Office of Research Administration

Updates and Navigation of the SUNY Downstate Process

November 9, 2015 Town Hall Meeting
We want to help you navigate
Office of Research Administration

The Office of Research Administration (ORA) provides oversight and support for all elements of Downstate’s research infrastructure including the Pre-Award and Post-Award Divisions, the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), the Office of Animal Welfare, the Office of Technology Commercialization, the Institutional Biosafety Committee (IBC), Clinical Trials, and the Division of Comparative Medicine.

We provide all research-related academic and administrative support functions for the SUNY Downstate community through the Research Foundation for SUNY. We work closely with sponsors and we assist the faculty in the preparation, submission and administration of their sponsored research, training and public service program applications and awards.

Downstate Colleges and Schools
College of Medicine
College of Nursing
College of Health Related Professions
School of Graduate Studies
School of Public Health

Incubator & Biotech Park
SUNY Downstate Medical Center is in the midst of an exciting, borough-wide initiative to transform Brooklyn into a center for biotech research and development by providing affordable commercial biotechnology space, a nurturing environment and a readily available workforce.

Research Foundation
The RF provides essential sponsored program administration and innovation support services to SUNY faculty and students whose ideas and research generate ground-breaking discovery.
Animal Research Involves the following offices:
  ◦ Pre-Award Division
  ◦ Post-Award Division
  ◦ IACUC
  ◦ IBC
  ◦ DCM

We all work to facilitate your research endeavors in different ways.
Provide an update on the grant management and compliance system.

Provide clarification of the overall process.

Better understand what we need to accomplish the process as a team – PI, Pre & Post–Award Division, IACUC, OAW, IBC, DCM.

Efforts to Reduce Regulatory Burden
- Revised Vertebrate Animal Section (VAS) for submissions to NIH
- Improve efficiency by submitting IACUC protocols for projects that receive a favorable score.
- Perform grant congruency only when required.
- Working to transition the requirement for the Annual Review to USDA–species protocols only.

Protect the PI by ensuring financial compliance once funds are awarded.
RF purchased a grant management and compliance system with 6 modules.
The expectation is that there will be module integration within the system.
All 32 campuses are working together to harmonize processes for implementation.
More information will become available as the process moves forward.
Process Overview

Pre–Award

Submit Grant
Favorable Score?
Submit IACUC Protocol
OAW Pre–Review
AV Consultation
Submit IBC Protocol

Submit Just–In–Time
Requires Grant Congruency

Notice of Award

Post–Award

Submit Payment Auth. Form
DCM
Submit SUNY/RF Award Account Created

Submit Grant
Process Overview

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DCM
Revised Vertebrate Animal Section (VAS) for Grant Submissions to the NIH

Anticipated Implementation Dates
- All but Fellowship/Training Grants: 1/25/16
- All Types: 3/25/16

NOT-OD-16-006: Summary of Changes
- A description of veterinary care is no longer required.
- Justification for the number of animals has been eliminated.
- A description of the method of euthanasia is required only if the method is not consistent with AVMA guidelines.
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.
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DCM
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.

- IACUC Review & Approval
  - OAW Pre-Review
  - AV Consultation – protocols with category D/E
  - IACUC Full Committee Review
Release of IACUC Approval is tied to IBC Approval of the following items:

- Use/Creation of Non-exempt Transgenic Animals
- Administration of the following to animals:
  - Radioisotopes/Ionizing Radiation
  - Infectious Agents
  - Recombinant DNA
  - Toxic/Hazardous Substances
Revised JIT Business Processes: “Beginning April 20, 2012, applications receiving an impact score of 40 or less will receive a standard notice and request for submitting JIT information. This level reflects NIH’s new Impact Scoring system and current tightened paylines, though it does not reflect any individual IC’s payline.”

NIH, NSF, HRSA, AHRQ funded research

JIT email notification is sent to the PI +/- Pre-Award Division depending on the funding source.

At notice of JIT, PI needs to notify the IACUC & provide grant information to perform grant congruency.

You have at least 45 days to submit, but funding Institute requests may vary.
Grant Congruency

- What is it?
- Why is it needed?
- How is it accomplished?
- Why should it be separate from the IACUC protocol review & approval process?
What is it?
- A state of agreement between the research described in the grant and the associated IACUC protocol(s).
- Species, experimental design, procedures, etc.

