

UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES



RESIN (Research Support Information Network)

Presented by: Office of the Vice Chancellor for Research

Date: March 25, 2011



Agenda

■ Updates & Timely Information from Research Support:

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



CCTR Translational Technologies

Paul Duguid, MPH

Program Goal

- Maintain high-quality, cost-efficient core facilities supporting clinical and translational research
- Build a network of core resources, enhanced by a centralized infrastructure and oversight, to promote collaboration, education and training of the UAMS research community.



CCTR Translational Technologies

Paul Duguid, MPH

Translational Technologies and Resources Support Center (TTR Center)

- Enhance cores' effectiveness and establish a more centralized infrastructure to:
 - Facilitate interactions between technology experts and translational researchers
 - Strengthen existing cores through regular assessments
 - Encourage adoption of new technologies for clinical and translational research by establishing new cores, streamlining existing cores, and eliminating redundancies to meet evolving needs of CCTR investigators



CCTR Translational Technologies

Paul Duguid, MPH

Accomplishments to Date

- Assumed administration of the annual assessment process for all UAMS cores
- Streamlined the assessment submission and review process
- Consolidated redundant services
- Supported changes to increase the efficiency of existing cores
- Consolidated websites of UAMS cores and represent all cores on the CCTR web site (In progress)



CCTR Translational Technologies

Paul Duguid, MPH

Accomplishments to Date (cont.)

- Formalized a centralized process for establishing and promoting new cores to support clinical and translational research.
 - Clinical Research Center (New Core)—provides clinical research services, including nursing support, study coordination, data safety and monitoring, informatics, etc.



CCTR Translational Technologies

Paul Duguid, MPH

Accomplishments to Date (cont.)

- Crystallography Core (New Core)—offers a full range of crystallography services (e.g., crystallization, diffraction, data collection) to support the understanding of protein structure in the molecular basis of diseases and in designing drugs or developing treatments
- Promoting core use and access through the CCTR Pilot Research Award program cores



CCTR Translational Technologies

Paul Duguid, MPH

Program Contacts

- **Philip Mayeux, PhD, Program Director**
- **Jennifer Bufford, Program Manager**
501-526-0368 (office)
501-319-2407 (cell)



Grant and Cost Accounting

Tyrone Stephens, CPA, MBA

Director of Cost Accounting

Types of Expense: Direct –vs- Indirect

- Direct Expense
 - Costs that can be identified specifically with a particular sponsored project, or that can be assigned easily with a high degree of accuracy
- Facility and Administrative (Indirect) Expense
 - Costs that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or other institutional activity.

OMB Circular A-21 D1; E1

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Grant and Cost Accounting

Tyrone Stephens, CPA, MBA

Director of Cost Accounting

Sponsor Payment of Expenses:

- Direct Expense
 - Costs that can be identified specifically with a particular sponsored project are direct charged and reimbursement of the specific cost is requested from the sponsor
- Facility and Administrative (Indirect) Expense
 - Costs that are incurred for common or joint objectives, but support the research project and research enterprise are included in the F&A rate calculation and are reimbursed through the 47% F&A rate charged to federal grants.



Grant and Cost Accounting

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Director of Cost Accounting

What Costs are What?

- A-21 provides some “suggestions” as to the appropriate treatment of various costs in section F6b...
 - *The salaries of administrative and clerical staff should normally be treated as F&A costs.*
 - *Items such as office supplies, postage, local telephone, and memberships shall normally be treated as F&A costs.*



Grant and Cost Accounting

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Director of Cost Accounting

What Costs are What?

- A-21 provides additional guidance as to the appropriate treatment of various costs in section J18b...

...expenditures for general purpose equipment are unallowable as direct charges

- Based on this guidance, the normal treatment of file cabinets, printers, computers, or other general purpose equipment is that the expense cannot be direct charged to federal grants.



Grant and Cost Accounting

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Director of Cost Accounting

Requirement for Consistent Treatment

- OMB Circular A-21 lists as a fundamental requirement for treatment of costs on federal grants:

“All costs incurred for the same purpose, in like circumstances, are either direct costs only or indirect costs only with respect to final cost objectives. No final cost objective shall have allocated to it as an indirect cost any costs, if other costs incurred for the same purpose, in like circumstances, have been included as a direct cost of that or any other final cost objective...”

