SUNY RF
The Research Foundation for
The State University of New York
Downstate Medical Center

Fundamentals of Research Administration

Office of Research Administration
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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; signtory 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

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