Certified Pre-Award Research Administrator (CPRA)

Exam Review Material/Study Guide

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Table of Contents

III. BUDGET DESIGN AND DEVELOPMENT

I Research Partnership and Funding

A. Settings for research administration

- Universities/colleges
- Non-profits
- Hospitals
- Foundations
- Independent Research Institutions
- For-Profits / Industry

In these settings, research administrators play a crucial role in facilitating and managing research activities. They handle the administrative aspects of research projects, ensuring compliance, managing budgets, and coordinating with researchers and external entities. They might be involved in proposal development, grant management, budget oversight, and regulatory compliance, ultimately enabling research teams to focus on their scientific work.

In some cases such as foundations, the organization may be the sponsor and research administrators help write the funding opportunity, answer questions from proposers and make the awards.

B. Roles and Responsibilities

1. **Research administrator** (facilitator, gatekeeper, resource locator, team builder, motivator)

   Facilitator – helping PI apply for funding. Interprets sponsors rules and regulations and disseminates information that can be understood by the researchers and others that need this information.

   Gatekeeper - act as vital intermediaries between researchers, funding agencies, and institutions, their position can sometimes be perceived as a "gatekeeper" function, controlling access to resources, processes, and approvals necessary for research to proceed.

   Resource locator – Assist PI with funding opportunity information;

   Team builder – Serves as interface between researchers and administration, between researchers and sponsor and between researchers and collaborators from other institutions.

   Motivator – Encourages faculty in the preparation of their proposal and in the success of their research. As serves as a communicator and problem solver.

2. **Sponsored Programs Office** Sponsored programs offices, also known as offices of research and sponsored programs (ORSP), have various roles and responsibilities related to managing research funding and projects. They assist with identifying funding opportunities, preparing and submitting proposals, negotiating awards, and managing funds and compliance post-award.

3. **Principal Investigator and Other Key Personnel**

   Direct and oversee all research activities and foster a culture of research integrity. Responsible for fiscal and administrative management of research. Conduct research in an objective and unbiased manner in compliance with policies and regulations.

4. Institution

Research institutions have several roles and responsibilities related to research conduct, data management, ethical guidelines, and compliance with regulations. They also play a crucial role in supporting research staff, providing resources, and fostering a culture of research integrity.

5. **Sponsor** A federal research sponsor is a federal agency that provides funding for research projects, typically through grants, contracts, or cooperative agreements. These sponsors play a crucial role in advancing scientific knowledge and supporting research activities at universities, research institutions, and other organizations.

C. Perspectives for Seeking and Awarding Sponsored Funding (institutions, sponsor's, principal investigator's, interdependency, common goals, relationships)

Why do Research? University Perspective

- Advance and disseminate knowledge
- Expand fundamental knowledge base - through basic research
- Creation of new knowledge
- Foster innovation
- Strengthen institutional presence - local, national and international
- Recruit faculty and students
- Improve programs and infrastructure

Why do Research? Sponsor Perspective

- Support funding-agency specific mission
- Expand fundamental knowledge base
- Foster innovation
- Benefit economy
- Improve laboratory and facility infrastructure
- Promote educational opportunities
- Recruit future employees

D. Collaborations (role, determining criteria, required proposal documentation)

1. Multiple/Collaborating PIs

Principal Investigator (PI) identifies the individual responsible for activities on a research project or activity, particularly those funded by a grant, a cooperative agreement, a training or public service

project, a contract, or other sponsored mechanism. Responsibilities include the intellectual conduct of the project, fiscal accountability, administration, and compliance. It is possible that the PI may share these responsibilities with a multi-investigator team.

Multiple Principal Investigator (MPI) identifies two or more individuals who share responsibility for the conduct of the project.

Co-Principal Investigator (Co-PI) identifies a senior member of the key personnel team who shares administrative, fiscal, and scientific conduct with the PI on research projects. The Co-PI can be named in the proposal and on project documentation as a co-PI provided this role is accepted by the sponsor.

Co-Investigator (Co-I) identifies a member of the project team who conducts the scientific portion of a research project. Co-Is can be named in the proposal provided the sponsor accepts the role.

2. Subrecipients

Subrecipients are entities that receive a portion of a research grant or contract from the primary recipient (the institution that received the award) to carry out a specific part of the project's work. Subrecipients are distinct from contractors or vendors, as they are responsible for their own programmatic decision-making and compliance with federal requirements. They typically collaborate with the prime recipient in fulfilling the project's objectives.

For the proposal and eventual agreement, the following items are needed.

- **Statement of Work** for the subrecipient work on the project
- Budget and Budget Justification for the subrecipient
- copies of rate agreements for indirect costs, fringe benefits, or other requested rates. For entities participating in the **FDP Clearinghouse**, we will collect this information from your **FDP Clearinghouse** profile.

3. Independent contractors

In research administration, independent contractors are hired for specialized skills or expertise not readily available within an institution's regular workforce. They are typically engaged for a specific, limited-term project or task. The IRS employs various factors, including behavioral control, financial control, and the relationship of the parties, to determine whether an individual is properly classified as an independent contractor.

4. Teaming agreement

Government contractors may establish a team arrangement with another company as part of a contract win strategy. Such arrangements represent a common way to combine complementary capabilities and resources to compete effectively for contracts. In essence, a team arrangement moves a potential subcontractor’s active involvement forward into the pursuit stage.

Government prime contracts may contain a broad scope of work that requires the research, development, production, integration, and implementation of a complex system. The scope and complexity may involve technology and expertise beyond the capabilities of any one company. Also, the requirements for presenting a bid or proposal may mandate the fulfillment of certain socio-economic goals, including the use of small and disadvantaged businesses to satisfy contract requirements. By using a team arrangement, the past performance and experience of the entire team, and not just of the prime contractor, can be highlighted in the proposal and evaluated by the Government customer.

A Teaming Agreement (TA) is a binding agreement between one or more organizations that are joining together to propose a new cooperative research program to a prime sponsor—often a federal or foreign government agency—in response to a competitive request for proposal (RFP). The lead proposing organization usually drafts the TA and requests that the other team members agree to it

TAs specify the RFP which will be addressed by the team, the objectives for each member of the team, the proposal to be generated by the team, and the actions and deliverables required from each party. Organizations that request TAs often ask the Institute to agree to partner exclusively with them in responding to the RFP. However, most universities will not agree to this condition, as they will not bar PIs who are not named participants in the TA from joining other organizations to respond to the same RFP. Some institutions will agree, however, that the institution's specified participants in the TA will not engage with another organization to respond to that RFP

TAs require that if the RFP is awarded to the lead proposing organization, that organization will issue a subcontract to the teaming members share of the proposed research unless the prime sponsor specifically disallows their participation

The resulting proposal may or may not win the award; under a TA, teaming members receive no funding for its proposal preparation efforts.

There is no fixed form or content for TAs; their content is determined by their objectives. Generally, TAs are drafted by the lead organization preparing the proposal for the prime sponsor

The time period for reaching agreement on a TA is usually driven by the proposal submission deadline. TAs typically expire when the prime sponsor selects or rejects the team's proposal.

E. Professional skills development for research administrators (customer service, project management, multi-tasking, time management, training for career development

As important as it is to hire the right staff, once they are hired it is equally as important to development and train them. Career development planning benefits the individual employee as well as the organization by aligning employee training and development efforts with the organization's mission, goals, and objectives. An individual development plan (IDP) is a tool to assist employees in achieving their personal and professional development goals. Many organizations have their positions structured with career ladders/advancement steps to provide their employees the opportunity to advance in their positions. Such as a Proposal Administrator I for a beginner and then a Proposal II, Senior Proposal Administrator I

and Senior Proposal Administrator II for those that have obtained a number of years of experience and handle a higher workload or increased levels of responsibility.

Needed Skills

Customer Service - Research administrators require strong customer service skills as they often act as the liaison between researchers and various departments or funding agencies.

Multitasking

- Responding to multiple inquiries: Research administrators might receive emails, phone calls, or in-person questions from different individuals with varied needs, requiring them to quickly assess and address each inquiry.
- Balancing different responsibilities: Beyond customer interactions, research administrators handle a wide range of tasks, such as assisting with grant proposals, managing research accounts, and ensuring compliance, all of which demand the ability to switch between tasks efficiently.
- Meeting deadlines: In the fast-paced research environment, administrators need to manage their time effectively to meet deadlines for proposals, reports, and other administrative tasks.

Time Management

- Handling multiple requests: Research administrators often face multiple requests from different sources, which can be overwhelming. Prioritizing tasks based on urgency and importance is essential to stay focused and avoid burnout.
- Balancing competing demands: Research administrators need to balance project demands with daily administrative tasks. Effective time management helps them allocate time to high-priority tasks and reduce time spent on activities that don't add value.

Internal Training

Most institutions have a training program for employees that are new to research administration. Many institutions hold internal training on research administration topics for their employees.

External Training

With the changes to rules and regulations it is important to provide training to staff so they can keep abreast of the changes. Organizations such as the National Council of University Research Administrators (NCURA) and the Society of Research Administrators International (SRAI) hold state, regional and national meeting that provide education sessions. They also have traveling workshops that will come to the institution. They along with other vendors offer webinars on a variety of research administration subjects. Online training is also available.

Master Programs

Several Universities have created on-line master programs in Research Administration.

The Research Administrators Certification Council (RACC). The Council is a private, independent, nonprofit organization that develops and administers a voluntary program for the certification of individuals who meet the requirements established by the Council. They offer the Certified Research Administrator® (CRA), Certified Pre-Award Research Administrator (CPRA®), or Certified Financial Research Administrator (CFRA) certifications. Benefits of Certification are:

- Professional recognition

- Personal satisfaction
- Indicator of expertise and knowledge
- Opens opportunities for employment
- Increased credibility with colleagues and clients
- Serve as a role model to others

F. Funding and Research Development

1. **Funding opportunities** (characteristics, key features)

a. Solicited

Solicited proposals are those that are **written and submitted in response to the issuance of a "Request for Proposals" (RFP)**, a document that identifies a specific research problem of interest to the funding agency for which they are specifically seeking a solution

b. Unsolicited/PI-initiated

An Unsolicited Proposal is a **written application for a new or innovative idea submitted to a Federal agency** on the initiative of the offeror for the purpose of obtaining a contract with the government, and that is not in response to a Request for Proposals, Broad Agency Announcement, Program Research and Development Announcement, or any other Government-initiated solicitation or program.

c. Limited submissions –The solicitation guidelines may limit the number of proposals that an individual PI or institution may submit. Typically an institution will have an internal review process to select the proposal to be submitted.

2. Funding information (background, content, best practices)

a. **Sources** (characteristics, key features)

i. Catalog of Federal Domestic Assistance (CFDA): *with the 11/12/2020 revision to Uniform Guidance this term has now changed to "Assistance Listing"*: Funding opportunities for federal assistance awards like grants, co-operative agreements (**note: not for contracts**) Describes major funding programs *not* individual opportunities. The Catalog of Federal Domestic Assistance is a government-wide compendium of Federal programs, projects, services, and activities that provide assistance or benefits to the American public. It contains financial and nonfinancial assistance programs administered by departments and establishments of the Federal government. As the basic reference source of Federal programs, the primary purpose of the Catalog is to assist users in

identifying programs that meet specific objectives of the potential applicant and to obtain general information on Federal assistance programs.

ii. Federal **Register***:* Published by the Office of the Federal Register, National Archives and Records Administration (NARA), the Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents

iii. FedBizOpps.gov: for contracts, procurements, bids. Single government point - of-entry for federal government procurement (over $25k), This was moved to SAM.gov and is now known as Contract Opportunities.

iv. Grants.gov: The official site for the listing of federal financial assistance funding opportunities. This site allows applicants to download funding opportunity announcements (FOAs), download and prepare the application package and submit the application package. Program announcement/Funding Opportunity Announcement (FOA) /solicitation/RFP (Request for proposal)

v. FedConnect.net: provides full lifecycle support including the ability to post opportunities, receive responses, deliver awards, and communicate throughout the pre-award, award, and post-award phases using secure 2-way messaging. Used by some areas of Department of Energy and other agencies.

vi. Agency websites Most federal agencies will have descriptions of their programs as well as published funding opportunities.

vii. Foundation directories and reports

Foundation Center is the leading source of information about philanthropy worldwide. *Foundation Directory Online* offers a free search tool, FDO Quick Start, providing free, public access to essential information to about over 100,000 foundations.

Foundation Reports: Annual reports provides information on what activities the non-profit participated in. It may list the various awards they made. Non-profits

have to file an annual information form with the IRs called a 990. The 990 which must be made public can detail its accomplishments of the previous year

viii. Other Businesses and Industry - Proposals to businesses and industries generally originate with the proposer, not with an announced program. Therefore, extensive communication with the business or industry representative is crucial in determining project goals and expectations.

b. Use of expertise databases and funding search tools

***Pivot*:** Formerly known as Community of Science is a database of funding opportunities that can be searched. PIVOT will also provide weekly funding alerts that match the search query. User can create a create profile.

***Grant Forward*:** Institutional subscription. Funding opportunity database that can be combined with a researcher profile for targeted searches.

***SPIN*:** InfoEd has a product, SPIN which is a funding opportunities database. SPIN contains opportunities from federal, state, non-profit, private and international sponsors. Has the ability for the user to create customized searches. A companion product SMARTS (SPIN Matching and Research Transmittal Service) allows researcher to develop a profile with key words. Funding opportunities will automatically be matched to the profiles and electronically disseminated to the researcher

***GrantSelect*:** Ability to develop individual profile (matches delivered via email)

3. Announcements/solicitations

a. General components included in funding announcements

Section 200.204- Notices of Funding Opportunities

- Announcement will be in a standard format & posted
  - Specified summary data
  - Specified full text announcement data
- Proposal application forms pre-approved by OMB

- For competitive grants and cooperative agreements, Federal agencies must announce specific funding opportunities by posting a public notice on the OMB-designated government-wide web site *(Grants.gov)*
- Specifies a set of six data elements that must be included in the public notice
  1. Federal Awarding Agency Name

2. Funding Opportunity Title
3. Announcement Type (whether the funding opportunity is the initial announcement of this funding opportunity or a modification of a previously announced opportunity);
4. Funding Opportunity Number
5. Catalog of Federal Domestic Assistance (CFDA) Number(s);

Key Dates. Key dates include due dates for Applications

b. Types and traits of funding announcements/solicitations (RFA/RFP)

An Request for Proposal (RFP) solicits bids for contracts while a Request for Assistance (RFA) solicits proposals for grants

A Federal RFP (Request for Proposal) is a solicitation document used by government agencies to inform potential contractors about a specific project or need and to invite them to submit proposals outlining how they can fulfill those requirements. These RFPs are used to determine the best qualified vendor through negotiation or by evaluating proposals based on factors beyond just the lowest price.

Sometimes a RFP is in fact a binding contract that can be executed and awarded by the agency without further negotiation. Thus at the proposal stage it is important to have a contract negotiator review the RFP terms and conditions and submit any exceptions to the terms as part of the proposal submission.

For NIH a RFA is a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s).

c. Identification of key points from announcements and communication to investigators

Key points for understanding funding announcement in research administration include identifying the type of funding opportunity, understanding its scope and purpose, and noting any special requirements or instructions

- Due Date for proposal
- Amount of award, average amount or any limitations

d. Communication methods and delivery to appropriate audience (newsletters, electronic tools, listserv)

Internal communication use newsletters, email and listserv to reach researchers
External communication use publications and Reports. Public-facing content such blogs, social media and press releases.

