

Office of Research Administration

Updates and Navigation of the
SUNY Downstate Process

November 9, 2015 Town Hall Meeting



We want to help you navigate





SUNY
DOWNSTATE
Medical Center

Office of Research Administration

[ORA](#) [Administration](#) [Compliance](#) [Funding](#) [Policies](#) [Resources](#) [Search](#) [Home](#)

Research at SUNY Downstate
A partnership for advancing science and health care for all.

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 programs administration and innovation support services to SUNY faculty and students whose ideas and research generate ground-breaking discovery.

[More »](#)

research.downstate.edu/index.html#researchCarousel

Office of Research Administration

- ▶ 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.

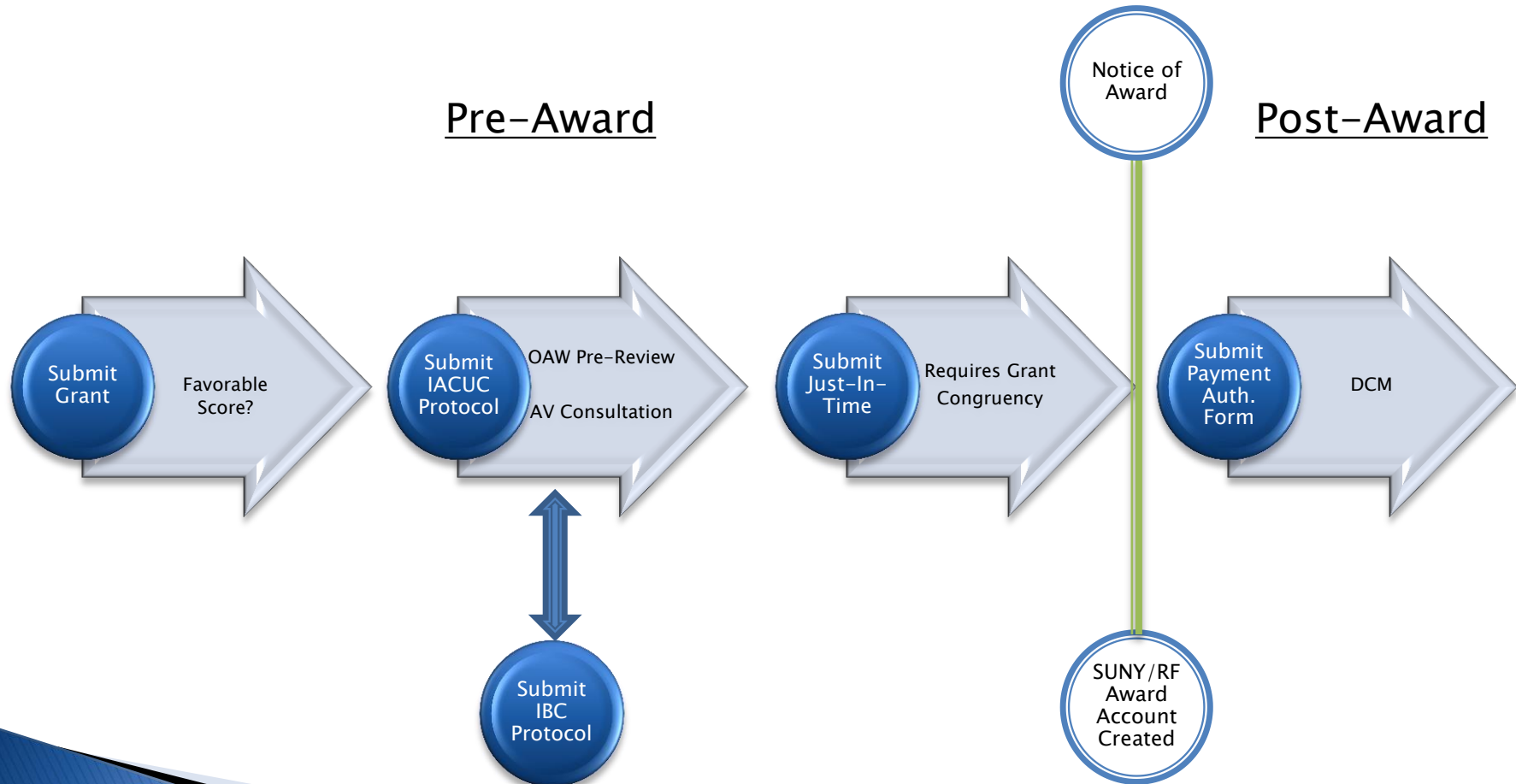
Goals

- ▶ 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.

