

UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES



RESIN (Research Support Information Network)

Presented by: Office of the Vice Chancellor for Research

Date: October 28, 2011



Agenda

■ Research Updates & Timely Information:

⊕ Office of the VCR

RSC

⊕ IRB

IACUC

COM Finance & Admin

UAMS Library

BioVentures

COI

ORSP

⊕ ORC

DLAM

⊕ OGSP

CCTR/Core Facilities

⊕ CAVHS



CAVHS Research Service

Richard R. Owen, MD – Acting ACOS for Research

■ VA—Academic Affiliate Interactions

■ Overview

- CAVHS IRB History
- CAVHS IRB/R&D Committee Processes
- Recent Office of Research Oversight Guidance



CAVHS Research Service

Richard R. Owen, MD – Acting ACOS for Research

■ CAVHS IRB History

- Developed September-December 2007
- First meeting – December 2007
- AAHRPP Accreditation – March 2011
- New VHA Handbook on human subjects research – March 2011



CAVHS Research Service

Richard R. Owen, MD – Acting ACOS for Research

■ CAVHS IRB and R&D Committee Processes

- IRBNet electronic submission and review system
- 2011 statistics – average time from initial submission to approval:
 - Full IRB review: 56 days (national average—49 days)
 - Expedited review: 27.1 days (national average—30 days)
- Streamlined R&D Committee approval



CAVHS Research Service

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■ New Office of Research Oversight Guidance

- On research data disclosures for “collaborative studies,” (i.e., done at both a VA site and academic affiliate)
- To facilitate implementation of the principles articulated by the Working Group on Information Technology Security and Privacy in VA and NIH-Sponsored Research (AAMC)
- Addresses challenges to: records retention, disclosure of data under HIPAA, data ownership, and data security, multi-site (VA-university) research



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■ Key Points

- HIPAA authorization can permit VA to disclose subject's data to academic affiliate for a research project
 - VA retains complete record of data
- With waiver of informed consent, data transfer may still be possible, with appropriate approvals
 - HIPAA waiver + Data Use Agreement and VHA data security and privacy approvals
 - Limited dataset



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- **“Collaborative Research”** (i.e., VA data combined with affiliated data)
- Under interim ORO guidance, this research activity is viewed as **multi-site study**, with activities clearly defined for each site, including:
 - Separate protocols and IRB approvals at VA and affiliate with separate data sets
 - Separation of VA and affiliate activities for investigators with dual appointments
 - Defined data coordination activities at VA **or** affiliate



CAVHS Research Service

Richard R. Owen, MD – Acting ACOS for Research

■ Contact

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- Amy Lallier, IRB Administrator
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IRB

Jennifer Sharp, J.D. , Director

- **Proposed New Rule for Human Protection in Research**
 - Advance Notice of Proposed Rulemaking
 - RFI, ANPRM, NPRM, Final Comment
 - Last substantive changes – 1981
 - Goal: Enhancing Protections, Reducing Burden, Delay and Ambiguity
 - 74 Questions+



IRB

Jennifer Sharp, J.D. , Director

- **Proposed Changes for Expedited Review**
 - Revise list of Expedited Categories?
 - Assume it is Minimal Risk if on “List”?
 - Reduce Section .111 requirements?
 - Omit Continuing Review?

- **“Excused” rather than “Exempt”**
 - Registration Form?
 - Informed consent (sometimes)?
 - Data Security requirements?
 - Mandated institutional auditing?



IRB

Jennifer Sharp, J.D. , Director

- Single IRB review for certain multi-site studies?
- Biospecimen Research
 - Written consent for any biospecimen research?
 - What should be done with pre-existing biospecimen?
 - Open ended consent for future research? Exclude some types of research?
- Consent
 - Require PIs to assess understanding?
 - Revise waiver of consent? Revise waiver of consent documentation?
 - Limit length? Mandate clauses? Restrict clauses? Mandate template?