4. Funding Programs (key purposes, characteristics, requirements, restrictions)

a. Research

Research grants make up the largest category of funding and support by NIH. These grants may be awarded to universities, medical and other health professional schools, colleges, hospitals, research institutes, for-profit organizations, and government institutions that sponsor and conduct biomedical research and development. Research grants make up the largest category of funding and support by NIDCD. These grants may be awarded to universities, medical and other health professional schools, colleges, hospitals, research institutes, for-profit organizations, and government institutions that sponsor and conduct biomedical research and development.

b. Fellowship and training

Individual fellowship programs provide mentored research experience to students and scientists at various stages of their careers.

These fellowships may provide a stipend, institutional allowance to help support the costs of training, tuition and fees, and childcare costs.

NIH Training grants - Institutional training programs (often referred to as the "T" series) provide domestic, nonprofit, and private or public graduate-level academic institutions with funds for research training opportunities, including international, for trainees at the undergraduate, graduate, and postdoctoral levels.

c. Equipment/instrumentation

NSF MRI program supports the acquisition of a *multi-user* research instrument that is commercially available through direct purchase from a vendor, or for the personnel costs and equipment that are required for the development of an instrument with new capabilities

d. Program project/Center

- NIH – Core Center grants - Supports shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem.
- NIH – Program/Project grants - supports a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme.
- Generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective.

- A program project is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort.

e. Career development

NSF has the Faculty Early career Development Program (CAREER) - is a Foundation-wide activity that offers the National Science Foundation's most prestigious awards in support of early-career faculty who have the potential to serve as academic role models in research and education and to lead advances in the mission of their department or organization.

NIH K Awards - to provide individual and institutional research training opportunities (including international) to trainees at the undergraduate, graduate, and postdoctoral levels.

f. Internal

Intramural grants are research grants the institution provides to support research projects conducted by its faculty and students

g. Other

NIH – Supplemental funding - For currently funded NIH grants, supplemental funding may be available through competing revisions to expand a project's scope and administrative supplements to meet unanticipated costs or support career re-entry without a change of scope.

Community Development Block Grants (CDBG): Supports community development projects in areas like housing and economic development.

Small Business Innovation Research (SBIR): Helps small businesses conduct research and development (R&D) through contracts or grants.

Corporate grants: Provided by corporations for social initiatives that align with their business values.

G. Overview of Grants Regulatory Framework and Legislative Process (statutory requirements, program requirements, administrative requirements)

1. Federal budget process

The US federal budget process is a multi-step process that begins with the President submitting a budget request to Congress, which then debates and amends the request before passing it into law. This process typically involves multiple phases, including budget formulation, congressional action, execution, and audit

The annual budget covers three spending areas:

- Mandatory spending - funding for Social Security, Medicare, veterans benefits, and other spending required by law. This typically uses over half of all funding.
- Discretionary spending - federal agency funding. Congress sets funding levels for these each year. This usually accounts for around a third of all funding.
- Interest on the debt.

Offices that are involved in the budget process

- Office of Management and Budget (OMB) - part of the executive branch of government. OMB gives guidelines to federal agencies instructing them how to prepare their strategic plans and budgets.
- Office of Science and Technology Policy (OSTP) - Science programs also receive budget guidance from the Office of Science and Technology Policy (OSTP), formally through a joint OMB/OSTP guidance memo
- Government Accountability Office (GAO) - is an independent, nonpartisan agency that works for Congress. GAO operates as an auditor of the federal government, and investigates how the federal government spends taxpayer dollars.
- Congressional Budget Office (CBO) - is the non-partisan branch of Congress that provides analysis and materials related to the federal budget process, and objective analyses needed for economic and budgetary decisions related to programs covered by the federal budget.

Questions:

1. Which branch of government begins the federal budget process?

    a. legislative
    b. judicial
    c. executive
    d. congress

2. The requirement that agencies may not spend more that congress appropriates

    a. anti-spending act
    b. balanced budget act
    c. anti-deficiency act
    d. deficit spending act

3. Part of the executive branch of government which gives guidelines to federal agencies instructing them how to prepare their strategic plans and budgets.

    a. Office of Management and Budget
    b. Congressional Budget Office
    c. Inspector General's Office
    d. Budget Authorization Board

4. The statute that provides the authority for Federal agencies to incur obligations to and make payments out of the U.S. treasury for specified purposes.
    a. Appropriation act
    b. Balanced budget act
    c. Deficient spending act
    d. Carryforward act

Answers: 5c, 6c, 7a, 8a

2. Congressionally directed funding (distinguishing features, lobbying implications)

Congressionally Directed Spending (CDS), also known as Community Project Funding (CPF), or more commonly known as "earmarks" is a process where Members of Congress can request direct federal funding for specific projects in their states or districts. This funding, included in federal appropriations legislation, is typically targeted at local projects benefiting communities and is an alternative to funding through traditional grant programs.

3. OMB circulars (OMB A-133, OMB A-102) (purpose, requirements, Implementation, and Uniform Guidance)

2CFR 200 - Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards

Effective December 26, 2014, new federal guidance went into effect eliminating the Office of Management and Budgets Circulars A-21, A-87, A-122, A-50, A-102, A-89, A-133, A-110. These Circulars were replaced by Uniform Guidance 2CFR 200. Uniform Guidance is a combined version of 8 previous circulars, the purpose of which was to streamline administrative burdens, and to strengthen oversight of federal funds to reduce fraud, waste, and abuse.

- Subpart A: Acronyms and Definitions
- Subpart B: General Provisions (Section 200.1xx)
- Subpart C: Pre-award Requirement (Section 200.2xx)
- Subpart D: Post Award Requirement (Section 200.3xx)

- Subpart E: Cost Principles (Section 200.4xx)
- Subpart F: Audit Requirements (Section 200.5xx)

Subpart A: Acronyms & Definitions – See separate list of key definitions.

Subpart B: General Provision

Section 200.100 purpose: 2 CFR Part 200 establishes uniform administrative requirements, cost principles, and audit requirements for all types of non-federal entities

- Federal awarding agencies must not impose additional or inconsistent requirements, unless…
  - Requirement based on Federal statute, regulation, or executive order
  - OMB permits an exception in accordance with 200.102
  - OMB approves information in the Federal award in accordance with 200.211

Section 200.101 Applicability

- Describes the applicability of each subpart to types of Federal awards.
- The requirements established in this part apply to Federal agencies that make Federal awards to non-Federal entities.
- The Federal awarding agency will determine applicability and state the applicable requirements in the terms and conditions of the Federal award
- Likewise, the pass-through entity must state the applicable requirements for its sub recipients in the terms and condition of each sub award

Section 200.102, Exceptions

- No exceptions from audit requirements
- Only OMB may allow exceptions for classes of Federal awards or non-Federal entities
- In the interest of maximum uniformity, OMB will permit exceptions only in unusual circumstances
- Exceptions on a case-by-case basis may be authorized by the Federal awarding agency
- The Federal awarding agency may apply more restrictive requirements when approved by OMB, or required by Federal statutes or regulations
- Throughout this part when the word ‘‘must’’ is used it indicates a requirement. Whereas, use of the word ‘‘should’’ or ‘‘may’’ indicates a best practice or recommended approach rather than a requirement and permits discretion.

4. Code of Federal Regulations (CFR) (2 CFR Part 215, 2 CFR Part 220, 2 CFR Part 230, 2 CFR Part 225)

This is now included in Uniform Guidance – 2CFR Part 200

5. Federal Acquisition Regulation (FAR) (purpose, requirements in contracts)

Introduction: The FAR is used by the government to guide them in procurement, use of contracts in the same way that Uniform Guidance is used for grants and cooperative agreements.

- Uniform policies and procedures used by all federal agencies in their acquisition (procurement) of supplies and services
- "Contracting by regulations" – 90% or more of the clauses in government contracts are prescribed by regulation
- All branches of the government influence the FAR
- The FAR System consists of the FAR and agency regulations that implement or supplement it

Agency compliance with the FAR is the responsibility of the Secretary of Defense (for the military departments and defense agencies), the Administrator of General Services (for civilian agencies other than NASA), and the Administrator of NASA (for NASA activities).

Official FAR at 48 CFR (Code of Federal Regulations)

- Part 1-51: Guidelines for use of clauses (Chapter 1)
- Part 52: Solicitation provisions & contract clauses
- Part 53: Forms
- Part 200 & Up: Agency specific supplements

- Agency specific supplements - agency regulations that implement or supplement it. The purpose of the FAR was to consolidate numerous individual agency regulations into one comprehensive set of standards that could be applied government wide. Nearly every major cabinet-level department and the agencies below them have issued regulations. The best-known example of an agency supplement is the Defense Federal Acquisition Regulation Supplement (DFARS) used by the Department of Defense. Examples:
    - Department of Defense Federal Acquisition Regulation Supplement (DFARS)
    - Department of Education Acquisition Regulation (EDAR)
    - Department of Energy Acquisition Regulation (DEAR)

FAR – What does it do? By establishing uniform policies and procedures for acquisition for all federal agencies, the FAR:

- Satisfies the government's needs as a consumer in terms of cost, quality, and timeliness
- Minimizes administrative costs
- Upholds the government's integrity as a market participant by conducting business fairly and openly

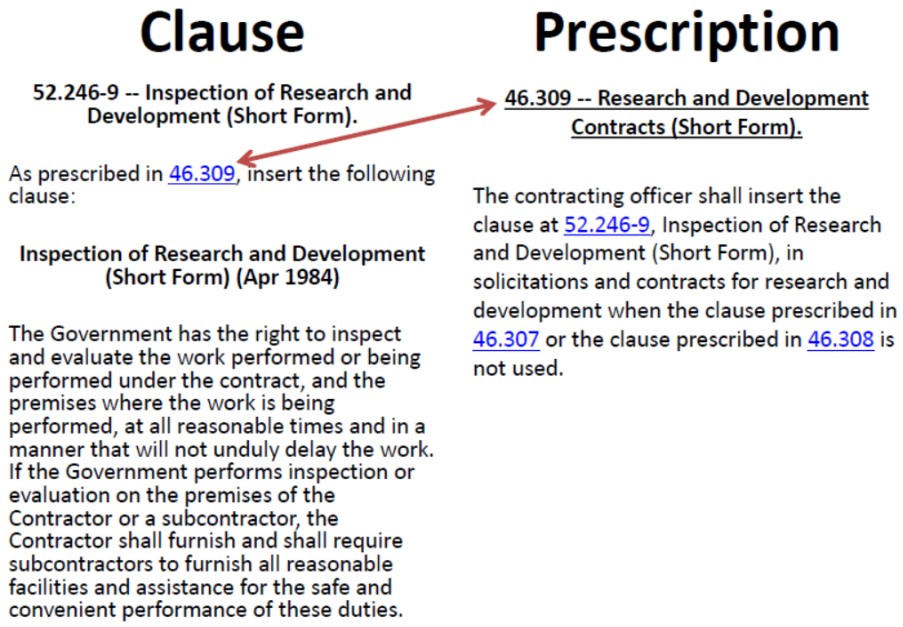
- Fulfills public policy objectives of Congress and the President

Need to consult the FAR when:

- Responding to an federal Request for Proposal (RFP) procurement solicitation
- Completing Reps & Certs
- Receiving a federal prime contract
  - Incorporated in full text
  - Incorporated by reference
- Receiving a subcontract under a federal prime
- Issuing a subcontract under a federal prime

Reading the Prescriptions

Clauses may be included in the contract that are not appropriate for R&D work or for a non-profit institution of higher education. When questioning a clause, review the prescription. This provides the rationale for its inclusion in the contract—identifies when it is required. Will assist the University in the determination as to whether they can challenge its inclusion and request that it be removed.



What to look for: Clauses that impact the University's ability to:

- Publish
- Retain title to intellectual property (no "work for hire")
- Retain title to property and equipment
- Apply appropriate cost principles
- Determine allowable costs

- Authorize the use of foreign nationals (faculty and students)

Definitions

- Contracting officer (CO) - means a person with the authority to enter into, administer, and/or terminate contracts and make related determinations and findings.
- Contracting officer's representative (COR)" means an individual, including a contracting officer's technical representative (COTR), designated and authorized in writing by the contracting officer to perform specific technical or administrative functions.

FAR – Types of Contracts - Selecting the type of contract is generally a matter for negotiation and requires sound judgment. Two broad categories of contracts commonly used are:

- Fixed-Price (Part 16 – Types of Contracts; Subpart 16.2)
- Cost-Reimbursement (Part 16 – Types of Contracts; Subpart 16.3)

Fixed-Price - Provides for a firm price for acquiring commercial items or other supplies or services on the basis of reasonably defined functional or detailed specifications when fair and reasonable prices can be set at the outset by:

- Adequate price competition, or
- Reasonable price comparisons with prior purchases, or
- Available cost or pricing information permits realistic estimates, or
- Performance uncertainties can be identified and reasonable estimates of their cost impact can be made
- Imposes on contractor maximum incentive to control costs, but with minimum administrative burden. **Less risk for the government but greater risk for the performing organization as they must perform regardless of cost of performance.**

Cost-Reimbursable - Procurement of non-commercial items which cannot be based on reasonably definite functional or detailed specifications. Appropriate for research and development (R&D) work. **There is no incentive for contractor to control costs, thus Government imposes tighter controls. Best efforts basis: when you run out of funds, you stop working. Greater risk for the government, less risk for performing organization.**

- Provides for payment of allowable incurred costs to the extent prescribed in the contract
- Establishes an estimate of total costs for the purpose of obligating funds and establishing a ceiling that the contractor may not exceed without approval
- Work toward "reasonable efforts" (most preferred for R&D) or "best efforts"

Limitation of Costs / Limitation of Funds -Cost Reimbursable Contract Clause:
FAR Clause: 52.232-20 or 52.232-22. The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that (1) The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated

cost specified in the Schedule; or (2) The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

Other types of contracts (Part 16 – Types of Contracts)

- **Incentive contracts** (Subpart 16.4) Incentive contracts are designed to obtain specific acquisition objectives by--(1) Establishing reasonable and attainable targets that are clearly communicated to the contractor; and (2) Including appropriate incentive arrangements designed to --
    - (i) motivate contractor efforts that might not otherwise be emphasized and
    - (ii) discourage contractor inefficiency and waste.
- **Indefinite-delivery contracts** (Subpart 16.5) - Three types of indefinite-delivery contracts: 1)definite-quantity contracts, 2)requirements contracts, and 3)indefinite-quantity contracts. Delivery-order contract" means a contract for supplies that does not procure or specify a firm quantity of supplies (other than a minimum or maximum quantity) and that provides for the issuance of orders for the delivery of supplies during the period of the contract
- **Time and materials contracts (**Subpart 16.6) A time-and-materials contract provides for acquiring supplies or services on the basis of—Direct labor hours at specified fixed hourly rates that include wages, overhead, general and administrative expenses, and profit; and (2) Actual cost for materials.
- **Labor hour contracts** (Subpart 16.6) - A labor-hour contract is a variation of the time-and-materials contract, differing only in that materials are not supplied by the contractor
- **Letter Contracts** (Subpart 16.6) - A letter contract is a written preliminary contractual instrument that authorizes the contractor to begin immediately manufacturing supplies or performing services
- **Prohibited Type of Contract - FAR 16.102(c) - Cost-plus-a-percentage-of-cost contracts -** Because that type of contract would encourage wasteful spending rather than fiscal responsibility. The higher the cost a company incurs, the more profit they would make. The Government wants to encourage cost savings not cost escalation.