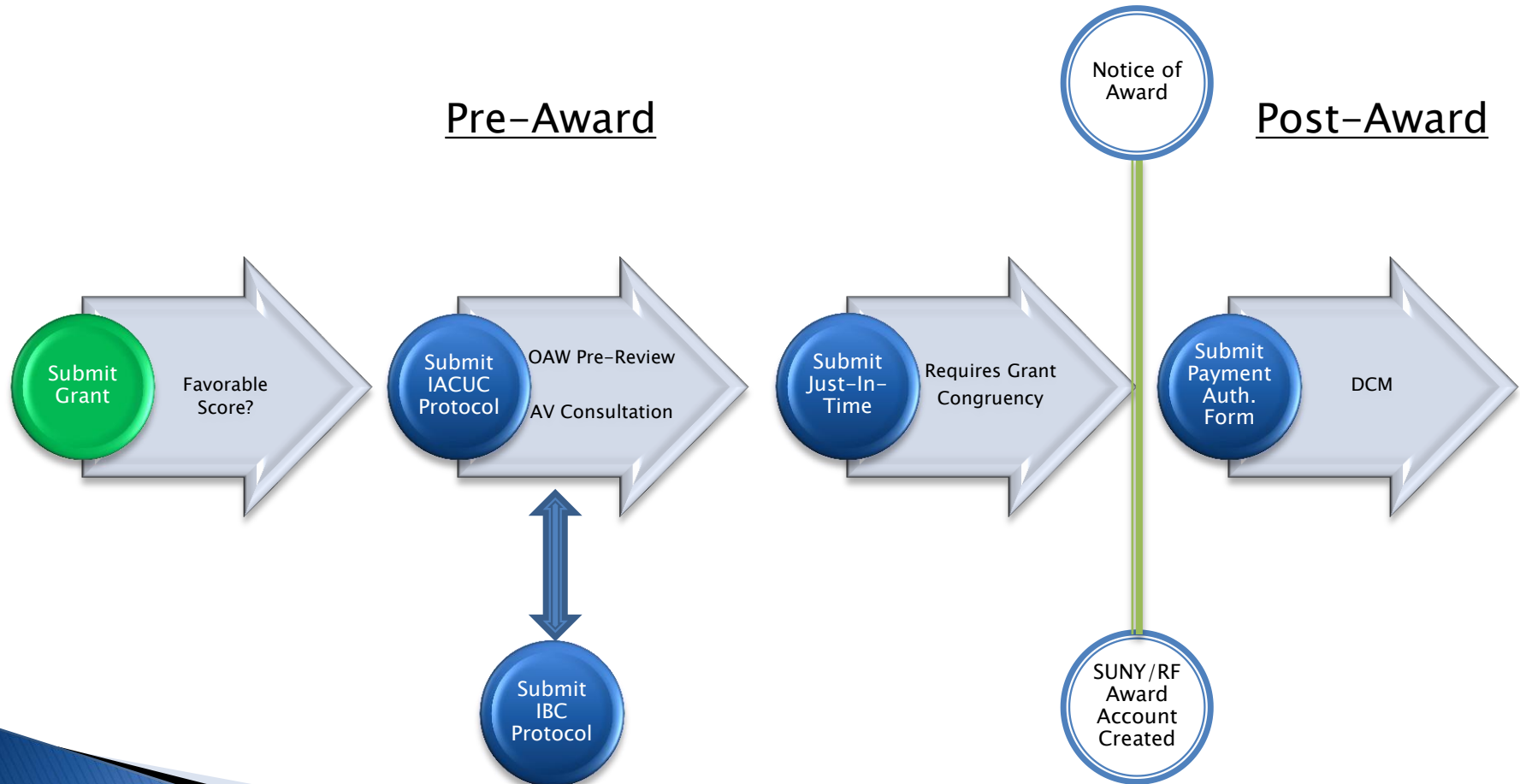
Quick Update

- ▶ 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



Process Overview



Grant Submission

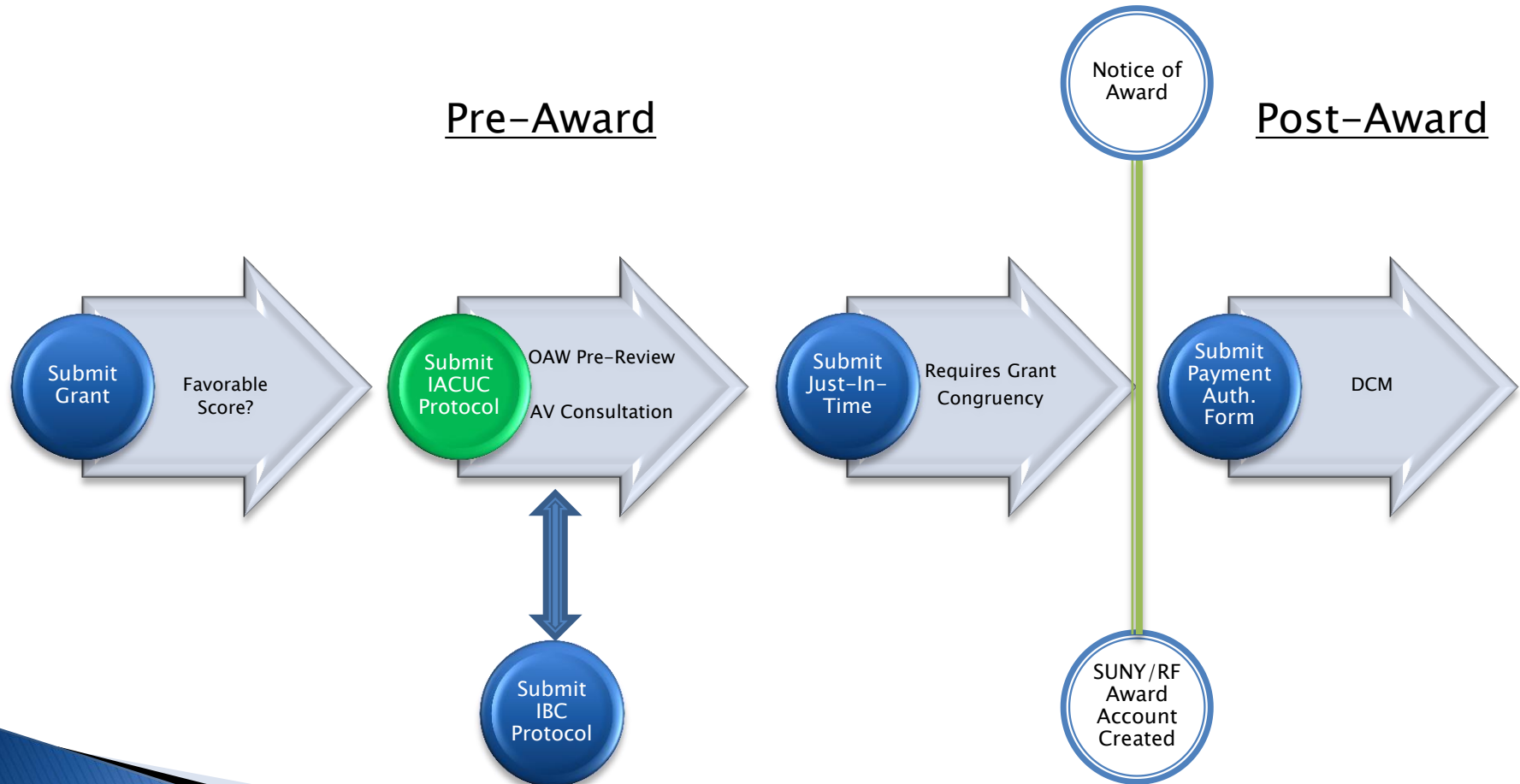
- ▶ Revised Vertebrate Animal Section (VAS) for Grant Submissions to the NIH
- ▶ Anticipated Implementation Dates
 - All but Fellowship/Training Grants: 1/25/16
 - All Types: 3/25/16
- ▶ NOT-OD-16-006: **Summary of Changes**
 - A description of veterinary care is no longer required.
 - Justification 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.



