Fundamentals of Research Administration and Management - Annual Meeting



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Let's Get Started!

- Introductions
- Materials Provided
- Topics to be Covered
- Learning Objectives
- Questions are encouraged throughout
- Breaks



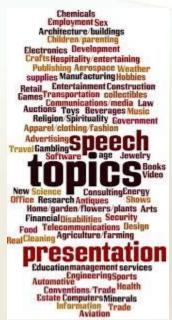
Materials Provided

- Workshop slides
- Acronyms & Terminology
- Websites
- Sample budget justification
- Sample F&A rate agreement
- Exercises



Topics to be Covered

- Definitions; Roles, Responsibilities of Research Administration
- Pre-Award Administration
 - Regulations, Agreements
 - Funding Opportunities
 - Proposal Preparation
 - Budget Preparation & Justification
 - Proposal Submission
 - Sponsor Actions





Topics to be Covered (cont'd)

- Representations, Certifications, and Compliance
- Post-Award Administration
 - Award Review
 - Subawards
 - Project Monitoring
 - Cost Transfers and Other Changes
 - Close-out/Audit
- Responsibilities & Ethics



Learning Objectives

- Overview of Research Administration
- Understanding of
 - Pre-award administration
 - Post-award administration
 - Compliance issues
 - Responsibilities and Ethics
- Sharing of Procedures & Forms



Definitions

Roles and Responsibilities of Research Administration

Research

- What are research & sponsored projects?
- What is research administration (RA)?
- Who are the players in RA?





Research Administration Service Units

- Pre-award
- Post-award
- Compliance
- Intellectual Property
- Partnership Development
- Research Accounting
- Academic, Institute, or Hospital Research
 Office
- Advancement or Development Office, Government Relations



Other Related Activities and Offices

- Compliance committees and staff
- Fiscal responsibilities— invoicing, compliance, and reporting
- Negotiation of indirect cost/F&A rate agreement
- Research support program
- Fixed assets and annual reporting
- Technology transfer and knowledge mobilization



Partnership development

Sampling of RA Services

- Identify sources of funding
- Assist with developing proposals
- Develop/Review budgets
- Review proposals for compliance with federal, state, and institutional policies and procedures
- Submit proposals to sponsors
- Liaise with faculty and Pls
- Negotiate/accept/manage awards
- Develop industry and community partnerships

- Manage intellectual property
- Negotiate contracts/subcontracts
- Produce financial reports for various agencies
- Provide administrative support for compliance committees
- Ensure that all licenses, certificates, registrations are current
- Ensure that all institutional policies governing the use of sponsored funds are current

Roles and Responsibilities

- Principal Investigator
- Departmental Administrator
- Sponsored Programs Administrator
- Vice President/Provost/Vice Chancellor for Research/Sponsored Programs
- Authorized Institutional Official



Principal Investigator*

- Develops and proposes the project
- Oversees project integrity
- Complies with sponsor regulations
- Executes scope of work and financial management
- Completes the project (both scientifically & administratively)
- Manages personnel (mentoring & oversight)
- Meets the reporting requirements
- Presents and publishes results



Departmental Administrator*

May assist PI with:

- Finding funding opportunities
- Proposal development and assembly
- Budget development
- Securing approvals
- Institutional administrative issues
- Purchasing and property management
- Closing out the project
- The DA may have other department responsibilities

Sponsored Programs Administrator*

- Usually associated with central administration
- Similar responsibilities of departmental administrator and may
 - Approve proposed project and its submission
 - Have other administrative duties (oversight of sub-units)
 - Review proposal applications for adherence with institutional policies, sponsor requirements and governing regulations



SP Administrator (cont'd)*

- Negotiates and accepts award
- Oversees post award execution
- Ensures proper closeout
- Reviews technology disclosures and pursues patents
- Assures sponsor that institution functions appropriately
- Negotiates F&A and fringe benefit rates

SP Administrator (cont'd)*

- Certifies:
 - that institution meets requirements
 - the accuracy of particular information
 - compliance with governing regulations
- Establishes SP policies and procedures to ensure compliance
- Educates employees regarding SP policies and procedures
- Provides training for research administration and institutional compliance

VP/Provost/VC for Research*

- Establishes/defines the culture for the institution
- Oversees entire institutional research enterprise
- Understands laws, regulations and institution
- Aligns and approves policies with applicable regulations



Who is the Authorized Institutional Official?

- The person designated to approve proposals and accept awards, sign contracts, etc.
- This responsibility typically resides with the Sponsored Programs Administrator, the Provost, and/or the VP for Research
- AKA signature authority, authorized organizational official, etc.
- Authorized to legally bind organization
- Could be multiple people
- The Principal Investigator is NOT an authorized institutional official!
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Examples of Service Models

- Sponsors or disciplines
- Faculty/departments served
- Assignment based upon next-in-line rotation
- Your institution may be different





Checks and Balances

- Project directors/principal investigators/staff → Dept/Dean (or HR)
- Fiscal business unit → CFO
- Policies → Internal auditors



PRE-AWARD ADMINISTRATION REGULATIONS AND AGREEMENTS

Legal Framework for Research

- Source of funding
- National
- Local
- State-sponsored institution
- Academia, hospital
- Profit or Non-Profit



Code of Federal Regulations (CFR)

- Published in Federal Register
- Administrative law of federal government
 - Federal Agency Rulemaking
- Title 2 CFR Grants and Agreements
 - Section 200 Uniform Guidance
- Title 48 CFR Subchapter H, Part 52 Solicitation Provisions and Contract Clauses

2 CFR Part 200

- Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards
- http://www.ecfr.gov/cgi-bin/textidx?node=2:1.1.2.2.1
 - Office of Management and Budget Circulars https://www.whitehouse.gov/omb/circulars/



Uniform Guidance Organization

- Subpart A-Acronyms and Definitions
- Subpart B-General Provisions
- Subpart C-Pre-Federal Award Requirements and Contents of Federal Awards
 - Includes use of grant agreements, notice of funding opportunities and federal financial assistance programs, merit review process of applications, application requirements, and other requirements of federal funding agencies

