



SUNY
DOWNSTATE
Medical Center

SUNY Downstate Animal Research Updates

April 18, 2016 Town Hall Meeting



Agenda

- ▶ 2016 Personnel Changes
- ▶ Modification of IACUC Forms
- ▶ Transition to Annual Renewal forms for USDA-covered species only
- ▶ IACUC Amendment Processing
- ▶ IACUC Notifications
- ▶ IBC to IACUC protocol association
- ▶ Disaster Management Plan Revision
- ▶ Generation of Custom Antibodies
- ▶ Grant Updates from previous Town Hall
- ▶ Post-Approval Monitoring (PAM)



Personnel Changes

- ▶ Change in Institutional Official
 - As of January 1, 2016
 - Ms. Astra Bain–Dowell
 - Executive Vice President
 - Chief Operating Officer
 - Operations Manager

- ▶ Assistant Director, Office of Animal Welfare
 - Ms. Meagan Eastman, BS, LATG, CPIA
 - Meagan.Eastman@Downstate.edu
 - 718–330–5568



IACUC Forms

- ▶ **Modification of IACUC Forms:**
 - Annual Renewal – complete, available online
 - Do you wish to continue the project?
 - Brief summary of progress toward scientific goals
 - Unanticipated adverse events or animal death
 - Exception from social housing of social species
 - Exception from providing environmental enrichment
 - Protocol Template – in progress
 - Amendments – next
 - Reminder to submit necessary amendments for IACUC approval prior to initiating the new work, new personnel, etc.
- ▶ **Future transition to Annual Renewal forms for USDA–covered species only (RPM3.0)**



IACUC Amendments

- ▶ IACUC Amendment Review Process
 - No amendments will automatically be sent to Full Committee Review (FCR)
 - Amendments requiring IACUC review will be processed by Designated Member Review (DMR)
 - IACUC members are notified and the amendment is provided to them by email
 - Members have the opportunity to call for FCR
 - If no member requests FCR, the amendment is approved once the DMR comments (if any) are resolved



IACUC Notifications

- ▶ Additional Notifications will be sent for:

- ▶ Expiring Protocols – 3–year renewals
 - To prevent interruption of current work; renew prior to expiration and avoid having animals transferred to an approved protocol.
 - If animals are on site, specific items need to be addressed.
 - DCM holding protocol
 - short term use until protocol is approved
 - routine husbandry
 - breeding to maintain critical lines
 - Cannot use Federal funds for per diems

- ▶ Outstanding Training
 - New personnel amendments
 - New procedure amendments
 - IACUC Policy Subcommittee will be creating a Training Policy



IBC:IACUC Protocol

- ▶ **IBC to IACUC protocol association**
 - Can now amend existing IBC protocol to associate it with new IACUC protocols when appropriate
 - Details of agent/use are the same
 - Personnel are approved
 - Same species (exception – rats/mice can usually be associated with the same IBC protocol if the details of use are the same for each species)

- ▶ **Example – Paraformaldehyde (PFA) use in rodents**
 - If you have an approved IBC protocol describing the use of PFA in rats, you can submit an amendment to your IBC protocol to associated new IACUC protocols that include administration of PFA to rats or mice.
 - Personnel using PFA in animals on the IACUC protocol need to be approved on the IBC protocol.
 - A new IBC protocol is no longer needed.



Disaster Plan

- ▶ **Disaster Management Plan Revision**
 - DCM disaster plan revision to include more operational details
 - Identification of critical animals – recently identified as a program deficiency
 - Need PI input on the most efficient and effective mechanism to accomplish this
 - Working group volunteers



Custom Antibodies

- ▶ Generation of Custom Antibodies
- ▶ OLAW FAQ A2: <http://grants.nih.gov/grants/olaw/faqs.htm#587>
Does the PHS Policy apply to the production of custom antibodies or to the purchase of surgically modified animals?
 - Antibodies are considered customized if produced using antigen(s) provided by or at the request of the investigator (i.e., not purchased off-the-shelf).
 - The generation of custom antibodies is an activity involving vertebrate animals and covered by PHS Policy.