IRB

Jennifer Sharp, J.D. , Director

- **Comparison of Existing Rules with Changes Being Considered**
 - <http://www.hhs.gov/ohrp/humansubjects/anprmchangetable.html>
- **Over 600 comments** submitted by institutions, organizations and individuals
- **More Information**
 - <http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>



Enhancing Your Peer Review

DeAnn Hubberd, MA, Associate Director, Office of Grants & Scientific Publications

- **Panel discussion/Q & A about NIH peer review**
 - Features 5 NIH Study Section Members from UAMS

- **Panelists will:**
 - Share their experiences regarding the NIH peer-review process
 - Take questions
 - Offer advice about making the process work for you



Enhancing Your Peer Review

DeAnn Hubberd, MA, Associate Director, OGSP

- **Alan Budney, PhD**
Professor, Dept. of Psychiatry, Center for Addiction Research
- **Gwen Childs, PhD**
Professor and Chair, Dept. of Neurobiology & Developmental Sciences
- **Paul D. Drew, PhD**
Professor, Dept. of Neurobiology & Developmental Sciences
- **Kevin Raney, PhD**
Professor and Chair, Dept. of Biochemistry & Molecular Biology
- **Jerry Ware, PhD**
Professor, Dept. of Physiology and Biophysics



Enhancing Your Peer Review

DeAnn Hubberd, MA, Associate Director, OGSP

Thursday, November 10, 2011

2:00 to 3:00 p.m.

Walton Auditorium
10th Floor, Walker Tower, Winthrop P.
Rockefeller Cancer Institute



Enhancing Your Peer Review

DeAnn Hubberd, MA, Associate Director, OGSP

■ Contact

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Animal Use Protocol Submission & Review

Larry Cornett, Ph.D., Vice Chancellor for Research

- **Proposed New Administrative Procedures for Animal Use Protocol Submission & Review**
- **HHS Grants Policy Statement (1/07)**
 - Applications proposing to use vertebrate animals in HHS-supported activities institutions must file a written Animal Welfare Assurance with OLAW
 - Institutional IACUC must approve sections of an application involving the use of vertebrate animals



Animal Use Protocol Submission & Review

Larry Cornett, Ph.D., Vice Chancellor for Research

- **Congruency Required Between AUP and Sections of Application Describing Animal Research**
 - **What?**
 - Species/Strain
 - # of Animals
 - Surgical Procedures
 - Anesthesia
 - Euthanasia methods
 - **Who?**
 - IACUC
 - IACUC Staff
 - Research Compliance Staff



Animal Use Protocol Submission & Review

Larry Cornett, Ph.D., Vice Chancellor for Research

- **Proposed Procedure to Insure Compliance**
 - **Application Submission**
 - **Reviewed/fundable score – Submit AUP**
 - **Just-in-Time Request**
 - **Grant Awarded**
- **Accounts used for animal purchases/
per diem matched to NIH grant**
- **Grant funds released only with IACUC
approved AUP**



2020 Vision: UAMS Health Care Leadership for Arkansas

Larry Cornett, Ph.D., Vice Chancellor for Research

- **April 2010 – Chancellor’s Cabinet Strategic Retreat**
- Focus groups (>200 campus leaders, alumni, donor) provided input
- Plan modified by Chancellor’s Cabinet
- Plan distributed to campus for review/comment



2020 Vision: UAMS Health Care Leadership for Arkansas

Larry Cornett, Ph.D., Vice Chancellor for Research

■ 2020 Vision

■ UAMS Mission Statement

■ To Improve the Health and Healthcare of
Arkansans

■ Core Values

- Integrity
- Respect
- Diversity
- Teamwork
- Creativity
- Excellence



2020 Vision: UAMS Health Care Leadership for Arkansas

Larry Cornett, Ph.D., Vice Chancellor for Research

■ 2020 Vision Goals

- **Goal 1** - Create an integrated patient-centered health care environment...
- **Goal 2** - Educate culturally competent health professionals...
- **Goal 3** - Continue to develop nationally recognized multi-disciplinary research programs aligned with health needs in the state & nation
- **Goal 4** - Develop research, educational and technical assistance expertise in population health strategies....
- **Goal 5** - Support the talent-rich environment at UAMS...



2020 Vision: UAMS Health Care Leadership for Arkansas

Larry Cornett, Ph.D., Vice Chancellor for Research

■ 2020 Vision Goal 3 Objectives

- Achieve NCI Designation for the Cancer Institute
- Achieve renewal of the NIH CTSA award
- Enhance national prominence of UAMS research programs
- Enhance capacity in clinical and translational research
- Align research & educational programs to train the next generation of researchers
- Increase # of patents and start-up companies
- Increase \$ value of research endowments



2020 Vision: UAMS Health Care Leadership for Arkansas

Larry Cornett, Ph.D., Vice Chancellor for Research

- **2020 Vision: Moving Forward**
 - Chancellor's Cabinet members assigned to each goal
 - Quarterly meetings of goal leaders
 - Five year budget planning related to goals



Next RESIN

Next RESIN

- **January 27, 2012 @ 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