OMB A-21 Appendix A CAS 9905.502



Grant and Cost Accounting

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Director of Cost Accounting

What Costs are What – Golden Rule

- Direct Charging Golden Rule
 - *Identification with the sponsored work, (i.e. scope of work) rather than the nature of the goods and services is the determining factor in distinguishing direct from F&A costs of sponsored projects.*
- Golden Rule supports allowances for differing (inconsistent) treatments due to ‘unlike circumstances’.
 - Unlike circumstances must be documented with a justification in order to support inconsistent treatment of costs.



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Examples of 'Unlike Circumstance'

- Computers are common use equipment - INDIRECT
 - A computer required to operate a piece of equipment in the laboratory used for meeting the scope of the project is not common use. DIRECT
- Postage and Office Supplies are provided by the department for Instruction or Dept Research INDIRECT
 - Postage required for a large survey mail out or for shipping samples associated with a sponsored project are necessary to meet the scope of the project. DIRECT



Grant and Cost Accounting

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Director of Cost Accounting

Normal Treatment of Selected Expenses

Normally Direct Charged to Grants	Normally included in F&A Costs	Unallowable Costs
<p>Compensation & Employee Benefits</p> <p>Faculty, technicians, research associates and assistants, including graduate research assistants and other students performing scientific or technical work, post doctoral associates and other technical and programmatic personnel necessary to meet the goals of the project.</p>	<p>Compensation & Employee Benefits</p> <p>Administrative or clerical positions such as administrative assistants, accountants, office personnel, purchasing agents, executive assistants, grant writers, and other administrators.</p>	<p>Compensation & Employee Benefits</p> <p>Internal Consulting</p>
<p>Travel & Meals</p> <p>That which is required to carry out the objectives of the sponsored project including travel to scientific sites. Non-travel meals should be part of a formal meeting complete with an agenda where breaking for meals would disrupt the confluence of the meeting.</p>	<p>Travel & Meals</p> <p>That which is related to administrative activities, food & drink during a lab meeting, “lunch meetings”, “working lunches”</p>	<p>Travel & Meals</p> <p>Entertainment and alcoholic beverages; Airfare charges in excess of customary standard coach price</p>
<p>Supplies</p> <p>Scientific supplies, including laboratory notebooks, glassware, chemicals, field supplies, compressed gases and liquids, software. Parts and supplies related to scientific and technical equipment.</p>	<p>Supplies</p> <p>Office supplies, custodial supplies, parts and supplies associated with repair and maintenance of general purpose equipment and facilities, computer supplies, paper, pads, pens, pencils, markers, printer and fax paper toner, and ink cartridges.</p>	<p>Supplies</p> <p>Goods and Services for Personal Use, gifts and awards, promotional items</p>



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 Director of Cost Accounting

Normal Treatment of Selected Expenses

Normally Direct Charged to Grants	Normally included in F&A Costs	Unallowable Costs
Animals & Hazardous Materials Animal purchases, animal per diems; and hazardous and radioactive materials	Animals & Hazardous Materials Hazardous and radioactive waste disposal	
Communications Documented long distance calls, project-dedicated lines (e.g. "hot lines")	Communications Local calls, telephone equipment purchases and installation/repair, cell phones and use, pagers, and line, voice mail, and network charges	
Postage & Mailing Express service for time-sensitive samples; Mass mailings of surveys, data requests, or other grant related items	Postage & Mailing Express service of proposals and progress reports, local postage costs, international postage, bulk mail services and University mail services.	
Equipment Scientific and technical equipment required for scope of project and budgeted in award	Equipment General purpose equipment, including computers and printers. (unless used specifically and exclusively for scientific purposes).	
Equipment maintenance and service contracts Maintenance and service contracts on scientific and technical equipment with specific identification to the grant	Equipment maintenance and service contracts Maintenance and service contracts on facilities and general purpose equipment.	



Grant and Cost Accounting

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Director of Cost Accounting

UAMS Administrative Guide Policy 8.3.17

UAMS Administrative Guide Policy 8.3.17 provides all definitions associated with direct costing policies, several examples of costs normally treated as indirect, and several examples of “unlike circumstance” justifications. Questions can be directed to Ty Stephens at stephenstyroned@uams.edu or 501-526-7452.



RSC

Tracy L. Gatlin, B.S.

UAMS ClinicalTrials.gov Administrator

What is ClinicalTrials.gov?

- The FDA Modernization Act of 1997- clinical trials investigating drug efficacy in serious or life threatening diseases.
- FDA Amendments Act 2007
 - Expanded the original act of 1997 by
 - Added new requirements for registering clinical trials with ClinicalTrials.gov
- Goal: To ensure patients and health care professionals have access to all available clinical trials.



