

UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES



Presented by: Office of the Vice Chancellor for Research
Date: February 3, 2015



Agenda

■ Updates & Timely Information from Research Support:

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



NIH Shared Instrumentation Grants Samuel Mackintosh, Ph.D., UAMS Proteomics Core Facility

■ NIH S10 Program

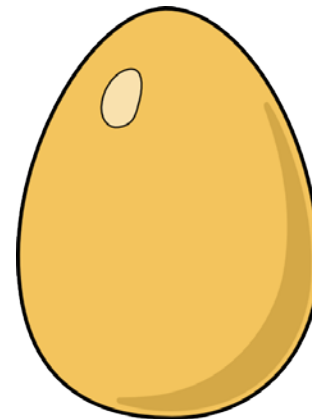
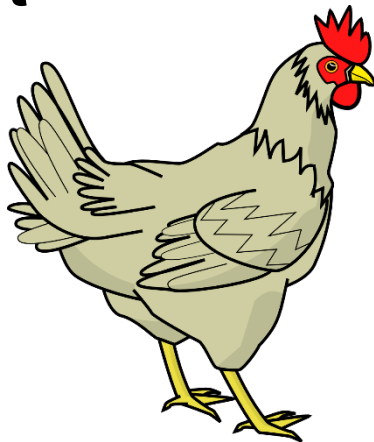
- Allows groups of NIH-supported investigators to purchase or upgrade specialized instrument systems
- Shared Instrument Grants
 - Maximum award is \$600,000
 - One funding opportunity per year
 - Next submission date is May 29, 2015
- High-End Instrument Grants
 - Maximum award is \$2,000,000
 - One funding opportunity every two years
 - Next submission date not yet announced
 - Last submission date was September 13, 2013



NIH Shared Instrumentation Grants

Samuel Mackintosh, Ph.D., UAMS
Proteomics Core Facility

- A major user group of three or more individuals must be identified
- Each major user must be the PI of an NIH R01, DP1, DP2, P01, P50, R37, or U01 grant





NIH Shared Instrumentation Grants Samuel Mackintosh, Ph.D., UAMS Proteomics Core Facility

