UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

Research Support Information Network (RESIN)

Presented by: Office of the Vice Chancellor for Research

Date: May 2, 2017

Agenda

- **Updates & Timely Information from Research Support:**
  - Office of the VCR
    - RSC
    - IRB
    - IACUC
  - TRI
  - Biostatistics
    - BioVentures
  - Office of Compliance
    - SciCom
  - ORSP
    - ORRA
    - DLAM
    - OSPAN
    - Core Facilities
    - Biomedical Informatics

Mentor Training Workshop

Beatrice A. Boateng, PhD, TRI

- **Topics**
  - Maintaining effective communication
  - Aligning expectations
  - Assessing understanding
  - Addressing equity and inclusion
  - Fostering independence
  - Promoting professional development

Mentor Training Workshop

Beatrice A. Boateng, PhD, TRI

- **Mentor Training Workshop**
  - Date: Thursday, June 22nd, 2017
  - Time: 8:30 – 3:30 pm
  - Venue: 1190 Institute of Aging (IoA)
  - Registration open. See TRI Communications

Reporting Preprints and Other Interim Research Products

Suzanne Alstadt, DPA, CRA, Director, ORSP

- **Interim Research Products are complete, public research products that are not final**
  - Preprint: a complete and public draft of a scientific document. Preprints are typically unreviewed versions of peer-reviewed journal articles.
  - Preregistered protocol: public declaration of key elements of a research protocol in advance.

Reporting Preprints and Other Interim Research Products

Suzanne Alstadt, DPA, CRA, Director, ORSP

- **Citing Interim Research Products in Proposals and Progress Reports**
  - **Interim research products can be cited anywhere other products are listed:**
    - R&R Other Project Information Form, Bibliography & References Cited
    - R&R Senior/Key Person Profile (Expanded) Form, Biographical Sketch
    - PHS 398 Research Plan, Progress Report Publication List
    - PHS 398 Career Development Award Supplemental Form, Progress Report Publication List
    - PHS Fellowship Supplemental Form, Progress Report Publication List
    - RPPR, section C - Products

Reporting Preprints and Other Interim Research Products

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- **Citation should include:**
  - Digital Object Identifier (DOI)
  - Object type (preprint, protocol)
  - Information about the document version
  - Date the product was cited (if relevant)

- *Example*: Bar DZ, Atkatsh K, Tavarez U, Erdos MR, Gruenbaum Y, Collins FS. Biotinylation by antibody recognition- A novel method for proximity labeling. BioRxiv 069187 [**Preprint**]. August 11, 2016 [cited 2017 Jan 12]. Available from: https://**doi**.org/10.1101/069187.

Reporting Preprints and Other Interim Research Products

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- **To claim an interim research product as a product of an NIH award, the NIH expects that you will:**
  - Make the product publicly available. To maximize the impact of an interim research product, the NIH strongly encourages selecting a Creative Commons Attribution (CC-BY) license or dedicating work to the public domain.
  - **In the text of the document:**
    - Acknowledge NIH funding in accordance with NIH Grants Policy Statement Chapter 8.2.1
    - Clearly state that the work is not peer-reviewed
    - Declare any competing interests, as for any journal article

Reporting Preprints and Other Interim Research Products

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- Proposals for May 25, 2017 due date and after – interim research products can be listed on the progress report publication list.
- RPPRs submitted on or after May 25, 2017 – interim research products can be listed in the Products section.
- Please see NOT-OD-17-050 for additional information:

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-050.html

New Appendix Policy for NIH/AHRQ/NIOSH Applications

Suzanne Alstadt, DPA, CRA, Director, ORSP

Effective January 25, 2017
Allowable Appendix Materials

For applications proposing clinical trials (unless the funding opportunity announcement (FOA) provides other instructions for these materials):

- Clinical trial protocols
- Investigator's brochure from an Investigational New Drug (IND) application, as appropriate for the goals of the research proposed in the application.

For all applications:

- Blank informed consent/assent forms
- Blank surveys, questionnaires, and/or data collection instruments
- Other items only if they are specified in the FOA as allowable

New Appendix Policy for NIH/AHRQ/NIOSH Applications

Suzanne Alstadt, DPA, CRA, Director, ORSP

- **No other items are allowed in the Appendix.**
- Relocating disallowed materials to other parts of the application will result in a noncompliant application (NOT-OD-11-080).
- Applications submitted for due dates on or after January 25, 2017, will be withdrawn as noncompliant if they are submitted with Appendix materials that are not specifically listed in NOT-OD-16-129, NOT-OD-17-035 or specified in the individual FOA as allowed or required.
- For additional information: https://grants.nih.gov/grants/policy/appendix_policy.htm#5084

Avoiding Noncompliance in Animal Research

Darri Scalzo, Research Compliance Officer

Our Animal Care and Use Program is regulated in part by the PHS Policy on Humane Care and Use of Laboratory Animals, which can be found at https://grants.nih.gov/grants/olaw/references/phspol.htm

The NIH Office of Laboratory Animal Welfare, which has responsibility for the general administration and coordination of the PHS Policy, provides specific guidance, instruction, and materials to institutions that must comply with the Policy, including how to handle noncompliance.

Avoiding Noncompliance in Animal Research

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- Per the OLAW Guidance on Prompt Reporting to OLAW Under the PHS Policy on Humane Care and Use of Laboratory Animals at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html , Examples of reportable situations:
  - conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
  - conduct of animal-related activities without appropriate IACUC review and approval;
  - failure to adhere to IACUC-approved protocols;
  - Implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;

Avoiding Noncompliance in Animal Research

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- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;

Avoiding Noncompliance in Animal Research

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- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO 2);
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide* , or the institution's Animal Welfare Assurance.