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.

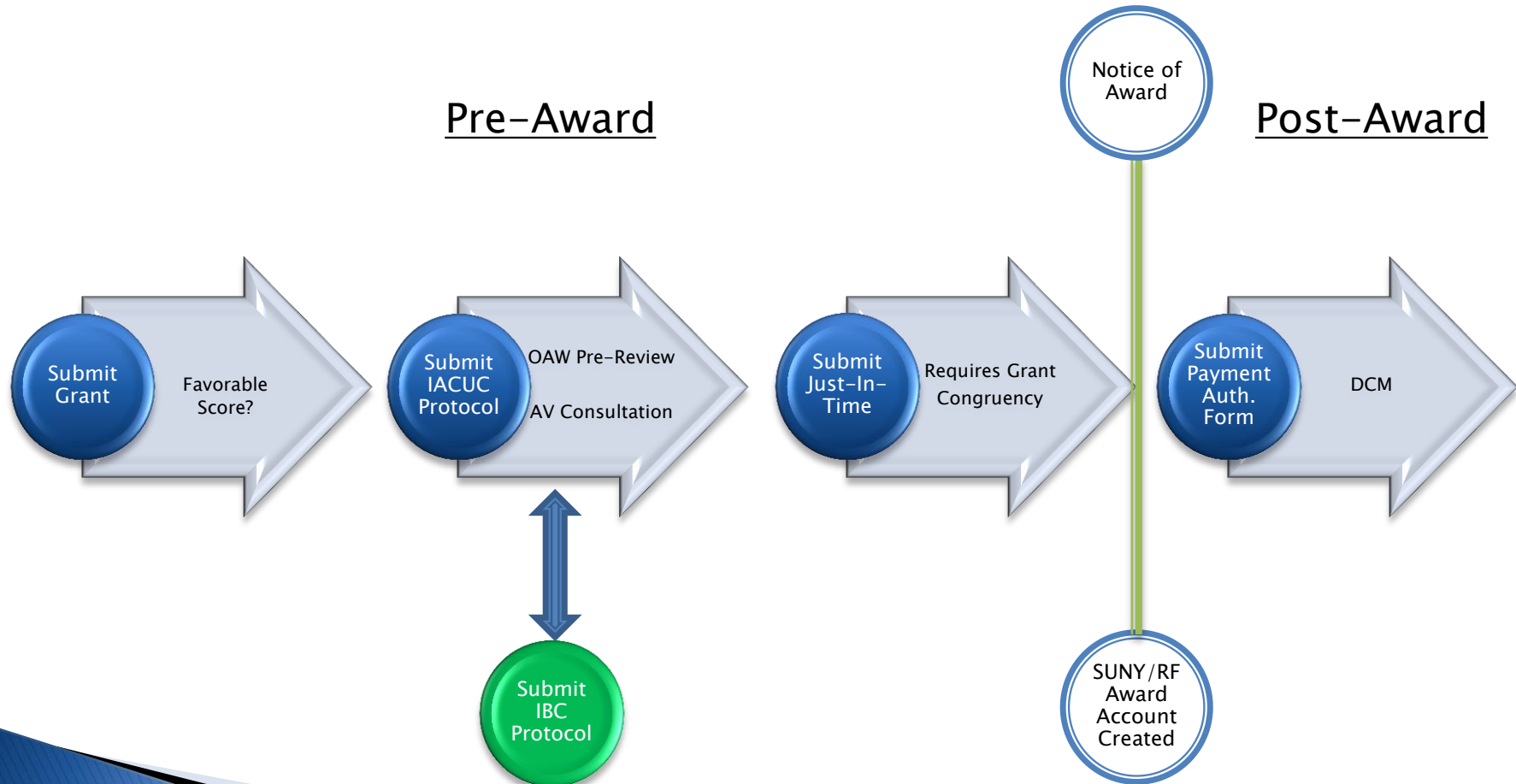
Process Overview



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

Process Overview

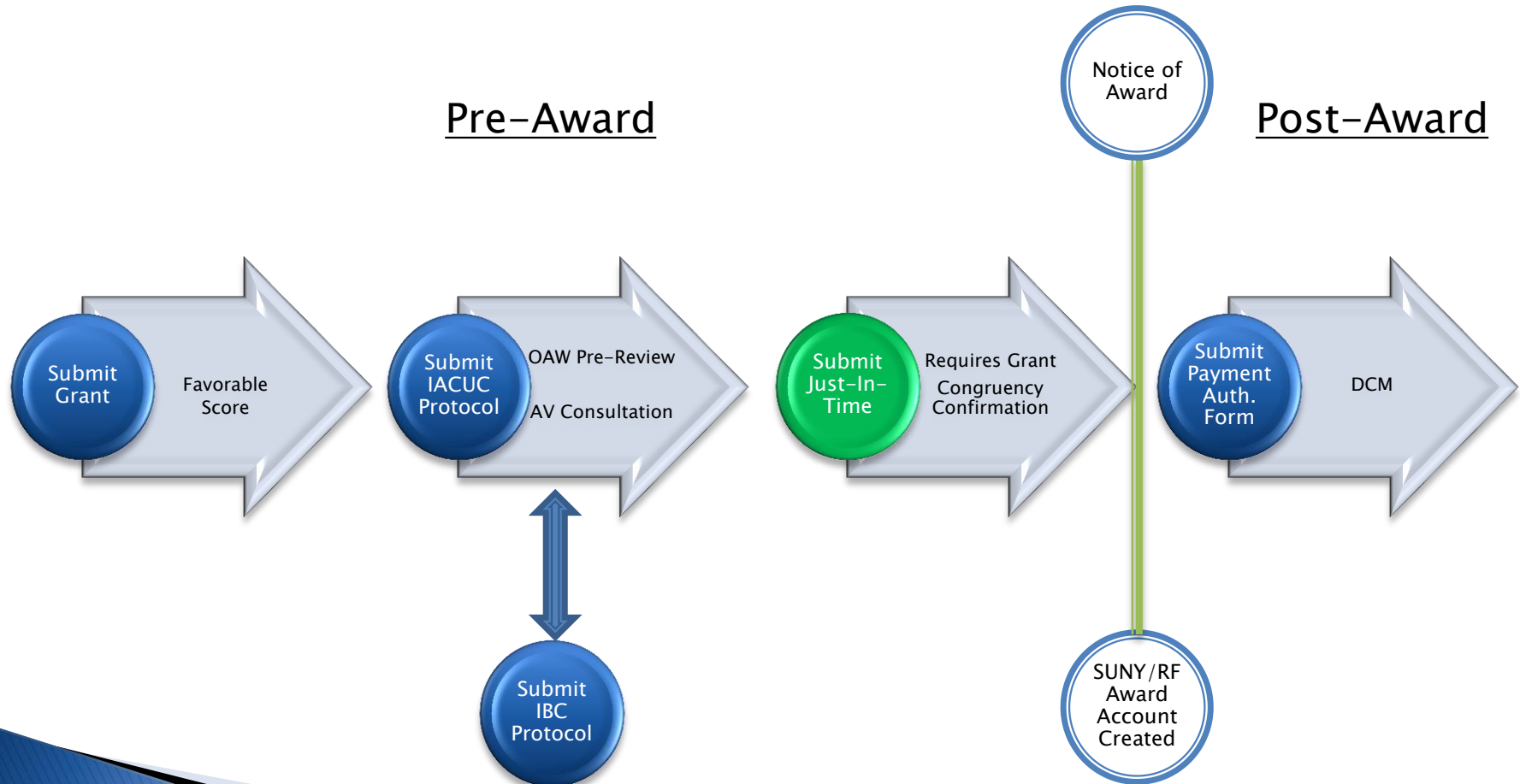


IBC Triggers

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

Process Overview





Just-In-Time (JIT)

- ▶ NOT-OD-12-101
 - **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?

Grant Congruency

▶ 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.

Grant Congruency

▶ 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

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

Grant Congruency

- ▶ 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.

Grant Congruency

▶ Sample Congruency Letter



Office of Animal Welfare
IACUC@Downstate.edu
office 718-270-4645

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

Grant Congruency

- ▶ 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.