Why is it needed?
- Contractual obligations
  - Institution with the NIH to meet the terms of the Grants Policy Statement (Part II, Terms & Conditions)
  - PI with the Institution to meet the requirements of PHS Policy
- Financial Compliance – Ensures that the research to be funded is congruent with IACUC approved protocols.
Responsibility

- **Institution – Prior to award:**
  - Must ensure that the information the IACUC reviews and approves is congruent with what is in the grant application/proposal.
  - When the Institution provides the IACUC approval date, the funding agency considers this verification of congruency.

- **PI and Institution:**
  - To notify NIH of any IACUC required modifications
  - To notify NIH of any changes in scope after award
  - PI – to notify the IACUC of changes in scope as a result of NIH review
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*
How is it accomplished?

One-way comparison
- What is in the grant, needs to be in the protocol.
- The protocol can contain additional work such as pilot studies.

PI receives JIT notification

PI contacts IACUC@Downstate.edu with
- Grant Information –
  - PI
  - Title
  - Grant #
  - Documents: Specific Aims, VAS, possibly others
- Protocol Information –
  - PI
  - Title
  - Protocol #
Grant Congruency

- How is it accomplished? – continued...
- OAW will perform the congruency review between the identified grant and protocol(s) within 3 business days.

- If congruent:
  - A congruency letter is created and emailed to the PI and the Pre–Award Division.
  - Approval date of the associated protocol is submitted with JIT.
  - Any IACUC modifications that were required to secure approval also will be detailed in the letter.
CONGRUENCY REVIEW

IACUC Protocol Information:
Principal Investigator
Protocol Number
Protocol Title
IACUC Approval Dates
  - Initial
  - Annual Review #1
  - Annual Review #2

Funding Source Information:
Principal Investigator
Funding Source
Grant Number
Grant Title

The above referenced documents were reviewed and found to be congruent on <<INSERT DATE OF REVIEW>>.

<<IF NEEDED>> The IACUC required the following modifications to the protocol, which differ from what is described in the grant:

* Federally funded projects require that congruency be confirmed prior to award and with any subsequent changes in scope.
* Changes in scope:
  - Change in the direction, type of research or training from the aims, objectives, or methods of the project as specified in the proposal or grant application or letter of intent.
How is it accomplished? – continued…

If not congruent:

◦ OAW will communicate the details to the PI.
◦ Depending on the details –
  • A separate protocol may be needed (for a different species).
  • A protocol amendment may be needed to address the non-congruent item(s).
  • An explanation may be sufficient if, for example, subsequent procedures will be based upon initial results.
How is it accomplished? – continued...

Once the details are resolved, making the grant and protocol(s) congruent:

- A congruency letter is created and emailed to the PI and the Pre-Award Division.
- Approval date of the associated protocol is submitted with JIT.
- Any IACUC modifications that were required to secure approval also will be detailed in the letter.
- Any explanations also will be detailed in the letter.
Why should it separate from the IACUC protocol review & approval process?
- Grant and protocol review cycles are not always in sync.
  - 3-year renewal of protocol: non-competing grant renewal
  - Currently approved protocol: competing grant renewal – this requires a congruency review with the new grant submission.
- Funding sources change when grants close/expire.
- Funding sources change when new funding is obtained – e.g., departmental support to grant funds.
- Will capture changes in scope that occur independent of the IACUC protocol review cycle.

Downstate’s revised process will be independent of IACUC protocol submission and review to facilitate the overall of the process.
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Post–Award

DCM
Pre-Award Division
- Reviews compliance requirements (e.g., IACUC approval, COI)
- Issues institutional approval to RF Central (RFC) to create the award and account # for receipt of funds.

RFC communicates the account # to Pre/Post-Award
Pre/Post-Award communicate the account # to the PI.
Award numbers are also available to PIs in Oracle.
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- Submit Grant
PI completes and submits the Payment Authorization Form to communicate the award # to the IACUC & DCM.

What do you do when an award expires?

- Complete a new Payment Authorization Form & submit to the IACUC & DCM for subsequent charges related to animal research.
- Post–Award Division meets with your Departmental Grant Manager to capture all expenditures for the award before it is closed.
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.
DCM is currently the only “specialized service facility” (SSF) on the Downstate College of Medicine campus.

A SSF is defined by the Federal Government as an operating unit established for the primary purpose of providing complex or specialized service to a select group of users (the educational and research community) rather than the general campus community.

