RESIN (Research Support Information Network)

Presented by: Office of the Vice Chancellor for Research

Date: April 27, 2012
Agenda

Research Updates & Timely Information:

- Office of the VCR
  - RSC
- IRB
- IACUC
  - COM Finance & Admin
  - UAMS Library
  - BioVentures
- W.P. Rockefeller Cancer Institute

COI
- ORSP
- ORC
- DLAM
- OGSP
- TRI/Core Facilities
- Office of Development & Alumni Affairs
Proteomics Core Facility
Sam Mackintosh, PhD, Assistant Core Director

- Identification and Characterization of Proteins
  - Tandem (MS/MS) Mass Spectrometry
  - Post-Translational Modifications
  - Quantitative Comparisons

- Proteomics Core Directors
  - Rick Edmondson, MIRT
  - Alan Tackett, Biochemistry and Molecular Biology
  - Research Assistant: Linley Moreland
Proteomics Core Facility
Sam Mackintosh, PhD, Assistant Core Director

- Thermo LTQ Orbitrap Velos Mass Spectrometer
  - High-Throughput Protein ID
  - 5 ppm Resolution
  - Sub-fmol Sensitivity
  - nanoAcquity UPLC
GeLC Analysis of Complex Biological Samples
LTQ Orbitrap Velos – nanoAcquity Chromatogram

RT: 0.00 - 44.99

Relative Abundance

Time (min)

0 5 10 15 20 25 30 35 40 45 50 55 60

37.90 38.24 39.71

37.18 34.01 32.90 30.75 26.49 25.11 22.78 19.74

15.54 12.38 13.54 12.38 12.75 8.03 7.92 7.84 6.87 0.78

Proteomics Core Facility
Sam Mackintosh, PhD, Assistant Core Director
Proteomics Core Facility
Sam Mackintosh, PhD, Assistant Core Director

LTQ Orbitrap Velos – GeLC Analysis

UV image – Sypro stain

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1163 protein IDs from L2
Isotope-Based Quantification

Cells Grown in Light Isotope-containing Media

Cells Grown in Heavy Isotope-containing Media + Treatment

Harvest & Lyse Cells

Quantitate Protein

Mix Cell Lysates

Excise Bands

Trypsin Digestion

LC-MS/MS

m/z Ratio Determination

SDS-PAGE
LTQ Orbitrap Velos – Isotope Comparison

F: FTMS + p NSI Full ms [375.00-1500.00]
Label-Free Quantification – Spectral Counting

RT: 0.00 - 29.99

This protein is present in different amounts in the 2 samples.
Proteomics Core Facility
Sam Mackintosh, PhD, Assistant Core Director

- Label-Free Quantification – Peak Alignment
Recent UAMS Publications Containing Core Data

IACUC UAMS Internal Website

http://iacuc.ad.uams.edu
IACUC Update
Bill Gurley, PhD, Chair, UAMS IACUC

IACUC
Institutional Animal Care and Use Committee

IACUC Chairman:
Billy J. Gurley, Ph.D.
gurleybil@uams.edu

IACUC Office:
Linda Laney, IACUC Administrator
Biomedical Research Center II, room
106-2
686-5347
laneylinda@uams.edu

HOW TO SUBMIT A NEW ANIMAL PROTOCOL:
Due date for submission of a new animal protocol is on or before the first Friday of each month. New submission is done by e-mail to the IACUC Administrator laneylinda@uams.edu. If your AUP submission is part of a grant please include the vertebrate animal methods section of the grant. New protocols received after the due date will be held until the following month. If you do not have auto signature for the face page you may send the signed and dated face page by PDF or it can be faxed to 626-7465. All submission require a fully signed and dated face page before full approval can be received.

If you are submitting an ACHRI AUP please e-mail a copy to Tanise Goodwin tegoodwin@uams.edu

If you have questions concerning animal housing at UAMS please contact the Division of Laboratory Animal Medicine at 686-5285 and ask to speak with Dr. Mildred Randolph, Director.

If you have questions concerning animal housing at AC-IRI please contact Mr. Blake Harrison at 364-2700.

