

# UAMS

UNIVERSITY OF ARKANSAS  
FOR MEDICAL SCIENCES



**Presented by: Office of the Vice Chancellor for Research**  
**Date: December 4, 2012**



# Agenda

## ■ Updates & Timely Information from Research Support:

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



# Winthrop P. Rockefeller Cancer Institute

## Genomics Core Lab

Stewart MacLeod, PhD

### ■ Personnel

- **Co-Directors** – Susan Kadlubar, PhD and Charlotte Hobbs, MD, PhD
- **Technical Director** – Stewart MacLeod, PhD
- **Bioinformatics** – Vinay Raj, PhD
- **Research Assistants** –
  - Mohammad Karim, MD, PhD
  - Christopher Randolph, BS
  - Donald Turner, BS



# Winthrop P. Rockefeller Cancer Institute

## Genomics Core Lab

Stewart MacLeod, PhD

### ■ Location

- Winthrop P. Rockefeller Cancer Institute, Room 338

### ■ Contact

- Stewart MacLeod, [macleodstewartl@uams.edu](mailto:macleodstewartl@uams.edu)
- Office – 501-364-4616
- Cell – 501-626-5729



## ■ **Genomics Core Services**

- Isolation of RNA and DNA
- RNA analysis by Agilent BioAnalyzer-RIN report
- Gene Expression analysis by Illumina arrays-human and mouse
- Human SNP/CNV analysis by Illumina arrays-GWAS -up to 5 million SNPs /sample
- Custom SNP arrays



# Winthrop P. Rockefeller Cancer Institute

## Genomics Core Lab

Stewart MacLeod, PhD

### ■ Sequencing Services

- Sample preparation for high throughput sequencing
- High-throughput sequencing using Illumina cBot and Genome Analyzer Ix or HiScanSQ
  - *De novo* or targeted resequencing
  - RNA sequencing
  - ChIP-Seq
  - Sequencing-based methylation analysis



# Winthrop P. Rockefeller Cancer Institute

## Genomics Core Lab

Stewart MacLeod, PhD

### ■ Genomics Core services

- Bioinformatics and statistical support
- Investigator consultation-assistance in project planning

### ■ Contact

- Stewart MacLeod
- [macleodstewartl@uams.edu](mailto:macleodstewartl@uams.edu)
- Office – 501-364-4616
- Cell – 501-626-5729



# TRACKS Update

Suzanne Alstadt, Director, ORSP

## ■ Brief History

- Late 2009 – CCR Software Solutions Subcommittee formed
- March 2010 – Click Commerce chosen as commercial solution for COI and Grants Management
- November 2010 – COI Module went live
- 2011- Present – Grants Management Development





# TRACKS Update

Suzanne Alstadt, Director, ORSP

## ■ Current Development & Testing

- Pre-award development mostly complete
- Post-award development in process
- Development to be completed by December 10
- Testing throughout December
- Pilot groups trained through late December and January
- Pilot groups use live system in late January



# TRACKS Update

Suzanne Alstadt, Director, ORSP

## ■ Training & Go-Live

- Users trained throughout January and February
  - Training is mandatory
  - Separate trainings for faculty and others creating new proposals; approvers; and post-award users
- System live in late February



# TRACKS Update

Suzanne Alstadt, Director, ORSP

## ■ Cons

- Any new system seems scary and requires getting acclimated
- Multiple clicks to get from one part of the pre-award process to the next



# TRACKS Update

Suzanne Alstadt, Director, ORSP

## ■ Pros

- System is faster
- Less duplication of effort
- Stable
- Interfaces with other systems on campus
- No more ARIA!



# TRACKS Update

Suzanne Alstadt, Director, ORSP

## Questions?



# Data Use Agreements

## For Disclosure of Limited Data Set

Dori Wong-Scoggins, J.D.

### ■ What Is True De-identified Data Under HIPAA

- If any **one** of the following identifiers are present, it is **NOT** truly de-identified

Names

Street Addresses (town, city, zip code)

Telephone Numbers

Fax Numbers

E-mail Addresses

Social Security Numbers

Medical Record Numbers

Health Plan Beneficiary Numbers

Dates directly related to an individual  
(ex: Birthdates, admission date, discharge date)

and all elements of dates indicative of age

except may be aggregated into a single category of age 90 or older

Certificate/License Numbers

Vehicle Identifiers and Serial Numbers, License Plate

Device Identifiers and Serial Numbers

Web URLs

IP Address Numbers

Biometric Identifiers (including finger and voice prints)

Full Face Photo (or comparable images)

Any other unique identifying number, characteristics or code (does not mean unique code assigned by the investigator to code the data)



# Data Use Agreements

## For Disclosure of Limited Data Set

Dori Wong-Scoggins, J.D.