Standard Form 33, Solicitation, Offer and Award is the **solicitation**/contract **form** used by the federal government, not only to solicit orders, but also to **award** a contract, since it is a bilateral (two-signature) document.

DATA Protection

FAR 15.609 Limited use of data

(a) An unsolicited proposal may include data that the offeror does not want disclosed to the public for any purpose or used by the Government except for evaluation purposes. If the offeror wishes to restrict the data, the title page must be marked with the following legend:

Use and Disclosure of Data

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed - in whole or in part - for any purpose other than to evaluate this proposal. However, if a contract is awarded to this offeror as a result of - or in connection with - the submission of these data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in these data if they are obtained from another source without restriction. The data subject to this restriction are contained in Sheets [*insert numbers or other identification of sheets*].

(b) The offeror shall also mark each sheet of data it wishes to restrict with the following legend: Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

6. Statutory requirements (NIH salary cap)

Congress legislatively mandates a limitation on salary for individuals under NIH grant and cooperative agreement awards. The mandate appears in the annual appropriation act that provides authority for NIH to incur obligations for a given fiscal year (FY). The amount of salary that can be provided to an individual through grant and cooperative agreement funds cannot exceed Executive Level II of the Federal Executive Pay Scale (Office of Personnel Management Salaries & Wages).

7. America COMPETES Act (requirements, implementation)

This bill contains major policy provisions and authorizes funding levels for the National Science Foundation (**NSF**), Department of Energy (DOE) Office of Science, and National Institute of Standards and Technology (NIST), as well as a number of other issues related to competitiveness.

8. Other – See the Regulation and Compliance handout for a listing of regulations.

H. Sponsors

1. Types and Characteristics of Sponsors

Research sponsors can be categorized by their source and responsibilities. Sponsors can be governmental, corporate, or private foundations, each with different motivations and potential impacts on the research. A common characteristic of research sponsors is their financial investment in the project, which can be substantial. Additionally, sponsors often have specific deliverables, intellectual property rights, and reporting requirements for the research.

- **Federal -** One of the missions of government is to provide for the common welfare. It is within this context that federal agencies and Congress appropriate funds for support of education, engineering, defense, health, the arts and social services. In most cases, an agency's mission is inherent in its name.

- **State and Local Government -** State agencies exist to fulfill specific legislated missions narrower in scope than that of federal agencies. Local agencies exist to meet local needs. State agencies fund projects promising benefit to the people of the state; local agencies fund projects that help people of a particular locale. Funded projects are usually very specific; the scope of work is often determined by the agency.
- **Non-Profits -** A wide range of nonprofit public service organizations supports university programs. This category includes associations, societies, institutes, councils and centers. Nonprofits typically support research and other activities in their own field only.
- **Private Foundations -** Private foundations, established to support charitable purposes, can be research sponsors. They typically receive funding from a single source, like a family or corporation, and award grants to other nonprofits, including research institutions. These foundations often have specific grantmaking priorities and may focus on particular areas of research, such as medical research or cancer research.
- **For profit entities -** Generally, companies support projects that are reasonably likely to strengthen their competitive position in the marketplace. Funding is typically provided in the form of contracts with specific objectives and fairly short time frames.
- **International (foreign) entities -** A foreign sponsor of research is an organization, company, or government from a country other than the one where the research is being conducted, that provides financial or other support for a research project. These sponsors can include foreign governments, international organizations, or private companies. Researchers should be aware of potential restrictions and requirements associated with foreign sponsorship, including disclosure obligations, export control regulations, and concerns about foreign influence.

a. Federal government

i. Structure and agency missions (executive departments, independent agencies)

- **Executive Branch Agencies**
  - Department of Agriculture (USDA)
  - Department of Commerce (DOC)
  - Department of Defense (DOD)
  - Department of Education (ED)
  - Department of Energy (DOE)
  - Department of Health and Human Services (DHHS)
  - Department of Homeland Security (DHS)
  - Department of Housing and Urban Development (HUD)
  - Department of Justice (DOJ)
  - Department of Labor (DOL)
  - Department of State (DOS)

- Department of the Interior (DOI)
- Department of the Treasury
- Department of Transportation (DOT)
- Department of Veteran Affairs (VA)

Brief description of each agency and some of their programs that fund research

Department of Agriculture (USDA)

Provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best available science, and effective management. The U.S. Department of Agriculture (USDA) is made up of 29 agencies Selected Agencies are as follows:

- **Agricultural Marketing Service (AMS)** AMS facilitates the strategic marketing of agricultural products in domestic and international markets while ensuring fair trading practices and promoting a competitive and efficient marketplace.
- **Agricultural Research Service (ARS)** ARS is USDA's principal in-house research agency. ARS leads America towards a better future through agricultural research and information.
- **Animal Plant and inspection Service (APHIS)** APHIS provides leadership in ensuring the health and care of animals and plants. The agency improves agricultural productivity and competitiveness and contributes to the national economy and the public health.
- **Food safety and Inspection Service (FSIS)** FSIS enhances public health and well-being by protecting the public from foodborne illness and ensuring that the nation's meat, poultry and egg products are safe, wholesome, and correctly packaged.
- **National Institute of Food and Agriculture (NIFA)** NIFA’s mission is to invest in and advance agricultural research, education, and extension to solve societal challenges.
    - **National Research Initiative (NRI)** is the flagship competitive grants program at USDA
    - **Cooperative State Research and Cooperative Extension (CSREES)** funds competitive grants, formula grants to land grant institutions

Department of Commerce The Department of Commerce works with businesses, universities, communities, and the Nation’s workers to promote job creation, economic growth, sustainable development, and improved standards of living for Americans.

- **National Institute of Standards and Technology (NIST)** - The National Institute of Standards and Technology promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology
- **National Oceanic & Atmospheric Administration (NOAA)** works to understand and predict changes in climate, weather, oceans, and coasts.
- **Economic Development Administration (EDA)** works directly with local economic development officials to make grant investments that are well-defined, timely, and linked to a long-term, sustainable economic development strategy.

Department of Defense (DOD)

DOD uses Broad Agency Announcements (BAA) as one mechanism to solicit proposals. Generally the PI will contact a program manager and/or submit white paper (informal short paper to gauge the interest of the program manager. If encourage to submit a full proposal then it can be submitted under the BAA. The BAA can be open for several fiscal years.

- DOD budget categories (types of funds)
  - 6.1 Basic Research
  - 6.2 Applied Research
  - 6.3 Advanced Technology Development

- **Defense Advanced Research Projects Agency (DARPA)** serves as the central research and development organization of the Department of Defense. Reaching for outsized impact means taking on risk, and high risk in pursuit of high payoff is a hallmark of DARPA's programs.

- **Office of Naval Research (ONR)**
  - Naval Research Lab - is the corporate research laboratory for the Navy and Marine Corps and conducts a broad program of scientific research, technology and advanced development.

- **Army Research Office (ARO)** The U.S. Army Research Laboratory's Army Research Office (ARO) mission is to serve as the Army's principal **extramural basic research** agency in the engineering, physical, information and life sciences;
  - **Army Research Laboratory Directorates**
    - **Army Medical Research and Materiel Command (USAMRMC)** Responsibility for medical research, development, and acquisition and medical logistics management. Ensuring our armed forces

remain in optimal health and are equipped to protect themselves from disease and injury, particularly on the battlefield

- **Army Corps of Engineers:** Supports flood control and storm mitigation research. Military construction, environmental support to military installations.

- **Air Force Office of Scientific Research (AFOSR)** As a part of the Air Force Research Laboratory (AFRL), AFOSR's technical experts foster and fund research within AFRL, universities, and industry laboratories to ensure the transition of research results to support USAF needs.

Department of Education (ED)- ED offers three kinds of grants: **Discretionary grants:** awarded using a competitive process. **Student loans or grants:** to help students attend college. **Formula grants:** uses formulas determined by Congress and has no application process. The Institute of Education Sciences (IES) has established 12 programs of research (topics) under its Education Research Grants Program. Each of these topics accepts applications once per year. Application deadlines are announced in the Federal Register and on the IES website. EDGAR is the Education Department General Administrative Regulations that govern grants.

Department of Energy: The mission of the Energy Department is to ensure America's security and prosperity by addressing its energy, environmental and nuclear challenges through transformative science and technology solutions.

- **Office of Science** - Fundamental research programs in basic energy sciences, biological and environmental sciences, and computational science. Largest supporter of basic research in the physical sciences (energy physics, nuclear physics, and fusion energy sciences.) Manages 10 National Laboratories.

- **Office of Nuclear Energy, Science and Technology** - Develop new nuclear energy technologies to meet energy and climate goals. Support the development of academic programs that advance nuclear science and technology education.

- **Office of Fossil Energy - National Energy Technology Laboratory (NETL)** coordinates R&D solicitations. Research devoted to fossil energy research including domestic coal, natural gas, and oil.

- **Office of Energy Efficiency and Renewable Energy (EERE)** - mission is to strengthen America's energy security, environmental quality, and economic vitality in public-private partnerships that: Enhance energy efficiency and productivity; Brings clean, reliable and

affordable energy technologies to the marketplace; National Renewable Energy Laboratory (NREL) is managed by EERE. NREL conducts research in the following areas: Renewable electricity: solar, water, wind and geothermal energy. Sustainable Transportation: vehicle technologies, hydrogen and biofuels. Electricity Grid integration and distributed energy systems.

Department of Health and Human Services (DHHS) ***see separate study guide for DHHS and NIH***

Department of Homeland Security (DHS) - The DHS Science and Technology Directorate (S&T) is the primary research and development arm of the Department of Homeland Security and manages science and technology research.

Department of Housing and Urban Development (HUD) - HUD awards discretionary funding through over 20 Grant programs that support HUD initiatives, including Affordable Housing Development and Preservation, Community and Economic Development, Environment and Energy, Fair Housing, Homelessness, Homeownership, Rental Assistance, and Supportive Housing and Services. **Notice of Funding Availability (NOFA)** - The Notice of Funding Availability (NOFA) is a notice published each year in Grants.gov for HUD's Discretionary Funding Programs.

Department of the Interior - protects and manages the Nation's natural resources and cultural heritage; provides scientific and other information about those resources; and honors its trust responsibilities or special commitments to American Indians, Alaska Natives, and affiliated island communities.

- Bureau of Indian affairs - IA currently provides services (directly or through contracts, grants, or compacts) to approximately 1.9 million American Indians and Alaska Natives.
- Bureau of Land Management
- Bureau of Ocean Energy Management
- Bureau of Reclamation
- National Park Service
- Office of Surface Mining Reclamation and Enforcement - OSMRE has protected the environment and people while regulating surface coal mining in the United States, and funded the restoration of abandoned coal mines
- US Fish and Wildlife Service
- US Geological Survey

Department of Justice (DOJ) - offers funding opportunities to support law enforcement and public safety activities in state, local, and tribal jurisdictions; to assist victims of crime;

to provide training and technical assistance; to conduct research; and to implement programs that improve the criminal, civil, and juvenile justice systems.

- **Office of Justice Programs (OJP)** provides innovative leadership to federal, state, local, and tribal justice systems, by disseminating state-of-the art knowledge and practices across America, and providing grants for the implementation of these crime fighting strategies

Department of Labor (DOL) - Mission - To foster, promote, and develop the welfare of the wage earners, job seekers, and retirees of the United States; improve working conditions; advance opportunities for profitable employment; and assure work-related benefits and rights.

- **Occupational Safety and Health Administration (OSHA) –** Purpose is to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. Susan Harwood Training Grants provide training and education for workers and employers on workplace safety and health hazards, responsibilities and rights. Target audiences include underserved, low-literacy, and high-hazard industry workers and employers.

Department of State (DOS)

The Bureau of Educational and Cultural Affairs' (ECA) mission is to increase mutual understanding between the people of the United States and the people of other countries by means of educational and cultural exchange that assist in the development of peaceful relations. ECA awards grants and cooperative agreements to non-profit organizations to support academic, cultural, and professional exchange programs to promote mutual understanding.

Department of the Treasury - The mission of the Department of the Treasury is to maintain a strong economy and create economic and job opportunities by promoting the conditions that enable economic growth and stability at home and abroad; strengthen national security by combating threats and protecting the integrity of the financial system; and manage the U.S. Government's finances and resources effectively.

Department of Transportation (DOT)

- **Federal Aviation Administration (FAA)**
  The Airport Cooperative Research Program (ACRP) is an industry-driven, applied research program that develops practical solutions to problems faced by airport operators. ACRP is managed by the Transportation Research Board (TRB) of the National Academies and sponsored by the FAA.

- **Federal Highway Administration**
- **Federal Railroad Administration**
- National Cooperative Highway Research Program: is a national research program carried out through the collaborative efforts of the Federal Highway Administration (FHWA), the National Academy of Sciences, Engineering, and Medicine (NASEM), and the American Association of State Highway and Transportation Officials (AASHTO). NCHRP is administered by the Transportation Research Board (TRB) and sponsored by the individual State Departments of Transportation (DOTs) of the AASHTO in cooperation with the FHWA.
- **The Pipeline and Hazardous Materials Safety Administration (PHMSA)** sponsors Research & Development (R&D) projects focused on providing near-term solutions that will increase the safety and reliability of the nation's pipelines and hazardous materials transportation.
- **University Transportation Centers:** DOT invests in the future of transportation through its University Transportation Centers (UTC) Program, which awards and administers grants to consortia of colleges and universities across the United States.

- **Department of Veteran Affairs (VA):** VA research is different from research sponsored by other federal research agencies: VA Research is the only research program focused entirely on Veterans' needs. VA Research is *intramural*, meaning only VA employees can conduct research under VA's sponsorship. Typically, VA researchers collaborate with academic institutions.

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Independent Agencies

- National Science Foundation (NSF) *see separate NSF study guide*
- National Aeronautics and Space Administration (NASA)
- National Endowment for the Arts (NEA)
- National Endowment for the Humanities (NEH)
- Environmental Protection Agency (EPA)
- U.S. Agency for International Development (USAID)

National Aeronautics and Space Administration (NASA) responsible for the civilian space program, as well as aeronautics and aerospace research. Supporting research in science and technology is an important part of NASA's overall mission. NASA solicits this research through the release of various research announcements in a wide range of science and

technology disciplines. NASA uses a peer review process to evaluate and select research proposals submitted in response to these research announcements.

NSPIRES is the NASA Solicitation and Proposal Integrated Review and Evaluation System. This web-based system supports NASA research from the release of solicitation announcements through the peer review and selection processes.