Please direct all other questions to the IACUC office at 686-5347 or laneylinda@uams.edu

Downloadable Forms:
Animal Use Protocol (AUP) UAMS Form  download
Animal Use Protocol (AUP) ACHRI Form  download
AUP Addendum Approval Form  download
UAMS IACUC Policies  download

RESIN 4/27/2012
Guide for the Care and Use of Laboratory Animals

- New edition (8th) recently approved
- Several new changes will impact UAMS
- “Musts” vs. “Shoulds”
Pharmaceutical grade chemicals

- Agreement between OLAW and USDA
- “pharmaceutical grade chemicals should be used, when available, for all animal-related procedures.”
- NIH definition of pharmaceutical grade compound: “drug, biologic, reagent, etc., which is approved by the FDA or for which a chemical purity standard has been written/established by USP/NF, BP”
- “ensures research animal health and welfare, as well as validity of scientific results.”
Non-pharmaceutical Grade Chemicals

- Can be used, based upon:
  - Scientific necessity
  - Non-availability of acceptable pharmaceutical-grade
  - Specific review and approval by IACUC

- Cost savings alone are not an adequate justification!
Non-pharmaceutical grade chemicals

Justification for non-pharmaceutical compounds:

- Purity
- Formulation of final product
- Sterility
- Pyrogenicity
- Osmolality
- Route of administration
- Pharmacokinetics
- Others
Priority for selection of compounds/drugs

When selecting compounds, the following order of choice should be applied:

1. FDA approved veterinary or human pharmaceutical compounds;
2. FDA approved veterinary or human pharmaceutical compounds used to compound a needed dosage form;
3. USP/NF or BP pharmaceutical grade compound used in a needed dosage form;
4. Analytical grade bulk chemical used to compound a needed dosage form;
5. Other grades and sources of compounds (requires justification)

**NOTE:** For new investigational drugs, the grade/formulation is not optional, but the investigator and ACUC can verify health and safety issues described above.
IACUC Update
Bill Gurley, PhD, Chair, UAMS IACUC

- NIH Veterinary Pharmacist Web Address
  - http://dvrnet.ors.od.nih.gov/internal/pharmacy.asp

- Guidelines posted on UAMS IACUC website
Questions?
Striving Toward NCI Designation

Dorothy Graves, PhD
Special Projects Coordinator, Cancer Institute
Draft of 2013 CCSG Guidelines

- “..support research infrastructure that enhances collaborative, transdisciplinary research productivity.”
- “...funding for formalized cancer research programs, shared research resources, scientific and administrative management, planning and evaluation activities, development of new scientific opportunities and centralized clinical trial oversight and functions.”
- “...an NCI-designated cancer center links state-of-the-art research and care...”
- Required: Minimum base of $10 million in annual direct costs of peer-reviewed, cancer-related funding
Winthrop P. Rockefeller Cancer Institute  Dorothy Graves, PhD Special Projects Coordinator

- **Director** – Peter Emanuel, MD
- **Deputy Director** – Tom Kieber-Emmons, PhD
- **Associate Directors:**
  - Clinical Research – Laura Hutchins, MD
  - Shared Resources – Marie Chow, PhD
  - Administration – Shirley Gray, MA
  - Basic Research; Cancer Control and Population Sciences – TBN
- **Associate Directors:**
  - PRMC – Jeanette Lee, PhD
  - Audit/Quality Control - TBN

RESIN 4/27/2012
Winthrop P. Rockefeller Cancer Institute
Dorothy Graves, PhD Special Projects Coordinator

Cancer Institute Research Programs

- Cancer Control and Population Sciences
  - R. Henry-Tillman, MD
  - S. Kladlubar, PhD
    - NCI funding: $2.4M
- Experimental Therapeutics
  - R. Griffin, PhD
  - V. Zharov, PhD
    - NCI funding: $1.9M
- Radiation Sciences
  - M. Hauer-Jensen, MD, PhD
  - D. Zhou, MD
    - NCI funding: $1.5M
- Hematological Malignancies
  - J. Epstein, D.Sc.
  - F. van Rhee, MD, PhD
    - NCI funding: $3.8M
Shared Resources (still being evaluated)
- Genomics
- Proteomics
- Experimental Pathology
- Biostatistics/Bioinformatics
- Animal Imaging
- Cancer Clinical Trials Office (CCTO)
Evaluation and Metrics

