Fundamentals of Research Administration

Office of Research Administration
Sharon Levine-Sealy, Pre-Award Director
Elliot Feder, Post-Award Director
Agenda

- Miscellaneous Agreements and Contracts
- The Offices Involved
- What do these Agreements mean?
- Who is the Responsible Party?
- The Signature Process
- Internal Requirements – What’s Necessary?
Agreement Matrix

- List of Miscellaneous Agreements and Contracts
- Identifies the office on campus responsible for the review
- Identifies the office on campus responsible for the signature of these Agreements
- Identifies responsible party in each office for a particular action
## Agreements Matrix

<table>
<thead>
<tr>
<th>Agreement Type</th>
<th>Pre-Award</th>
<th>Responsible Party</th>
<th>Post-Award</th>
<th>Responsible Party</th>
<th>IRB</th>
<th>Responsible Party</th>
<th>Technology</th>
<th>Responsible Party</th>
<th>Office of Compliance and Audit Service (OCAS)</th>
<th>Responsible Party</th>
<th>State @ DMC</th>
<th>Responsible Party</th>
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</thead>
<tbody>
<tr>
<td>Business Associate Agreements (BAAs)</td>
<td>X</td>
<td>Signature by Pre-Award Director</td>
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<td>Review by Privacy Officer (Shoshana Milstein)</td>
<td>X</td>
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<td>Negotiate by General Counsel's Office (Kevin O'Mara)</td>
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<tr>
<td>Clinical Research Agreements (CRAs)</td>
<td>X</td>
<td>Contract Manager reviews and negotiates; RFC to execute</td>
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<td>Clinical Trial Agreements (CTAs)</td>
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<td>Confidentiality Disclosure Agreements (CDAs)</td>
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<td>X Alexandre Dudman &amp; David Schoenhaut review, negotiate and David executes</td>
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<td>Consultant Agreements (Clinical)</td>
<td>X</td>
<td>Contract Manager reviews; AD or Director executes</td>
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<td>Consultant Agreements (Non-Clinical)</td>
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<td>Contract Manager reviews alongside RFC; RFC to execute</td>
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<tr>
<td>Contracts (NYC &amp; NYS)</td>
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<tr>
<td>Data Use Agreements (DUAs)</td>
<td>X</td>
<td>Contract Manager reviews; Signature by Pre-Award Director</td>
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<td>X Review by Privacy Officer (Shoshana Milstein)</td>
<td>X (General Counsel) to review and negotiate</td>
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<tr>
<td>Inbound Vendor Contracts</td>
<td>X</td>
<td>RFC reviews; Director executes</td>
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<tr>
<td>Inbound Subcontracts</td>
<td>X</td>
<td>Contract Manager and Project Associate review and negotiate alongside RFC; RFC to execute</td>
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<td>X Alexandra Dudman &amp; David Schoenhaut review, negotiate and David executes</td>
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<td>Nondisclosure Agreements (NDA)</td>
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<td>Contract Manager reviews and negotiates; Director executes</td>
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<td>X Alexandra Dudman &amp; David Schoenhaut review, negotiate and David executes</td>
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<tr>
<td>Other Sponsored Research Agreements</td>
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<td>Contract Manager reviews and negotiates; RFC to execute</td>
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<td>Other Non-Sponsored Research Agreements</td>
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<td>Contract Manager reviews; RFC to execute (dependent upon type)</td>
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<td>X (General Counsel) to review and negotiate (dependent upon type)</td>
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<td>Outbound Subcontracts</td>
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<td>Project Associate and RFC prepare; RFC issues and negotiates with institution; RFC executes</td>
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<tr>
<td>Purchase Service Agreements (PSAs) - Inbound</td>
<td>X</td>
<td>Prepared by Contract Manager</td>
<td>X Signed by Director, Post Award</td>
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<tr>
<td>Purchase Service Agreements (PSAs) - Outbound</td>
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<td>Reviewed by Contract Manager; signature will be campus or RFC dependent on terms</td>
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<td>Reliance Agreements</td>
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<td>Kevin Nellis reviews</td>
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<td>X Signature by President's Office</td>
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Business Associate Agreement (BAA)

- A contract between a HIPAA covered entity and a HIPAA Business Associate (BA)

- The contract protects personal health information (PHI) and personal health records (PHR) in accordance with HIPAA guidelines

- Should explicitly spell out how a BA will report and respond to a data breach, including data breaches caused by a business associate's subcontractors
Business Associate Agreements (BAA)

- Reviewed by the Privacy Officer (OCAS)
- Reviewed by General Counsel
- Signed by the Pre-Award Director

http://www.downstate.edu/compliance/policies.html
Clinical Research – What is it?