DCM is subject to the terms and conditions of Federal OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements (2 CFR 200), Section 200.468.
The Division of Comparative Medicine (DCM)

DCM Service Center [http://www.rfsuny.org/Information-For/Service-Centers/](http://www.rfsuny.org/Information-For/Service-Centers/)

Division of Comparative Medicine

Forms - Internet Explorer is the only browser that is compatible with the fillable pdf forms
(the Google browser will not provide form functionality)

- Policy Regarding Eligibility to Use the DCM Facility (2/18/2014 & 5/12/2014)
- Animal Disposition (pdf)
- Import Rodents from Non-commercial Vendor (pdf)
- Order Animals and Fillable Research Foundation Purchase Requisition Form (pdf)
- Transfer Animals to Another Protocol (pdf)
- Request Shipment of Mice to Another Institution (pdf)

Please note that all forms must be downloaded and saved to your computer before completing; otherwise you will not be able to save the information entered onto the form.
DCM operates in accordance with cost principles of the OMB Uniform Administrative Requirements, Section 200.468 (2 CFR 200) which states:

- "The costs of such services, when material, must be charged directly to applicable awards based on actual usage of the services on the basis of a schedule of rates or established methodology."
RPM (Colibri Solutions LLC) – why it’s use is important

- Designed to be compliant with U.S. Federal Government guidance on how to operate service centers
  - **Cost Analysis and Rate Setting for Animal Care Facilities**
    Provided by The National Center for Research Resources (NCRR) at the National Institutes of Health (NIH).

- AAALAC accreditation 2008 required Downstate to implement computerized protocol and animal use tracking records

- Campus service centers have come under increased scrutiny in Federal audits. RF Central conducts enhanced monitoring.
RPM (Colibri Solutions LLC) – why it’s use is important

- Designed to be compliant with U.S. Federal Government guidance on how to operate service centers
  - Tracks all SSF charges incurred directly to individual protocols and linked award:
    - animal purchases, per diem and technical charges, and drug/supply purchases
  - Tracks all DCM expenses for annual cost analysis
- Provides fully integrated and real time info to PIs 24/7
- Breeding tracking software available to PIs –no charge
- Electronic animal ordering and technical services requests
- Wireless use to be implemented in facility
- RF Central and AAALAC accreditation – robust reviews: RPM provides detailed, thorough and transparent financial compliance
Division of Comparative Medicine
The mission of the Division of Comparative Medicine (DCM), with the oversight of the Institutional Animal Care and Use Committee, is to promote excellence in all animal research and teaching at SUNY Downstate Medical Center (DMC) while promoting the highest standards of ethical and responsible use of animals.

The Division has professional, technical and office personnel to carry out the animal care program in accordance with the standards established by the NYS Department of Health, the US Public Health Service, the US Department of Agriculture and the Association for Assessment and Accreditation of Laboratory Animal Care International.
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DCM
Who To Contact

- Pre & Post-Award Division
## Who To Contact

### Pre–Award Division
- [http://research.downstate.edu/resources/assignments.html](http://research.downstate.edu/resources/assignments.html)
- researchgrants@downstate.edu
- Ms. Sharon Levine–Sealy, Director

### Post–Award Division
- [http://research.downstate.edu/resources/assignments.html](http://research.downstate.edu/resources/assignments.html)
  - Mr. Elliot Feder, Director

### IACUC
- IACUC@Downstate.edu
  - Dr. Diana Dow–Edwards, IACUC Chair
  - Dr. Julie Sharp, OAW Director
  - Ms. Lydia Bailey, IACUC Coordinator

### IBC
- IBC@Downstate.edu
  - Dr. Haseeb Siddiqi, IBC Chair
  - Ms. Lydia Bailey, IBC Coordinator

### Grant Congruency
- IACUC@Downstate.edu

### DCM
- RPM access/questions – Ms. Rachel Bryson or RPM@downstate.edu
- Payment authorization/award updates and invoices – Mr. Ron Cohen
- Dr. Carol Novotney, Director
Downstate Internal Policies

Below are a set of research-related policies approved by Downstate’s Advisory Council for Research.

- Cost Sharing Policy »
- Conflicts of Interest Policy »
- Direct Costing Policy »
- Effort Reporting Policy »
- Institutional Base Salary Policy »
- Scientific Misconduct Policy
- Service Center Policy »
Vertebrate Animal Section

- NOT-OD-16-006
- VAS webpage
  http://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm
IACUC & IBC Approval

- NOT-OD-11-053

Grant Congruency

The relevant sections/specific links will be included in an email attachment for future reference.

- NIH Grants Policy Statement (Part II Terms & Conditions)
- PHS Policy
- OLAW – FAQs D10, B13, D20
- OLAW – Grants Policy & Congruency, 2012 Webinar
Authorized Payment Form:
http://research.downstate.edu/_pdf/iacuc/PaymentAuthorizationForm.pdf
Questions?