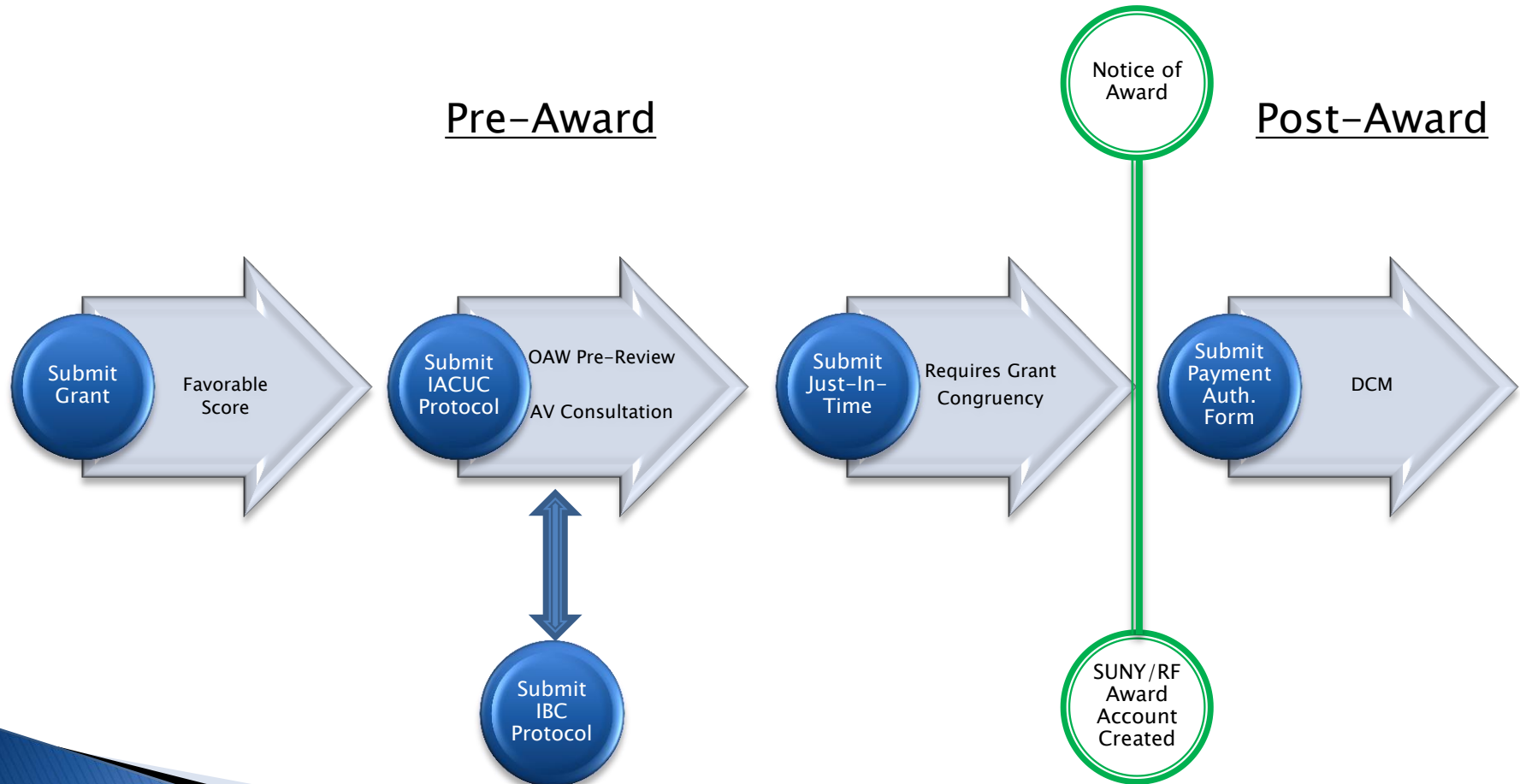
Grant Congruency

- ▶ 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.

Grant Congruency

- ▶ 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.

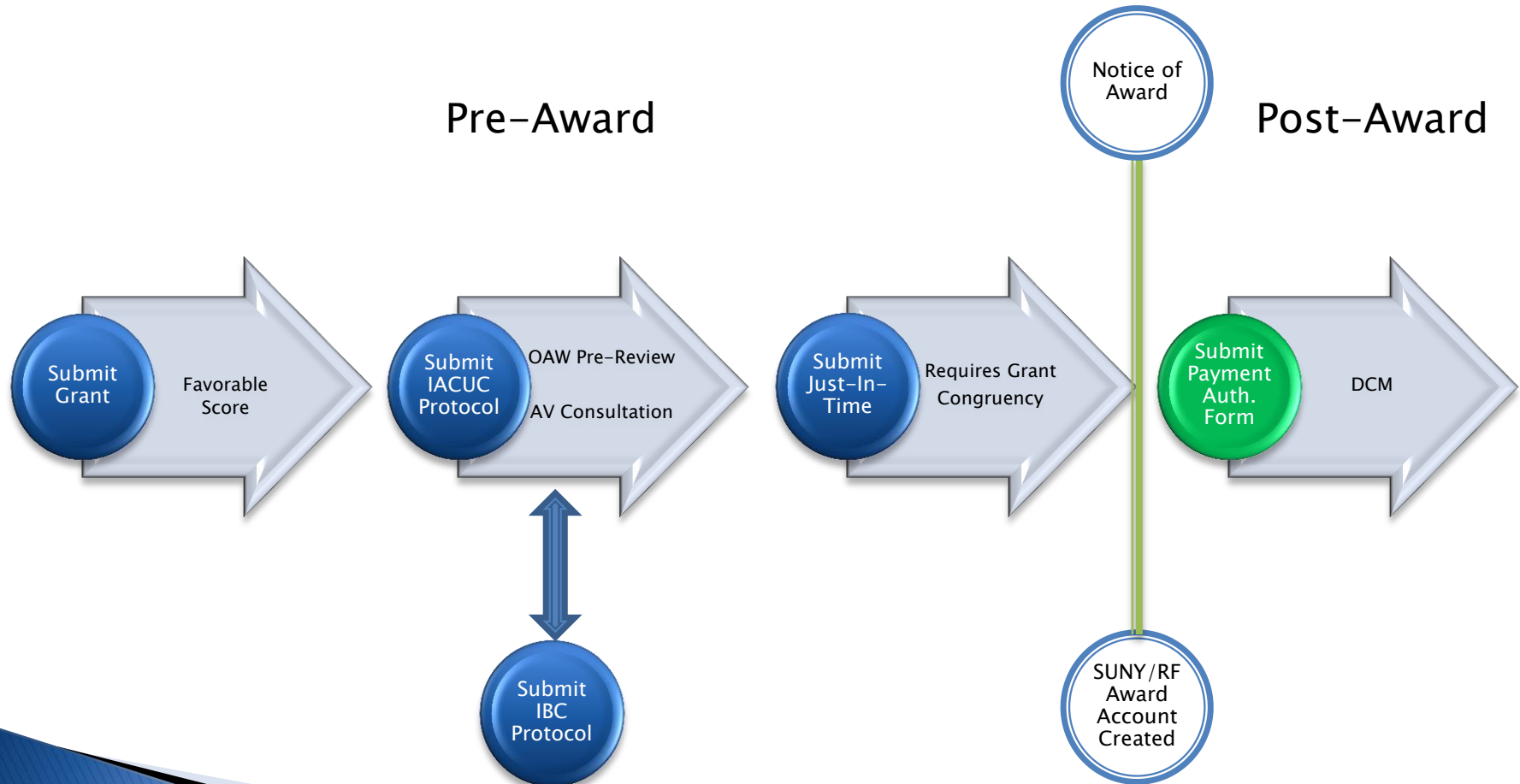
Process Overview



Award & Account # Creation

- ▶ 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.

Process Overview



Payment Authorization Form

- ▶ 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.



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.

The Division of Comparative Medicine (DCM)

- ▶ 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.



SUNY
DOWNSTATE
Medical Center

The Division of Comparative Medicine (DCM)

DCM Service Center <http://www.rfsuny.org/Information-For/Service-Centers/>

The screenshot shows a web browser window with the address bar displaying research.downstate.edu/dcm/comparative-medicine-forms.html. The page header includes the SUNY Downstate Medical Center logo and the SUNY RF (The Research Foundation for The State University of New York) logo. A navigation bar contains links for ORA, Administration, Compliance, Funding, Policies, and Resources. Below the navigation bar is a breadcrumb trail: Home / Administration / Comparative Medicine / Forms.

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 menu

- Home
- FAQs
- Per Diem Rates
- Forms**
- Helpful Links

Institutional Animal Care and Use Committee

The bottom of the screenshot shows a Windows taskbar with various application icons and a system clock indicating 10:51 AM on 11/9/2015.



The Division of Comparative Medicine (DCM)

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."