Subpart D - Post Federal Award Requirements

- Standards for Financial and Program Management
- Property Standards
- Procurement Standards Micro-Purchase Threshold (MPT), consultant agreements over \$10K
- Performance and Financial Monitoring and Reporting
- Subrecipient Monitoring and Management
- Record Retention and Access
- Remedies for Non-Compliance
- Closeout
- Post-Closeout Adjustments and Continuing Responsibilities
- Collection of Amounts Due



Subpart E - Principles

- General Provisions
- Basic Considerations
 - Composition of Costs (allowable, applicable, reasonable)
- Direct and Indirect (F&A) Costs
- Special Considerations for States, Local Government and Indian Tribes
- Special Considerations for Institutions of Higher Education
- General Provisions of Selected Items of Cost



Subpart F - Audit Requirements

- Purpose
- Responsibilities
- Management decisions
- Appendicies I to XII





Federal Acquisition Regulations



FAR – 48 CFR
 Subchapter H, Clauses
 and Forms, Part 52
 https://www.acquisition.gov/far/current/html/FARMTOC.html

 Applicable to contracts (not grants)

PRE-AWARD ADMINISTRATION

FUNDING OPPORTUNITIES

Types of Funding Opportunities

- Call for Proposals
- RFP Request for Proposal
- RFQ Request for Quotation
- RFA Request for Application
- BAA Broad Agency Announcement
- Unsolicited Proposals
 - Program Announcement (PA)
 - Funding Priorities
- Foundation Initiatives



Searching for Funding

On-line Information Systems

- No charge systems
 - FedBizOpps Federal Opportunities
 - Grants.gov
 - Commerce Business Daily (BidNet.com)
 - Federal Register
 - FedConnect
- Subscription-based systems
 - SPIN -Sponsored Programs Information Network
 - The Grant Advisor Plus
 - PIVOT
 - *Research (international)
 - U.S. Foundation Directory (foundationcenter.org)



Searching for Funding (cont'd)

U.S. Federal Agency Sites

- NSF- http://www.nsf.gov/
- EPA- http://www.epa.gov/
- DOD- http://www.defenselink.mil/
- NIH- http://www.nih.gov/
- DARPA- http://www.darpa.mil
- DEd https://www2.ed.gov/fund/grants-apply.html?src=pn
- DOE https://energy.gov
- DOJ https://www.justice.gov/



Searching for Funding (cont'd)

International sources:

- European Research Council http://erc.europa.eu/
- National Research Foundation (Singapore) http://www.nrf.gov.sg/
- United Nations <u>www.un.org/en/index.html</u>
- *Research: Research professional http://info.researchprofessional.com/
- European Commission Funding/Horizon 2020 http://ec.europa.eu/programmes/horizon2020/



Searching for Funding (cont'd)

Personal contacts and networking

- Sponsors
- Professional organizations
- Regional seminars
- Social networks





Foundations and Other Sponsors

- Tie funding request to mission and focus of foundation
- Foundation sponsor may OR may not allow expense items that the government allows – check guidelines
- Budget format may differ
- Know the difference between family foundations, community foundations etc.

Foundations

Every foundation is unique

- Eligibility
- Submission criteria
- Format for proposal
- Format for budget
- Review of purchases
- Terms and conditions



Foundations - Special Considerations

- Indirect/F&A Costs
 - Usually restricted or not allowed
 - Policies on unrecovered F&A
 - Impact on Institution, College, Department, Pl
- Intellectual Property issues
- Gift vs. sponsored project
- Cost sharing
- Eligibility



For-profit Sponsors

- Check for financial viability
- Indirect/F&A Rate rate
 - Higher rate than federal is allowable
- Contract vs. Sponsored Project
- Terms and Conditions
 - Intellectual property
 - Publication clauses
 - Other T&Cs specific to for-profit companies

International Sponsors

- Understand negotiations/legal process
- Currency and language used
- Exchange rate fluctuations
- Dispute resolution
- Other factors
 - Anti-corruption
 - Export controls
 - Anti-terrorism
 - Risk assessment





PRE-AWARD ADMINISTRATION

PROPOSAL PREPARATION

A Successful Proposal...

- Follows directions
- Meets sponsor needs
- Contains specific, reasonable scope of work
- Has clearly stated goals, objectives and methods
- Researcher or team has track record, expertise
- Budget matches proposed research

Types of Proposals

- Preliminary submission aka letter of interest or intent, white paper, concept paper
- Invited submission
- Limited submission (know institutional process)
- Full submission
- May be optional or required



Review the Guidelines - Exercise

Locate the following:

- Eligibility criteria
- Due dates
- Dollar range/number of expected awards
- Project fit
- Award information
- Proposal preparation & submission instructions
- Review/evaluation criteria
- Award conditions



Determine Roles

Who will be responsible for what part(s) of the proposal?

- Principal Investigator vs. Research Administrator
 - Set clear expectations
 - Technical proposal vs. business proposal
 - Protocols
 - Abstract
 - Facilities and resources
 - Coordinating with collaborators
 - Proposal editing and assembly
 - Obtaining approvals



Common Proposal Elements

- PI demographic information
- Home organization information
- Abstract or research summary
- Research plan
- Bibliography or references cited
- Facilities and other resources
- Data management or resource sharing plan
- Post-doc mentoring plan
- PI / key personnel curriculum vitae or biosketch, current and pending support
- Budget / Budget Justification
- Human / Animal Subjects information



Proposal Prep Step One: Gather Information

- Sponsor information (e.g., RFP, call for proposal, guidelines, etc.)
- Project particulars from PI (project dates, personnel commitments, budget items, partners, etc.)
- Collect data to complete institutional and sponsor forms
- Use checklists



Proposal Prep Step Two: PI/DA/RA Teamwork

- RFP/guidelines review
- Identification of key proposal components & deadlines
- Identification of proposal formatting and compilation requirements
- Develop budget and justification
- Compliance elements
- Special forms or letters



Proposal Prep Step Three: Communicate with Stakeholders

- Share/obtain other required information:
 - Obtain information of key personnel from your institution (vitae, current and pending statements, work task statements and budgets, etc.)
 - Contact subrecipients/partners for key information (budgets, statement of work, authorization to participate, vitae, current and pending statements, letters of support etc.)
 - Work with foundation/government/alumni relations if applicable
 - Contact other administrative units if needed

PRE-AWARD ADMINISTRATION

BUDGET PREPARATION

Budget Defined

- "Budget means the financial plan for the project or program that the Federal awarding agency or pass-through entity approves during the Federal award process or in subsequent amendments to the Federal award. (2 CFR 200.8)
- Business Side-What do I need in order to accomplish the goals of this project?