RSC

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UAMS ClinicalTrials.gov Administrator

Why do I have to register my study?

- Registration required by law under Section 113 of the FDA Modernization Act of 1997 and the FDA Amendments Act of 2007
- Registration required for journal publication by the International Committee of Medical Journal Editors.
 - <http://www.icmje.org>



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UAMS ClinicalTrials.gov Administrator

What types of studies are required to register?

- All applicable drug and device clinical trials
 - Applicable drug clinical trial means all drug trials except for phase 1 studies.
 - Applicable device clinical trial means all device trials other than feasibility studies

<http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>



RSC

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UAMS ClinicalTrials.gov Administrator

<https://register.clinicaltrials.gov>

ClinicalTrials.gov
Protocol Registration System



Login

Welcome to the [ClinicalTrials.gov](https://register.clinicaltrials.gov) Protocol Registration System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 04/30/2012
[Burden Statement](#)

Organization:

User Name:

Password: [Forgot password](#)

Login



RSC

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UAMS ClinicalTrials.gov Administrator

RSC Responsibilities	PI Responsibilities
User accounts	Registering your study before the first subject is enrolled.
Assistance with registration and maintenance	Maintaining your study-minimum every 6 mos.
Notification of study maintenance and follow-up	Entering in results-one year allowed from date of completion



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UAMS ClinicalTrials.gov Administrator

RESOURCES:

INFORMATION ON REGISTERING CLINICAL TRIALS:

<http://prsinfo.clinicaltrials.gov>

ClinicalTrials.gov Web Site:

<http://www.ClinicalTrials.gov>

The International Committee of Medical Journal Editors
policy on trial registration:

http://www.icmje.org/clin_trialup.htm



RSC

Tracy L. Gatlin, B.S.
UAMS ClinicalTrials.gov Administrator

Contact Information

Tracy Gatlin, UAMS ClinicalTrials.gov Administrator
Research Support Center, Slot 813

Phone: 686-6803

Email: tlgatlin@uams.edu



ORC

Darri Scalzo, Research Compliance Officer

Audits of Animal Use Protocols – What and Why?

- Animal Use Protocols approved by the IACUC will be subject to audit beginning in late spring 2011
- In order to help ensure compliance with applicable regulations, policies, and procedures
- Also to help researchers improve their processes



ORC

Darri Scalzo, Research Compliance Officer

Audits of Animal Use Protocols – What and Why?

- Joint effort between IACUC, DLAM, and ORC
- We will first review your IACUC approved protocol
- We will then look at your research jointly with DLAM:
 - Protocols present and visible in lab
 - DEA licenses, drug logs, and drug storage as applicable
 - Animal facilities – cages labeled, animal in/out records



ORC

Darri Scalzo, Research Compliance Officer

**For more information, please call or
email us:**

Darri Scalzo

686-8062

DLScalzo@uams.edu

Nancy Rhea

686-6340

RheaNancyL@uams.edu



BioVentures

Michael Douglas, Ph.D. Director

UAMS BioVentures - Two Major Functions

- License UAMS Technologies
 - Invention disclosures, patents, marketing/licensing technologies
- Develop business opportunities for UAMS technologies
 - IP development, people, money



BioVentures

Michael Douglas, Ph.D. Director

Intellectual Property Protection

- Best when started early with investigators
- Work with BioVentures from the inception of a research program – Award Summary Program
- The best action sequence:
 1. Invent
 2. Disclosure www.uams.edu/bioventures/
 3. File
 4. Publish and/or Present (abstracts)



BioVentures

Michael Douglas, Ph.D. Director

Patent and Copyright

- Online application for invention disclosure
https://aria.uams.edu/patents/index.lasso?page=disclosure&-session=uams_pcc:901E14501d9131926CpsM3CE9DB7
- Committee meets within 30 days to patent or copyright or to release to inventor
- Decision based on uniqueness, non-disclosed, market being addressed (recommendation to Chancellor)
- Patents assigned to University Board of Trustees
- University will monitor prosecution and market invention for commercialization



BioVentures

Michael Douglas, Ph.D. Director

Invention Disclosure Management

■ Technology Assessment

- Science
- Product/Market assessment
- Patent “prior art” reviews and recommendations

■ Patent and Copyright Committee

- Authority for patenting resides with Chancellor
- Patent conversions and prosecution
- Inventor shares in net revenues (costs paid first)



Next RESIN

Next RESIN

- **April 22, 2011 @ 1:30p.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