- A study of health and illness in people
- The way we learn how to prevent, diagnose and treat illness
- Involves human participants and helps translate basic research (done in labs) into new treatments and information to benefit patients
- Research in epidemiology, physiology and pathophysiology, health services, education, outcomes and mental health
Clinical Research Agreement (CRA)

- An Agreement that manages the relationship between a sponsor and the institution

- Outlines the following terms:
  - Allocation of Risk and Responsibility
  - Terms of Collaboration
  - Funding Obligations
  - Indemnification and/or Liability
  - Protection of Academic, Legal and Intellectual Property
  - Export control and other laws and regulations
Clinical Research Agreements (CRAs)

- Reviewed by Pre-Award Division, Contracts Manager
- Budget and Scope of Work are reviewed by Sponsored Project Associate (sPA) in Pre-Award Division
- Institutional Routing Documents are required
  - Proposal Tracking / Signature Worksheet
  - Cost Share Template (as required)
- Signed by RF Central Office upon approval of Pre-Award Division
Clinical Trial – What is it?

- A subset of Clinical Research

- An experiment designed to answer specific questions about possible new treatments **OR** new ways of using existing treatments

- A study to determine whether new drugs or treatments are safe and effective

- Research for the prevention, treatment, diagnosis **OR** for the relief of symptoms of a disease
Clinical Trials

- Research studies performed with human subjects to evaluate the following:
  - Medications
  - Devices
  - Diagnostic products
  - Treatment regimens
Clinical Trial Agreements (CTAs)

- Address the following Terms and Conditions (T&C)
  - Responsibilities of the parties
  - Requirements for payment and reimbursement
  - Publication and Intellectual Property
  - Indemnification, Liability and/or Insurance
  - Subject Injury coverage
  - Guidelines for dispute resolution
  - Grounds for termination of contract and/or amending contract terms
  - **Export control and other laws and regulations**
Clinical Trial Agreements (CTAs)

- Reviewed by Pre-Award Office, Contracts Manager

- Budget and Scope of Work are Required and reviewed by Sponsored Projects Associate (sPA)

- Institutional Routing Documents are required
  - Proposal Tracking / Signature Worksheet
  - Cost Share Template (as required)

- Signed by RF Central Office
Export – What is it?

- An export occurs whenever any item or information is sent from the U.S. to a foreign destination.
- An export occurs when any item is provided to a foreign national here or abroad.
- The manner in which the transfer or release of the item or information occurs does not matter.
- Examples of an export:
  - Shipment of items
  - Written or Oral communications
  - Hand-carrying items when traveling (i.e. laptops, mobile phone)
  - Providing access to or visual inspection of equipment or facilities
  - Providing professional services
Deemed Export – What is it?

- Refers to the release or transmission of information or technology to any foreign national in the U.S.

- Treated as an export to that person’s home country

- Includes:
  - Students
  - Post-Docs
  - Faculty
  - Visiting Scientists
  - Training Fellows
Other Export Control definitions

- **Foreign National – What is this?**
  - Any natural person who is not a U.S. citizen or is not a lawful permanent resident of the U.S.

- **Foreign Entity – What is this?**
  - Any corporation, business, or other entity that is not incorporated to do business in the U.S.
Regulate the shipment or transfer of:

- Controlled items / Software / Technology / Services outside the U.S.

Apply to all International activities regardless of funding status or source

Does NOT apply to “Fundamental Research” (15 CFR§734.8)

Are critically important for university personnel to identify when their activities may trigger export controls

- Must be identified in the T&C of certain types of Agreements (i.e. Sponsored Research Agreements: CTAs, CRAs, MTAs, etc.)
Fundamental Research – Definition

- Basic or Applied research in science and engineering
- Results are ordinarily published and free of any publication restrictions
- Results are shared broadly within the scientific community
- The research must be conducted without any access or dissemination restrictions
Fundamental Research Exclusion

- Research must be based at an Accredited Institution of Higher Education located in the United States

- If your research includes work done outside the U.S., it may not qualify for the Fundamental Research Exclusion
  - Export licenses may not be required, but a determination needs to be done before the work begins

- Research results developed or generated are exempt from export controls and can be freely shared with foreign nationals both here and abroad
  - Any materials, items, technology, or software generated as a result of the research ARE NOT exempt from export controls
Educational Information Exclusion

- Information that is normally taught or released by the University as part of normal instruction
  - Catalog Course
  - Associated Teaching Laboratory
- Under federal regulations (15 CFR§734.3(b)(iii)), is NOT subject to export controls
Published Information Exclusion

- Under the federal regulations (15 CFR § 734.7 and 15 CFR § 734.11), is NOT subject to export controls.