■ S10OD018445: Orbitrap Fusion Tribrid Mass Spectrometer

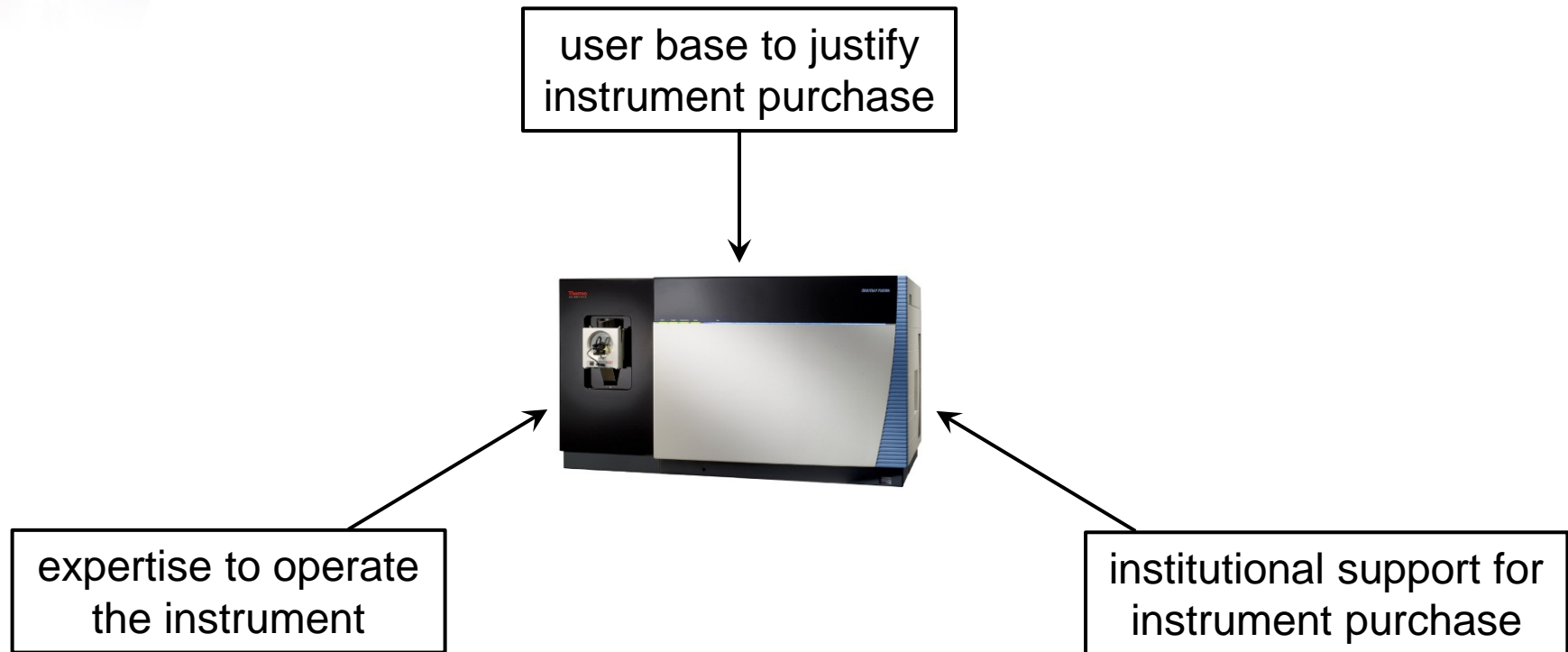


Major User	NIH Grant	Project Title
Alan Tackett, Ph.D.	R01GM106024	ChAP-MS to study chromatin composition
Kevin Raney, Ph.D.	R01GM098922	DNA helicase mechanism and function
Karen Abbott, Ph.D.	U01CA168870	Glycoproteomics of ovarian cancer
Tim Chambers, Ph.D.	R01CA109821	Bcl-2 proteins in anti-mitotic drug action
Mayumi Nakagawa, M.D.,Ph.D.	R01CA143130	HPV vaccine response
Jon Blevins, Ph.D.	R01AI087678	RpoS-mediated virulence in Borrelia
Roy Morello, Ph.D.	R01AR060823	Leprecan genes in skeletal formation



NIH Shared Instrumentation Grants Samuel Mackintosh, Ph.D., UAMS Proteomics Core Facility

■ Elements of a successful S10 application





NIH Shared Instrumentation Grants Samuel Mackintosh, Ph.D., UAMS Proteomics Core Facility

- **Core facilities well positioned to take advantage of the S10 mechanism**
- **UAMS Proteomics Core**
 - User base of ~50 labs
 - Older model of S10 instrument already in use
 - Specialized facility already in place
 - Experienced core staff
 - Established record of institutional support
 - Established financial plan for instrument support



NIH Shared Instrumentation Grants Samuel Mackintosh, Ph.D., UAMS Proteomics Core Facility

■ If you have questions contact:

■ Samuel Mackintosh, Ph.D.

Asst. Director, Proteomics Core Facility

Instructor, Dept. of Biochemistry and Molecular Biology

Experience writing S10 grant applications

■ Alan Tackett, Ph.D.

Director, Proteomics Core Facility

Professor, Dept. of Biochemistry and Molecular Biology

Experience serving on S10 study sections



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

Bill Gurley, Ph.D., IACUC Chair

■ Purpose of the IACUC

- Oversee animal welfare at UAMS
- Prevent any violations regarding animal welfare that might jeopardize animal research at UAMS



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

Bill Gurley, Ph.D., IACUC Chair

- **Foundational legislation for the IACUC**
 - Animal Welfare Act (AWA)
 - Covers all vertebrates except birds, mice, rats, farm animals, cold-blooded animals.
 - Public Health Service Policy on the Humane Care and Use of Laboratory Animals
 - Covers those vertebrate species used in research not covered by the AWA.
 - PHS policy for establishing an animal research program is set forth in the *Guide for the Care and Use of Laboratory Animals* (8th Ed.)



