Information from Research Support:

- Office of the VCR
- ⊕ RSC
- ⊕ IRB
- IACUC
- HIPAA
- ⊕ UAMS Library
- BioVentures
- ⊕ COI
- ORSP
- ⊕ ORC
- DLAM
- ⊕ OGSP
- CCTR
- Medical Informatics



RSC

Dori Wong Scroggins, J.D.

- **Clinical Trials with Industry**
 - When is a contract needed?
 - Fully sponsored trial
 - PI initiated but supported by industry with funds, drug, or device
 - Data supplied back to industry



RSC

Dori Wong Scroggins, J.D.

- **Contracts should be sent to:**
ResearchContracts@uams.edu
- **Confidentiality or Non-Disclosure Agreement – CDA/NDA**
 - Disclose information to those with the “Need to Know”
 - Use of information for evaluation purpose only
 - Non-disclosure and non-use obligation for 3 – 10 years



RSC

Dori Wong Scroggins, J.D.

- **Documents in Word format**
 - Clinical Trial Contract
 - Informed Consent Form / HIPAA Authorization (original and revised)
 - Proposed Budget from Sponsor
 - Exhibits (payment terms)
 - Contact Information: CRO, ICF, Budget, & Contract Negotiator



RSC

Dori Wong Scroggins, J.D.

- **ARIA**
- **CRIMSON**
 - Budget entered into CRIMSON before negotiation with Sponsor
- **Contracts Module**
 - Go to your study to view LOG for status
 - Automatic emails for notices and signature process



RSC

Dori Wong Scroggins, J.D.

■ Consent Form Negotiation

- Cost Statement
- Subject Injury Language
- ClinicalTrials.gov registration
- SponsorLegal FINAL (PDF) approved version uploaded by Legal into CRIMSON for IRB review
- Send additional changes to Legal for re-negotiation



RSC

Dori Wong Scroggins, J.D.

■ New Language for Consent Form

- A description of this study will be available on <http://www.ClinicalTrials.gov>, as required by US law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results of the study. You can search this Web site at anytime.



RSC

Dori Wong Scroggins, J.D.

- **Contract Negotiation**
 - Contractual terms
 - Payment language in Exhibit
 - Budget must match CRIMSON budget
- **Other Requirements**
 - CRIMSON approval
 - IRB approval
 - Intellectual Property Waiver
 - Current COI Disclosure
 - Award Letter for Accounting to set up research account



RSC

Dori Wong Scroggins, J.D.

■ Legal Contacts

- Dori Wong Scoggins
dwong@uams.edu 526-6247
- Joe Underwood
junderwood@uams.edu 686-8846
- Rai Smith
smithrai@uams.edu 686-5503
- Jana Bennett
jsbennett@uams.edu 603-1580



RSC

Joe Underwood, J.D.

- **What is a Material Transfer Agreement (MTA)?**
 - Contract governing the transfer of proprietary material from one party to another.
 - Protects the Provider from liability
 - Apportions rights in the results of research using the material transferred
 - Restricts the use and subsequent transfer of the material



RSC

Joe Underwood, J.D.

- **Types of MTAs for UAMS**
 - Transfer between UAMS and another academic institution
 - Transfer from UAMS to industry
 - Transfer from industry to UAMS



RSC

Joe Underwood, J.D.

■ Provider vs. Recipient

- When UAMS is a provider, we use our template MTA. As a provider, we limit our liability and retain rights.
- When UAMS is the recipient, we typically use the provider's MTA template. As a recipient, we ensure our contractual obligations are consistent with the University's mission.



RSC

Joe Underwood, J.D.

- **When is an MTA needed?**
 - When is the material proprietary, infectious, hazardous or otherwise regulated?
 - Does the provider want to limit liability, protect future rights and limit transfer?
 - Does the provider want recognition in publications?



RSC

Joe Underwood, J.D.

- **Common Issues in MTAs**
 - Confidentiality
 - Ownership of results and intellectual property
 - Publication restrictions
 - Indemnification
 - Choice of law



RSC

Joe Underwood, J.D.

■ Who can Sign an MTA?