- **Cooperative Agreement Notice (CAN)** This is used to solicit ground-based research opportunities in which a fairly high degree of cooperation and interaction is expected between NASA and the selected institutions for completion of proposed research activities
- **NASA Research Announcement** (NRA) is used to announce research interests in support of NASA's programs. After peer or scientific review, based on factors in the NRA, proposals are selected for funding. Unlike an RFP containing a statement of work or specification to which offerors are to respond, an NRA provides for the submission of competitive project ideas, conceived by the offerors, in one or more program areas of interest. NRAs may result in grants, contracts or cooperative agreements.
- **Research Opportunities in Space and Earth Sciences (ROSES) solicitation**. ROSES is an omnibus solicitation that includes many individual program elements, each with its own due dates and topics.

National Endowment for the Arts: (NEA) is an independent agency **of** the United States federal government that offers support and funding for projects exhibiting artistic excellence.
Art Works: These grants support artistically excellent projects that celebrate our creativity and cultural heritage, invite mutual respect for differing beliefs and values, and enrich humanity. Matching grants generally range from $10,000 to $100,000. A minimum cost share/match equal to the grant amount is required.

- Challenge America: These grants support projects that extend the reach of the arts to underserved populations. Matching grants are for $10,000. A minimum cost share/match equal to the grant amount is required.
- Research: Art Works: These grants support research that investigates the value and/or impact of the arts, either as individual components of the U.S. arts ecology or as they interact with each other and/or with other domains of American life.

National Endowment for the Humanities (NEH): is one of the largest funders of humanities programs in the United States. NEH grants typically go to cultural institutions, such as museums, archives, libraries, colleges, universities, public television, and radio stations, and to individual scholars. "The term 'humanities' includes, but is not limited to, the study and interpretation of

the following: language, both modern and classical; linguistics; literature; history; jurisprudence; philosophy; archaeology; comparative religion; ethics; the history, criticism and theory of the arts; those aspects of social sciences which have humanistic content and employ humanistic methods; and the study and application of the humanities to the human environment.

The Environmental Protection Agency (EPA) protects people and the environment from significant health risks, sponsors and conducts research, and develops and enforces environmental regulations. The Office of Research and Development (ORD) is the scientific research arm of EPA, whose leading-edge research helps provide the solid underpinning of science and technology for the Agency.

The U.S. Agency for International Development (USAID) is an independent federal agency that receives overall foreign policy guidance from the **Secretary of State**. USAID is the lead U.S. Government agency that works to end extreme global poverty and enable resilient, democratic societies to realize their potential Areas of support:

- Agriculture and Food Security
- Democracy, Human Rights and Governance
- Economic Growth and Trade
- Economic Policy and Analysis
- Environment and Global Climate Change
- Global Health

ii. Types of programs and award mechanisms

Research Grants

Career Development Awards

Research Fellowships

Research Training

Instrumentation / Equipment Grants

Program Project /Center Grants

In its most broad definition, an award constitutes financial support for a specific research project, training program, equipment purchase or other research-related activity. The federal government uses three primary types of awards: Assistance Awards (including grants and cooperative agreements), Contracts and Other Transaction Agreements. Each is defined below:

Contract: Legally binding document signed by authorized officials from both parties providing support for a specific set of tasks for the direct benefit of the sponsor. A contract contains a narrowly focused statement of work and detailed terms and conditions.

Grant: Financial assistance for a specific purpose or specific project without expectation of any tangible deliverables other than a final report. The sponsor does not play an active role in the research project and there are only few general terms and conditions.

Cooperative Agreement: A contract whereby the sponsor is substantially involved in the project and the outcome of the research results. The sponsor and university work collaboratively and the reporting requirements are usually more strict.

Other Transaction Awards: These are funding instruments which do not incorporate the standard terms and conditions of the OMB Circulars but rather, all terms and conditions are negotiated between the federal sponsor (currently only the Department of Defense and NNIH are authorized to award OTAs) on a case-by-case basis.

b. State and local government

- State-specific initiatives: State agencies may fund research in areas aligned with their priorities, such as environmental quality, health, education, or transportation.
- Targeted research programs: States can establish specific grant programs to support research in areas like nursing education or economic development.
- Federal pass-through funds: States receive federal funding and then allocate portions as grants to various entities, including researchers.
- Community-based research: Local governments, including cities and counties, may provide grants for research projects focusing on specific community needs like local parks or neighborhood revitalization.
- Local initiatives: Municipalities can fund research projects related to local issues like public safety or infrastructure development.
- Legislative appropriations: State legislatures can allocate specific funds to support research activities, particularly at higher education institutions.

In summary, state and local governments fund research through a combination of grants, direct funding, and appropriations, often with a significant role played by federal pass-through funds.

c. Private foundations

Private foundations offer various types of funding for research, including grants for specific projects, broad research programs, career development, and even travel to conferences. They also provide seed funding, which is smaller amounts to help researchers test the viability of their ideas.

Foundations often have specific areas of focus, so it's important to research their mission and funding priorities.

Examples of Private Foundations:

- **Alfred P. Sloan Foundation:** Focuses on research in science, technology, engineering, and mathematics (STEM).
- **Ford Foundation:** Supports a wide range of social justice issues and research.
- **Andrew W. Mellon Foundation:** Funds research in the humanities and higher education.
- **National Endowment for the Humanities (NEH):** Supports research in the humanities.
- **Robert Wood Johnson Foundation:** Focuses on healthcare and public health research.
- **Russell Sage Foundation:** Supports research in the social sciences.
- **William T. Grant Foundation:** Funds research on youth development and education.
- **Spencer Foundation:** Supports research in education.

Societies and Associations

- American Cancer Society
- American Heart Association
- American Chemical Society

d. For profit business and industry

Commodity boards at the state and national level also offer their own funding opportunities for research and outreach projects.

  - Cotton Inc.
  - National Corn Growers Association

Corporations, industry, business - Much of this industry funding of academic research is directed toward applied research.

Questions:

5. The lead U.S. Government agency that works to end extreme global poverty and enable resilient, democratic societies to realize their potential.
    a. Department of Education
    b. Department of the Interior
    c. National Science Foundation
    d. USAID

6. Branch of the U.S. Government that conducts the majority of federally funded research.
    a. Executive
    b. Legislative
    c. Judicial
    d. Independent agencies

7. For DOD 6.1 funding indicated funding designated for what?
    a. Basic Research
    b. Applied Research
    c. Advanced Technology Development
    d. Both a & b

8. What agency works to understand and predict changes in climate, weather, oceans, and coasts.
    a. National Oceanic & Atmospheric Administration (NOAA)
    b. Bureau of Reclamation
    c. U.S. Agency for International Development (USAID)
    d. National Science Foundation

9. Supports solar energy research.
    a. NASA
    b. Office of Energy Efficiency and Renewable Energy (EERE
    c. Office of Fossil Energy
    d. National Institute of Standards and Technology (NIST)

Answers: 21-d, 22-a, 23a, 24-a, 25-b,

2 Differentiation between public and private sources of funding

Advantages of Private Funding

- More rapid turnaround of the award. Many private organizations have a set schedule of proposal reviews and presenting awards. With fewer levels of review, awards may be made more rapidly.
- Possibly fewer regulations than federal awards. This can stretch from length and cost allowability to programmatic reporting of results.
- Fewer applicants in proposal pool. Although the available funds may be much less, there are normally fewer proposals to consider. A grants management system can be used to generate reports that measure increased success rates.
- Private sources may focus on emerging issues, new needs, populations emerging as "special interests" and be more willing to adapt by collaborating with other sources, providing alternative forms of assistance, and considering experimental activities.

Disadvantages of Private Funding

- Awards are often smaller and less likely to cover all project costs, and many don't cover indirect costs
- Unless the foundation is big, there may be less support for questions, policies/procedures, and fewer opportunities for personal contact and/or site visits
- Areas of focus may change rapidly, so continual funding may be hard to predict
- At some institutions, private funding may not be "prized" as highly as federal funding because of perceptions that the review isn't as rigorous as that of federal grants/contracts

Advantages of Federal Funding

- Federal agencies tend to have more funds available, although the number of applicants may offset this advantage
- Funds are available for a wide range of organizations, both lead and partners
- More likely to pay "all" project costs and/or cover indirect costs
- Support during concept development and proposal design is easily available
- You know the possibilities of renewal up front
- Application process and deadlines are public and very firm
- "Common" application forms and prescribed formats to decrease re-learning appropriate content and form

Disadvantages of Federal Funding

- Lengthy proposal requirements and complex application, administration, and compliance processes
- Often required institutional cost-sharing. This is becoming less of a federal issue but still arises frequently with state and other public agencies.
- Reviewers may tend to favor established applicants
- Difficulty in proposing new or high risk approaches to a problem
- Cost to institution may be higher due to complexity of applications and stricter compliance requirements

I. Identification of Internal Capacity

To identify internal capacity for research, organizations can assess their current resources, skills, and support structures. This involves evaluating staff expertise, existing research infrastructure, and the organization's commitment to evidence-based decision-making. A comprehensive assessment can reveal areas where capacity needs to be built and resources allocated

J. **Public Relations**

University public relations for research involves using communication strategies to share research findings with a wider audience, promote the university's research reputation, and build relationships with stakeholders. This includes developing communication materials, using social media and other digital channels, organizing events, and engaging with media outlets.

1. **Freedom of information (FOIA)** Since 1967, the Freedom of Information Act (FOIA) has provided the public the right to request access to records from any federal agency. It is often described as the law that keeps citizens in the know about their government. Federal agencies are required to disclose any information requested under the FOIA unless it falls under one of nine exemptions which protect interests such as personal privacy, national security, and law enforcement.
    - What generally will be released
        - Application information only after the initial award
        - Notice of Grant Award information
        - Interim and terminal progress reports
        - Reports of expenditures
        - Final report of grantee performance conducted by grantor
    - What generally will not be released
        - Pending or disapproved applications
        - Financial information pertaining to a specific individual such as salaries
        - Information subject to the Privacy Act of 1974

- Confidential personal or medical information
- Summaries of discussion of application by advisory bodies
- Proprietary information

2. **Public records laws**

Freedom of Information Act FOIA

Since 1967, the Freedom of Information Act (FOIA) has provided the public the right to request access to records from any federal agency. It is often described as the law that keeps citizens in the know about their government. Federal agencies are required to disclose any information requested under the FOIA unless it falls under one of nine exemptions which protect interests such as personal privacy, national security, and law enforcement.

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  - Information subject to the Privacy Act of 1974
  - Confidential personal or medical information
  - Summaries of discussion of application by advisory bodies
  - Proprietary information

Uniform Guidance 200.334 Record retention requirements.

The recipient and subrecipient must retain all Federal award records for three years from the date of submission of their final financial report. For awards that are renewed quarterly or annually, the recipient and subrecipient must retain records for three years from the date of submission of their quarterly or annual financial report, respectively. Records to be retained include but are not limited to, financial records, supporting documentation, and statistical records.

3. **Media relations and interactions with special interest groups**

University research, media relations, and special interest groups (SIGs) are interconnected components in the dissemination and promotion of academic findings and expertise. Here's a breakdown of how they relate:

Media Relations

- University media relations offices play a crucial role in disseminating this research to the public and the media.
- They work to raise awareness of groundbreaking discoveries, expert insights, and the overall impact of university research.
- Strategies include issuing press releases, coordinating interviews with researchers, and engaging with journalists to generate media coverage

Special interest Groups (SIG)s

- Definition: SIGs are communities formed by individuals with a common interest in a particular field of study, teaching, or research.
- Role in University Research & Media Relations:
- Promotion of Research: SIGs can act as valuable networks for promoting specific research areas and related university activities.
- Facilitating Collaboration: They provide a forum for collaboration among researchers, which can lead to larger-scale projects and more impactful findings.
- Connecting with External Groups: SIGs can connect university research with external groups, such as industry partners, policymakers, and the public, facilitating communication and engagement.
- Providing Expertise: Members of SIGs often have specialized knowledge and expertise that can be valuable for media relations efforts.
- Building Community: They foster a sense of community among researchers with shared interests, which can encourage the exchange of ideas and the development of new research projects

In summary: University media relations act as the bridge between research and the wider public, while SIGs can serve as internal and external catalysts, fostering collaboration, promoting research, and facilitating communication within specific fields of interest. This symbiotic relationship helps universities effectively communicate their research and its broader impact.

Steven's Amendment - requires acknowledgement of sponsorship in publication

Is intended to give the federal government public credit for federally funded programs and projects. It requires federal grant recipients to include funding information on all publications related to projects that use federal funds, including statements, press releases, signs at construction sites, requests for proposals, bid solicitations, and other documents that

describe projects or programs funded in whole or in part with federal money. This law applies to grants and cooperative agreements but not to contracts.

4. **Environmental concerns/impacts (chemical hazardous waste, Material Safety Data sheets [MSDS], environmental safety, management of public relations associated with potential hazards)**

Laboratories contain valuable research equipment, samples, work in progress, notes and data. They also contain potentially hazardous materials, such as chemicals, biological agents, and radioactive substances. All of these institutional assets must be protected from unauthorized access or removal, theft, or mishandling.

- Secure important research documents, equipment and experimental materials (e.g., lab notebooks, samples, hazardous substances) in locked areas.
- Secure devices capable of storing sensitive information or data (such as computer disks, magnetic tape, flash drives, smartphones, or tablets) in locked areas.

The **Occupational Safety and Health Act of 1970 (OSH Act)** was passed to prevent workers from being killed or seriously harmed at work. This law created the Occupational Safety and Health Administration (OSHA), which sets and enforces protective workplace safety and health standards. OSHA also provides information, training, and assistance to employers and workers. Under the OSH Act, employers have the responsibility to provide a safe workplace.

Chemical Safety: OSHA Lab Standard

- Affects all facilities using hazardous chemicals (even those using small quantities)
- Institutional Chemical Hygiene Plan must minimize employee exposure
- Information and training
- Medical exam for persons showing symptoms of chemical exposure

Hazard Communication Safety Data Sheets. The Hazard Communication Standard (HCS) requires chemical manufacturers, distributors, or importers to provide Safety Data Sheets (SDSs) (formerly known as **Material Safety Data Sheets** or **MSDSs**) to communicate the hazards of hazardous chemical products. SDS contains information on the potential hazards (health, fire, reactivity and environmental) and how to work safely with the chemical product.

II. PROJECT DEVELOPMENT AND PROPOSAL SUBMISSION

A. Proposal Writing

1. Types of proposals (characteristics, key elements)

a. Pre-proposal/pre-application/letter of intent

Preliminary Proposal

Some NSF program solicitations require or request submission of a preliminary proposal in advance of submission of a full proposal. The three predominant reasons for requiring submission of a preliminary proposal are to:

- reduce the proposers' unnecessary effort in proposal preparation when the chance of success is very small. This is particularly true of exploratory initiatives when the community senses that a major new direction is being identified, or competitions that will result in a small number of awards;
- increase the overall quality of the full submission; and
- assist NSF program staff in managing the review process and in the selection of reviewers.
- One of the following two types of decisions may be received from NSF upon submission of a preliminary proposal. The program solicitation will specify the type of decision to be rendered for a particular program.
- a. Invite/Not Invite Decisions
- This type of mechanism is used when the NSF decision made on the preliminary proposal is final, affecting the organization's eligibility to submit a full proposal. Only submitters of favorably reviewed preliminary proposals are invited and eligible to submit full proposals. The PI and the organization's Sponsored Projects Office (SPO) (or equivalent) will be electronically notified of NSF's decision to either invite submission of a full proposal or decline NSF support.
- b. Encourage/Discourage Decisions
- This type of mechanism is used when the NSF decision made on the preliminary proposal is advisory only. This means that submitters of both favorably and unfavorably reviewed preliminary proposals are eligible to submit full proposals. The PI and the organization's SPO will be notified of NSF's decision to either encourage or discourage submission of a full proposal.

