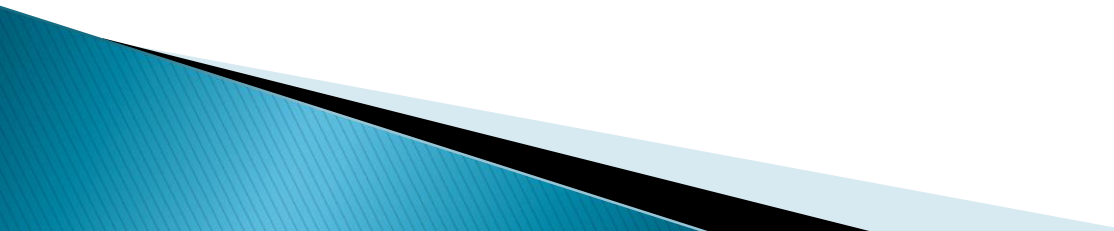


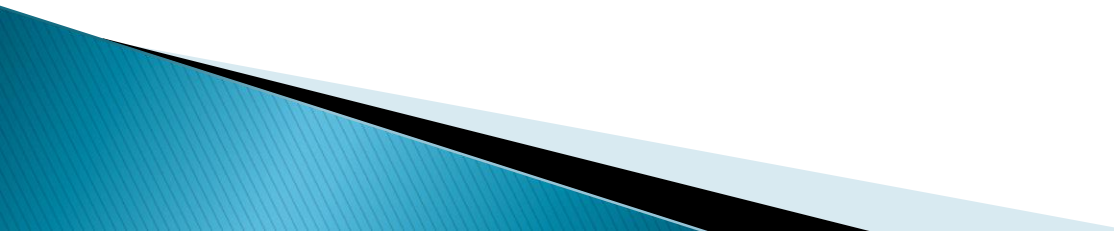
Fundamentals of Research Administration

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?
- 

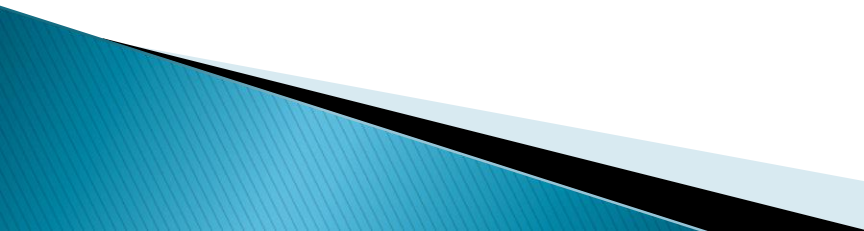
Agreement Matrix

- ▶ 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

Agreement Type	Pre-Award	Responsible Party	Post-Award	Responsible Party	IRB	Responsible Party	Technology	Responsible Party	Office of Compliance and Audit Service (OCAS)	Responsible Party	State @ DMC	Responsible Party
Business Associate Agreements (BAAs)	X	Signature by Pre-Award Director							X	Review by Privacy Officer (Shoshana Milstein)	X (General Counsel)	Negotiate by General Counsels Office (Kevin O'Mara)
Clinical Research Agreements (CRAs)	X	Contract Manager reviews and negotiates; RFC to execute										
Clinical Trial Agreements (CTAs)	X	Contract Manager reviews and negotiates; RFC to execute										
Confidentiality Disclosure Agreements (CDAs)	X (Clinical)	Contract Manager reviews and negotiates; Director executes					X (Non-Clinical)	Alexandra Dudman & David Schoenhaut review, negotiate and David executes				
Consultant Agreements			X	Grant Manager reviews; AD or Director executes								
Contracts (NYC & NYS)	X	Contract Manager reviews alongside RFC; RFC to execute										
Data Use Agreements (DUAs)	X	Contract Manager reviews; Signature by Pre-Award Director							X	Review by Privacy Officer (Shoshana Milstein)	X (General Counsel)	Kevin O'Mara (General Counsel) to review and negotiate
Inbound Vendor Contracts			X	RFC reviews; Director executes								
Inbound Subcontracts	X	Contract Manager and Project Associate review and negotiate alongside RFC; RFC to execute										
Material Transfer Agreements (MTAs)							X	Alexandra Dudman & David Schoenhaut review, negotiate and David executes				
Nondisclosure Agreements (NDAs)	X (Clinical)	Contract Manager reviews and negotiates; Director executes					X (Non-Clinical)	Alexandra Dudman & David Schoenhaut review, negotiate and David executes				
Other Sponsored Research Agreements	X	Contract Manager reviews and negotiates; RFC to execute										
Other Non-Sponsored Research Agreements	X	Contract Manager reviews; RFC to execute (dependent upon type)									X (General Counsel)	Kevin O'Mara (General Counsel) to review and negotiate (dependent upon type)
Outbound Subcontracts	X	Project Associate and RFC prepare; RFC issues and negotiates with institution; RFC executes										
Purchase Service Agreements (PSAs) – Outbound	X	Prepared by Contract Manager	X	Signed by Director, Post Award								
Purchase Service Agreements (PSAs) – Inbound	X	Reviewed by Contract Manager; signatory will be campus or RFC dependent on terms										
Purchase Orders			X	Requisition is reviewed by Grant Managers; Purchasing executes								
Reliance Agreements					X	Kevin Nellis reviews					X	Signature by President's Office