- An MTA is only valid if it is signed by an authorized institutional official
- If you are not an authorized institutional official and you sign a contract, you may be personally liable for the contractual obligations. Some obligations may be harsh.
- A researcher who provides/receives the materials must acknowledge the MTA.
 - He/she will be responsible for using or providing the material.



RSC

Joe Underwood, J.D.

- **How to Process an MTA**
 - Email contract to researchcontracts@uams.edu.
 - Include contact information of the provider and the recipient.
 - If possible, provide a brief summary of the materials to be transferred and intended uses of the materials.



UAMS Library

Susan Steelman, MLIS

Coordinator, Research & Clinical Search Services

■ The 3 R's

- **Replacement** - replace animals with non-animal methods or with “lower” animals.
- **Reduction** - Minimize the number of animals used.
- **Refinement** –to minimize pain and distress.



UAMS Library

Susan Steelman, MLIS

Coordinator, Research & Clinical Search Services

■ Search Strings - PubMed

- animal use alternatives OR animal testing alternatives OR biological models OR "animal alternative" OR "alternative animal use" OR "animal testing alternative" OR "animal replace" OR "animal reduction" OR "computer model" OR "computer simulation" OR software OR "mathematical model" OR "animal welfare" OR "animal pain" OR "animal distress" OR "animal stress" OR "animal suffering" OR "animal housing" OR caging OR "3Rs" OR "three Rs" OR "Reduction Refinement Replacement"



UAMS Library

Susan Steelman, MLIS

Coordinator, Research & Clinical Search Services

Science Citation Index Animal Alt. Search String (advance search format)

- TS=("animal use alternative" OR "animal testing alternative" OR "biological model" OR animal alternative* OR "alternative animal use" OR "animal testing alternative" OR "animal replace" OR "animal reduction" OR "computer model" OR "computer simulation" OR software OR "mathematical model" OR "animal welfare" OR "animal pain" OR "animal distress" OR "animal stress" OR "animal suffering" OR "animal housing" OR caging) OR (TS=reduction SAME TS=refine* SAME TS=replace*)

AGRICOLA on EBSCO (paste into the first search box and hit search)

- (ZU "ANIMAL USE ALTERNATIVES") or (ZU "ANIMAL USE REDUCTION") or (ZU "ANIMAL USE REPLACEMENT") or (ZU "ANIMAL WELFARE") or (ZU "ANIMAL STRESS") or (ZU "ANIMAL SUFFERING") or (ZU "ANIMAL TESTING ALTERNATIVES") or (ZU "ANIMAL DISTRESS") or (ZU "ANIMAL HOUSING") or (ZU "ANIMAL CAGES") or (ZU "ANIMAL CARE")



UAMS Library

Susan Steelman, MLIS

Coordinator, Research & Clinical Search Services

■ The Table

DATABASE	YEARS COVERED	RESULTS	DATE SEARCHED
PubMed (includes MEDLINE)	1947 - 2010	18 citations	June 20, 2010
Science Citation Index Expanded via WOS	1945 - 2010	1 citation	June 20, 2010



UAMS Library

Susan Steelman, MLIS

Coordinator, Research & Clinical Search Services

PubMed Search Hx u/ Advanced Search

PubMed Advanced Search

[◀ Back to PubMed](#)

Search Box

#1 AND #2 AND #3

[Limits](#) [Details](#) [Help](#)

Search

Preview

Clear

Search Builder

Search History

Most Recent Queries

Search	Time	Result
#4 Search #1 AND #2 AND #3	14:32:21	31
#3 Search prion* OR prion disease OR scrapie	14:28:30	17239
#2 Search monoclonal antibodies	14:16:48	191822
#1 Search animal use alternatives OR animal testing alternatives OR biological models OR "animal alternative" OR "alternative animal use" OR "animal testing alternative" OR "animal replace" OR "animal reduction" OR "computer model" OR "computer simulation" OR software OR "mathematical model" OR "animal welfare" OR "animal pain" OR "animal distress" OR "animal stress" OR "animal suffering" OR "animal housing" OR caging OR "3Rs" OR "three Rs" OR "Reduction Refinement Replacement"	14:14:43	800635

Clear History

[Search History Instructions](#)