Letter of Intent

An LOI is not a binding document. The predominant reason for its use is to help NSF program staff gauge the size and range of the competition, enabling earlier selection and better management of reviewers and panelists. In addition, the

information contained in an LOI is used to help avoid potential conflicts of interest in the review process.

An LOI normally 44ontainns the PI's names, a proposed title, a list of possible participating organizations (if applicable), and a synopsis of one page that describes the work in sufficient detail to permit an appropriate selection of reviewers.

b. New, continuation, renewal, resubmission

NIH definitions:

New – A request for financial assistance for a project or activity that is not currently receiving NIH support and must compete for support. A new application is being submitted for the first time.

Renewal – A request for additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be fully developed as though the applicant is applying for the first time.

Resubmission – An unfunded application that the applicant has modified following initial review and resubmitted for new consideration. Before a resubmission application can be submitted, the PD/PI must have received the summary statement from the previous review.

Revision – A request for an increase in support in a current budget period for expansion of the project's approved scope or research protocol.

c. Competing, noncompeting

Competing – for NIH a new application, renewal, revision, and resubmission are all considered competing" because, through the peer review process, the application must compete for available funding with other applications.

A non-competing progress report is required to continue support of a PHS grant for the second or subsequent budget period within an approved competitive segment

d. Seed grant/pilot project/internal

Seed grants and pilot grants are both small-scale funding opportunities, often used to support preliminary research or development. They are designed to provide initial funding for projects that could potentially lead to larger, more comprehensive research projects or grant applications.

2. Nonfinancial components of a proposal (purpose, key features, essential information)

a. Personnel/key persons

Senior/key personnel include the individuals designated by the proposer/recipient organization and approved by NSF[52], who contribute in a substantive, meaningful way to the scientific development or execution of a research and development project proposed to be carried out with a research and development award

b. Title/abstract/executive summary/introduction

A proposal summary, often called an executive summary, is a concise overview of a proposal that summarizes the key points and provides a quick overview for the reader. It aims to grab the reader's attention, highlight the proposal's value, and convince them to read further.

For NSF – The Project Summary consists of an overview, a statement on the intellectual merit of the proposed activity, and a statement on the broader impacts of the proposed activity.

c. Needs/problem statement

A problem statement is a crucial component of a proposal, serving as the foundation for the project and outlining the need for its solution. It clearly defines the issue, its implications, and why it needs addressing, justifying the proposed project and guiding its development.

d. Goals/objectives/statement of work/implementation plan/ methods/sustainability/evaluation plan/data sharing plan/letters of support

NSF – The Project Description should provide a clear statement of the work to be undertaken and must include the objectives for the period of the proposed work and expected significance; the relationship of this work to the present state of knowledge in the field, as well as to work in progress by the PI under other support.

Data Management and Sharing Plan – NIH requires all applicants planning to generate scientific data to prepare a DMS Plan that describes how the scientific data will be managed and shared. Other agencies including NSF also require a plan as part of the proposal.

e. Other

A biographical sketch (also referred to as biosketch) documents an individual's qualifications and experience for a specific role in a project.

Information on other active and pending support may be requested (often as part of Just-in-Time procedures for grant applications or in progress reports) to ensure there is no scientific, budgetary, or commitment overlap. "Other Support" is sometimes referred to as "current and pending support" or "active and pending support."

Other Support includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.

References cited – Reference information is required. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication

Postdoctoral Researcher Mentoring Plan. For NSF Each proposal that requests funding to support postdoctoral researchers must upload under "Mentoring Plan" in the supplementary documentation section of Research.gov

3. Characteristics of a successful proposal

A successful research proposal:

1. Is innovative

2. Includes specific aims

3. Includes preliminary data

4. Describes approach

5. Indicates the significance of the proposal with regard to the specific award and conveys its impact on science and your personal growth.

4. Unique characteristics of proposals submitted to industry sponsors

Proposals from universities to industry often emphasize the value proposition, demonstrating how the research or expertise can benefit the industry. They typically include a clear statement of the problem, a detailed methodology, a realistic timeline, and a budget, with emphasis on the potential for commercialization or practical application.

A detailed budget is not typically included in the proposal. A tsk budget or a overall amount may be shown. Indirect cost may be rolled up into each budget category rather than be show as a separate line item.

B. Effective Management of Proposal Teams (timeline, organization)

The Proposal Management Plan (PMP) documents the roles, responsibilities, tasks, schedules, and deadlines before contributors start developing proposal sections, volumes, and ultimately the complete proposal. The plan becomes the "evergreen" guide to keep the team on track and accountable.

Effective research proposal team management involves establishing a formal, collaborative process with clear roles, objectives, and timelines, supported by open communication, regular feedback, and a focus on leveraging diverse individual strengths

C. Understanding and Interpretation of Agency Guidelines (key features, requirements, proposal content, other information)

1. Broad agency announcement (BAA)

A Broad Agency Announcement (BAA) is a U.S. government mechanism used to solicit proposals for basic and applied research, rather than developing a specific product or system. It's a way for agencies to seek innovative ideas and approaches to advance scientific knowledge or address specific areas of interest.

2. Invitation to bid

A formal notice issued by a company or organization to potential vendors or service providers, inviting them to submit a bid for a specific project or contract.

3. Request for Applications/Proposals (RFA/RFP)

- **Request for Applications** is a formal document issued by a funding agency to invite applications for grants, usually for specific research or project objectives.
- It outlines the requirements, criteria, and guidelines for submitting applications, including eligibility, funding amount, and application deadlines.
- RFAs are often used when an agency seeks to fund projects or initiatives that align with specific goals, such as research, development, and public service.

- **Request for Proposals** is a document that a business, non-profit, or government agency creates to outline the requirements for a specific project or service.
- It is used to solicit proposals or bids from vendors to determine which one is best qualified to complete the project.

- The RFP process helps secure offers from different vendors and provides a structured way to evaluate proposals based on specific criteria.

4.Request for quotation (RFQ)

Request for quote (RFQ) is a process wherein an enterprise asks a set of potential suppliers or service providers to submit their price quotations and stand a chance to supply or provide goods or services.

5.Program announcements (solicited, unsolicited)

The term “program announcement” refers to formal NSF publications that announce NSF programs. Program announcements utilize the generic eligibility and proposal preparation guidelines specified in Part I of the PAPPG and incorporate the NSB-approved merit review criteria.

The term “program solicitation” refers to formal NSF publications that encourage the submission of proposals in specific program areas of interest to the Foundation. They generally are more focused than program announcements, and normally apply for a specified period of time. Competition among proposals is more precisely defined than with program announcements, and proposals received compete directly with each other for NSF funding.

D. Documentation to Meet Sponsor Requirements

1. Subcontractor/collaborator documentation

- Subrecipient Commitment Form – A letter signed by the subrecipient’s business official (OPAS equivalent) endorsing the work referenced in an attached statement of work and budget
- Statement of Work (or Scope of Work) describing the work to be done by the subrecipient’s personnel only
- Detailed budget (use sponsor format if required). Budgets should include detailed yearly and cumulative budgets (itemized budget should include salaries and wages, fringe benefits, equipment, travel, materials and supplies, and other costs as allowable).
- Budget justification
- Biographical sketch in sponsor format for all senior personnel
- Current and Pending Support/Other Support forms for all senior personnel (if required).
- Collaborator and Other Affiliations Form/List of Conflicts of Interest for Selection of Reviewers (if required).
- Facilities/Resources/Equipment statement following sponsor format

- Negotiated Indirect Cost Rate Agreement (if the subrecipient is charging indirect costs).
- Fringe rate agreement (if charging fringe benefits) or link to a PDF.
- Additional sponsor forms, including certifications as applicable

2 .Just-in-time documentation and process

NIH – term – These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information (both active and pending) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement

3. Current and pending support

NIH Other Support. Information on other active and pending support will be requested as part of the **Just-in-Time** procedures. Other support includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.

NSF requires information on all current and pending support for ongoing projects and proposals. This document contains a list of an individual's proposed and active projects and sources of support. It is used by NSF to assess:

- The capacity of the individual to carry out the proposed research.
- Any potential scientific and budgetary overlap or duplication across projects.
- The potential the individual is overcommitting themselves with the proposed project.

4. Required proposal components

Most proposals contain the following:

- **Cover or Title Page**: Contains specific information about the proposal and the Institute and requires specific authorizations/signatures.
- **Abstract or Project Summary**: Outlines the proposed research, including the objectives, methodology, and significance of the research.
- **Statement of Work (SOW)**: Provides a full and detailed explanation of the proposed research, and typically includes a project timetable. The SOW describes **how** the work will be done, **where** the work will be done, and **who** will do the work.

- **Budget**: Must include an estimate of the resources necessary to conduct the project. Most sponsors require a detailed breakdown of the budget into defined categories and a detailed budget justification, explaining what costs will be paid for and how the expense was calculated.
- **Curriculum Vitae or Biographical Sketch**: Include for all key project personnel.
- **Bibliography**: Lists all references cited in proposal.

E. Institutional Clearances and Approvals

1. Internal proposal review

An institution's proposal review process ensures key issues are reviewed by all stakeholders before submitting a proposal to a sponsor. This process includes checking compliance with institutional policies and requirements, ensuring the proposal meets the sponsor's guidelines, and addressing potential issues like financial conflicts of interest and research restrictions.

2. Approvals and documentation of institutional commitments

Areas of review include: facilities and space commitments, conflict of interest, involvement of human subjects and/or vertebrate animals, and cost sharing commitments.

3. Records retention

The recipient and subrecipient must retain all Federal award records for three years from the date of submission of their final financial report.

Federal agencies or pass-through entities may not impose any other record retention requirements except for the following:

(a) The records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken if any litigation, claim, or audit is started before the expiration of the three-year period.

(b) When the recipient or subrecipient is notified in writing by the Federal agency or pass-through entity, cognizant agency for audit, oversight agency for audit, or cognizant agency for indirect costs to extend the retention period.

(c) The records for property and equipment acquired with the support of Federal funds must be retained for three years after final disposition.

(d) The three-year retention requirement does not apply to the recipient or subrecipient when records are transferred to or maintained by the Federal agency.

(e) The records for program income earned after the period of performance must be retained for three years from the end of the recipient's or subrecipient's fiscal year in

which the program income is earned. This only applies if the Federal agency or pass-through entity requires the recipient or subrecipient to report on program income earned after the period of performance in the terms and conditions of the Federal award.

(f) The records for indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates) must be retained according to the applicable option below:

(1) ***If submitted for negotiation.*** When a proposal, plan, or other computation must be submitted to the Federal Government to form the basis for negotiation of an indirect cost rate (or other standard rates), then the three-year retention period for its supporting records starts from the date of submission.

(2) ***If not submitted for negotiation.*** When a proposal, plan, or other computation is not required to be submitted to the Federal Government to form the basis for negotiation of an indirect cost rate (or other standard rates), then the three-year retention period for its supporting records starts from the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

F. Electronic Research Administration

1. Institutional capability to electronically submit funding applications

- Access to high-speed internet.
- Required systems login.

2. Key features of online proposal submission systems

- Assigns a unique proposal number
- Uploading of proposal documents

3. Common electronic proposal submission systems

a. Grants.gov

Grants.gov is a website that serves as a central portal for finding and applying for federal government grants and cooperative agreements. It's the single source for information on federal grant opportunities, making it easier for applicants to navigate the application process.

b. FastLane (Research.gov)

Research.gov is the National Science Foundation's (NSF) grants management system, serving as a centralized platform for research information and services. It's a modernization of FastLane, providing a streamlined experience for submitting proposals, managing grants, and accessing related resources.

c. eRA Commons (ASSIST)

ASSIST, or the Application Submission System & Interface for Submission Tracking, is a web-based system used by the National Institutes of Health (NIH) to prepare and submit grant applications electronically. It operates within the eRA Commons platform and utilizes the SF424 Research & Related form set. ASSIST allows users to submit applications to NIH and other participating agencies through Grants.gov.

d. NSPIRES

NSPIRES (NASA Solicitation and Proposal Integrated Review and Evaluation System) is a web-based system that manages the entire lifecycle of NASA research solicitations and awards. It's a platform used for researchers to find, submit, and manage proposals to NASA.

e. FedConnect

FedConnect is a web-based platform that helps federal agencies and vendors connect and streamline the process of doing business with the government. It's essentially an online marketplace where agencies post opportunities and create awards, with vendors able to view and submit proposals electronically.

f. ProposalCENTRAL

ProposalCentral is a one-stop website for finding, applying for and tracking grants offered by more than 100 non-profit and government funding organizations in health, biomedical and scientific research

g. Other (system-to-system interfaces)

System-to-system (S2S) proposal submission refers to a process where a proposal is submitted to a funding agency (like Grants.gov) directly from a research institution's internal system (like Kuali, Cayuse, or myResearch Grants), rather than through a manual process of re-keying data. This streamlined approach offers benefits like reduced errors, faster submission, and improved data accuracy. Cayuse 424 is one such product.

4. Other electronic tools related to funding application development and submission

a. NIH RePORTER

NIH RePORTER is a searchable database that allows users to access information on projects funded by the National Institutes of Health (NIH) and other related agencies. It provides details about funded projects, investigators, publications,

and patents resulting from NIH funding. Essentially, it's a tool for discovering and understanding NIH-funded research.

b. USAspending.gov

USAspending.gov is a government website operated by the U.S. Department of the Treasury that provides open, searchable data on federal spending. It includes information on federal awards like contracts, grants, and loans, allowing users to analyze government spending by recipient, industry, agency, location, and time.

c. Other (state, private)

Some state agencies, private sponsors and foundations will have their own portal for proposal preparation and submission.

5. System-to-system Interfaces

System-to-system (S2S) proposal submission refers to a process where a proposal is submitted to a funding agency (like Grants.gov) directly from a research institution's internal system (like Kuali, Cayuse, or myResearch Grants), rather than through a manual process of re-keying data. This streamlined approach offers benefits like reduced errors, faster submission, and improved data accuracy. Cayuse 424 is one such product.

G. Deadlines and Target Dates

NSF proposals have different due date types: target dates and deadline dates. Target dates allow proposals to be submitted after the date but may not be considered for a particular panel meeting. Deadline dates are firm and proposals submitted after this date will not be reviewed

H. Unfunded and Revised Proposals

Unfunded grant proposals that are revised and resubmitted are common practice. Revise the proposal based on feedback from the funding agency, and resubmit it with the necessary changes.

III. BUDGET DESIGN AND DEVELOPMENT

A. Budget Preparation

1. Process for development of a budget

Identify all the costs that are ***necessary*** and ***reasonable*** to complete the work described in your proposal.

The budget should list all cost details for the year or another appropriate period of time. It should include any applicable salaries & wages, fringe benefits, services, supplies, equipment, publications, travel, other direct expenses, and any facility and administrative costs.

2. Role of budget in proposal and characteristics of an effective budget

An effective research proposal budget is well-planned, realistic, clearly communicated, and justifiable. It should accurately reflect the costs of personnel, materials, equipment, travel, and other direct and indirect expenses. The budget must be aligned with the research project's goals and provide a clear breakdown of how funds will be used.