The Division of Comparative Medicine (DCM)

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.

The Division of Comparative Medicine (DCM)

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



SUNY
DOWNSTATE
Medical Center

The Division of Comparative Medicine (DCM)

The screenshot shows a web browser window with the address bar displaying `research.downstate.edu/dcm/comparative-medicine.html`. The page header features the SUNY Downstate Medical Center logo and the SUNY Research Foundation logo. A navigation bar includes links for ORA, Administration, Compliance, Funding, Policies, and Resources. Below the header, a breadcrumb trail reads: [Home](#) / [Administration](#) / [Comparative Medicine](#).

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.

DCM menu

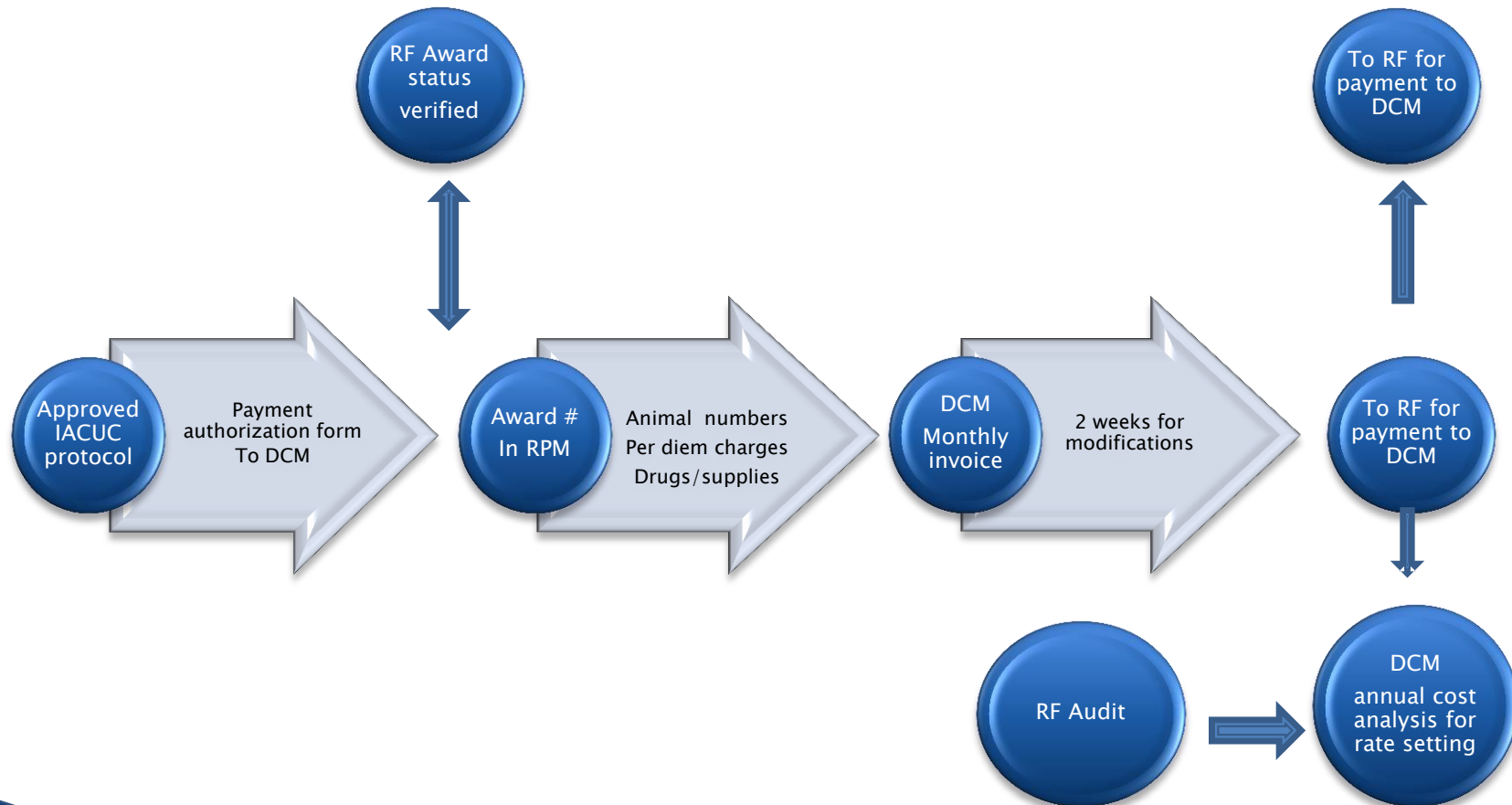
- Home
- FAQs
- Per Diem Rates
- Forms
- Helpful Links
- Institutional Animal Care and Use Committee

A blue arrow points to the "Per Diem Rates" link in the DCM menu.