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- **UAMS has an Animal Welfare Assurance on file with the Public Health Service (#A3063-01)**
 - Assurance Statement describes our “Institutional Commitment”:
 - “UAMS will comply with all applicable provisions of the AWA and other Federal statutes and regulations relating to animals.”
 - “UAMS guided by the U.S. Government Principles for the *Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*”
 - “UAMS accepts responsibility for care and use of research animals and ensures individuals involved in animal care and use understand their individual and collective responsibilities with this Assurance...”
 - “UAMS will establish and maintain a program for activities involving animals according to the Guide for the Care and Use of Laboratory Animals.”
 - All performance sites and subcontracts have an Animal Welfare Assurance and all activities are IACUC approved.



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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■ UAMS Assurance states that the IACUC will:

- Review at least once every 6 months the institution's program for humane care and use of animals, using the Guide as a basis for evaluation...
- Inspect at least once every 6 months all of the institution's animals facilities including satellite and surgical suites, using the Guide as a basis for evaluation...
 - **UAMS IACUC inspections occur every April and October.**
- Prepare reports of IACUC evaluations according to PHS Policy IV.B.3 and submit to the Institutional Official (IO)
- Review concerns involving animal care and use at UAMS
- Make written recommendations to the IO regarding any aspect of the institution's program, facilities, or personnel training
- Review and approve, require modifications, or withhold approval of PHS-supported activities...
- Review and approve, require modifications, or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C (The Addendum Process)



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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■ The AUP Approval Process at UAMS

- AUPs due 1st Friday of every month; AUPs reviewed 3rd Friday of the month.
- AUPs are assigned to a primary and secondary reviewer on the IACUC.
 - AUPs are evaluated for clarity and animal welfare issues; science is not critiqued.
- 9 pairs of eyes will see your AUP: primary and secondary reviewers; veterinarian; IACUC statistician; IACUC librarian; two lay persons; compliance officer, IACUC chair.
- A verbal presentation of the AUP is presented to the IACUC by the primary and secondary reviewers along with their comments.
- Comments are then solicited from the reviewing veterinarian, statistician, librarian, and lay persons.
- Comments from the other IACUC members are then solicited.
- Following discussion, a recommendation for “full approval,” “revisions required,” or “tabling” is made by the primary reviewer.
- A second is obtained and a vote is taken.



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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- **The AUP approval process at UAMS** (cont.)
 - Investigators are notified via email of AUP approval status
 - 30 days to respond to revision requests or tabled protocols
 - Revisions undergo designated member review (DMR) while tabled protocols receive full committee review (FCR)
 - If revision requests are adequately addressed, DMR usually takes no more than one day. Turnaround time is dependent upon the PI.



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■ The AUP Approval process at UAMS

- “Revisions required” is the most common recommendation.
- The number of revisions and their detail is a function of the quality and completeness of the AUP.
 - Poorly written AUPs garner the most revision requests, or they may be tabled.
- Treat your AUP as you would a peer reviewed manuscript or grant proposal.
 - It is being reviewed as such – not for science, but for animal welfare issues.
- If your technicians, post-docs, or graduate students write your AUP, PROOFREAD IT!
- Do you allow your technicians, post-docs, or graduate students to write your manuscripts or grant proposals without proofreading them?
- 30 days to respond to revision requests or tabled protocols
- Revisions undergo DMR while tabled protocols receive FCR



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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■ UAMS IACUC Website

- WE HAVE ONE! (<http://iacuc.ad.uams.edu>)
- Guidelines and tips for writing an AUP provided
 - **Most importantly, view the AUP Checklist! A link is provided on the AUP.**
- Current AUP forms (UAMS and ACHRI) available on the website
 - **Beginning March 2015, AUPs submitted on the old forms will be returned and not reviewed.**
- AUP addendum request forms available on the website
- Useful links regarding various guidelines and policies provided
- **Tips for a Sensible Animal Number Justification** provided
 - PowerPoint: **How many animals? Sample Size Determination in Animal Studies**
- Link to the Guide for the Care and Use of Laboratory Animals (8th ed.)
- Other educational information for investigators available



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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- **UAMS Assurance states the IACUC will:**
 - Notify the investigators and institution in writing of its decision to approve or withhold approval of activities related to the care and use of animals.
 - Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review once every 3 years according to PHS Policy IV.C.1-5.
 - Annual review forms sent to investigators before each protocol reaches its 1st and 2nd anniversary date (regardless of species). This assures that any proposed changes to the protocol have been properly reviewed and approved...Triennial review requires a complete *de novo* review.
 - Authorizes IACUC to suspend an activity involving animals according to PHS Policy IV.C.6.