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And per the OLAW Frequently Asked Questions at https://grants.nih.gov/grants/olaw/faqs.htm#592 :

B.9. May an IACUC suspend (stop) animal activities that it did not initially approve?

- Yes, the PHS Policy, Guide, and the USDA Animal Welfare Regulations presume that all ongoing animal activities have received the required prospective review and approval. An activity that has been undertaken without prior approval should be halted and subsequently reported to OLAW because it constitutes serious noncompliance.

Avoiding Noncompliance in Animal Research

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Also note that all personnel working with the animals must be listed on the IACUC-approved protocol.

- If you will be adding summer students in your lab, please submit an addendum to the IACUC to add them to your protocol.
- Yes, they must do the required training, but they may start the CITI training prior to their arrival on campus.

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Per a conference call with OLAW recently, the bottom line is that **nothing** can be done to or with an animal without IACUC approval.

- There does not have to be a welfare issue for work without IACUC approval to be reportable noncompliance.
- Number of animals does not matter.
- It does not matter if the procedure was non-invasive.
- Intent also does not matter.

Avoiding Noncompliance in Animal Research

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However, per the same OLAW Guidance on Prompt Reporting,

"The underlying foundation of the PHS Policy is one of institutional self-evaluation, self-monitoring and self-reporting. Public Law 99-158 (https://grants.nih.gov/grants/olaw/references/hrea1985.htm) requires that institutions be provided a reasonable opportunity to take corrective action before a grant or contract is suspended or terminated, and it is OLAW's role to assess whether the corrective actions reported by institutions under IV.F.3 are adequate. OLAW will assist the reporting institution in developing definitive corrective plans and schedules if necessary. Compliance actions affecting an award are rare because institutions are usually able to address incidents successfully and take appropriate actions to prevent recurrence."

Reporting noncompliance reflects the effectiveness of our animal care and use program!

Avoiding Noncompliance in Animal Research

Darri Scalzo, Research Compliance Officer

When we report noncompliance to OLAW, we do not use any individual names.

If the work is PHS-funded, we must include the grant number and notify the Program Officer. Again, the notification is intentionally vague and does not identify any individual by name.

Avoiding Noncompliance in Animal Research

Darri Scalzo, Research Compliance Officer

- Resources Available to Help You Avoid Noncompliance:
  - Training from DLAM or Compliance – you can contact us to request training tailored to your individual/lab needs
  - DLAM Training AUP – available to help you learn new techniques or procedures before submitting an AUP or an addendum. Contains most common procedures; others can be added easily if not already listed. You must contact DLAM to do work under their Training AUP.

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- VVC – Veterinary Verification and Consultation – available for changes in:
  1. Anesthesia, analgesia, sedation, experimental substances
  2. Euthanasia in accordance with AVMA Guidelines
  3. Duration, frequency, number, and variation of non-surgical procedures as long as no new procedures are being added
- VVC cannot be used for a change that would significantly increase animal pain or distress
- Changes eligible for VVC can be approved by the Vet(s). The Vet(s) may refer the request to Addendum Committee if more input is needed.
- Submit VVC request on the same form as an addendum request.

Avoiding Noncompliance in Animal Research

Darri Scalzo, Research Compliance Officer

IACUC Addendum Committee meets once a week to review and approve changes that are not eligible for VVC.

Submit an addendum request by Wednesday at noon for review on Friday.

Avoiding Noncompliance in Animal Research

Darri Scalzo, Research Compliance Officer

For other questions or issues (housing, husbandry, post-op care, etc.) consult with DLAM, the IACUC, or Research Compliance to explore available options.

We will help you do what you need to do without risking a noncompliance situation.

Avoiding Noncompliance in Animal Research

Darri Scalzo, Research Compliance Officer

Contact Information

DLAM

686-5255

IACUC Office

686-8542 (Kerrey)

686-6279 (Dr. Gurley)

Research Compliance

686-6340 (Kim)

686-8062 (Darri)

Development Enhancement Awards for Proposals (DEAP)

Paula Roberson, Ph.D., UAMS Research Committee

- **Purpose**

  To provide funds of up to $25,000 for up to 12 months for new and established faculty members (≥50% FTE) from all UAMS colleges **who have received a score** and comments from an unsuccessful proposal submitted to a federal agency or foundation which provides **full indirect costs** in order to address comments & strengthen reapplication.

Development Enhancement Awards for Proposals (DEAP)

Paula Roberson, Ph.D., UAMS Research Committee

- **DEAP Program Awards**
  - Funding is intended to assist investigators to conduct pilot studies and/or collect additional data to directly respond to reviewers' comments and increase competitiveness of revised application
  - Submission guidelines on Research website http://research.uams.edu/files/2015/11/2014_DEAP_Grant_Program_final_11-17.pdf

Development Enhancement Awards for Proposals (DEAP)

Paula Roberson, Ph.D., UAMS Research Committee

- **DEAP Awards Update**
  - Since February 2015, have made 9 awards to faculty in 3 UAMS colleges totaling $208,325
  - 3 of these have resulted in successful resubmissions so far

Showcase of Medical Discoveries – Inventors

Linda Williams, M.S., Research Liaison

- Showcase of Medical Discoveries – Inventors
- Tuesday, June 6, 2017
- 4:30 – 6:00 p.m.
- 10 posters
- 10th floor Winthrop P. Rockefeller Cancer Institute

Next RESIN

- **Next RESIN**
  - **June 6, 2017 @ 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