

UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES



Research Support Information Network (RESIN)

Presented by: Office of the Vice Chancellor for Research

Date: April 7, 2015



Agenda

■ Updates & Timely Information from Research Support:

★ Office of the VCR

URC

IRB

IACUC

HIPAA

★ UAMS Library

BioVentures

★ Cost Accounting

COI

ORSP

★ ORRA

DLAM

OGSP

TRI

Procurement Services



OGSP - Fund My Grant!

DeAnn Hubberd, MA, Assoc. Director, OGSP

Fund My Grant!

Learn How to Make It Happen from a Panel of Expert Reviewers

Come hear a panel of NIH and PCORI study section members from UAMS share their experiences as reviewers and respond to your questions about the NIH peer-review process — **and learn how to make this information work for you.**

TODAY! April 7, 2015 2:00 – 3:30 p.m.

Rayford Auditorium

Biomedical Research Center II, Room 106-2

Panelists

Pamela Holtzclaw Williams, JD, PhD, RN

Alan Tackett, PhD

Lee Ann MacMillan-Crow, PhD

Phil Mayeux, PhD

Mick Tilford, PhD

Sponsored by the Office of Grants & Scientific Publications

For additional information, call DeAnn Hubberd, 686-6004

4/7/2015



New NIH Biosketch Format

Amy Jo Jenkins, Translational Research Institute
(TRI)

■ New Biosketch Format

- Required for grants with due dates on or after
May 25, 2015
- Research, training, and career development grants
- NIH notice #NOT-OD-15-032
(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html>)



New NIH Biosketch Format

Amy Jo Jenkins, Translational Research Institute
(TRI)

■ What's Different?

- May include a link to your complete listing of publications in SciENcv or My Bibliography
- May describe up to 5 of your most significant contributions to science, along with the historical background that framed your research



New NIH Biosketch Format

Amy Jo Jenkins, Translational Research Institute
(TRI)

- **What's Different?** (cont.)
 - May list up to 4 relevant peer-reviewed publications or other non-publication research products for each scientific contribution
 - Allows up to 20 publications and/or other non-publication research products



New NIH Biosketch Format

Amy Jo Jenkins, Translational Research Institute
(TRI)

Old Format	New Format
4-page limit	5-page limit
Personal statement	Personal statement + up to 4 references
	5 contributions to Science + up to 4 references for each contribution
15 selected references	Up to 24 selected references
	Link to online bibliography ("in a publicly available digital database")



New NIH Biosketch Format

Amy Jo Jenkins, Translational Research Institute
(TRI)

- **Tips and tools located on TRI's website:**

<http://tri.uams.edu/>

- If you need additional assistance, please email the TRI Portal:

TRIServices@uams.edu



CORE Charges to Grants

Ty Stephens, Director, Cost Accounting

2 CFR 200_.502 (k)

Period of availability of funds. Where a funding period is specified, a recipient may charge to the award only allowable costs resulting from actual costs incurred during the funding period ...



CORE Charges to Grants

Ty Stephens, Director, Cost Accounting

2 CFR 200.303

Internal controls. The non-Federal entity must establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award.



CORE Charges to Grants

Ty Stephens, Director, Cost Accounting

- **Proposed requirements for CORE invoices**
 - CORE invoices cannot be submitted until after work is completed
 - Specific date of performance will be required on all invoices
 - Only services for which rates have been calculated should be invoiced. Any “misc. fees” added to a calculated rate must be specifically identified on the invoice.



CORE Charges to Grants

Ty Stephens, Director, Cost Accounting

- **Advanced Billings Are Disallowed**
 - Any CORE found to be invoicing grants for CORE activity prior to actual performance, will be subject to disciplinary action or closure.
 - Please don't put our CORE directors in an awkward position by asking for advanced billings.



Federally Funded Grant Public Access Compliance

Jessie Casella,
MLIS, UAMS Library

- **NSF Requirements**
- **NIH Public Access Policy**
 - Reminders
 - Updates



Federally Funded Grant Public Access Compliance

Jessie Casella,
MLIS, UAMS Library

- **National Science Foundation (NSF)
Public Access Requirements**
 - Note: NSF's infrastructure for depositing is still in-process
 - Data Management Plan required
 - Starting January 2016
 - Will use the Department of Energy's PAGES system as designated repository



Federally Funded Grant Public Access Compliance

Jessie Casella,
MLIS, UAMS Library

- **National Science Foundation (NSF)**
 - Be available for download, reading and analysis free of charge no later than 12 months after initial publication
 - Possess a minimum set of machine-readable metadata elements in a metadata record to be made available free of charge upon initial publication



Federally Funded Grant Public Access Compliance

Jessie Casella,
MLIS, UAMS Library

- **National Science Foundation (NSF)**
 - Be managed to ensure long-term preservation
 - Be reported in annual and final reports during the period of the award with a persistent identifier that provides links to the full text of the publication as well as other metadata elements.



Federally Funded Grant Public Access Compliance

Jessie Casella,
MLIS, UAMS Library

■ NIH Public Access Policy Reminders

- Book chapters from items with ISSN numbers fall under the policy
- Please link eRA Commons and My NCBI accounts - eRA Commons no longer supports bibliographic management of publications



Federally Funded Grant Public Access Compliance

Jessie Casella,
MLIS, UAMS Library

■ NIH Public Access Policy

- National compliance average is approx. 85%
- UAMS compliance is currently **96%!!!!**



Federally Funded Grant Public Access Compliance

Jessie Casella,
MLIS, UAMS Library

Questions?