A good budget....

- Is complete
- Is adequate to cover the scope of work
- Is within sponsor norms
- Follows sponsor guidelines
- Is consistent with the narrative
- Is clearly justified
- Follows institutional guidelines



Characteristics of Costs 2 CFR 200 Uniform Guidance

- Allowable according to policies and procedures
- Reasonable and necessary for performance of the award
- Allocable
- Consistently Applied



Is a Cost Allowable?

- Benefits the project
- Advances the work being performed
- Routine costs included in indirect/Facilities and Administrative (F&A)costs
- Is permissible according to sponsor, federal, and institutional policies and regulations



Is a Cost Reasonable?

- Test Is the expense necessary?
- Prudent person test cost
- Is it normal for this type and level of expense to be charged on projects of a similar nature?
- Market Value-Appropriate bids with arms-length negotiation



Is a Cost Allocable?

- Was the cost incurred solely for the advancement of the project?
 - If not, is assigned cost in proportion to the benefit received by project?
- Can the expense be clearly identified with the project?
- Assigning inappropriate expenses is fraud (False Claims Act)!

Is a Cost Treated Consistently?

- Like expenses should be treated in the same manner under like circumstances
- Direct vs. indirect/F&A
 - Duplicating, telephone, utilities
 - Office supplies
 - Administrative costs



Cost Mini-Quiz

- 1. The process of acquiring quotes for larger purchases demonstrates which of the following standards for costs?
 - A. Reasonable
 - B. Allocable
 - C. Allowable
 - D. Consistent



Cost Mini-Quiz (cont.)

- 2. A cost is allowable on a research project if:
 - A. It is specifically identified in Uniform Guidance
 - B. There is sufficient budget available to cover the cost
 - C. The cost was incurred solely for the advancement of the project
 - D. A. B and C



Cost Mini-Quiz (cont.)

3. Local calls generally cannot be charged to a federal project because

- A. They are not allocable
- B. They are unallowable
- C. They are part of the indirect/F&A cost base
- D. All of the above



Budgets

- Direct Costs (2 CFR Part 200.413)
 - Clearly identifiable costs related to a specific project

- Indirect/F&A Costs (2 CFR Part 200.414)
 - Costs related to expenses incurred in conducting or supporting research or other externally-funded activities but not directly attributable to a specific grant

Elements of Direct Costs

Salaries & Wages

- Institutional & sponsor policies on academic year and summer salary recovery - based on Institutional Base Salary (IBS)
- NIH salary cap <u>NOT-OD-23-056</u>: Guidance on <u>Salary Limitation for Grants and Cooperative</u> <u>Agreements FY 2023 (nih.gov)</u>
- Graduate student support-salaries, stipends, tuition
- Technical support
- Administrative support
- Undergraduate students
- Post-doctoral associates





Fringe Benefits

- Federal rate agreement
- Review institutional policy re: graduate students
- Institutional guidelines
- Employment vs. Non-employment



Equipment

- Sponsor requirements/regulations
- Institutional capitalization policy/threshold
- Usually exclusive use by project
- Should be itemized and justified quotes may be needed and can help with justifications
- Ownership can be with sponsor or institution





Small Computing Devices

- Uniform guidance provides flexibility as materials and supplies
- 2 CFR Part 200.453 In the specific case of computing devices, charging as direct costs is allowable for devices that are essential and allocable, but not solely dedicated, to the performance of a Federal award.



Travel

- Institutional/state policy
- Sponsor guidelines
 - Fly America Act-Federal funds
- Foreign travel





Subcontracts

- Scope of Work
 - Substantial contribution to project
- Detailed Budget and Justification
- Commitment to perform (with authorized signature)
- Other information as needed
- Beware of subs >50% of project



Consultants

- Know your institution's policy
- Justify contribution to project and budget
- Include name and affiliation
- Include all costs including travel & per diem
- Include biographical sketches
- Watch for daily rate limitation



Other

- Communications
- Publications and dissemination activities
- Animal care per diem
- Computing services
- User fees
- Rental of equipment or facilities
- Maintenance or service Contracts
- Renovation/Construction costs
- Participant support costs
- Human subject payments
- Patient care
- Tuition remission
- Other



Indirect / Facilities & Administrative (F&A) Costs

"Indirect (F&A) costs are those that are incurred for common or joint objectives and therefore cannot be identified readily and specifically assigned to a particular sponsored project, an instructional activity, or any other institutional activity." 2 CFR 200.56



Indirect / F&A Costs (cont.)

- Two broad categories
 - Facilities
 - Administration
- Federal rate set by your cognizant agency in negotiation with your institution
 - Applies to subcontracts with federal prime



Indirect / F&A Costs (cont.)

- Know sponsor's terms/restrictions
- Know institution policy and procedures
- Federal vs. nonfederal
- Types of rates
 - On campus vs. Off Campus
 - Activity type (research, instructional, other)
- De minimus rate 10% (may be revised stay tuned)

Indirect / F&A Costs (cont.)

Most common calculations are...

- Salaries and Wages (S&W)
- Modified Total Direct Cost (MTDC)
- Total Direct Costs (TDC)



Indirect / F&A Calculations

Modified Total Direct Cost Base:

Total Direct Costs Less:

- Equipment & capital expenditures
- Patient care
- Rental costs
- Tuition remission, scholarships and fellowships
- Participant support costs
- Portion of sub-awards in excess of \$25,000 (may be revised stay tuned)
- On-site vs. Off-site rate



Check sponsor terms

Indirect / F&A Costs Quiz

An investigator on an NSF grant has permission to rebudget \$150,000 of capital equipment funds into graduate student tuition. If the institution's facilities and administrative cost rate (based on MTDC) is 54%, how much money will be available for graduate student tuition:

- A. \$69,000
- B. \$81,000
- C. \$97,403
- D. \$150,000



Budgeting Case Study





Cost Sharing

- "...the portion of project costs not paid by Federal funds (unless otherwise authorized by Federal statute)"*. 2 CRF 200.29, and references 2 CFR 200.306
- Sponsor requirements vary
- Collaborations may require matching or cost sharing



Types of Cost Share

- Mandatory –Required as a condition of obtaining an award
- Voluntary Committed –Cost sharing not required by the sponsor but quantified in the proposal budget or narrative; some sponsors forbid the use of Voluntary Committed Cost Sharing

Beware of these commitments!