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>



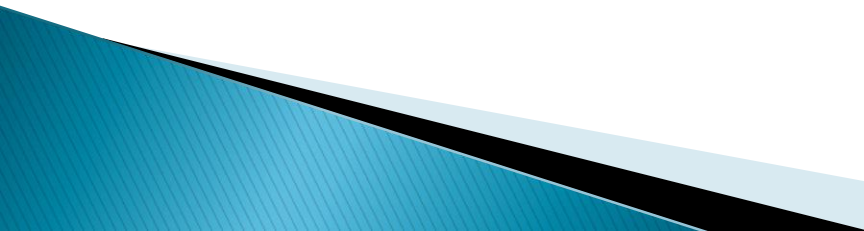
Clinical Research – What is it?

- ▶ 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.

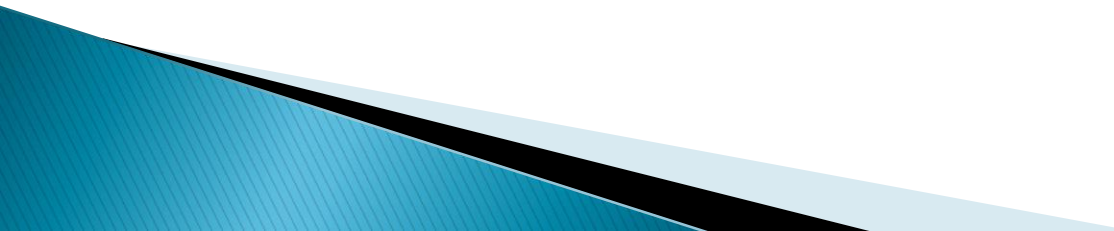
▶ **Foreign Entity – What is this?**

- Any corporation, business, or other entity that is not incorporated to do business in the U.S.

Export Controls – Federal Regulations

- ▶ 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

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:
 - 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.

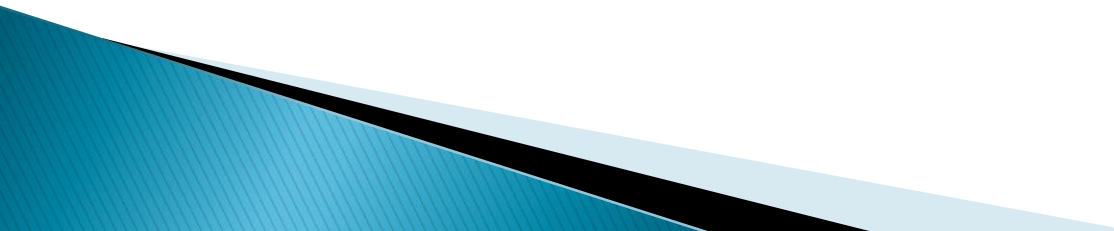
When may Export Control be applicable?