More Resources

[MeSH Database](#)



UAMS Library

Susan Steelman, MLIS

Coordinator, Research & Clinical Search Services

■ WOS – Adv Sch for Sch Hx

Restrict results by any or all of the options below:

All languages	All document types
English	Article
Afrikaans	Art Exhibit Review
Arabic	Bibliography

Search History

Set	Results		Combine Sets
# 4	1	#1 AND #2 AND #3 <i>Databases=SCI-EXPANDED Timespan=All Years</i>	<input type="checkbox"/>
# 3	15,709	TS=(prion* OR prion disease* OR scrapie) <i>Databases=SCI-EXPANDED Timespan=All Years</i>	<input type="checkbox"/>
# 2	>100,000	TS=(monoclonal antibod* OR antibod* monoclonal) <i>Databases=SCI-EXPANDED Timespan=All Years</i>	<input type="checkbox"/>
# 1	>100,000	TS=("animal use alternative" OR "animal testing alternative" OR "biological model" OR animal alternative* OR "alternative animal use" OR "animal testing alternative" OR "animal replace" OR "animal reduction" OR "computer model" OR "computer simulation" OR software OR "mathematical model" OR "animal welfare" OR "animal pain" OR "animal distress" OR "animal stress" OR "animal suffering" OR "animal housing" OR caging) OR (TS=reduction SAME TS=refine* SAME TS=replace*) <i>Databases=SCI-EXPANDED Timespan=All Years</i>	<input type="checkbox"/>

Save History / Create Alert Open Saved History

Combine Sets
 AND OR
Combine



UAMS Library

Susan Steelman, MLIS

Coordinator, Research & Clinical Search Services

Science Citation Index

Set	Results	Combine Sets	Delete Sets
	<p style="text-align: center;"> Save History / Create Alert Open Saved History </p>	<input type="radio"/> AND <input type="radio"/> OR Combine	Select All Delete
# 4	1 #1 AND #2 AND #3 Databases=SCI-EXPANDED Timespan=All Years	<input type="checkbox"/>	<input type="checkbox"/>
# 3	15,709 TS=(prion* OR prion disease* OR scrapie) Databases=SCI-EXPANDED Timespan=All Years	<input type="checkbox"/>	<input type="checkbox"/>
# 2	>100,000 TS=(monoclonal antibod* OR antibod* monoclonal) Databases=SCI-EXPANDED Timespan=All Years	<input type="checkbox"/>	<input type="checkbox"/>
# 1	>100,000 TS=("animal use alternative" OR "animal testing alternative" OR "biological model" OR animal alternative* OR "alternative animal use" OR "animal testing alternative" OR "animal replace" OR "animal reduction" OR "computer model" OR "computer simulation" OR software OR "mathematical model" OR "animal welfare" OR "animal pain" OR "animal distress" OR "animal stress" OR "animal suffering" OR "animal housing" OR caging) OR (TS=reduction SAME TS=refine* SAME TS=replace*) Databases=SCI-EXPANDED Timespan=All Years	<input type="checkbox"/>	<input type="checkbox"/>



UAMS Library

Susan Steelman, MLIS

Coordinator, Research & Clinical Search Services

■ Statement of Review

STATEMENT: I reviewed the results of this search and was unable to find any animal alternative methods of reduction, replacement or refinement that could be used in this research protocol.

[Customize this statement based on findings in search results.]



UAMS Library

Susan Steelman, MLIS

Coordinator, Research & Clinical Search Services

■ Important Links

**Animal Care Resource Guide (June 2000) -
Consideration of Alternatives to**

Painful/Distressful Procedures USDA Policy #12

http://www.aphis.usda.gov/animal_welfare/downloads/policy/policy12.pdf

**Guide for the Care and Use of Laboratory Animals:
Eighth Edition (2010)**

http://www.nap.edu/openbook.php?record_id=12910&page=1



UAMS Library

Susan Steelman, MLIS

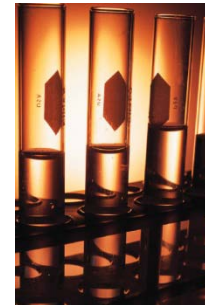
Coordinator, Research & Clinical Search Services