- 6 essential characteristics
- Catchment area – to ensure our research serves our population and clinical trial enrollment is appropriate
- Intra- and interprogrammatic publications
- Extramural peer-reviewed funding

Timeline...
VA and OHRP Regulations that Impact Oversight of Human Research at UAMS

- UAMS IRB Policy 1.4 – Definitions and Determinations

- OHRP Guidance – The OHRP Guidance on Engagement gives several scenarios where an Institution is “engaged” in human subject research and several where an Institution would not be engaged. [http://www.hhs.gov/ohrp/policy/engage08.html](http://www.hhs.gov/ohrp/policy/engage08.html)

- If UAMS is minimally engaged in a project, UAMS retains oversight responsibility. However, in certain circumstances, the UAMS IRB may defer IRB review to an AAHRPP IRB.

- VA Handbook 1200.5(5)(e)(2) – “A VA facility’s own internal IRB cannot serve as an IRB of record for any non-VA entity except…”
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?
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?
Comparison of existing rules with some of the 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
Changes in UAMS Policy 16.1.13

- The Office of Research Compliance (ORC) is assuming oversight responsibility from the Office of Occupational Health and Safety (OHS)
- ORC staff will be conducting biannual inventories
- ORC staff will also be reviewing controlled substance records and drug expiration dates during the IACUC semi-annual facility inspections
- Revised policy will have up to date links and information
Changes in DEA Regulations and Practices

The DEA has begun conducting random, unannounced site visits for researchers licensed to use controlled substances

- They will review your records and security of your drugs
- They may ask questions about your license and your background
- Call ORC if you receive notice of a DEA site visit
Changes in Drug Disposal Procedures

- Contact UAMS Police Department to have unused or expired controlled substances surrendered to the Arkansas Department of Health (ADH)
- Complete ADH form PHA:DC-1 Report of Drugs Surrendered (obtained from ADH) and send with drugs
- Also complete DEA Form 41 and retain in records
Please contact us with any questions, if you need help, or if you have been notified of a DEA site visit:

Darri Scalzo, 686-8062, DLScalzo@uams.edu

Nancy Rhea, 686-6340, RheaNancyL@uams.edu
Opportunities for Philanthropy to Support Research
Lance Burchett, Vice Chancellor for Development and Alumni Affairs

- **Historical Perspective**
  - Over $48 million secured since 2000
  - Not including over $18 million processed by Office of Research and Sponsored Programs during Campaign Imagine
Opportunities for Philanthropy to Support Research

Lance Burchett, Vice Chancellor for Development and Alumni Affairs

- Private Funding vs Government Funding
  - Primary focus is on private funding
  - Occasionally participate in government funding
    - $3.1 million U.S. Department of Labor Grant for CON
Opportunities for Philanthropy to Support Research

Lance Burchett, Vice Chancellor for Development and Alumni Affairs

- **Fundraising Strategies**
  - Coordinated and strategic process
    - Involves Chancellor, Cabinet and UAMS Leadership
    - Based on priorities at UAMS
  - Bridge Fund
    - Supplement NIH cut-backs
    - 152 investigators lost to reduced funding
College/Institute Fundraising

- Support goals of each college/institute
  - Development officers focus on funding priorities
    - Example: RIOA $5.6 million research “quasi-endowment” fund
Central Office Fundraising

Stephen Schafer, Ph.D. – Director of Corporations and Foundations

- Matches faculty to foundations
- Participates in COM Magnet Meetings
- Vets and reviews foundations
Looking to the Future

- Vision 2020
- Preparing for next capital campaign
  - Research funding will be a key component
  - Committed to medical research
  - Look forward to collaboration
Next RESIN

- June 22, 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](http://www.uams.edu/research/RESIN_Achive.asp)