3. Interpretation of sponsor guidelines related to budget limitations and exclusions

Carefully read the funding opportunity for budget criteria. You should look for limits on the types of expenses (e.g. no construction allowed), spending caps on certain expenses (e.g. travel limited to $10,000), and overall funding limits (e.g. total costs cannot exceed $300,000 per year).

4. Understanding of sustainability of project

Financial sustainability for a research project means having the capacity to secure and manage sufficient resources to effectively execute the research project and achieve its goals over time. This involves ensuring the project's financial needs are met throughout its lifecycle, from initial planning to completion and beyond, if applicable.

5. Budget categories

Personnel

Equipment

Supplies

Travel

Subawards

Tuition

Other Direct Costs

6. Budget justification

A budget justification in a research proposal explains the need for each budget item, demonstrating how the requested funds will support the research project. It provides a detailed narrative, linking budget items to the project's tasks and highlighting their relevance to the research objectives. A strong justification builds credibility and increases the likelihood of funding.

7. Budget forms

NSF 1030 Budget form used in Research.gov

SF-424A R&R Budget Form used for Grants.gov submissions

NIH PHS 398 Modular or Detail budget form

8. Use of budget template and spreadsheets

Most institutions have developed their own budget templates and spreadsheets. The most common spreadsheet software for creating proposal budgets is Excel. These spreadsheets include calculation for escalation of costs, salary and effort calculations, fringe benefits, tuition, calculating modified total direct costs, indirect costs and the total project cost.

9. Budget calculation

These spreadsheets include calculation for escalation of costs, salary and effort calculations, fringe benefits, tuition, calculating modified total direct costs, indirect costs and the total project cost.

See separate worksheets for Examples of budget calculations.

B. Project Costs

1. Definitions of direct and indirect costs

Direct Costs are those costs that can be identified specifically with a particular final cost objective, such as a Federal award. They can also be directly assigned to such activities relatively easily with a high degree of accuracy.

Sometimes called “overhead,” Indirect Costs (IDC) are those costs incurred for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved.

2. Definition of major projects and unlike circumstance

OMB Circular A-21 defines "major project" as a project requiring extensive administrative or clerical support, exceeding the routine level provided by academic departments. This typically includes large, complex programs, projects with extensive data handling, projects involving large travel arrangements, and projects focused on producing manuals, reports, or books.

Where direct charges for administrative and clerical salaries are made, care must be exercised to assure that costs incurred for the same purpose, **in like circumstances**, are consistently treated as direct costs for all activities. **Unlike circumstances** must be clearly identified, justified and detailed in the application.

Salaries of Administrative and Clerical Staff

- ❑ Should normally be treated as indirect (F&A) costs.

3. Understanding of total project costs (sponsor and matching costs)

Total project costs encompass all expenses associated with a project, including both the sponsor's contributions and any matching or cost-sharing contributions made by other parties. If the sponsor requires 50% of the total project costs to be provided as cost sharing or matching then you need to come up with an equal share of funding from the institution as you are requesting from the sponsor.

4. Cost sharing

Cost Sharing: Represents the portion of total project costs related to a sponsored project that is not provided by the sponsor.

a. **Allowable and unallowable costs –** For a cost to be used for cost sharing it must be allowable just as it would have to be allowable if charged directly to the project. If a cost is unallowable as a direct charge to the project then it is unallowable to be used as cost sharing.

b. Types of cost sharing (mandatory, voluntary committed, voluntary uncommitted)

- **Cost Sharing: Mandatory**
  - Represents contributions to a sponsored project or program required by the sponsor as a condition of award
    - May be a fixed percent or specific level of participation negotiated between the institution and the sponsor
    - Must be included in the proposal and be provided by someone other than the sponsor
    - Is binding and must be accounted for
    - May be reportable to the sponsor

- **Cost Sharing: Voluntary**

  Under Federal research proposals, voluntary committed cost sharing is not expected. It cannot be used as a factor during the merit review of applications or proposals, but may be considered if it is both in accordance with Federal awarding agency regulations and specified in a notice of funding opportunity

    - Represents contributions to a sponsored project or program not required by the sponsor as an award condition

  - **Committed/ Mandatory:** quantified contributions reflected in the proposal. These are binding commitments and must be accounted for. They may be reportable to the sponsor
  - **Uncommitted:** contributions not quantified or reflected in the proposal. These are not binding commitments and do not require documentation or reporting. Does not have to be included in the F&A rate.

C. Documentation and institutional approvals

Cost sharing criteria

a. Must be verifiable from records
b. Mandatory/Committed cost sharing must be monitored, verified and included in the F&A calculation.
c. Cost share is a direct cost to the institution and **could have the effect of lowering the F&A rate and decreasing the recovery of F&A revenue.**
d. Are allowable under Subpart E—Cost Principles of this part
e. Provided for in approved budget
f. Only used for one award
g. Conforms to Federal rules & regulations
h. Unrecovered F&A costs may be included with agency approval
i. One federal award cannot be used as cost sharing on another Federal award

- **Examples of Cost sharing**
  - Effort-faculty, staff or student (e.g., 30% effort with 10% salary charged to the project)
  - Cash
  - Third party contributions
  - Unrecovered F&A costs (can be used if agency has approved)
  - Volunteer Services or Donations
  - Values for contributions of services and property must be established in accordance with applicable cost principles.

- Other employee services (valued at regular rate of pay plus fringe benefits.
- Donated supplies (fair market value)

- **Cost sharing –Not allowable**
  - Salaries over salary cap
  - Cost overruns, overdrafts
  - Purchase price of equipment in current inventory

Note: Unrecovered indirect costs, including indirect costs on cost sharing or matching may be included as part of cost sharing or matching only with the prior approval of the Federal awarding agency.

Unrecovered IDC means the difference between the amount charged to the award and the amount which could have been charged under the organization's Negotiated Indirect Cost Rate Agreement (NICRA).

Value of Donated Property

Value of the donated property for cost sharing or matching must be the lesser of:

(1) The value of the remaining life of the property recorded in the non-Federal entity's accounting records at the time of donation

(2) The current fair market value.

Volunteer Services - may be counted as cost sharing or matching:

- if the service is an integral and necessary part of an approved project or program
- Rates for third-party volunteer services must be consistent with those paid for similar work by the non-Federal entity

Third Party Cost Share

Services must be valued at the employee's regular rate of pay plus an amount of fringe benefits that is reasonable, necessary, allocable, and otherwise allowable and indirect costs at the entity's NICRA

May include such items as equipment, office supplies, laboratory supplies, or workshop and classroom supplies.

Value assessed to donated property included in the cost sharing or matching share must not exceed the fair market value of the property at the time of the donation.

Third Party Donated Land, Buildings or Equipment

Method for determining cost share value may differ according to the purpose of the Federal award.

(1) If the purpose is for the acquisition of equipment, buildings or land, the aggregate value of the donated property may be claimed as cost sharing or matching.

(2) If the purpose of the Federal award is to support activities that require the use of equipment, buildings or land, normally only depreciation charges for equipment and buildings may be made.

With agency approval, fair rental charges for land may be allowed.

- The value of donated land and buildings must not exceed its fair market value at the time of donation.
- Value of donated equipment must not exceed the fair market value of equipment of the same age and condition at the time of donation.
- Value of donated space must not exceed the fair rental value.
- Value of loaned equipment must not exceed its fair rental value.

5. Understanding of general cost principles

a. Criteria for determining allowable and unallowable costs (2 CFR Part 220, allowable, allocable, reasonable, consistently applied, prudent person test)

The allowability of costs. Costs charged to awards must be allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds.

A cost is allocable to a particular cost objective (project), if the goods/services involved are chargeable or assignable to such cost objective in accordance with relative benefits received.

- It is incurred specifically for the work under the sponsored agreement;
- It benefits both the sponsored agreement and other work of the institution, in proportions that can be approximated through use of reasonable methods; or
- It is necessary to the overall operation of the institution and is assignable in part to the award

A cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost.

- Market prices for comparable goods/services for the geographic area.
- Whether the individuals concerned acted with prudence in the circumstances considering their responsibilities.
- Whether the non-Federal entity significantly deviates from its established practices and policies

Consistently Treated - Treating like costs the same in like circumstances. It is essential that each item of cost incurred for the same purpose be treated consistently in like circumstances either as a direct or an indirect (F&A) cost in order to avoid possible double-charging of Federal awards.

b. Typical allowable and unallowable costs

Subpart E of the UG – Cost Principles provides a detailed listing of items that are typically allowable and unallowable.

Examples of costs normally considered allowable include:

- Salary and Wages
- Fringe Benefits
- Equipment
- Supplies
- Travel
- Tuition
- Publication Costs

Examples of costs normally considered unallowable include:

- Advertising and public relations
- Alcoholic beverages
- Convocations or other events related to instruction
- Donations
- Entertainment
- Fines and penalties
- Fully depreciated assets or assets gifted by the federal government
- General purpose equipment, buildings, and land
- Housing and personal living expenses
- Insurance and indemnification
- Legal costs
- Lobbying

- Memberships in any civic or community organization
- Royalties or patents

c. Cost Accounting Standards (CAS)

Section 200.419 Cost Accounting Standards (CAS) and Disclosure Statement (DS2)

Required if:

- IHE receives **$50 million** or more in Federal awards in a fiscal year.
- must comply with the CASB's CAS located at 48 CFR 9905.501, 9905.502, 9905.505, and 9905.506.
- **Four Basic requirements**
    - CAS 501: Consistency in estimating, accumulating and reporting costs
    - CAS 502: Consistency in allocating costs incurred for the same purpose
    - CAS 505: Accounting for unallowable costs
    - CAS 506: Accounting period

- must disclose their cost accounting practices by filing a Disclosure Statement (DS-2)

The DS-2 must be submitted to the cognizant agency for indirect costs with a copy to the IHE's cognizant agency for audit. IHE is responsible for maintaining an accurate DS-2 and complying with disclosed cost accounting practices. An IHE must file amendments to the DS-2 to the cognizant agency for indirect costs six months in advance of a disclosed practice being changed to comply with a new or modified standard, or when a practice is changed for other reasons. Amendments of a DS-2 may be submitted at any time. Resubmission of a complete, updated DS-2 is discouraged except when there are extensive changes to disclosed practices

6. Cost price analysis

The non-Federal entity must perform a cost or price analysis in connection with every procurement action in excess of the Simplified Acquisition.

Cost Analysis is a breakdown and examination of constituent costs.

Price Analysis is the process of deciding if the asking price for a product or service is fair and reasonable, without examining the specific **cost** and profit

calculations the vendor used in arriving at the price. It is basically a process of comparing the price with known indicators of reasonableness.

7. Program income

200.80 Program Income – Definition

> Defines program income as "gross income earned by a recipient that is directly generated by a sponsored activity or earned as a result of the award during the period of performance."

Program income includes but is not limited to income from fees for services performed, the use or rental or real or personal property acquired under Federal awards, the sale of commodities or items fabricated under a Federal award, license fees and royalties on patents and copyrights, and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income.

Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them.

Program Income - Examples

- Fees earned from services performed under the project, such as laboratory tests.
- Conference fees charged when a grant funds the conference.
- Income from registration fees, consulting, and sales of educational materials.

Program Income - Is Not

- Taxes, special assessments, levies, fines, raised by a non-Federal entity.
- Proceeds from the sale of real property, equipment, or supplies.
- license fees and royalties for copyrighted material, patents, trademarks, and inventions.
- Earned after the period of performance

<u>Three treatments of program income, Deduction, Addition, Cost Sharing or Matching</u>

Program Income - Deduction

Default if method is not specified and awardee is Not a IHE or non-profit

- (1) *Deduction.* Ordinarily program income must be deducted from total allowable costs to determine the net allowable costs. Program income must be used for current costs unless the Federal awarding agency authorizes otherwise.
- Reduces the federal contribution.

Program income that the non-Federal entity did not anticipate at the time of the Federal award must be used to reduce the Federal award and non-Federal entity contributions rather than to increase the funds committed to the project.

Program income funds are deducted from the total project or program allowable costs to determine the net allowable costs on which the sponsor's share of costs is based.

EXAMPLE: The initial project budget was $100,000. $10,000 of program income is earned. The adjusted project budget amount from the sponsor is reduced to $90,000 after gross program income is taken into account. Total project costs remain at $100,000. ($90,000 on the parent budget and $10,000 on the program income sub-budget.)

Program Income - Additive

- Standard for awards made to IHEs and nonprofit research institutions, if not otherwise specified in the award.
- Program income may be added to the Federal award by the Federal agency and the non-Federal entity.

Program income funds are added to the funds committed to the project by the sponsoring agency and used to further eligible project or program objectives.

EXAMPLE: the initial project budget was $100,000. $10,000 of program income is generated. The total project costs may now be $110,000. ($100,000 expensed on the parent budget and $10,000 expensed on the program income sub-budget.)

Program Income – Cost Sharing or Matching

- With prior approval of the Federal awarding agency, program income may be used to meet the cost sharing or matching requirement of the Federal award.
- The amount of the Federal award remains the same.

Program income funds are used to finance the non-sponsor share of the project or program (mandatory or committed cost sharing).

EXAMPLE: The initial project budget was $100,000 with cost sharing committed at $20,000. $10,000 of program income is generated. The expenditure of the program income may be used to account for $10,000 of the committed cost sharing

Program Income Example Funds Not Reportable to Agency

Three months after ending date of Navy award, a follow-up conference was held. Participant fee was $500 and 100 participants attended, yielding $50,000 in conference fee revenue. Even though conference was related to Navy project, as it was held after the ending date of Navy award, there is no accountability to Navy

C. Direct Costs

1. Personnel

a. Salaries and wages (application of salary cap)

The NIH salary cap restricts the amount that can be charged to an NIH grant for the direct salary of an individual. It is a maximum annual rate of pay for an individual's full-time effort, not a limit on the total amount an institution can pay an individual. The salary cap for FY25 is $225,700, and recipients may rebudget funds to accommodate this increase if available.

How it's applied:

- Individual's Effort:

  The salary cap applies to the portion of an individual's salary that is charged to an NIH grant.

- Direct Salary:

  The cap is on the monthly pay rate that can be charged to an NIH grant, not on the total amount an institution pays an individual.

- No Limit on Institutional Pay:

  Institutions can pay individuals above the salary cap, but they cannot charge more than the cap to the NIH grant.

- Rebudgets:

  If an institution has available funds, they may rebudget funds to accommodate the salary cap increase in existing awards.

- No Additional Funds:

No additional funds will be provided to existing grant awards for the salary cap increase.