 Voluntary Uncommitted – Commitments above and beyond that which is committed in the proposal and award



Cost Sharing Eligibility Criteria:

- Are verifiable from the non-Federal entity's records;
- Are not included as contributions for any other Federal award;
- Are necessary and reasonable for accomplishment of project or program objectives;
- Are allowable under Uniform Guidance;
- Unless authorized, are not paid by the Federal government under another Federal award
- Are provided for in the approved budget when required by the Federal awarding agency;



Myths

- "It will help me get the award."
- "If it's not required, I can offer cost-sharing and I don't have to document it."
- "If it's not in the budget, but in the narrative, I don't have to document it."
- "I can cost share the same expense over several proposals."



Allowable types:

- In-Kind Faculty time and associated fringe benefits
- Cash contributions cash provided to the project by the recipient or funds provided by third parties to the program.
- Donated/volunteered services and/or property non-federal public agencies and institutions, private organizations and individuals who provide services and/or property to the program at no charge.
- Associated Indirect/F&A costs when allowed by the sponsor.

Unallowable sources/costs:

- Can't use federal funds as a cost share for a federal award unless authorized by statute
- Items or services provided to the project or purchased by the project outside (before/after) the funding period of the program.
- Cost sharing already included in another project



Acceptable forms of documentation:

Pre Award:

- Letter from third party contributor
- Memorandum from department chairperson or dean
- Identification of other sponsored programs with the ability to contribute
- Must have appropriate approvals for cost sharing. Cannot simply put cost sharing into the budget and hope to find resources later. Don't have a hidden agenda that forces departments and deans to provide cost sharing at a later date.



Acceptable forms of documentation:

Post Award:

- Payment documents (invoices and operating ledgers showing payment)
- Letter and paid documents from third party contributor
- Effort reports and assigned time verification
- F&A foregone calculations and supporting documentation



Common challenges

- Over commitment of faculty time
- Undocumented expenses
- 3rd party contributor fails to adhere to collaboration agreement
- Offered services/goods performed/obtained outside the awarded program timeframe
- Cost sharing commitments offered multiple times
- Proposal commitment of cost sharing was not approved by the department and/or Dean
- Inappropriate use of federal funds or federal pass-through funds as cost sharing
- Volunteering someone else to pay

Cost Sharing Case Study



Why Budget Compliance is Critical

- Audit findings
- Return of funds
- Loss of institutional reputation



PRE-AWARD ADMINISTRATION

BUDGET JUSTIFICATION

Budget Justification

Importance

- Helps explain the "why" of project costs
- Gives the reviewer supportive explanations
- Can clarify needs of unusual or projectspecific costs
- Further "tells the story" of the project



- Personnel
 - Role on project
 - Cost rates and basis
 - Fringe benefit rates and application
 - Fluctuations in effort
- Operating Expenses & Supplies
 - Application to the project
 - Cost basis



- Travel
 - Purpose
 - Relation to project
 - Cost basis
- Equipment
 - Description
 - Cost supported by quotes
 - Benefit to the project
- Dissemination Costs
 - Publications, websites, other



- Human Subjects
 - Payment structure & rate determination
- Animal care and use
 - Facilities
 - Care & Feeding
- Patient Costs
 - Rate determination and basis

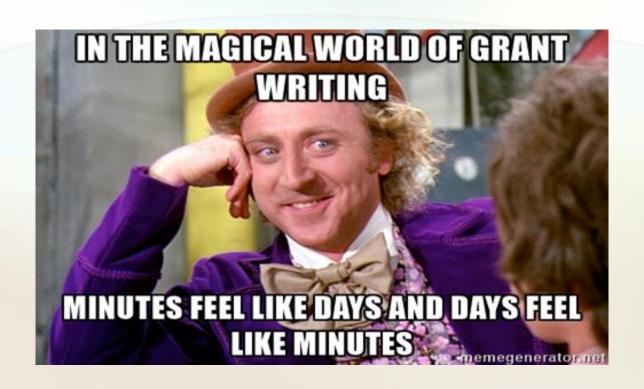


- Consultants
 - Application to project
 - Cost basis
 - Credentials
- Subawards
 - Application to project is discussed in proposal
 - Costs and justification provided by each recipient



- Cost Sharing
 - Mandatory cost elements
- F&A Costs/Overhead/Indirect Costs
 - Rates
 - Basis of calculation
 - Application to cost elements
- Anything else that is included in the budget







PRE-AWARD ADMINISTRATION

PROPOSAL SUBMISSION

Proposal Prep Step Four: Submission

- Institutional review and authorization
 - prior to submission to sponsor
- Submission to Sponsor
 - Via institution
 - Direct to sponsor
 - Electronic and/or Hardcopy



Proposal Submission Requirements

- Be aware of agency submission requirements
 - Online
 - U.S Government agencies many use Grants.gov;
 Research.gov, NIH ASSIST, agency-specific sites
 - Foundations and associations vary



Electronic Submission

What is Grants.gov?

 A centralized, online process to search and apply for 1000 grant programs from the 26 Federal grant-making agencies



Applying through Grants.Gov

- Make sure your institution is registered
- Search Grants.gov for funding opportunities
- Get application package
- Apply and submit using System to System or Workspace

For helpful tools and resources, see:

https://www.grants.gov/web/grants/home.html



What is Research.gov?