- Information already published or in the public domain is considered public information:
  - Books, newspapers, pamphlets
  - Publically available technology and software
  - Information presented at conferences, meetings, and seminars open to the public
  - Information included in published patents
  - Websites freely accessible by the public
A “Y” answer to any of the following indicates that your research **may** be subject to export controls and should be reviewed:

- Research involves export restricted science and engineering areas
- Research involves the use of export controlled information, items, or technology
- Research involves the transfer of project information, equipment, materials, or financial support out of the U.S.
When may Export Control be applicable?

- A “Y” answer to any of the following indicates that your research may be subject to export controls and should be reviewed:
  - Any part of the research that will take place outside the U.S. or will include international travel
  - Research that involves foreign national faculty, visiting scientists or collaborator(s), or other foreign entities
  - Foreign National graduate students, trainees, or other DMC employees that may be involved in the research
Export Controls

What might trigger an Export Control issue?

- **Traveling overseas**
  - Sanctioned or embargoed countries will require advance planning and coordination: Cuba, Iran, North Korea, Sudan, Syria
  - Any materials, items, technology, or software generated as a result of the research **ARE NOT** exempt from export controls
  - Before shipping or taking any item abroad, an export control determination needs to be done to determine if an export license is required to take or transfer the item
  - If the destination or end-user is a foreign national of a sanctioned country, any consulting activities would be prohibited regardless of the subject matter
Confidentiality Disclosure Agreements (CDAs) and Nondisclosure Agreements (NDAs)

- A contract that outlines confidential material, knowledge, or information the parties wish to share with one another but wish to restrict access to other parties.

- Typically provided by a sponsor wishing to engage PI to enter into a Clinical Trial.

- These agreements are also referred to as non-disclosure agreements (NDAs), proprietary information agreement (PIA), or secrecy agreements (SA).
Confidentiality Disclosure Agreements (CDAs) and Nondisclosure Agreements (NDAs)

- Clinical Agreements are reviewed and negotiated by Pre-Award Office, Contracts Manager
- Clinical Agreements are signed by Pre-Award Director
- Non-Clinical Agreements are reviewed and negotiated by the Office of Technology, Senior Licensing Associate and Director
- Non-Clinical Agreements are signed by the Director of Technology & Commercialization
Consultants / Independent Contractors

- A consultant is an individual who performs services for an organization whereby the organization owns the results of the work.

- Consultants are not employees of the organization where the work is performed.

- The organization controls the results of the work, not the means and methods of accomplishing the work.

- IRS basis for making the determination between an employee and a consultant.

Consultant Agreements

- Agreement should be signed prior to the consultants participation in the project

- Agreement should define the following terms:
  - Services to be performed
  - Compensation and Reimbursement
  - Indemnification / Liability
  - Intellectual Property
  - Confidential Information
  - Period of Performance
Consultant Agreements

- Requests include the Consultant package:
  - Single/Sole Source form
  - Independent Contractor Services form
  - Independent Contractor Agreement
  - Certification Regarding Debarment / Suspension
  - Working Relationship Form
  - IRS Factors of the Common Law Test
  - W–9
Consultant Agreements

- Consultant packages are sent to Grant Managers
- Grant Managers review for completion
- Once complete, the Post Award Assistant Director or Director executes the Agreement
Contracts (New York City)

- NYC agencies contract with nonprofits to the tune of $16 billion.
- 93% of human services contracts are registered with nonprofit organizations.
- These contracts play an important role in community development.
- Department of Education provides funding through this mechanism.
Contracts (New York City)

- Grant Applications
  - Applications submitted through NYC Health and Human Services (HHS) Accelerator System
    - Allows applicants to Apply for funding in response to specific RFPs
    - Provides application submissions electronically from within Accelerator
Contracts (New York City)

- City Council Discretionary Funding
  - The City Council awards $250 million in expense funding every year to nonprofit organizations.
  - Awards are issued each year to nonprofit organizations to meet local needs and fill gaps in City agency programs.
Contracts (New York City)

- Grant Applications are reviewed and submitted by the Pre–Award Office

- Contract itself is reviewed by Pre–Award Contract Manager in tandem with RF Central office