- ▶ 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)

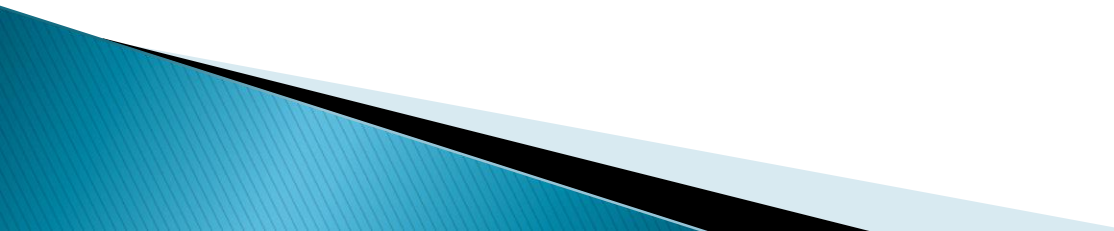
- ▶ Clinical Agreements are reviewed and negotiated by Pre-Award Office, Contracts Manager
 - ▶ Clinical Agreements are signed by Pre-Award Director
 - ▶ Non-Clinical Agreements are reviewed and negotiated by the Office of Technology, Senior Licensing Associate and Director
 - ▶ Non-Clinical Agreements 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

<https://www.irs.gov/businesses/small-businesses-self-employed/independent-contractor-self-employed-or-employee>

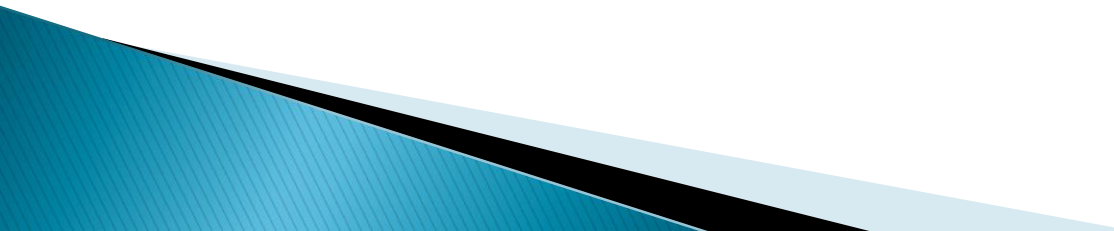
Consultant Agreements

- ▶ 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
- 

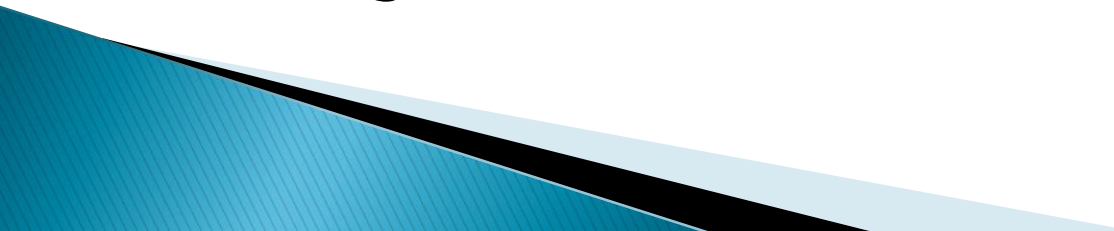
Consultant Agreements

- ▶ 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

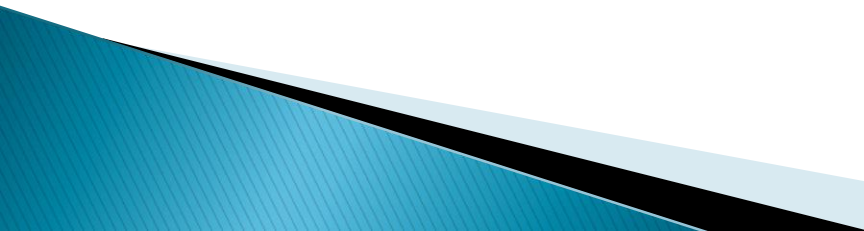
- Applications submitted through NYC Health and Human Services (HHS) Accelerator System
 - Allows applicants to Apply for funding in response to specific RFPs
 - Provides application submissions electronically from within Accelerator