- Research.gov replacement for FastLane
- Obtain your own log-in credentials
- Research.gov Proposal Preparation and Submission





System-to-System (S2S) Products

Purchase or subscribe:

- Huron (Click)
- Cayuse
- Kuali
- InfoEd
- Key Solutions
- SmartGrant
- Others





PRE-AWARD ADMINISTRATION

SPONSOR ACTIONS

The Review Process



Review Process - Overview

- Timeline and transparency
- Proposal assessment
 - compliance and conformance of components
 - technical review
 - evaluation criteria

Peer Review

- By definition, reviewers are individuals with expertise in the stated area of research
- Funding, publication decisions
- Impartial judgement
- Maintain confidentiality- whose idea is it?

Pre-Award Audits

- Verify salary, fringe and overhead
- Costs necessary and reasonable
- Travel who, when, where, why
- Equipment basis or quotes
- Further clarification on requested items
- Alignment with agency mandate
- May include site visits



Declination

- Declination letter (Not recommended for further consideration)
- Review committee comments
- Debriefing
- Reconsideration
- Appeal
- Rework/Resubmit







Awarding

- Notification (Just-In-Time)
- Award Finalization
 - Simple or complex
- Negotiation
- Change in scope or \$\$



PRE-AWARD ADMINISTRATION

REPS, CERTS AND COMPLIANCE

Representations & Certifications

Document that attests to institution's demographics, policies, and adherence to regulations such as:

- Debarment and Suspension
- Small Business involvement
- Drug Free Work Place (Work Force only classified awards)
- Lobbying
- Equal Opportunity
- Misconduct in Science/Responsible Conduct of Research
- Conflict of Interest
- Registration in SAM or other certifications

Areas of Compliance

- Responsible Conduct of Research (RCR)
- Human subjects
- Animal subjects
- Recombinant DNA
- Radiation Safety, Biosafety, Controlled Substances
- Export Controls, Controlled Goods Act
- Others...

Human Subjects

- Research means a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; (see 45 CFR 46.102(d)).
- Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
 - (1) data through intervention or interaction with the individual, or
 - (2) identifiable private information. (see 45 CFR 46.102(f))
- https://humansubjects.nih.gov/



Human Subjects (cont.)

- Oversight:
 - Office of Human Research Protections (OHRP) (a unit within the DHHS implements the regulations for the protection of human subjects)
 - OHRP website: http://www.hhs.gov/ohrp/
 - Federal wide Assurance Number
- NIH human subject education certification
- Your organization's Institutional Review Board (IRB)
 - IRB has primary mandate to protect rights and welfare of humans who participate in funded and unfunded research

Animal Subjects

- Basic principles governing the ethical conduct of research involving animals - proper care and treatment of animals used in biomedical/behavioral research
- Animal Welfare Act (AWA) United States
 Department of Agriculture (USDA)
 https://www.aphis.usda.gov/aphis/ourfocus/a
 nimalwelfare/SA AWA
 - Any animal live or dead—excludes birds, rats and mice, and cold blooded animals



Animal Subjects (cont.)

- Policy on Humane Care and Use of Laboratory
 Animals (PHS Policy) Office of Laboratory
 Animal Welfare (OLAW)
 http://grants2.nih.gov/grants/olaw/references/phspol.htm
- Institutional Animal Care and Use Committee (IACUC): your institution's administrative body established to protect animals in research



Misconduct in Science

Misconduct means

- Fabrication, falsification, plagiarism, or other serious deviations from accepted practices in proposing, carrying out, or reporting results from research
- Material failure to comply with federal requirements for the protection of researchers, human subjects or the public or for ensuring the welfare of laboratory animals
- Failure to meet other material legal requirements governing research



Misconduct in Science (cont.)

- Research organization must have procedures for handling allegations, conducting inquiries, and protecting whistleblowers
- Information relating to misconduct policies and regulations can be found at
 - http://ori.hhs.gov/



New Policies on Sexual Harassment

- The National Science Foundation: new term and condition regarding sexual harassment, other forms of harassment, or sexual assault.
 - Effective October 22, 2018
 - Reporting requirements for PI/Co-PI violations
 - Notification to NSF within ten business days from the date of the finding/determination, or the date of the placement of a PI or co-PI on administrative leave or the imposition of an administrative action, whichever is sooner.
 - Other federal agency responses (NASA,NIH)



Conflict of Interest

- Conflicts of interest (COI) occur when institution members are in a position to influence a decision on policy or purchases from which they may directly or indirectly receive financial benefits or provide improper advantage to associates
- Goal of COI policy is to promote objectivity



Conflict of Interest/ Financial Disclosure Statements

- Filing required for personnel who are in a position to influence the design, conduct and reporting of research
 - Generally, at minimum principal investigator and key personnel must file
- Types
 - Financial
 - Institutional
- Conflicts must be resolved prior to spending on federal grants
- Management Plan for identified conflict

Export Controls*

- Export Controls regulate the shipment or transfer, by whatever means, of controlled items, software, technology, or services out of U.S. (termed an "Export")
- The government restricts the release of certain information to foreign nationals here in the U.S. (referred to as a "Deemed Export")
- Export control policies and regulations
 - Protect national security
 - Safeguard economic interests and foreign policy concerns
 - Complicated network of multi-federal agency inter-related regulations

Why Do Research Institutions Care About Export Controls?

- Obligated to follow the law
- Regulations have strict requirements and big consequences for violations
- Unique exclusions available only to higher education institutions located in United States:
 - Fundamental Research Exclusion
 - Educational Instruction for Catalog Courses
- Export Administration Regulations (EAR) 5 CFR Parts 730-774
- International Traffic in Arms Regulations (ITAR) 22
 CFR Parts 120-130
- Embargo and Trade Sanctions 31 CFR Parts 500 598

Areas of Concern for Research Organizations

- Foreign travel
- Unsolicited requests to research or offers of assistance
- Visiting scientists/researchers
- International activities including joint venture, campuses, and collaborations
- Shipping or hand carrying to foreign countries
- Purchasing or procurement
- Human resources and Form I-129 reviews



POST-AWARD ADMINISTRATION AWARD REVIEW

What type of award?