Jessie Casella, MLIS

Education & Reference Department

UAMS Library

686-8517

JMCasella@uams.edu

<http://library.uams.edu/scholarly-resources/nih-public-access/>



Risk Based Monitoring

Tom Wells, MD, Director, Office of Research
Regulatory Affairs

- **Monitoring: oversight of an investigation involving an FDA regulated product**
 - Responsibility of the sponsor
 - Protect the rights, welfare, and safety of human subjects
 - Assure the quality of the data submitted to the FDA
 - Monitoring occurs while the study is ongoing



Risk Based Monitoring

- Role of Monitoring

Tom Wells, MD, Director, ORRA

- “Monitoring is a quality control tool for determining whether study activities are being carried out as planned, so that deficiencies can be identified and corrected.”
- “... monitoring findings should be evaluated to determine whether additional actions are necessary to ensure human subject protection and data quality...”

U.S. HHS, FDA, August 2013 OMB Control No. 0910-0733



Risk Based Monitoring

- FDA Guidance Document

Tom Wells, MD, Director, ORRA

- **Guidance Document released August 2013***
 - Provides recommendations for monitoring within a broad framework designed to achieve desired outcomes
 - Monitoring is only one aspect of the processes and procedures needed to ensure safety and quality

* U.S. HHS, FDA, August 2013 OMB Control No. 0910-0733



Risk Based Monitoring

- FDA Guidance

Tom Wells, MD, Director, ORRA

■ Guidance Documents

- Represent the FDA's current thinking on a topic
- Do not establish legally enforceable responsibilities
- They are viewed as recommendations (unless a specific regulatory or statutory requirement is cited)



Risk Based Monitoring

- Past Experience

Tom Wells, MD, Director, ORRA

- **Past approach for major clinical trials of efficacy conducted by industry:**
 - On-site monitoring at intervals of 4-8 weeks
 - 100% verification of all data
- **Academic trials:**
 - Often less extensive monitoring



Risk Based Monitoring

Tom Wells, MD, Director, ORRA

- **Goal: Tailor the monitoring plan to the needs of the trial**
- 3 steps (before the trial begins):
 - Determine critical data and processes to ensure safety and data quality
 - Risk assessment approach
 - Develop a monitoring plan that focuses on important and likely risks to the critical data



Risk Based Monitoring

Tom Wells, MD, Director, ORRA

- **Identification of Critical Data/Processes:**
 - Verification that informed consent was obtained properly
 - Adherence to protocol eligibility criteria
 - Procedures for documenting accountability and administration of the investigational product



Risk Based Monitoring

Tom Wells, MD, Director, ORRA

- **Identification of Critical Data/Processes:**
 - Document procedures and assessments for:
 - Study endpoints
 - Protocol-required safety assessments
 - Evaluating, documenting and reporting serious adverse events, unanticipated adverse events, deaths, early withdrawals, etc.
 - Document procedures essential to trial integrity (e.g. if the study blind was maintained)



Risk Based Monitoring

Tom Wells, MD, Director, ORRA

- **Identification of Critical Data/Processes:**
 - Recognition that some types of errors are more important than others (e.g. baseline age, concomitant treatment, concomitant illness vs. errors in collecting study endpoints)
 - Risk based monitoring focuses on the more important data
- Risk assessment then guides decisions regarding monitoring activities



Risk Based Monitoring

- Monitoring Plan

Tom Wells, MD, Director, ORRA

- **Factors to Consider in the Monitoring Plan:**
 - Complexity of the study design
 - Types of study endpoints
 - Clinical complexity of the study population
 - Relative safety of the investigational agent
 - Stage of the study
 - Quantity of data collected



Risk Based Monitoring - Monitoring Plan

Tom Wells, MD, Director, ORRA

- **Components of the Monitoring Plan:**
 - Description of monitoring approaches
 - Monitoring methods
 - Triggers for and timing of visits
 - Identification of deviations critical to study integrity
 - Communication of monitoring results
 - Management of noncompliance



Risk Based Monitoring

Tom Wells, MD, Director, ORRA

- **Begins May 1, 2015**
- Monitors will work with PI to develop a plan appropriate for the study
 - Identify critical data and processes
- Monitors will review CRFs prior to the start of the study
- SIV and initial monitoring visit will be planned



UAMS Student Research Day

Linda Williams, Research Liaison, Office of Research

■ Next Wednesday, April 15, 2015

(IDW – 1st & 2nd floors)

- 105 abstracts submitted in 2015
 - Participants (Graduate students, Professional students, Post docs and House staff)
 - **Poster sessions 10:00 – 11:30 a.m. and 1:15 – 2:45 p.m.**
- Keynote speaker, **Maureen Smith, MD, MPH, PhD**
 - “The Journey to a Learning Health System at an Academic Medical Center”
 - 12:00 p.m. – 1:00 p.m., Lunch for 200



UAMS Student Research Day

Linda Williams, Research Liaison, Office of Research

■ Keynote speaker Maureen Smith, MD, MPH, PhD



- Professor, Univ. of Wisconsin-Madison School of Medicine and Public Health, Depts. of Population Health Sciences, Family Medicine, and Surgery
- Dir. of UW [Health Innovation Program](#), Dir. of [Community Academic Partnerships](#) core of NIH-CTSA Institute for Clinical and Translational Research, and Assoc. Dir. for Population Sciences at [UW Carbone Cancer Center](#)
- Research examines effectiveness of health care system for aging and chronically ill persons



Next RESIN

■ Next RESIN

- **May 5, 2015 @ 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