Examples:

- If an individual's institutional base salary is $250,000, and they are working 50% effort on an NIH grant, the maximum amount that can be charged to the NIH grant for their direct salary would be $112,500 (50% of $225,700).
- If an individual's base salary is $250,000 and they are working 100% on an NIH grant, the maximum amount that can be charged to the NIH grant for their direct salary would be $225,700 (the salary cap).

b. Time and effort (understanding of concept of 100%)

Charges for work performed on Federal awards by faculty members during the academic year are allowable at the Institutional Base Salary (IBS rate). IBS is defined as the annual compensation paid by an IHE for an individual's appointment, whether that individual's time is spent on research, instruction, administration, or other activities. IBS excludes any income that an individual earns outside of duties performed for the IHE

Effort Reporting

Standards for Documentation of Personnel Expenses
(1) Charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed. These records must:

(i) Be supported by a system of internal control which provides reasonable assurance that the charges are accurate, allowable, and properly allocated;

(ii) Be incorporated into the official records of the non-Federal entity;

(iii) Reasonably reflect the total activity for which the employee is compensated by the non-Federal entity, not exceeding 100% of compensated activities (for IHE, this per the IHE's definition of IBS);

(iv) Encompass both federally assisted and all other activities compensated by the non-Federal entity on an integrated basis, but may include the use of subsidiary records as defined in the non-Federal entity's written policy;

(v) Comply with the established accounting policies and practices of the non-Federal entity (See
paragraph (h)(1)(ii) above for treatment of incidental work for IHEs.); and

(vi) [Reserved]

(vii) Support the distribution of the employee's salary or wages among specific activities or cost objectives if the employee works on more than one Federal award; a Federal award and non-Federal award; an indirect cost activity and a direct cost activity; two or more indirect activities which are allocated using different allocation bases; or an unallowable activity and a direct or indirect cost

Because practices vary as to the activity constituting a full workload (for IHEs, IBS), records may reflect categories of activities expressed as a percentage distribution of total activities.

It is recognized that teaching, research, service, and administration are often inextricably intermingled in an academic setting. When recording salaries and wages charged to Federal awards for IHEs, a precise assessment of factors that contribute to costs is therefore not always feasible, nor is it expected

Effort Reporting

- Required when an individual is compensated by or agrees to contribute time to a federally sponsored project
- Verifies payroll distribution and cost-shared/contributed effort
- Required by Cost Principles
- Noncompliance results in disallowances

c. Fringe benefits (typical components, different types of calculation base pooled, actual)

Fringe benefits are allowances and services employers provide to their employees as compensation in addition to regular salaries and wages. Fringe benefits include, but are not limited to, the costs of leave, employee insurance, pensions, and unemployment benefits.

Fringe benefit costs cover the University's cost for FICA, worker's compensation, unemployment benefits, and contributions to retirement and health insurance. Actual costs per person vary depending upon type of insurance coverage selected, type of retirement plan, and salary; figures are approximate, based on pooled averages. These averages are based on actual costs in prior years.
Fringe Benefit Costs include the following:

- FICA
- Unemployment/Worker's Compensation
- Insurance Premium Estimates
- Retirement Plan Contribution
- Benefit Replacement Pay

- Longevity Pay

Typically there are different rates for faculty and staff and usually a lower rate for graduate students who are no eligible for retirement contributions.

Calculation - Salary and Wages x fringe rate percentage = fringe benefits

Actual charges to a sponsor when a payment is made will be dependent on costs associated with the individual at the time of payment and are based on actual costs against the payroll account(s).

2. Travel

Travel costs are the expenses for transportation, lodging, subsistence, and related items incurred by employees who are in travel status on official business of the non-Federal entity

- may be charged on an actual cost basis,
- on a per diem or mileage basis in lieu of actual costs incurred,
- or on a combination of the two,

Lodging and subsistence - must be considered reasonable and otherwise allowable only to the extent such costs do not exceed charges normally allowed by the non-Federal entity in its regular operations

Commercial air travel. (1) Airfare costs in excess of the basic least expensive unrestricted accommodations class offered by commercial airlines are unallowable except when such accommodations would:
(i) Require circuitous routing;
(ii) Require travel during unreasonable hours;
(iii) Excessively prolong travel;
(iv) Result in additional costs that would offset the transportation savings; or
(v) Offer accommodations not reasonably adequate for the traveler's medical needs.

The non-Federal entity must justify and document these conditions on a case-by-case basis in order for the use of first-class or business-class airfare to be allowable in such cases.

3. Equipment

Means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost that equals or exceeds the lesser of the capitalization level established by the recipient or subrecipient for financial statement purposes, or $10,000. (Increased from $5,000 in October 2024.

4. Other direct costs

Scholarships, Fellowships
Costs of scholarships, fellowships, and other programs of student aid at IHEs are allowable only when the purpose of the Federal award is to provide training to selected participants and the charge is approved by the Federal awarding agency.

Tuition - tuition remission and other forms of compensation paid as, or in lieu of, wages to students performing necessary work are allowable provided that::

- (1) The individual is conducting activities necessary to the sponsored agreement;
- (2) Tuition remission and other support are provided in accordance with established educational institutional policy and consistently provided in a like manner to students in return for similar activities conducted in nonsponsored as well as sponsored activities; and
- (3) During the academic period, the student is enrolled in an advanced degree program at the institution or affiliated institution and the activities of the student in relation to the Federally sponsored research project are related to the degree program;
- (4) the tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work; and
- (5) it is the institution's practice to similarly compensate students in nonsponsored as well as sponsored activities.

Participants - generally means an individual participating in or attending program activities under a Federal award, such as trainings or conferences, but who is not responsible for implementation of the Federal award. Individuals committing effort to the development or delivery of program activities under a Federal award (such as consultants, project personnel, or staff members of a recipient or subrecipient) are not participants. Examples of participants may include community members participating in a community outreach program, members of the public whose perspectives or input are sought as part of a program, students, or conference attendees.

Participant Support Costs - means direct costs that support and their involvement in a Federal award, such as stipends, subsistence allowances, travel allowances, registration fees, temporary dependent care, and per diem paid directly to or on behalf of participants.

Note many federal sponsors, NSF for one, require sponsor approval before moving funds out of the participant support category to another budget category.

5. Subawards

Means an award provided by a pass-through entity to a subrecipient for the subrecipient to contribute to the goals and objectives of the project by carrying out part of a Federal award received by the pass-through entity. It does not include payments to a contractor, beneficiary, or participant.

6. Consultant

Costs of professional and consultant services rendered by persons who are members of a particular profession or possess a special skill and who are not officers or employees of the recipient or subrecipient are allowable

In determining the allowability of costs in a particular case, no single factor or any combination of factors is necessarily determinative. However, the following factors are relevant:

(1) The nature and scope of the service rendered in relation to the service required.

(2) The necessity of contracting for the service, considering the recipient's or subrecipient's capability in the particular area.

(3) The past pattern of such costs, particularly in the years prior to receiving a Federal award(s).

(4) The impact of Federal awards on the recipient's or subrecipient's business (meaning, what new problems have arisen).

(5) Whether the proportion of Federal work to the recipient's or subrecipient's total business influences the recipient or subrecipient in favor of incurring the cost, particularly where the services rendered are not of a continuing nature and have little relationship to work under Federal awards.

(6) Whether the service can be performed more economically by direct employment rather than contracting.

(7) The qualifications of the individual or entity providing the service and the customary fees charged, especially on non-federally funded activities.

(8) Adequacy of the contractual agreement for the service (for example, description of the service, estimate of the time required, rate of compensation, and termination provisions).

(c) To be allowable, retainer fees must be supported by evidence of bona fide services available or rendered in addition to the factors in paragraph (b) of this section.

D. Facilities and Administrative (Indirect) Costs

University facilities and administrative (F&A) costs, also known as indirect costs, are expenses incurred by universities that are not directly tied to a specific research project but are necessary for supporting the overall research enterprise. These costs are essential for maintaining infrastructure, ensuring compliance, and conducting research effectively

For major IHEs (Institutions of Higher Education), indirect (F&A) cost must be classified within two broad categories: "Facilities" and "Administration

Facilities costs include depreciation and use allowances, interest on debt associated with certain buildings, equipment and capital improvements used for sponsored projects, operation and maintenance of plant expenses incurred for space used for sponsored projects, and allocated library expenses.

Administrative expenses include the allocated portion of general administrative and general expense, departmental administration, sponsored project administration, and the allocated portion of student services administration.

1. Components of indirect costs

Examples include:

- Central services (e.g HR, Finance, Environmental Health), custodial services, data network security, building operations and maintenance.
- Depreciation, building and equipment
- Sponsored programs services, including compliance oversight
- Departmental administrative costs in support of research
- Office supplies and general use equipment
- Utilities, internet and telecommunications
- Library services

2. Use of appropriate indirect rate in proposals (purpose code, off/on campus rates, sponsor indirect cost rate limitations)

3. Calculation of indirect costs in proposal budgets (modified total direct costs [MTDC])

F&A costs are applied on a modified total direct cost (MTDC) base. The non-F&A-bearing costs in the budget must be identified so that project F&A can be accurately calculated.

The MTDC base excludes the following cost components:

- Tuition
- Capital expenditures
- Equipment (was $5,000 increased to $10,000 in UG on October 2024 and is effective when the institution negotiates its next rate agreement)
- Charges for Patient care
- Rental costs
- Tuition Remission
- Scholarships and fellowships
- Participant support costs
- Subaward expenditures in excess of (was $25,000 increased to $50,000 in UG on October 2024 and is effective when the institution negotiates its next rate agreement)

Example: When preparing a budget, the F&A rate is applied using the federally defined base using Modified Total Direct Costs (MTDC). The F&A rate is applied to MTDC which consist of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 (will be $50,000) of each subaward.

4. Unrecovered indirect costs

Unrecovered indirect costs refer to the portion of a university's facilities and administrative (F&A) costs that are not reimbursed by a funding agency (sponsor).

Typically universities do not cover the full cost of performing research. There are several reasons.

- The administrative portion of the F&A rate is capped at 26%
- Some governing statutes such as with USDA NIFA program limit the amount of indirect cost rate that can be charges.
- Non-profits and foundation may limit the rate of indirect cost that they will allow.

5. Waivers

An F&A cost waiver is an institutional decision that IDC costs will be applied at a rate lower than the university's negotiated agreement. A waiver of Indirect Costs may be appropriate in extraordinary circumstances when the project is of great benefit to the university and is directly related to the university's mission.

6. Indirect rates

a. General process for developing indirect rate proposal

Developing an indirect rate proposal generally involves accumulating costs, selecting an appropriate allocation base, calculating the rate, and submitting the proposal to the cognizant agency

b. Determination of appropriate indirect rate

i. On campus/off campus

The off-campus indirect cost rate for a university, also known as F&A (Facilities and Administrative) rate, is a percentage applied to direct costs to recover indirect costs associated with research or other sponsored projects performed off-campus. It is typically lower than the on-campus rate because it doesn't include the costs of university facilities and utilities.

Since it only includes the administrative portion of the rate and the administrative portion has been capped by the government at 26%, just about all universities will use 26% as their off-campus rate.

Off Campus: The off-campus IDC rate applies to projects which meet all three criteria:

1. Project activities must occur in a non-university owned or operated space
2. More than 50% of the project must be for the off-campus activities
3. Rent for the off-campus location must be directly allocated from the grant

ii. Purpose code (e.g. research, instruction, other)

It is important to code the sponsored activity correctly and apply the applicable rate. Typically there is a Research rate an Instruction rate and an Other Sponsored Activity Rate. Sometimes the research and Instruction rate are the same or grouped as one rate.

Organized Research: This IDC rate applies to all research and development activities that are separately budgeted and accounted for, such as federal and non-federal sponsored research and federally funded clinical trials.

Other Sponsored Activities: This IDC rate is limited in scope and should be applied to projects or programs which are not classified as organized research. This can be for service performed for the benefit of the public. Examples of such programs and projects are health service projects,

community service programs, non-credit community education, and conferences.

iii. Negotiation of indirect rates

The negotiation process for a university's Facilities and Administrative (F&A) rate agreement involves a multi-step process, including internal review, proposal submission, audit, negotiation, and final agreement. Universities negotiate F&A rates with cognizant agencies like the Department of Health and Human Services (DHHS) or the Office of Naval Research (ONR).

Here's a more detailed breakdown:

1. Internal Review and Proposal Development:

Data Collection:

Universities collect data on direct and indirect research costs, including salaries, benefits, space, utilities, and administrative costs.

Proposal Preparation:

This data is used to calculate a proposed F&A rate, reflecting the proportion of indirect costs to direct research costs.

Internal Review:

The proposal is reviewed by various university departments and stakeholders, including executive management, to ensure accuracy and completeness.

2. Submission and Audit:

Submission:

The proposed F&A rate is submitted to the cognizant agency (e.g., DHHS, ONR).

Audit:

The cognizant agency or a contracted agency like the Defense Contract Audit Agency (DCAA) performs an audit of the proposal. This audit can take several months.

3. Negotiation:

Review and Feedback:

The university reviews the audit report and provides feedback to the cognizant agency.

Negotiation:

Negotiations between the university and the cognizant agency take place, often involving a back-and-forth exchange of data and arguments.

Final Agreement:

A final agreement is reached, outlining the agreed-upon F&A rates and the period they will apply.

4. Agreement and Application:

Formal Agreement:

A formal agreement is signed between the university and the cognizant agency, outlining the negotiated F&A rates.

Application:

The agreed-upon F&A rates are then applied to sponsored awards, determining the portion of direct costs that will be used to cover indirect costs.

Key Considerations:

F&A rates are typically negotiated every four years, but can be renegotiated sooner if necessary.

Different types of F&A rates may be negotiated, depending on the type of research and the specific cognizant agency.

Space data is one of the most important factors in determining the F&A rate. University facility costs are primarily allocated to University functions, such as instruction and research, according to how University space is utilized, or functionalized. It is therefore critical that every department accurately classify its space according to established functional use definitions.

Types of Rates

Negotiated Facility and Administrative (F&A) rates are typically classified into three main types: provisional, predetermined, and fixed with carry-forward. Provisional rates are used temporarily until a final, predetermined, or fixed rate is established. Predetermined rates are based on estimated costs for a specific period and are not subject to adjustment. Fixed with carry-forward rates are set for a specific period and may include a provision for carrying forward any unspent portion to the next period.

If negotiated rate agreements do not extend through the life of the sponsored agreement at the time of the initial award, the negotiated rate for the last year of the sponsored agreement is extended through the end of the life of the sponsored agreement.

E. Budget Revisions (review, submission, implications to scope of work)

NSF – Revisions to Proposals Made During the Review Process

Negotiating budgets generally involves discussing a lower or higher amount of total support for the proposed project. The cognizant NSF Program Officer may suggest reducing or eliminating costs for specific budget items that are clearly unnecessary or unreasonable for the activities to be undertaken, especially when the review process supports such changes; however, this would generally not include faculty salaries, salary rates, fringe benefits, or tuition. Note: indirect cost (F&A) rates are not subject to negotiation. The NSF Program Officer may discuss with PIs the "bottom line" award amount, i.e., the total NSF funding that will be recommended for a project. NSF Program Officers may not renegotiate cost sharing or other organizational commitments.

When such discussions result in a budget reduction of 10% or more from the amount originally proposed, a corresponding reduction should be made in the scope of the project. A revised proposal budget, budget justification, as well as a Budget Impact Statement that describes the impact of the budget reduction on the scope of the project, must be provided.