Grant

- Transfer of money, property, services, or anything of value to recipient to accomplish a public purpose
- No substantial involvement with sponsor

Cooperative Agreement

- Transfer of funds to recipient to accomplish a public purpose
- Substantial involvement between sponsor and recipient

Contract

- Acquisition of property or services for benefit of or use by sponsor
- Purchase Order
- Fixed priced for a product or service



What is the difference?

Grant

- More flexibility re: research direction
- No restrictions on publications
- IP generally not tied to sponsor
- Payment independent of milestone reporting

Contract

- Research tasks clearly delineated
- Publication can be delayed
- Sponsor may have IP rights
- Funds often released after report is accepted

Sponsored Project or Gift?

- Terminology is <u>not</u> the determining factor
- What is the intent? Philanthropic or exchange transaction?
- Two considerations: intent of sponsor; who can best administer the project (OSP/Advancement)
- Gifts/Donations: Coordinated through the Development or University Advancement Office
- Deal Breakers? i.e., F&A, Overhead...

Sponsored Project or Gift?

SPONSORED PROJECT	CHARITABLE GIFT
The award is made by a governmental or quasi- governmental agency.	Philanthropic intent. An unrestricted, charitable, philanthropic or donated gift.
The award is from a private-sector sponsor that provides a subcontract or subgrant containing federal "flow down" provisions, e.g., federal, state or other governmental fiscal compliance policy governs the project.	Detailed financial reporting or accounting is not required; although a donor may request progress and final reports about utilization or impact of the gift, including expenditures and fund balances.
The award is from a private-sector entity (including individuals) for the work of a specific faculty member(s) and requires the completion of programmatic objectives (including reports) within a specific budget and time frame.	Although the donor intends the gift to be philanthropic and irrevocable, if the funds are not used for the intended purpose(s) with the specified period of time as stated in the gift agreement, the donor may request that a portion or the entire gift be returned.
The sponsor places restrictions on publication of data resulting from the work. This could include requirements that the sponsor review manuscripts, talks, etc., prior to submission for publication or presentation, and the potential for delays in publication or presentation until intellectual property can be protected.	The donor does not retain any reversionary interest or cannot be expected to receive any material deliverable from the act of donating funds. A deliverable is a service or a tangible product resulting directly from the use of funds for which the original payor of the funds will receive a material benefit to which it would not otherwise be entitled, such as

intellectual property or technical / scientific reports

prior to their availability to the public.

Sponsored Project or Gift?

- /		
1	SPONSORED PROJECT	CHARITABLE GIFT
1	The sponsor requests proprietary rights in data or inventions resulting from activities conducted under the award. This would include any reference to licensing options or arrangements for patents and/or copyrights developed during the work.	Funding opportunity includes a request for 501(c)(3) documentation.
	Studies are to be conducted on substances, processes and/or products, etc., owned by the sponsor.	
1	The sponsor requires detailed invoices and/or financial reports.	
1	The sponsor may refuse payment, impose penalties and/or revoke the award.	
	The sponsor includes a provision in the award for audits by or on behalf of the funding source.	

Definition of an Agreement

- A legally binding agreement between the university/institution and the sponsor
- Involves an exchange, where each party gives and receives something of value
- There is a risk of liability for nonperformance, non-compliance, other breaches of contract



Agreement Review Checklist

- Parties names, status, official address
- Scope of work
- Deliverables and milestones
- Timetable
- Budget
- Payment provisions
- Reporting requirements (financial/technical)
- Key contacts page (administrative, technical, financial, binding authority)
- Travel restrictions
- Cost Sharing requirements
 - It is necessary???



Agreement Review Checklist (cont'd)

- Proper F&A/overhead rate applied
- Intellectual Property Rights
 - Establish ownership, access rights by both parties
 - Patent costs, sharing of commercial benefits, etc.
- Publication Restrictions
- Confidentiality
 - What is confidential? How long does it remain confidential? Should protect both parties and have escape clauses.
- Warranties/Assurances



Agreement Review Checklist (cont'd)

- Liability and Indemnity
 - Identifies who indemnifies whom, for what.
 - Preferably each party is responsible for its own actions and for the misconduct of its agents during the project.
 - Cap liability
 - Sponsor is responsible for any use it makes of results, including product liability and infringement of third-party IP rights.
 - Insurance requirements
- Terms of Termination
 - Include start and end date, premature termination, financial and IP consequences, provisions and extensions etc.
- Conflict Resolution
 - Identifies procedures for arbitration and/or mediation
- Governing Law
 - Establishes whose law and what court will be used in an litigation. Try for your own jurisdiction.

Tips for Successful Agreement Negotiation

- Work closely with principal investigators (PIs)
 - Have PI review contracts
 - Keep them fully informed
 - Understand what the PI wants
- Know your institutional requirements required clauses
- Be open minded
 - Every situation is different and there are different ways to meet objectives.



Award Set Up

- Actions needed (roles may differ from institution to institution)
 - Review award document
 - Review with PI (kickoff meeting...)
 - Set up grant account in financial/reporting systems
 - Award notification to key stakeholders
 - Start the project





Collaborative Research within Your Institution

- Defined Roles and Responsibilities
- Management
 - Finances
 - Supervision
 - Compliance
 - Intellectual property, publications, data

Review with Principal Investigator

- Communicate award information
- Discuss personnel requirements
- Review reporting requirements
- Discuss resources
 - Personnel
 - Space
 - Equipment
 - Purchasing
- IP and publication requirements
- Initiate subaward set up
- Human, Animal Subjects and other safety issue approvals must be in place prior to spending



Reporting Requirements

- Financial expenditure profile should match funding profile
- Performance/Technical
- Impact of non-compliance





POST-AWARD ADMINISTRATION SUBAWARDS

Subawards, Consultants, Independent Contractors

- Confirm or procure required sponsor approval
- Award mechanisms & terms
- Sub agreements with commercial entities use FAR clauses in lieu of CFR or OMB Circular References



Subrecipient Agreements

- Communicate award receipt with subrecipients
- Confirm accuracy of costing information
- Confirm scope of work
- Refer to subrecipient commitment form
- Initiate subrecipient agreement
 - Flow down clauses



POST-AWARD ADMINISTRATION

PROJECT MONITORING

Financial Stewardship

- Managing Resources
 - Personnel effort
 - Purchases
 - Allocating Funding
 - Indirect Costs