- If any one of the 18 identifiers are present in your data set, then you must have a written consent in place indicating that the patient/subject has authorized the disclosure of his PHI
- Exception: Limited Data Set



# Data Use Agreements

## For Disclosure of Limited Data Set

Dori Wong-Scoggins, J.D.

### ■ Definition of Limited Data Set

A “limited data set” is a set of identifiable patient information as defined under HIPAA that may be disclosed to an outside party without a patient/subject’s authorization if the following conditions are met:

- For research purpose, public health, or health care operations only
- The person receiving the limited data set must sign a Data Use Agreement with the provider of the information





# Data Use Agreements

## For Disclosure of Limited Data Set

Dori Wong-Scoggins, J.D.

- What information may be disclosed under a Limited Data Set using a Data Use Agreement?
  - Dates: Date of Birth, Date of Death, Date of Admission, Date of Service, Date of Discharge
  - City, State, Zip Code
  - Age
- Data set remains PHI under HIPAA.
  - Not de-identified information
  - Still subject to Privacy Regulations requirement



# Data Use Agreements

## For Disclosure of Limited Data Set

Dori Wong-Scoggins, J.D.

- **Data Use Agreement** (PHI must meet the standards of the Privacy Regulations)
  - Establish permitted uses and disclosures of the limited data set
  - Identify who may use or receive the information
  - Prohibit recipient from using/further disclosing the information, except as permitted by the agreement or by law
  - Require recipient to use appropriate safeguards to prevent a use or disclosure not permitted by the agreement
  - Require recipient to report to the covered entity any unauthorized use or disclosure of which it becomes aware
  - Require recipient to ensure that any agents (e.g. subcontractor) to whom information provided will agree to same restrictions as provided in the agreement
  - Prohibit recipient from identifying the information or contacting the individuals



# Data Use Agreements

## For Disclosure of Limited Data Set

Dori Wong-Scoggins, J.D.

- **True De-identified Data** = none of the 18 identifiers are present **nor can it be ascertained**
- **Coded Data:** cannot be derived from any information related to the individual, or can the method to derive the code be disclosed
  - Example: Mary Ann Johnson (born May 14<sup>th</sup>) cannot be coded as MAJ0514
- **Re-identification or otherwise ascertained**
  - The recipient cannot have actual knowledge that the subject could be re-identified from the remaining PHI used in the research study. In other words, even if all 18 identifiers were removed but there is some way you can identify the subject based on the information provided, it is identifiable information.



# Data Use Agreements

## For Disclosure of Limited Data Set

Dori Wong-Scoggins, J.D.

### ■ RECAP

#### ■ Disclosure of Limited Data Set

- Data Use Agreement
- No need for consent and authorization

#### ■ Disclosure of PHI but does not qualify as a Limited Data Set

- Need full consent
- See IRB Policy 15.1
- See HIPAA Research Policy 3.1.27 (UAMS Administrative Guide)



# Data Use Agreements

## For Disclosure of Limited Data Set

Dori Wong-Scoggins, J.D.

- **UAMS Research HIPAA Privacy Officer**

Jennifer Sharp, J.D.

501-526-7559

SharpJenniferR@uams.edu



# Data Use Agreements

## For Disclosure of Limited Data Set

Dori Wong-Scoggins, J.D.

### ■ Research Support Center, Legal Unit Contacts

- Dori Wong Scoggins

[dwong@uams.edu](mailto:dwong@uams.edu) 526-6247

- Joe Underwood

[junderwood@uams.edu](mailto:junderwood@uams.edu) 686-8846

- Rai Smith

[smithrai@uams.edu](mailto:smithrai@uams.edu) 686-5503

- Jana Bennett

[jsbennett@uams.edu](mailto:jsbennett@uams.edu) 603-1580



# Avoiding Retrospective Reviews

Jennifer Smith, Director,  
Conflict of Interest

## ■ Retrospective Review

- Required if COI related to PHS-funded research was not disclosed in a timely manner by an investigator
- Required if COI related to PHS-funded research was not reviewed in a timely manner & managed by the institution
- Required if Investigator fails to comply with management plan