- Account is setup by your Sponsored Projects Associate (sPA)

- Carryover requests and Budget Modifications are handled by the Grants Manager in Post–Award
Contracts (New York State)

- State agencies purchase a variety of goods and services from the business community, including non-profits.
- The NYS Grants Gateway serves as the primary outlet for State agencies to post upcoming and available funding opportunities.
- Receive email notifications when specific types of grant opportunities are posted.
Contracts (New York State)

- A Master Contract for Grants was released to significantly reduce time and costs both for New York State and Grantees
  - Standard statewide Terms & Conditions eliminate redundant iterations of contract language across state agencies
  - Reduce the complexity grantees face in reviewing contract terms prior to entering into an agreement.
  - Streamlines approvals at both the State and grantee levels
  - Creates a known quantity; recipients know what to expect
  - Reduces discrepancies and inconsistencies
Contracts (New York State)

- Grants Reform Initiative was set up to fix a broken NYS Contracting System
  - Simplify grants management
  - Facilitate more timely payments to Non-Profits
  - Improve the effectiveness and accelerate performance of local grant programs
  - Improve compliance with State and Federal legal and audit requirements
Contracts (New York State)

- Applications are submitted through NYS Grants Gateway
  - Reviewed by your Sponsored Project Associate (sPA) in the Pre–Award division
  - Required internal documents
    - Proposal Tracking / Signature Worksheet
    - Cost Share Template (as applicable)
Contracts (New York State)

- MWBE requirements may be reviewed prior to contract issuance

- Review of application documents and campus approval is provided by Sponsored Project Associate (sPA) in Pre–Award Division

- **Coming Soon**: Contract Manager will be reviewing these contracts and providing campus approval

- Signed by RF Central Office
Data Use Agreements (DUAs)

- A type of contract document used for the transfer of data
- Data has been developed by nonprofit, government or private industry
- Data is non-public or is otherwise subject to restrictions on its use
Data Use Agreements (DUAs) – **FIX SLIDE**

- Reviewed by Contract Manager in Pre-Award office
- Reviewed by GC? OCAS? IT?
- Executed by Director of Pre-Award Division
Inbound Vendor Agreements

- An Agreement provided by a vendor with specific terms and conditions regarding the use, disposition, storage of the item
  - Equipment
  - Software (i.e. RedCap)
  - Outside storage space
- A document in addition to the Purchase Order
- Contract is reviewed by legal in RF Central Office
- Signed by the Director of Post-Award
Material Transfer Agreements (MTAs)

- A contract that governs the transfer of tangible research materials between two organizations
- Required when the recipient intends to use the materials for his/her own research purposes
- Defines the rights of the provider and the recipient with respect to the materials and any derivatives
- Most frequently transferred materials:
  - Biological materials (i.e. reagents, cell lines, plasmids, and vectors)
Material Transfer Agreements (MTAs)

- Three types of MTAs are most common at academic institutions:
  - Transfer between academic or research institutions
  - Transfer from academia to industry
  - Transfer from industry to academia
Material Transfer Agreements (MTAs)

- Reviewed and negotiated by the Office of Technology & Commercialization:
  - Senior Licensing Associate
  - Director

- May be reviewed by Pre-Award Director as back-up

- Signed by the Director in the Office of Technology and Commercialization
Other Sponsored Research Agreements (OSAs)

- A research agreement between two or more parties to describe non-human research

- Required terms and conditions include:
  - Scope of work and Budget
  - Payment obligations and timing
  - Schedules and deliverables
  - Publication, Licensing and Intellectual Property
  - Confidential Information
  - Export control and other laws and regulations
  - Termination clause
  - Insurance, Warranties, Liability, Governing Law
Other Sponsored Research Agreements (OSAs)

- Reviewed by Pre–Award Office, Contracts Manager

- Budget and Scope of Work are Required and reviewed by Sponsored Project Associate (sPA) in Pre–Award

- Campus Approval provided by Sponsored Project Associate (sPA)

- Institutional Routing Documents are required
  - Proposal Tracking / Signature Worksheet
  - Cost Share Template (as required)

- Signed by RF Central Office
Other Sponsored (Non-Research) Agreements (OSAs)

- Sponsored Service Agreements
  - Similar to Research Agreements in T&C; however a service is being provided (i.e. health assistance, school, outreach, etc.)