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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■ Why is ongoing review of animal activities necessary?

- Monitoring of animal care and use is required by the PHS Policy. The *Guide* ([p. 33](#)) describes methods for continuing review to include “continuing protocol review; laboratory inspections (conducted either during regular facilities inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments.”
 - **UAMS follows a self-reporting process for noncompliance items set forth by PHS.**
 - **USDA inspections are unannounced!**
 - Select AUPs are reviewed by USDA inspectors.
 - **AAALAC accreditation process occurs every 3 years.**
 - Select AUPs are also reviewed by AAALAC.



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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- **What is “continuing protocol review”?**
 - Continuing protocol review may consist of an annual update.
 - “Some institutions use the annual review as an opportunity for the investigator to submit proposed amendments for future procedures, to provide a description of any adverse or unanticipated events, and to provide updates on work progress.” ([Guide, p. 34](#))
 - The PHS Policy determines the maximum interval between IACUC review and approval as 3 years (i.e., a complete *de novo* review is required at least every 3 years). The review must encompass all of the criteria in the Policy at [IV.C.1.a-g](#). Animal work may not be administratively extended beyond the 3-year expiration date.



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- **Does the IACUC have authority over activities not supported by PHS?**
 - Institutions have discretion to subject animal activities to IACUC oversight regardless of the source of funding. This practice ensures uniform standards, appropriate oversight and accountability, and therefore is often in the best interest of the institution [and the animals].



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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- **Should institutions apply the PHS Policy to all animal activities regardless of the source of funding?**
 - There are many valid reasons for institutions to perform program oversight institution-wide using uniform and consistent standards for animal care and use. Likewise, it is generally impractical to separate activities based on the source of funding. Institutions must implement the PHS Policy for all PHS supported activities involving animals, and must ensure that any standards that might not be consistent with PHS Policy do not affect or pose risks to PHS supported activities.



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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- **Why is Post-approval Monitoring (PAM) necessary?**
 - “Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies...Post-approval monitoring consists of all types of protocol monitoring after the IACUC’s initial protocol approval ” (*Guide, p. 33*)
 - PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures. Methods include continuing protocol review; laboratory inspections; veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments.” (*Guide, p.34*)
 - “Regardless of the methods used or who conducts and coordinates the monitoring, PAM programs are more likely to succeed when the institution encourages educational partnership with investigators.” (*Guide, p.34*)



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■ What kind of training is necessary to comply with PHS Policy?

- The PHS Policy requires that institutions seeking an Assurance provide “a synopsis of training or instruction in the humane practice of animal care and use, as well as training or instruction in research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress, offered to scientists, animal technicians, and other personnel involved in animal care, treatment or use” ([IV.A.1.g.](#)); ...and that, “Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures” ([IV.C.1.f.](#)).



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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- **Why must we undergo CITI training for the IACUC?**
 - Short answer: It's the easiest, quickest, and most efficient training maintenance instrument. One hour every 3 years is not too burdensome.
- The need for training of animal researchers is also set forth in the 8th Edition of the *Guide for the Care and Use of Laboratory Animals* (the Guide).
- “All personnel involved with the care and use of animals must be adequately educated, trained, and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being....Institutions are responsible for providing appropriate resources to support personnel training, and the IACUC is responsible for providing oversight and for evaluating the effectiveness of the training program.” (*Guide*, p.15)



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

Bill Gurley, Ph.D., IACUC Chair

- **Why must we undergo CITI training for the IACUC?**
 - “Personnel caring for laboratory animals should also regularly engage in continuing education activities... On-the-job training, supplemented with institution-sponsored discussion and training programs and reference materials applicable to their jobs and the species in their care should be provided to each employee responsible for animal care.” (*Guide, p.16*)