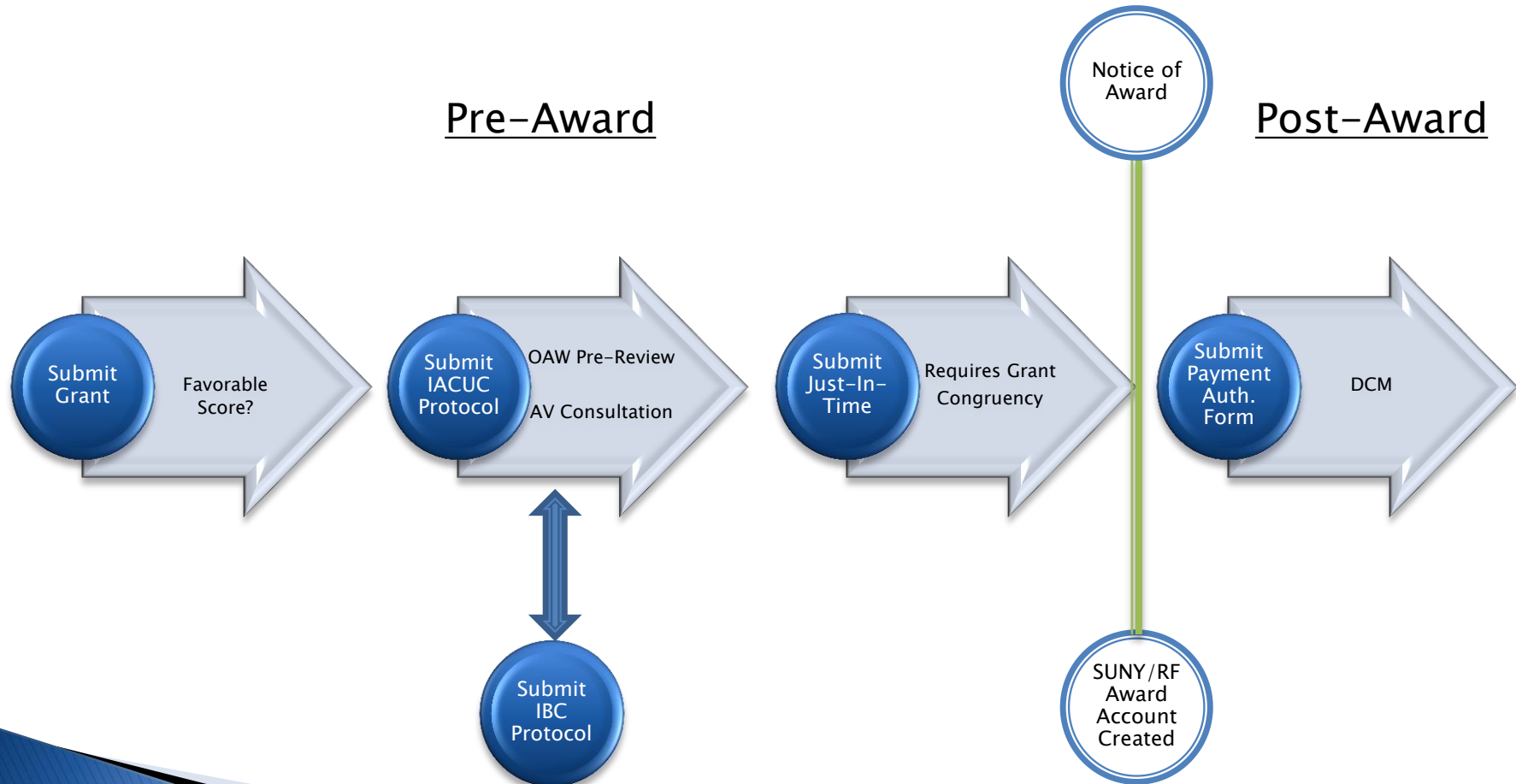
The Windows taskbar at the bottom shows various application icons and the system clock indicating 8:45 PM on 11/8/2015.