Custom Antibodies

- ▶ Generation of Custom Antibodies – FAQ continued
 - The vendor must have or obtain a PHS Assurance +/- a USDA registration when applicable
 - SUNY Downstate must provide verification of project-specific IACUC approval for the production of the antibodies
 - When both organizations hold Assurances, some latitude is allowed in determining which IACUC will review the proposal
 - SUNY Downstate always retains primary responsibility for ensuring compliance with PHS Policy



Custom Antibodies

- ▶ SUNY Process – Division of Pre-Award
 - Communicate with the PI at time of grant submission – "Will custom antibodies be purchased or produced as part of this work?"
 - If 'yes', Division of Pre-Award will forward the communications to IACUC@Downstate.edu
 - OAW will reach out and coordinate with the SUNY Downstate PI
 - this can occur after the grant is submitted
 - OAW will contact the vendor to obtain the necessary information and documentation.
 - Confirm current PHS Assurance, if applicable
 - Confirm current USDA Registration, if applicable
 - Confirm IACUC approval
 - Coordinate IACUC:IACUC MOU



Custom Antibodies

- ▶ SUNY Process – Division of Post–Award
 - If you need to purchase custom antibodies at any point after award, contact OAW to coordinate regulatory requirements before contacting the Division of Post–Award with a purchase requisition.
 - OAW will contact the vendor to obtain the necessary information and documentation.
 - Confirm current PHS Assurance, if applicable
 - Confirm current USDA Registration, if applicable
 - Confirm IACUC approval
 - Coordinate IACUC:IACUC MOU



Grant Updates

- ▶ Grant Updates from previous Town Hall:
 - Grant submission with/without IACUC approval date
 - Coordinate with OAW to determine what is needed for congruency based upon your specific situation
 - Change in scope
 - IACUC protocol & associated account information



Grant Submission

- ▶ Year 1 grant submissions –
 - If you have an approved IACUC protocol – the PI will provide the IACUC approval date they believe is appropriate for the grant.
 - If you do not have an approved IACUC protocol – the grant will be submitted with status of IACUC approval as ‘pending’
- ▶ The PI will coordinate with OAW to verify congruency.
- ▶ Having IACUC approval at time of submission does not impact your grant score or chances of being funded.
- ▶ The PI is the only recipient of the grant score. Pre-Award Division is not notified.

IACUC Protocol

- ▶ When to submit?
 - Before submitting the grant...
 - After submitting the grant, but before you receive any feedback...
 - After submitting the grant, but before you receive the score...
 - If your score is favorable...
 - ❖ Contact OAW to discuss what is needed for your specific situation before writing a new protocol.

Grant Congruency

- ▶ Change in Scope
 - The grantee must make the initial determination of the significance of the change and should consult with the Grants Management Officer of the NIH funding component as necessary.
 - Change in specific aims approved at the time of award
 - Substitution of one animal model for another
 - Change from the approved use of live vertebrate animals
 - Shift of the research emphasis from one disease area to another

- ▶ NIHGPS Part II: Subpart A:8.1.2.5

Grant Congruency

Change in Scope?

YES

PI, through the Authorized Organizational Representative (AOR), contacts NIH Grants Management Officer (GMO) to obtain approval of change

*grant congruency performed

NO

PI provides explanation that institution may file with congruency review

documentation

*grant congruency not performed



Post-Award Division

- ▶ Financial Compliance
- ▶ Expenditures are to be:
 - allocable,
 - accountable, and
 - appropriate.
- ▶ RPM3.0 will allow for the association of multiple accounts to a single protocol. This provides flexibility but also increased PI responsibility to ensure expenditures are appropriately allocated.
 - Future Town Hall to review this process in detail once RPM 3.0 is tested and available for use.
- ▶ Any association with a new account requires submission of a payment authorization form
- ▶ FYI – Cost transfers are only allowed for expenses incurred within the previous 90 days.