# Avoiding Retrospective Reviews

Jennifer Smith, Director,  
Conflict of Interest

## ■ Retrospective Review

- Must be completed within 120 days
- Must determine whether design, conduct, or reporting of PHS-funded research has been biased
- Interim management plan must be implemented to manage the conflict until the Retrospective Review complete





# Avoiding Retrospective Reviews

Jennifer Smith, Director,  
Conflict of Interest

## ■ Retrospective Review

- Requires examination of any research activities conducted during the period of noncompliance
- Must document “detailed methodology” used for the review process (composition of review panel, documents reviewed, analysis, rationale for findings)
- If bias found, report to PHS awarding component and implement mitigation plan (remove researcher from project, request external data analysis, retractions, suspend research, etc.)



# Avoiding Retrospective Reviews

Jennifer Smith, Director,  
Conflict of Interest

## ■ Institution

- Identify & manage COIs prior to expenditure of PHS funds and within 60 days for COIs that arise during an ongoing project

## ■ Investigators

- Disclose SFIs annually and within 30 days of a change
- Comply with management plans



# NIH PAP Announcement

Susan Steelman, MLIS – UAMS Library

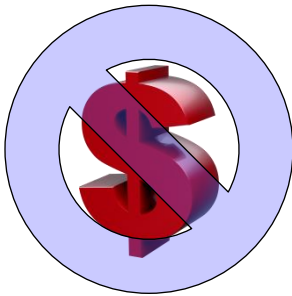
- **NIH Public Access Policy**
  - Compliance mandatory since 2008
  - NIH has provided outreach and assisted applicants with understanding the policy
  - Improvement of grantee compliance is necessary



# NIH PAP Announcement

Susan Steelman, MLIS – UAMS Library

- **Spring 2013 Enforcement Begins**
- Delay processing of:
  - Non-competing continuation grant awards
  - Compliance must be met for articles attached to those awards before award will be processed





# NIH PAP Announcement

Susan Steelman, MLIS – UAMS Library

## What Can You Do?

- Watch for customized Non-Compliance report
- Review article submission requirements at Library's website
- Schedule a presentation to your department



# NIH PAP Announcement

Susan Steelman, MLIS – UAMS Library

- <http://www.library.uams.edu/schpub/nihpolicy.aspx>

UAMS Library

## NIH Public Access Policy

### Overview

The [NIH Public Access Policy](#) was originally established in 2005, and compliance with the policy became mandatory in April of 2008. The policy requires that anyone receiving NIH funding (directly or indirectly) to support research projects (in whole or in part) must make the articles resulting from those projects available in the National Library of Medicine's PubMed Central (PMC) online repository of full-text journals within 12 months of publication in a peer-reviewed journal.



### Policy Requirements

<http://publicaccess.nih.gov/>

The following steps must be followed to be in compliance with the NIH Public Access Policy:

- Determine if articles are covered
- Retain the right to deposit final peer-reviewed manuscripts in PMC when negotiating copyright with publishers
- Deposit articles *upon acceptance* for publication, as articles must be *available* in PMC within 12 months of publication
- Include the PMID# when citing articles in NIH proposals, progress reports, biosketches, etc.

1/10/2013



# Showcase of Medical Discoveries

Lawrence E. Cornett, Ph.D.

- **Showcase of Medical Discoveries**
  - Poster Sessions with refreshments
    - Scientific exchange
    - Provide networking opportunities
  - University Relations
    - Philanthropy
    - Board of visitors





# Showcase of Medical Discoveries

Lawrence E. Cornett, Ph.D.

## First Showcase Event: A Focus on Cardiovascular Research



Wednesday, November 28, 2012, 4:00-5:30 pm  
Wine & Cheese event, Cancer Institute 10<sup>th</sup> Floor





# Showcase of Medical Discoveries

Lawrence E. Cornett, Ph.D.

## ■ Next Showcase of Medical Discoveries

### Nanomedicine

**February 27, 2013**

4:00-5:30 pm

Cancer Institute 10<sup>th</sup> Floor



# Next RESIN

## ■ Next RESIN

- **February 5, 2012 @ 12:00 p.m.**
- Location - **Walton Auditorium**, Winthrop P. Rockefeller Cancer Institute, 10<sup>th</sup> floor
- All RESIN presentations archived on the UAMS Research website
  - [http://www.uams.edu/research/RESIN\\_Achive.asp](http://www.uams.edu/research/RESIN_Achive.asp)