- Reliance Agreements
  - Reviewed by the IRB and signed by the Institutional Official (IO)
Other Sponsored (Non–Research) Agreements (OSAs)

- Inter-Campus Related Agreements (UPB / UHB / DMC / RF)
  - Some are signed by DMC Leadership
  - Some are signed by the Pre-Award Director

- Memorandum of Understanding (MOUs)
  - Review and signature based on terms and conditions
    - May be General Counsel
    - May be Office of Research Administration
    - May be DMC Leadership

NOT SURE?
Ask your Sponsored Project Associate in Pre-Award
Purchase Service Agreements (PSAs)

- A contract issued for the sole purpose of purchasing either an item or a service
- For Outbound agreements, review the Decision Tree
- For Inbound agreements, another institution is purchasing an item or service from your PI
- Should be in place for all instances where a service is being provided vs. programmatic decision making
Purchase Service Agreements (PSAs)

- All Agreements should include the following Terms & Conditions:
  - Statement or Scope of Work (SOW)
  - Roles and Responsibilities of the Parties
  - Requirements for payment and reimbursement
  - Publication and Intellectual Property
  - Indemnification, Liability and/or Insurance
  - Grounds for termination of contract and/or amending contract terms
Purchase Service Agreements (PSAs)

- Inbound PSAs
  - Reviewed by Pre-Award, Contract Manager
  - Budget Reviewed by Sponsored Project Associate (sPA)
  - Signed by RF Central Office

- Outbound PSAs
  - Prepared by Pre-Award, Contract Manager
  - Signed by Director of Post-Award
Subcontracts – Inbound

- A research contract awarded from one institution to another
- Assigns some of the programmatic obligations of the prime awardee
- Typically a Subcontract proposal was submitted to the prime at the time of application
  - Subcontract Proposal Facepage
  - Budget and Justification
  - Statement of Work
  - Internal Documents
    - Proposal Tracking / Signature Worksheet
    - Cost Share Template (if applicable)
Subcontracts – Inbound

- Typically outlines the following Terms and Conditions:
  - Allocation of Risk and Responsibility
  - Funding Obligations
  - Protection of Academic, Legal and Intellectual Property
  - Export control and other laws and regulations
  - Governing Law
  - Requirements for payment and reimbursement
  - Publication
  - Indemnification, Liability and/or Insurance
  - Guidelines for dispute resolution
  - Grounds for termination of contract and/or amending contract terms
Subcontracts – Inbound

- Subcontract is reviewed by Pre-Award Division
  - Contract Manager
  - Sponsored Project Associate (sPA)
  - Director of Pre-Award

- Budget and Scope of Work are reviewed by Sponsored Project Associate (sPA)

- Campus Approval is provided by Sponsored Project Associate (sPA)

- Signed by RF Central Office
The grant application called for collaboration with an outside entity

The collaboration is programmatic in nature

Decision Tree was used to confirm Subcontract vs. Purchase Service Agreement

A subcontract will be issued when RF receives the prime award (NOA)
Subcontracts – Outbound

- Standard Terms and Conditions include the following:
  - Allocation of Risk and Responsibility
  - Funding Obligations
  - Protection of Academic, Legal and Intellectual Property
  - Export control and other laws and regulations
  - Governing Law
  - Requirements for payment and reimbursement
  - Publication
  - Indemnification, Liability and/or Insurance
  - Guidelines for dispute resolution
  - Grounds for termination of contract and/or amending contract terms
Subcontract – Outbound

- Budget and Statement of Work are reviewed by the Sponsored Project Associate in Pre–Award
  - At the time of application
  - When a new subcontract is proposed

- RF Central Office prepares and issues Agreement after receipt of campus approval from Pre–Award Division

- RF Central Office signs

- Purchase Order is created by Purchasing in Post–Award
The Purchase Requisition

- The document prepared to request a Purchase Order

- Should be submitted to the Grants Manager in the Post Award Division, once signed by all parties

- The Grant Manager will review and approve the requisition

- The Purchasing Manager will review and execute the Purchase Order
The Purchase Order (POs)

- A contractual document created by a Purchasing Department as the result of submission of a requisition (either paper or electronic)

- Precipitated by the submission of a Purchase Requisition

- A system-generated form that serves as a **contractual** relationship between the parties

  - Obligates the supplier to provide the goods and/or services ordered in accordance with the Terms and Conditions specified by the Purchase Order

- Funds are encumbered in the award based on the costs indicated on the requisition
Contact Us

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- Sharon Levine–Sealy, Director of Pre–Award
  - Sharon.levine–sealy@downstate.edu

- Elliot Feder, Director of Post–Award
  - Elliot.feder@downstate.edu

http://research.downstate.edu/administration/pre-award.html