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

Bill Gurley, Ph.D., IACUC Chair

- **Why must we undergo CITI training for the IACUC?**
 - Training should be tailored to the particular needs of research groups; “However, all research groups should receive training in animal care and use legislation, IACUC function, ethics of animal use and the concept of the Three Rs (Reduction, Refinement, Replacement), methods for reporting concerns about animal use, occupational health and safety issues pertaining to animal use, animal handling, aseptic surgical technique, anesthesia and analgesia, euthanasia, and other subjects as required by statute. Continuing education programs should be offered to reinforce training and provide updates that reflect changes in technology, legislation, and other relevant areas.” (*Guide*, p.16-17)



Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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- **Why must we undergo CITI training for the IACUC?**
 - “The institution should provide appropriate education and training to members of research teams – including principal investigators, study directors, research technicians, postdoctoral fellows, students, and visiting scientists – to ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the species used.” (*Guide*, p.16-17)



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- **OLAW** <http://grants.nih.gov/grants/olaw/olaw.htm>
- **IACUC** <http://iacuc.ad.uams.edu/>





Application of PHS Policy Across All Animal Research at UAMS & ACHRI

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- PHS Policy directly applies to research funded by all PHS Agencies, including NIH, CDC and FDA.
- Many other funding agencies require adherence to PHS Policy.
- UAMS and many other institutions, choose to apply PHS Policy to all animal research, regardless of funding source.
- PHS Policy, and the IACUC, exist to ensure the humane care and use of animals.



Fees for Use of Outside IRB

Jennifer Holland, JD

IRB Director

- Local Context Review Process
- Industry Sponsored Studies only
- Exceptions must be approved by the Vice Chancellor for Research



Development Enhancement Awards for Proposals (DEAP)

Jean McSweeney, Ph.D., Chair, UAMS Research Com.

- **New UAMS Intramural Funding Program - Development Enhancement Awards for Proposals (DEAP)**
- **Purpose**
 - To provide funds to address comments & needed revisions for all PIs who have received a score and comments on a NIH proposal, but did not receive funding.



Development Enhancement Awards for Proposals (DEAP)

Jean McSweeney, Ph.D., Chair, UAMS Research Com.

■ Who can apply?

- All new and established UAMS faculty members who have received a competitive score and comments on a NIH proposal (or other significant federal program) but did not receive funding
- Awards will be made to full-time UAMS faculty members and part-time (50%+) faculty members, (including VA appointments), who are at the rank of instructor or above



Development Enhancement Awards for Proposals (DEAP)

Jean McSweeney, Ph.D., Chair, UAMS Research Com.

■ DEAP Program Awards

- Awards of \$10,000 to \$25,000
- Funding is intended to assist investigators in conducting pilot studies and/or collecting additional data that directly responds to reviewers' comments and strengthens a resubmission
- Awards are strictly limited to supporting and strengthening a reapplication following receipt of a scored proposal.



Development Enhancement Awards for Proposals (DEAP)

Jean McSweeney, Ph.D., Chair, UAMS Research Com.

■ DEAP Program Awards (cont.)

- Awards will be for up to one year
- Reviewer comments and a plan for how they will be addressed is required
- Submission guidelines posted on Research website

http://research.uams.edu/files/2015/01/2014_DEAP_Grant_Program_final.pdf

- DEAP RFP now available



Showcase of Medical Discoveries – Rare Diseases

Linda Williams, Research Liaison, Office of Research

■ Showcase – Rare Diseases

- As designated by NIH Office for Rare Diseases
<http://rarediseases.info.nih.gov/>

- **February 18, 2015**

- 4:30 p.m. to 6:00 p.m.

- 10th floor Winthrop P. Rockefeller Cancer Institute

- Research reception and 12 poster presentations



UAMS Student Research Day

Linda Williams, Research Liaison, Office of Research

- **April 15, 2015** (COPH and IDW)
 - Abstract submission deadline - March 24, 2015
 - 132 abstracts submitted in 2014
 - 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**
 - 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

- **March 3, 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