Post-Approval Monitoring

▶ Aims of PAM –

- Resource to the research community by disseminating information & answering questions
- Atmosphere for collegial dialogue & exchange of information between researchers & the IACUC
- Establish a relationship of advocacy between the laboratory, OAW, DCM, & the IACUC

▶ Aims – continued

- Acknowledge compliant laboratories on campus, resolving unintentional non-compliances, assisting laboratories with maintaining compliance with regulatory requirements & institutional policies, & assisting with protocol amendments as research projects evolve
- Facilitate PI work by helping to balance good science with good animal welfare
- Work to identify additional resources that may be needed to support unmet PI research needs



- ▶ Regulatory References for continuing review of activities
 - PHS Policy
 - USDA – Animal Welfare Act & Regulations
 - Guide for the Care and Use of Laboratory Animals
 - AAALAC, International FAQ
 - OLAW FAQ
- ▶ Provides flexibility for the process and mechanism of review
- ▶ Need a system for ensuring animal well-being, that personnel working with animals are appropriately trained & qualified, that animal procedures conform with the approved protocol, and provide an opportunity for refining procedures.



- ▶ Evolution of the SUNY Downstate PAM program
 - 2011 AAALACi site visit
 - Creation of IACUC PAM Subcommittee
 - 2 IACUC Faculty Members & DLAR Compliance Officer/Training Coordinator to more frequently monitor PI procedures & laboratories to assure compliance.
 - 2014 AAALACi site visit
 - Creation of a separate entity from DCM (currently has dual roles) to perform IACUC functions.
 - Creation of a separate entity to perform compliance functions for the IACUC.
 - 2015 – Creation of the Office of Animal Welfare
 - Primary functions – IACUC Administrative support & management, perform PAM



- ▶ Provide a level of protection to researchers from oversight agencies
- ▶ External & Internal Oversight of SUNY Downstate Animal Program
 - USDA – unannounced, at least annually
 - NYS DOH – unannounced, at least annually
 - OLAW – short-term notice, no required frequency
 - DEA – unannounced, no required frequency
 - AAALAC, International – planned, every 3 years
 - RF – annual financial audits



- ▶ Items of review by external & internal auditing agencies
 - Thorough review of research protocols & procedures
 - Observe & assess individual animals, their research use & their care
 - Assess the physical environment within DCM and laboratories where animals are housed and used
- ▶ Similar Focus for PAM visits
 - PI protocols & procedures
 - DCM animal husbandry procedures
 - DCM veterinary staff & involvement in PI procedures



- ▶ PAM Monitors will commonly include
 - OAW staff
 - IACUC Members
- ▶ PAM Frequency
 - Long Term Goals, based upon risk assessment
 - Once every 3 years
 - Non-USDA species, pain category C
 - Once annually
 - USDA species, pain category C
 - Non-USDA species, pain category D
 - Twice annually
 - USDA species, pain categories D & E
 - Non-USDA species, pain category E

- ▶ Types of PAM Visits
 - Formal PAM*
 - Not all procedures will reviewed/observed at each PAM
 - IACUC Semi-Annual Site Visit Follow-Up
 - Informal PAM
- ▶ Preparing for the visit
 - PAM Policy – Appendix A, Compliance Checklist
 - We will review the protocol, associated amendments, annual renewals, etc.
 - Can request a pre-IACUC site visit review

▶ IACUC Review

- Monthly review of PAM activities
- Semi-annual review of the PAM program
 - Evaluate effectiveness and appropriateness of the process
 - Review metrics to assess ongoing program needs
 - Identify program deficiencies, areas with unmet needs, and coordinate with the IO to develop a plan for correction

▶ PI Feedback

- Critical to IACUC evaluation and modification of the process
- Contact Dr. Dow-Edwards, Dr. Sharp, IACUC member