Contracts (New York City)

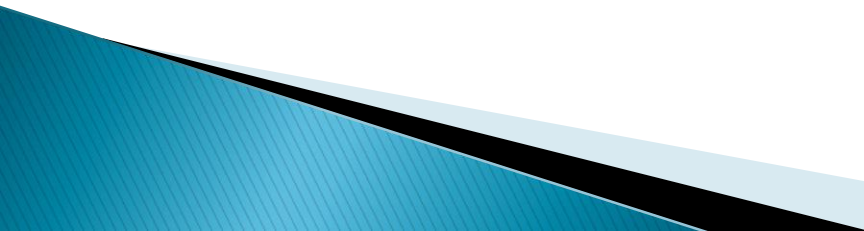
▶ City Council Discretionary Funding

- 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
- 

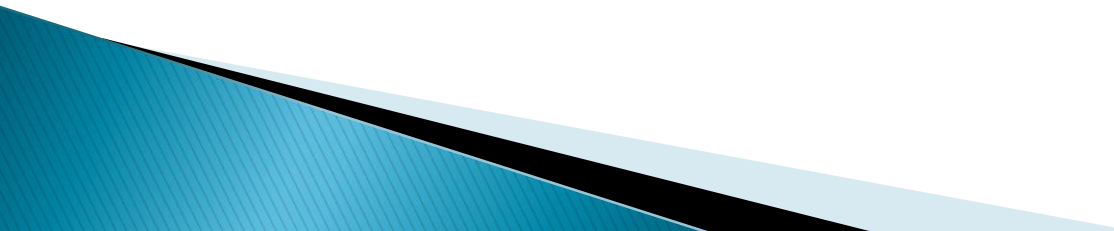
Contracts (New York State)

- ▶ 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
 - ▶ The Gateway went live on May 15th, 2013
 - ▶ 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
- 

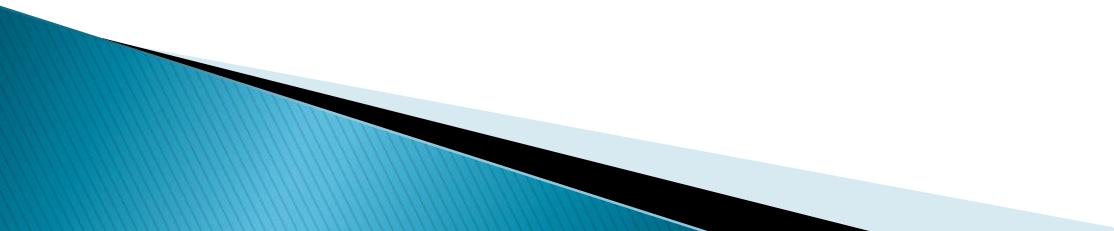
Contracts (New York State)

- ▶ 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)

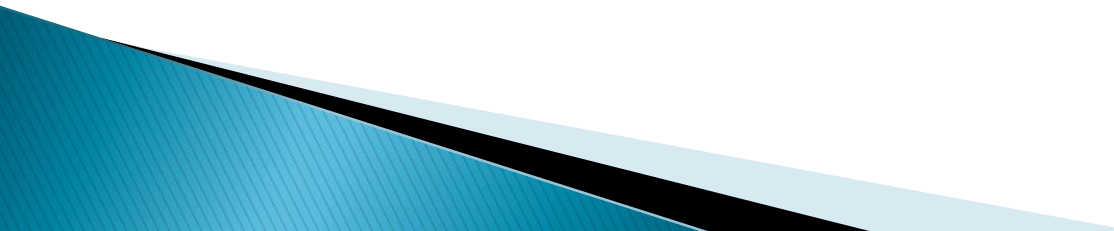
Contracts (New York State)