DCM Business Process Overview

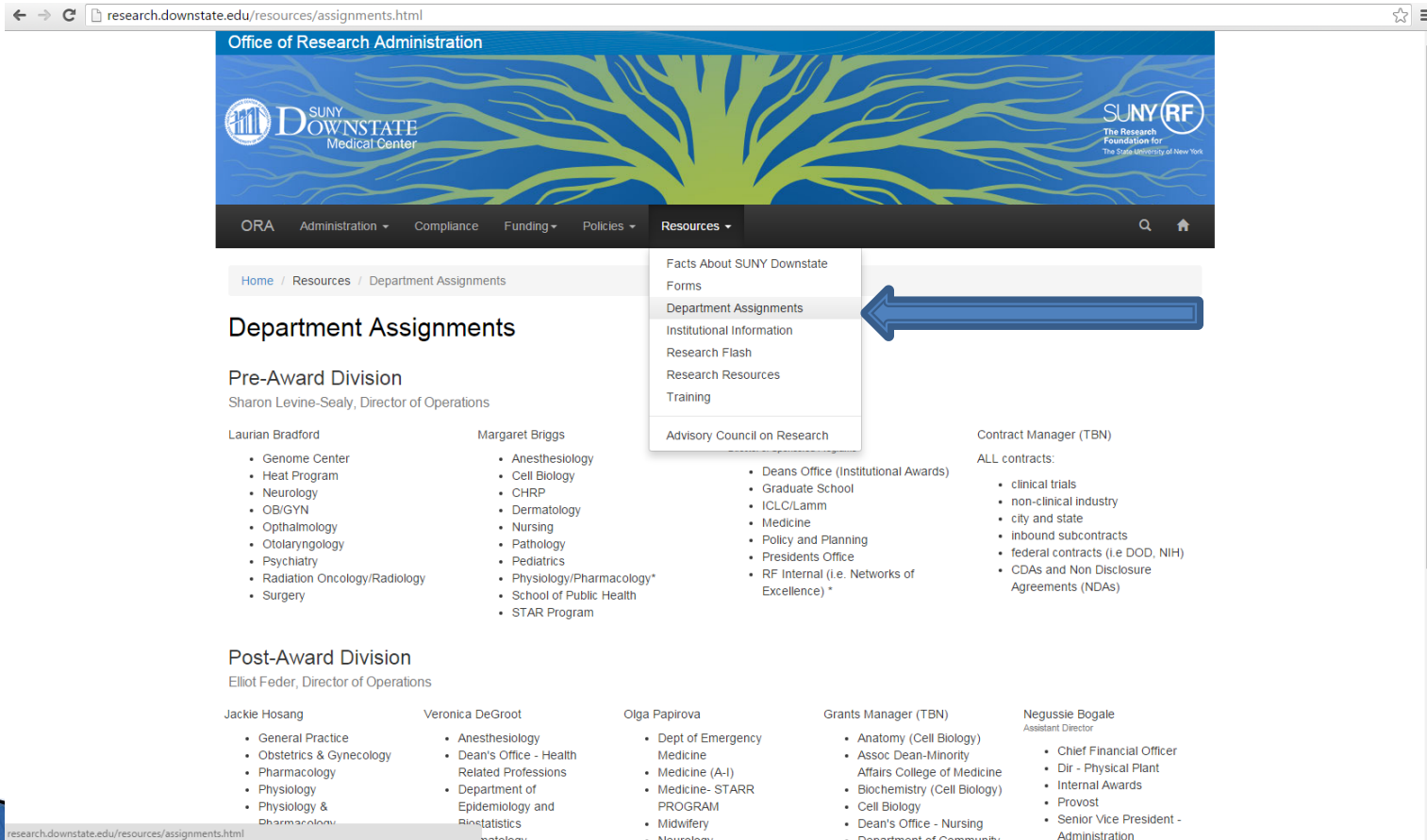


Process Overview



Who To Contact

► Pre & Post-Award Division



research.downstate.edu/resources/assignments.html

Office of Research Administration

SUNY DOWNSTATE Medical Center

SUNY RF The Research Foundation for The State University of New York

ORA Administration Compliance Funding Policies Resources

Home / Resources / Department Assignments

Department Assignments

Pre-Award Division

Sharon Levine-Sealy, Director of Operations

Laurian Bradford

- Genome Center
- Heat Program
- Neurology
- OB/GYN
- Ophthalmology
- Otolaryngology
- Psychiatry
- Radiation Oncology/Radiology
- Surgery

Margaret Briggs

- Anesthesiology
- Cell Biology
- CHRP
- Dermatology
- Nursing
- Pathology
- Pediatrics
- Physiology/Pharmacology*
- School of Public Health
- STAR Program

Deans Office (Institutional Awards)

- Graduate School
- ICLC/Lamm
- Medicine
- Policy and Planning
- Presidents Office
- RF Internal (i.e. Networks of Excellence) *

Contract Manager (TBN)

ALL contracts:

- clinical trials
- non-clinical industry
- city and state
- inbound subcontracts
- federal contracts (i.e DOD, NIH)
- CDAs and Non Disclosure Agreements (NDAs)

Post-Award Division

Elliot Feder, Director of Operations

Jackie Hosang

- General Practice
- Obstetrics & Gynecology
- Pharmacology
- Physiology
- Physiology & Pharmacology

Veronica DeGroot

- Anesthesiology
- Dean's Office - Health Related Professions
- Department of Epidemiology and Biostatistics

Olga Papirova

- Dept of Emergency Medicine
- Medicine (A-I)
- Medicine- STARR PROGRAM
- Midwifery
- Neurology

Grants Manager (TBN)

- Anatomy (Cell Biology)
- Assoc Dean-Minority Affairs College of Medicine
- Biochemistry (Cell Biology)
- Cell Biology
- Dean's Office - Nursing
- Department of Community

Negussie Bogale
Assistant Director

- Chief Financial Officer
- Dir - Physical Plant
- Internal Awards
- Provost
- Senior Vice President - Administration

research.downstate.edu/resources/assignments.html



Who To Contact

Pre-Award Division

- <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>
- 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




References

← → ↻ research.downstate.edu/policies-federal.html 🔍 ☆ ☰

Office of Research Administration

 **SUNY**
DOWNSTATE
Medical Center

 **SUNY RF**
The Research
Foundation for
The State University of New York

ORA Administration ▾ Compliance Funding ▾ Policies ▾ Resources ▾ 🔍 🏠

Home / Federal Policies

Federal Government