Roles and Responsibilities

- Role of PI/PD
 - PI/PD dual responsibility: technical and fiscal
- Role of the research administrator
 - RA dual responsibility: administrative and fiscal
 - sponsor regulations and requirements
 - institutional policies and procedures
 - fiscal management





Management Tools

- Sponsor Award Notice & Rules
- Reports
 - Financial: Summary; Detail; Object Code
 - Personnel: Labor Distribution
- Electronic databases/reminders
- Shadow systems / projections
- RA collaborative departments
- Meetings with PI & staff



Funding

- Actual and/or Projected Spending
 - vs. award gross
 - vs. budget category
- Frequency
 - every 60 days
 - upon request
 - 90 days prior to period end date
- Concerns





Ongoing Issues

- Personnel
 - Effort
 - Appointments and appointment expirations
 - Treatment of Students
- Equipment
- Transactions





Special Attention

- New and/or first-time PI/PD or sponsor
- Procurement- Uniform Guidance
- Cost sharing commitment(s)
- Subawards, consultants
- Milestone deliverables
- PI leave
- Program income
- Cost transfers
- Budget revisions



Encumbrances

- Subawards, Consultants, Independent Contractors
- Large Dollar Volume Expenses
- Maintenance of Encumbrances





Program Income

- Definition
 - Income generated from fees, use/rental of property, sale of goods and/or services, license fees, royalties on copyrights, interest on loans
- Treatment of Program Income
 - Additional Funds
 - Cost Sharing or Matching Funds
 - Deduction of Funds



Financial Management - Considerations

- Sponsor may request reduction in budget
 - Scope of work should be reduced accordingly
 - Cost sharing should be reduced accordingly
- Sponsor may agree to full budget but only allocate (incrementally fund) a portion of funding for specific time-frame
 - How can budget be adjusted to accommodate funding
- Sponsor may reduce funding
 - If expenses do not match budget
 - if funding not utilized consistent with the scope and duration

POST-AWARD ADMINISTRATION TRANSFERS AND OTHER CHANGES

Adopt a Policy of Compliance

"The first step in charging costs is to be certain that the initial charge is appropriate."

Cost Transfer Requirements

- Exception, not the rule
- 2 CFR Part 200.405 Allocable costs. Subsection 3.c states "Any cost allocable to a particular Federal award ...may not be charged to other Federal awards to overcome fund deficiencies, to avoid restrictions imposed by Federal statutes, regulations, or terms and conditions of the Federal awards, or for other reasons."

Cost Transfer Issues

- Issues that may result in a Cost Transfer:
 - Pre-award costs
 - Data entry errors
 - Unallowable costs



Budget Revisions

- Adjustments between budget categories
 - Personnel/Fringe Benefits and Other Direct Costs
 - Participant costs
 - Human subject costs



Budget Revision Process

- Two considerations
 - Why is the revision needed?
 - What is the impact on project?
- Check guidelines...
 - To be sure of sponsor's position
 - To check for 'category-to-category' restrictions
 - Change the budget in financial system





Grant Transfers/Relinquishments

- PI requests transfer from awarded institution
- If agreed, review sponsor requirements
- Estimate balance remaining
- Submit relinquishment notice to sponsor; submit final reports to sponsor (financial, technical)

POST-AWARD ADMINISTRATION

CLOSE OUT

Close Out of Award

...Begins the day the award is made ...





Award Close Out Issues

- Review financial transactions
 - Manage questionable costs
- Review labor commitment vs. actuals
- Review cost sharing commitment vs. actuals
- Address final balance
 - Overspent
 - Residuals
- Documentation



Close Out Actions

- Close encumbrances
- Ensure no outstanding charges
- Submit changes to accounts for ongoing expenses (recharges, personnel)
- Programmatic/Technical reports submitted



Close Out of Award

- Fiscal Reporting
 - Effort (promised and delivered)
 - Unallowable Expenses
- Cost Sharing
- Intellectual Property
- Equipment Reporting
- MBE/WBE Reporting
- Close financial ledgers
- Transfer of residual funds



After Close Out

- Data Retention and Access (Technical in nature)
 - Provide reasonable access
 - Retain for 3 years after final reporting or publication
 - Sponsor requirements may differ



A Few Words About Audits



Common Audits

- Federal compliance/single audit (Required for educational institutions, states, local governments and non-profits)
 - Compliance Supplement
 - >\$750,000 in federal expenditures
 - 2 CFR 200 Subpart F
- Sponsor
- Programmatic
- Internal
- Financial

Auditee Responsibilities

- Identify federal awards
- Good internal controls
- Comply with laws, regulations, etc.
- Financial statements
- Audit compliance
- Remedy audit findings

Auditee Responsibilities

The auditee must:

- (a) Procure or otherwise arrange for the audit required by this part in accordance with §200.509 Auditor selection, and ensure it is properly performed and submitted when due in accordance with §200.512 Report submission.
- (b) Prepare appropriate financial statements, including the schedule of expenditures of Federal awards in accordance with §200.510 Financial statements.
- (c) Promptly follow up and take corrective action on audit findings, including preparation of a summary schedule of prior audit findings and a corrective action plan in accordance with §200.511 Audit findings follow-up, paragraph (b) and §200.511 Audit findings follow-up, paragraph (c), respectively.
- (d) Provide the auditor with access to personnel, accounts, books, records, supporting documentation, and other information as needed for the auditor to perform the audit required by this part.

Audit Findings

- Definition
 - deficiencies auditor is required to report in the schedule of findings and questioned costs
- Reporting/Data Collection
- Findings
- Corrective action plans
- Future year reporting of findings

Example: Audit Risk Area

- Cost transfers:
 - A high volume of cost transfers could suggest a lack of proper award management
 - Raises questions on internal controls
 - Poor expenditure planning
 - Lack of monitoring
 - Charge "holding" or balance "floating"

Audit/Office of Inspector General Hot Topics

- Sub-Recipient Monitoring
 - Federal Funding Accountability and Transparency Act (FFATA)
- Compliance with Cost Principles (Cost Accounting Standard, Uniform Guidance)
 - Cost Transfers
 - Cost Sharing
 - Effort Reporting
- Internal Controls

RESEARCH ADMINISTRATION

RESPONSIBILITIES AND ETHICS

Responsibilities & Ethics

- Significant responsibility rests with the research administrator
- Many of the checks and balances of the system end with you
- Keep in mind that decisions you make can affect the entire institution
- Stewards of the funds!