- ▶ 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
- 

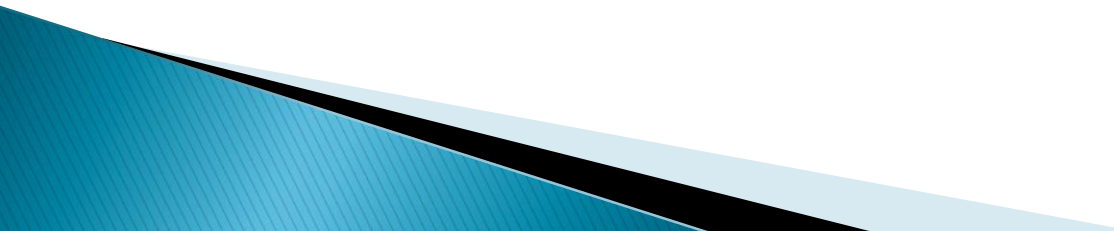
Inbound Vendor Agreements

- ▶ 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

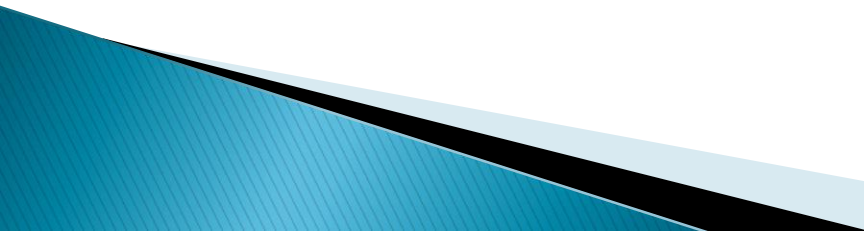
Material Transfer Agreements (MTAs)

- ▶ 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.)

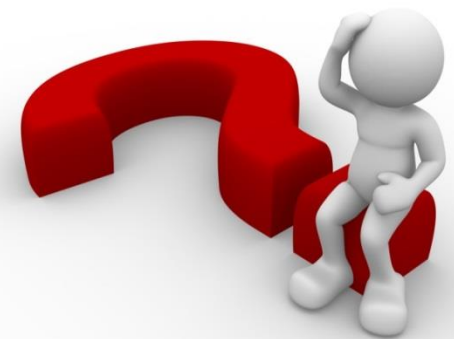
▶ Reliance Agreements

- 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

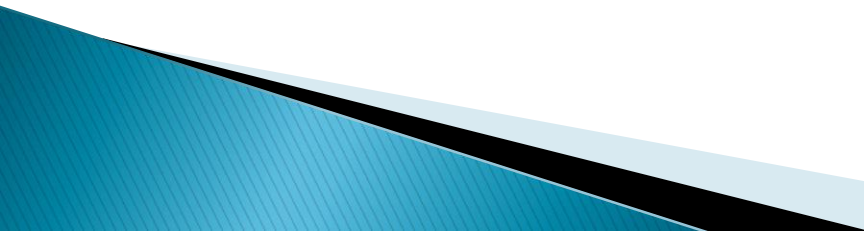
- ▶ Memorandum of Understanding (MOUs)
 - Review and signature based on terms and conditions
 - May be General Counsel
 - May be Office of Research Administration
 - May be DMC Leadership



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)

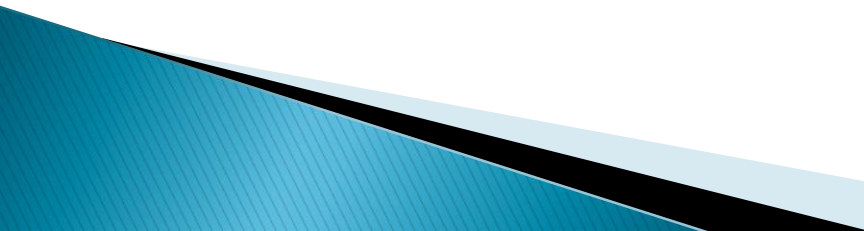
- ▶ All Agreements should include the following Terms & Conditions:
 - Statement or Scope of Work (SOW)
 - Roles and Responsibilities of the Parties
 - Requirements for payment and reimbursement
 - Publication and Intellectual Property
 - Indemnification, Liability and/or Insurance
 - Grounds for termination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