■ NEED HELP? RCSS

- Free AUP Searches
- One-on-one consultations
- Susan Steelman

686-6737

scsteelman@uams.edu



Search
Services



R
E
S
E
A
R
C
H
&
C
L
I
N
I
C
A
L



IRB

Jennifer Sharp, J.D., Director

- **Reminders regarding HIPAA Authorizations**
 - HIPAA regulations very specific about required elements for a valid HIPAA Authorization
 - Elements separate from requirements for informed consent
 - Authorization and informed consent elements may be combined into one document
 - Combining elements has pros and cons
 - Authorizations, or waivers thereof, are required when health information is obtained/collected
 - If you submit an authorization (or any other document), you ***must*** use it.



OGSP

Jan Wojcik, MEd, Director

■ NIAID Investigator Resources

- Complete information – from “Talk to a Program Officer” to “Manage Your Grant and Continue Funding”
- A section just for new investigators
- <http://funding.niaid.nih.gov/researchfunding/grant/pages/R01.aspx>



OGSP

Jan Wojcik, MEd, Director

■ NIAID - 4 Funded R01s (NIH Short Forms)

- <http://funding.niaid.nih.gov/researchfunding/grant/pages/appsamples.aspx>
- Available for each PI/grant
 - Summary statements & research plan
 - Full application (package)
- Variety
 - 4 different institutions
 - Early stage and experienced PIs
- Annotated to show key points



OGSP

Jan Wojcik, MEd, Director

- **Suggestions: How to Use the Samples**
 - Review grant in relation to summary statement
 - What did reviewers like?
 - What did reviewers *not* like?
- **Determine how PI developed his/her idea**
- **How did entire grant package contribute to grant's success?**



OGSP

Jan Wojcik, MEd, Director

- **Suggestions: How NOT to Use the Samples**
 - Do NOT use the copyrighted grants verbatim
 - Do NOT assume the grants are perfect in every way just because they were funded



OGSP

Jan Wojcik, MEd, Director

- **OGSP - Analysis of the Grant Samples**
- **OGSP Interactive Grant Writing Workshops**
 - 4 Thursdays in April (4/7 to 4/28)
 - 4 slots open
 - To register, contact Sharon Antoon (686-6004); antoonsharon@uams.edu
 - Possibly part of future RESIN meeting



OGSP

Jan Wojcik, MEd, Director

- **Want to work with an OGSP editor or budget specialist?**
 - Contact Jan Wojcik at 686-6004 or wojcikjanicel@uams.edu



COI

Jennifer Smith, JD, RN
Director

■ Contact Information

Jennifer L. Smith, JD, RN

Director of Conflict of Interest
Institutional Compliance

Central Building, Ground Floor, Room 147b

Office (501) 686-6447

Fax (501) 526-7958

jlsmith3@uams.edu



ORC

Edith Paal, Research Compliance Auditing Manager

NICE – New Investigation Consult & Education

- Like an audit, but *NICEr*
- Get research compliance feedback on proposed study documentation and processes, after IRB approval, but **before** subject enrollment
- NICE Reviews are particularly helpful for new researchers and for non-IND/IDE, investigator-initiated studies (but available and helpful to everyone)



ORC

Edith Paal, Research Compliance Auditing Manager

■ NICE Reviews are:

- Practical
- Pro bono
- Proactive
- Painless

■ NICE Reviews are particularly helpful for:

- New investigators or coordinators
- Investigators without study coordinators
- Researchers wanting assistance with study setup before enrollment begins



ORC

Edith Paal, Research Compliance Auditing Manager

- For more information or to schedule a NICE Review, please call the Research Compliance office at one of the following numbers:
 - 686-5809 (Trey Terry)
 - 686-5186 (Karen Barnwell)
 - 526-6270 (Edith Paal)



Next RESIN

- **Next RESIN**
 - March 25, 2011 @ 1:30p.m.
- **March RESIN** in [Walton Auditorium](#), Winthrop P. Rockefeller Cancer Institute
- All RESIN presentations archived on the UAMS Research website
 - http://www.uams.edu/research/RESIN_Achive.asp