Downstate Internal Policies

Federal Policies

Most Frequently Used Links

- [Federal Demonstration Partnership Agency-Specific Requirements](#)
- [Office of Management and Budget Circulars](#)
- [Legal Information Institute: U.S. Code](#)
- [Federal Acquisition Regulations \(FAR - Clauses in Research Contracts for Non-Profits\)](#)

Links By Federal Agency


- [US Department of Agriculture](#)
 - [Regulations and Policy](#)
 - [Agriculture Acquisition Regulation \(AGAR\)](#)
- [Department of Health and Human Services \(DHHS\)](#)
 - [HHS Grants Policy Directives \(GPDs\) - Phased Replacement of the GAM](#)
 - [HHS Grant Regulations - Title 45 Code of Federal Regulations](#)
 - [Objectivity in Research](#)
 - [Financial Conflict of Interest](#)
 - [Selected Extramural Policy Notices](#)
 - [Award Conditions and Information for NIH Grants](#)
- [National Institutes of Health \(NIH\)](#)
 - [OER Grants Policy and Guidance](#)
 - [Grants Policy and Guidance](#)
 - [NIH Guide to Grants and Contracts](#)
 - [NIH Grants Policy Statement](#)
 - [42 CFR Part 50 Subpart F \(Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought\)](#)
 - [45 CFR Part 94 \(Responsible Prospective Contractors\)](#)
 - [NIH Just-In-Time Process \(revised 9/10\)](#)




References

← → ↻ research.downstate.edu/policies-downstate.html

Office of Research Administration

 **SUNY DOWNSTATE**
Medical Center

 **SUNY RF**
The Research Foundation for
The State University of New York

ORA Administration ▾ Compliance Funding ▾ **Policies ▾** Resources ▾

Home / Downstate Internal Policies

Federal Government
Downstate Internal Policies

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 »](#)
- [Institutional Review Board Policy and Procedures Manual](#)
- [Scientific Misconduct Policy](#)
- [Service Center Policy »](#)

© 2015 SUNY Downstate Medical Center · [About](#)

[Back to top](#)

References

- ▶ Vertebrate Animal Section
 - NOT-OD-16-006
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html>
 - VAS webpage
http://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm

References

▶ IACUC & IBC Approval

- NOT-OD-11-053

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-053.html>

- Brown, P., Gibson, C. A word from OLAW and USDA. *Lab Animal (NY)*. 40, 295-298, (2011).

▶ 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

References

- ▶ Authorized Payment Form:
http://research.downstate.edu/_pdf/iacuc/PaymentAuthorizationform.pdf



SUNY
DOWNSTATE
Medical Center

Questions?