How are YOU Responsible?

- Know the impact of unallowable or unlawful actions on the big picture
- Listen to your gut...research further
- Don't let pressure drive decisions!
- You are not alone...
- Educate yourself
 - Case studies Responsible Conduct of Research for Research Administrators
- http://ori.hhs.gov/education/products/rcradmin/



How are YOU Responsible?

- Provide grants management training for new PIs and Research Administrators
- Provide refresher trainings for existing PIs and administrators
- Make it a requirement prior to award establishment or account access (if possible)
- Lead by example

Professional Associations

- Society of Research Administrators International (SRA)
- National Council of University Research Administrators (NCURA)
- National Association of College and University Business Managers (NACUBO)
- Public Responsibility in Medicine and Research (PRIMR)
- National Organization of Research Development Professionals (NORDP)



Resources for the Research Administrator

- RESADM-L Research Administrators Listserv
- To sign up send the command
 - SUBSCRIBE RESADM-L [insert first last name]to:
 - LISTSERV@LISTS.HEALTHRESEARCH.ORG
- To send a message to the list, send email to
 - RESADM-L@LISTS.HEALTHRESEARCH.ORG
- New list serve launched for International Research Administration
 - EURESEARCHADMIN-L@LISTSERV.UCOP.EDU



Discussion & Questions





Special thanks to the following contributors:
Sharon McCarl, CMU, Leslie Levine, CMU, Donna Marano, CMU, Denise
Murrin Macey, formerly CMU, Janet Stoeckert, Keck School of Medicine,
Jennifer Freeman, UOIT, J. Michael Slocum, Slocum Boddie, PC, Anne
Schauer, Miami University, and countless other dedicated research
administration professionals!

ADDITIONAL INFORMATION SLIDES

- Data Management
- Environmental Health and Safety
- Recombinant DNA
- Technology Transfer

Data Management

- Data Management Plans
- Ownership
 - Sponsor, Institution, Investigator, Source of data,
 Partner or Community
- Creation and Collection
 - Appropriate Methods, Attention to Detail, Authorization, Recording



Protecting Data

- Storage
 - Protecting lab notes, computer files, samples
 - Maintain Confidentiality
 - Data Retention 3-7 years depending
- Sharing
 - Research data is generally made available following publication
 - Methods of sharing (e.g., institutional repository, funder repositories, etc.)
 - Access to data
 - Open access data movement, controls or restrictions



Considerations

- Size
- Control
- National Security
- Ethical and legal considerations
 - IP and potential commercialization
- Dissemination



Environmental Health & Safety

EPA

- Environmental Protection Agency
- Title 40 Code of Federal Regulations (CFR), Protection of Environment

DOT

- Department of Transportation
- Title 49 CFR, Transportation

NRC

- Nuclear Regulatory Commission
- Title 10 CFR, US NRC Rules and Regulations

OSHA

- Occupational Safety Health Administration
- Title 29 CFR, Labor Safety

Note: U.S. Code of Federal Regulations may be found at:

https://www.govinfo.gov/help/cfr

Stem Cell Guidelines - https://stemcells.nih.gov/policy/2009-guidelings

Recombinant DNA in Research

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)
 https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/
- Biosafety, Biosecurity and Emerging Biotechnology Policy Division within NIH
 - https://osp.od.nih.gov/biosafety-biosecurity-andemerging-biotechnology/biosafety-andrecombinant-dna-activities/
- Institutional Policies and Procedures



Technology Transfer

- Responsible for commercialization of ideas created at institution through licensing and start-up of new companies
- Processes invention disclosures from the colleges/universities
- Example of university technology transfer office: Carnegie Mellon University

http://www.cmu.edu/cttec/index.html



Technology Transfer



What is intellectual property?

The term "intellectual property" is used to describe any intangible asset that consists of human knowledge and ideas.

• What is a patent?

A patent is the exclusive right, granted by the government, to make use of an invention or process for a specific period of time, usually 20 years. Patents protect new, non-obvious, useful ideas. They give the holder the right to exclude others from the manufacture, use, or sale of products incorporating the idea for a limited term, in exchange for disclosing the idea to the public.

• What is a copyright?

A copyright is the exclusive right to make and dispose of copies of a literary, musical, or artistic work. Copyrights protect the specific expression of ideas rather than the ideas themselves. In the university context, copyright might be used to protect educational materials or computer software. Copyright gives the holder the right to exclude others from, among other things, unauthorized copying, "public performance" (which translates depending on context into "use"), modification or creation of derivative works.

• What is a trademark?

A trademark is a distinctive name, symbol, motto, or design that legally identifies an organization or its products and services, and sometimes prevents others from using identical or similar marks. In a university context, trademarks may be used to protect the name of educational materials or software already well recognized in a non-profit context, when a for-profit roll-out is being prepared

Responsible Conduct of Research (RCR)

Nine Pillars of RCR

- Data acquisition, management, sharing and ownership
- Mentor/trainee responsibilities
- Publication practices and responsible authorship
- Peer review
- Collaborative science
- Human subjects
- Animal research
- Research misconduct
- Conflict of interest and commitment



Key Compliance Elements in Conflict of Interest Policy

- Disclosing potential conflicts
- Monitoring and reviewing research accuracy
 - Academic freedom and scientific/technical impact
- Management plan
 - Removing individual from decision making
 - Supervision of trainees



New Policies on Sexual Harassment

- The National Science Foundation: new term and condition regarding sexual harassment, other forms of harassment, or sexual assault.
 - Effective October 22, 2018
 - Reporting requirements for PI/Co-PI violations
 - Notification to NSF within ten business days from the date of the finding/determination, or the date of the placement of a PI or co-PI on administrative leave or the imposition of an administrative action, whichever is sooner.
 - Other federal agencies likely to release their own regulations soon.