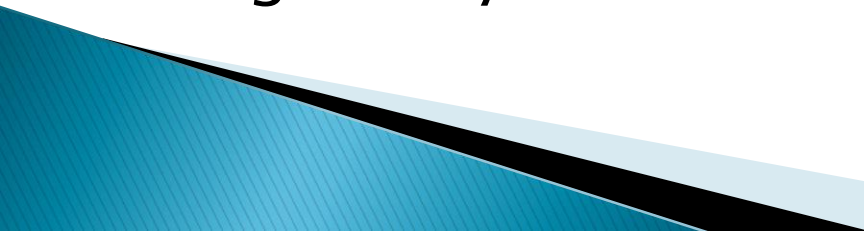
Subcontracts – Inbound

- ▶ 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)

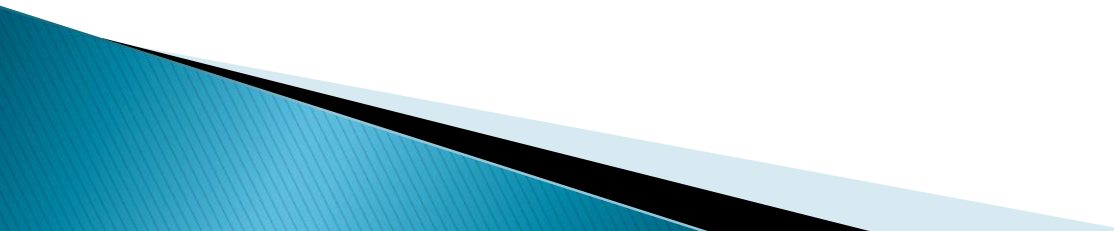
Subcontracts – Inbound

- ▶ 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
- 

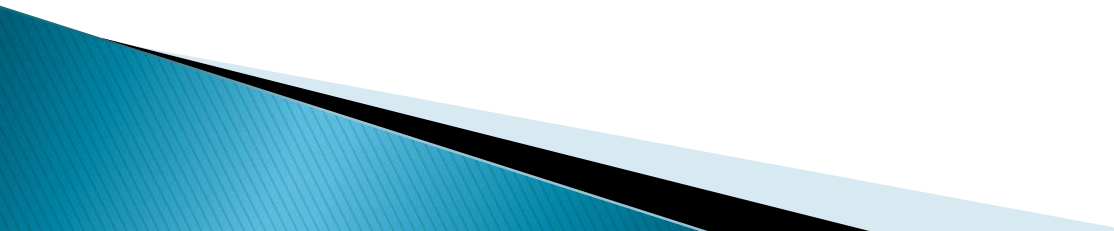
Subcontracts – Outbound

- ▶ 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)
- 

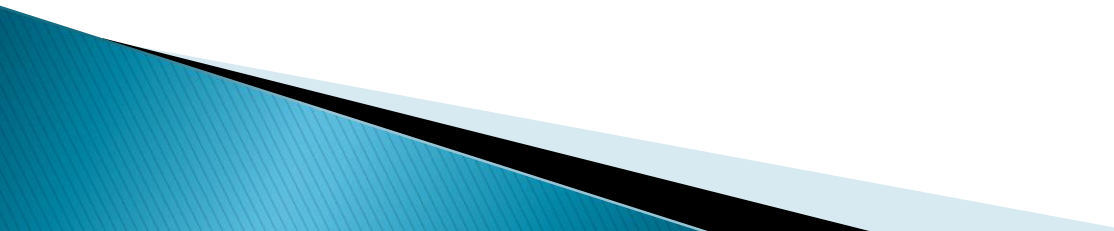
Subcontracts – Outbound

- ▶ 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
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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

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