IV. AWARDS AND PRE-AWARD COMPLIANCE CONSIDERATIONS

A. Sponsor Reviews (characteristics, composition of review committee, outcome)

1. In-house review

An in-house review of a research proposal involves internal experts within an organization or institution examining the proposal for its feasibility, merit, and alignment with organizational goals

2. Peer review

Peer Review for sponsored research funding is a process adopted by sponsors, including the NIH and other Federal Agencies, to gather feedback on the grant proposal from scientific experts best suited to objectively and rigorously evaluate the strength of proposed research plans. This process underpins the US sponsored research funding enterprise and attempts to ensure that only the most meritorious projects are funded

3. Modified peer review

Is a peer review process that is tailored or adjusted to fit specific circumstances, often when the standard peer review process is not applicable or appropriate. It's essentially a review that isn't a full-fledged, traditional peer review but still provides feedback or evaluation of a project, manuscript, or other work.

4. Other - Ad Hoc Panels: For specific, temporary needs, ad hoc panels are convened to review a batch of applications within a defined period

B. Site Visits (definition, preparation steps, responsibilities of parties)

NSF- The goals of a site visit are to assess:

- An awardee organization's capacity for award administration.
- An awardee organization's compliance with administrative regulations, public policy requirements and award terms and conditions, including those contained in the NSF program announcement/solicitation and the NSF grant or cooperative agreement.
- The extent to which an organization maintains a controlled environment where awards are likely to be administered in compliance with federal financial and administrative regulations and NSF agreement provisions.

C. Sponsored Project Awards (definition, purpose, use, key elements, support mechanisms)

1. Grant (assistance) means a legal instrument of financial assistance between a Federal agency and a recipient or between a pass-through entity and a subrecipient, consistent with 31 U.S.C. 6302, 6304:

Is used to enter into a relationship, the principal purpose of which is to transfer anything of value to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal agency or pass-through entity's direct benefit or use;

(2) Is distinguished from a cooperative agreement in that it does not provide for substantial involvement of the Federal agency in carrying out the activity contemplated by the Federal award.

2. Contract (procurement) means, for the purpose of Federal financial assistance, a legal instrument by which a recipient or subrecipient conducts procurement transactions under a Federal award

3. Cooperative agreement means a legal instrument of financial assistance between a Federal agency and a recipient or between a pass-through entity and subrecipient, consistent with 31 U.S.C. 6302-6305:

(1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal Government or pass-through entity's direct benefit or use;

(2) Is distinguished from a grant in that it provides for substantial involvement of the Federal agency or pass-through entity in carrying out the activity contemplated by the Federal award.

4. Subcontract

An outgoing subaward is a formal written agreement made between flow-through and a subrecipient to perform a portion of your statement of work under a sponsored award. An outgoing subaward is written and negotiated by the Research Administrator contract Negotiator.

5. Other

An Other Transaction Agreement (OTA) is a unique type of legal instrument other than a contract, grant, or cooperative agreement. Generally, this awarding instrument is not subject to the FAR, nor grant regulations unless otherwise noted for certain provisions in the terms and conditions of award. It is, however, subject to the OTA authority that governs the initiative as well as applicable legislative mandates.

D. Negotiations

1. Typical negotiation process and sponsor interface

The negotiation process for sponsored research awards involves a comprehensive review of the terms and conditions proposed by the sponsor, often with the goal of reaching a mutually acceptable agreement. This process typically involves several steps, including initial review, potential negotiation with the sponsor, and finalization and execution of the award document.

2. Terms and conditions (common preferred positions, implications of restrictive terms

a. Use of name

University policy prohibits any statement or implication in any publication or other published announcement that the university has approved any product that is or might be manufactured, sold, or otherwise distributed. The university also requires that its name not be used in connection with any advertisement, press release, or other form of business promotion or publicity, or refer to a research agreement, without its prior written approval.

b. Publication

University research agreements typically include clauses regarding publication, aiming to balance the need for academic freedom with potential sponsor interests (like intellectual property protection). While the university generally retains the right to publish, there may be provisions for sponsor review before publication and potential delays to allow for patent filing.

c. Warranty

Disclaimer of Warranties. Sponsor acknowledges that research is, by definition, experimental in nature and so the outcome of the Project is inherently uncertain and unpredictable. As such, [Member] has not made and does not make any representation, guarantee, or warranty, express or implied, regarding the results of the Project. Except as expressly provided in this Agreement, [Member] makes no warranties of merchantability or fitness for a particular purpose, or any other warranties, express or implied, and hereby disclaims all such warranties as to any matter including, without limitation, warranties as to: (a) the Project and any results of the Project; (b) data, reports, information, or research provided by [Member] or Sponsor; and (c) any invention, copyrightable work, or product, or ownership thereof, whether tested, conceived, discovered, or developed in the Project or in connection with conducting the Project.

d. Indemnification

Generally, a state university subject to state law is unable to indemnify the sponsor.

e. Payment

The payment provision of a contract sets forth the payment terms and mechanisms by which institution is to be paid for the work completed. The payment structure must be designated at the outset, approved by the Office of Research Administration, and may be either fixed-price or cost-reimbursable. Fixed-price agreements have fixed payments based on a milestone payment schedule or the submission of deliverables. Cost-reimbursement agreements are paid as costs are incurred and invoiced, typically monthly or quarterly.

f. Other

Governing law

The governing law provision in a contract indicates what law will apply and where any arbitration or litigation will take place should there be a dispute that ends up in court. Generally if the entity is a state-controlled institution of higher education, state law is always preferred when making the decision as to which state's law will apply.

Confidentiality

The confidentiality provision of a contract designates how sensitive or proprietary information is to be handled and places restrictions on sharing such information. Institutions of Higher Education rarely accepts confidentiality terms that would restrict the public disclosure of research results. The university's contract officers negotiate language to protect researchers and institution against any claims of breach or infringement.

Deliverables

If a contract has deliverables based on a statement of work/budget, the deliverables listed in the document must be clearly defined, specific, and realistic. Creating a clear and concise list helps to manage the expectations of all parties, especially when it comes to timelines and budgets. Be aware that some deliverables may be subject to additional regulations, such as export control, that may require additional processing steps.

Use and Ownership of results and rights in data

Research results beyond copyrights and patents may be generated, developed, or produced during a project and require protection. These other research results include intangible results such as undocumented findings, know-how, conclusions, methods, and techniques as well as tangible research results such as raw data, findings, samples and prototypes, biological materials, and chemical intermediates.

Generally the performing institution owns data and the results it generates under an agreement but may provide a license to a sponsor to use it for general internal purposes. The ownership of results and data is essential in the academic world to allow such information to be used in publications and future research ventures.

E. Intellectual Property

Definition: Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.

1.Applicable regulations (e.g. Bayh-Dole Act, 37 CFR 401)

Bayh-Dole Act

Historical Perspectives

- Problem- no government-wide policy on ownership of grantee-made inventions
- Resolution- Patent and Trademark Law Amendment Act (Bayh-Dole Codification in 37 CFR 401

Bayh-Dole Act fundamentally changed the nation's system of technology transfer by enabling universities to retain title to inventions and take the lead in patenting and licensing groundbreaking discoveries. Enacted on December 12, 1980, the Bayh-Dole Act (P.L. 96-517, Patent and Trademark Act Amendments of 1980) created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally-funded research programs. The Bayh-Dole Act endeavors to use patent ownership as an incentive for private sector development and commercialization of federally funded research and development (R&D).

Major provisions of the Act include:

- Non-profits, including universities, and small businesses may elect to retain title to innovations developed under federally-funded research programs

- Universities are encouraged to collaborate with commercial concerns to promote the utilization of inventions arising from federal funding
- Universities are expected to file patents on inventions they elect to own
- The government retains a nonexclusive, nontransferable, irrevocable, paid up license non- to practice the patent throughout the world
- The government retains march-in rights - March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

2. Types and characteristics (copyright, patent, license)

Types of Intellectual Property (IP)

- Patents
- Copyrights
- Trademarks
- Trade secrets

Patents

What is a patent?

- A form of intellectual property
- Excludes others from making, using, and selling for 20 years from date on which the application for the patent was filed in the United States
- Patentable items must be
  - Useful
  - Novel
  - Non-obvious

Patent Regulations (37 CFR 401)

- Applies to grants, contracts, cooperative agreements
- Requires written agreements with PI and staff
- Must disclose new invention to agency within two months of discovery
- Decision to retain title within two years after disclosure
- Must file within one year of electing to retain title
- Must provide government with non-exclusive license
- Portion of license revenue to inventor(s) remaining to support scientific research or education
- US patent protection not recognized by foreign entities

What is not patentable?

- Substitution of one material for another
- Mere change in size or shape
- Merely to make something portable
- Mere reversal of parts
    - Substitution of an equivalent element for another element

Types of Patents

- Utility Patents
    - New machines and processes
    - Manufactures
    - Composition of matter
    - Improvements thereon
- Design Patents (how it looks) Ornamental (non-useful) articles of manufacture 14 year term (from issue
- Plant Patents (asexually reproduced) 20 year term (from filing)

Background Patent is a patent that is necessary to practice (make or use) a process, machine, or composition

Joint Inventorship - Unless there is an agreement between all of the Inventors, any of the Inventors are free to do what they want with the Invention

Trademark

A trademark is a word, phrase, symbol, and/or design that identifies and distinguishes the source of the goods of one party from those of others. Usually registered and protected by law.

Copyrights

What is a copyright?

- Protects certain original works against copying
    - Literacy works, musical & dramatic works (including software)
    - Pantomimes & choreographic works
    - Pictorial, graphic, and sculptural works
    - Motion pictures & other audiovisual works
    - Sound recording
    - Architectural works

What can't be copyrighted?

- Works not fixed in a tangible form of expression
- Titles, names, short phrases, and slogans; familiar symbols or designs
- Ideas, procedures, methods, discoveries, etc.
- Works of common property with no original authorship

Copyrights in Grants & Contracts

- Grantee free to arrange Copyright unless prohibited by terms/conditions
- Royalty-free license to the federal government
- Grantees should adopt policy that will:
  - Encourage the creative energies
  - Permit portion of royalties to the institution
  - Serve the public interest

3. Classified research

Classified Research and Clearances

What is a Security Clearance?

Security clearances are essentially issued in two different categories. The first is a Personnel Security Clearances (PCL) and the second is a Facility Security Clearance (FCL). From these two types of security clearances, an individual or company can be granted one of three levels of clearance. The three levels of clearance are Confidential, Secret, and Top Secret.

Confidential (C) : Applies to information that could cause damage to the national security if disclosed to unauthorized sources.

Secret (S) : Applies to information that could cause serious damage to the national security if disclosed to unauthorized sources.

Top Secret (TS) : Applies to information that could cause exceptionally grave damage to the national security if disclosed to unauthorized sources.

What is a classified contract?

Classified contract" is defined by 48 CFR 2.101 as any contract in which the contractor or its employees must have access to classified information during contract performance. A contract may be a classified contract even though the contract document itself is unclassified.

What is a DD Form 254?

The intention of a DD Form 254 is to convey security requirements, classification guidance and provide handling procedures for classified material received and/or generated on a classified contract. The DD Form 254 is a resource for providing security requirements and classification guidance to a contractor.

4. Proprietary information

Trade Secret
A trade secret is a formula, practice, process, design, instrument, pattern, commercial method, or compilation of information not generally known or reasonably ascertainable by others by which a business can obtain an economic advantage over competitors or customers.

- is not generally known to the public;
- confers economic benefit on its holder *because* the information is not publicly known; and
- is the subject of reasonable efforts by the holder to maintain its secrecy

F. Assurances, Certifications, and Disclosures (purpose, key requirements)

1. Institutional registration and identification

You register your entity to do business with the U.S. federal government by completing the entity registration process at SAM.gov. Active registration in SAM.gov provides your entity the ability to apply for federal grants or loans or bid on government contracts.

a. Representations and Certifications (Reps and Certs)

Offerors and quoters are required to complete electronic annual representations and certifications in SAM accessed via https://www.sam.gov as a part of required registration (see FAR 4.1102).

All registrants are required to review and update the representations and certifications submitted to SAM as necessary, but at least annually, to ensure they are kept current, accurate, and complete. The representations and certifications are effective until one year from date of submission or update to SAM.

b. System for Award Management

The System for Award Management (SAM.gov) is an official website of the U.S. Government. There is no cost to use SAM.gov. You can use this site to:

- Register to do business with the U.S. Government
- Update, renew, or check the status of your entity registration
- Search for entity registration and exclusion records
- Search for assistance listings (formerly CFDA.gov), wage determinations (formerly WDOL.gov), contract opportunities (formerly FBO.gov), and contract data reports (formerly part of FPDS.gov).
- View and submit BioPreferred and Service Contract Reports
- Access publicly available award data via data extracts and system accounts

c. Employer Identification Number (EIN) and DUNS number

Note the Unique Entity ID has replaced the EIN and DUNS number for registering to do business with the government.

The EIN is a unique nine-digit number that identifies your entity for tax and reporting purposes. The EIN number is a Taxpayer Identification Number (TIN) assigned by the federal government. The TIN/EIN is used for individual entities.

A D-U-N-S (Data Universal Numbering System) number is a unique nine-digit identifier assigned by Dun & Bradstreet (D&B) to businesses worldwide. It's used for various purposes, including identifying businesses, establishing creditworthiness, and facilitating interactions with government agencies and large corporations.

Each entity has to register to do business with the U.S. Government via SAM.gov. If you want to apply for federal awards as a prime awardee, you need a **registration**. A registration allows you to bid on government contracts and apply for federal assistance. As part of registration, we will assign you a **Unique Entity ID.**

The Unique Entity ID does not expire. However, registrations must be updated and renewed each year to remain in the “active registration” status. If you do not update or renew your registration, it will be in an “inactive” status, but your entity will still have its same Unique Entity ID. **Note**: No awards or payments can be processed while the registration is in "inactive" status.

Getting a Unique Entity ID only

Some entities who do business with the government may choose not to register in SAM.gov, for example, sub-awardees. In this case, those entities cannot bid directly on federal contracts as a prime contractor or seek federal assistance as

a prime awardee. If this is the goal of the entity, they can go to SAM.gov and get a Unique Entity ID only (no entity registration required). The information required for getting a Unique Entity ID without registration is minimal. It only validates your organization's legal business name and address.

2. Affirmative Action/Equal Employment Opportunity (EEO)

EEO, or Equal Employment Opportunity, refers to federal laws and regulations that prohibit discrimination and ensure fair treatment in the workplace. It's enforced by the U.S. Equal Employment Opportunity Commission (EEOC). These laws protect employees and job applicants from discrimination based on various factors, including race, color, religion, sex (including pregnancy, transgender status, and sexual orientation), national origin, age (40 or older), disability, or genetic information.

3. Federal drug-free workplace and drug-free schools

The Drug-Free Workplace Act of 1988 (41 U.S.C. 81) is an Act of the United States which requires some federal contractors and all federal grantees to agree that they will provide drug-free workplaces as a precondition of receiving a contract or grant from a Federal agency.[1]

The Drug-Free Schools and Communities Act (DFSCA) of 1989- also known as the Drug-Free Schools and Campuses Act- requires institutions of higher education to establish policies that address unlawful possession, use, or distribution of alcohol and illicit drugs.

4. Federal debt delinquency

"Federal debt delinquency" refers to a situation where an individual or entity owes money to a federal government agency but fails to repay it by the specified due date or according to the terms of a payment agreement.

5. Federal debarment/suspension

Suspension and debarment are both actions taken by the government to exclude individuals or entities from participating in government contracts, but they differ in their duration and purpose. Suspension is a temporary measure, often imposed pending an investigation, while debarment is a more permanent action, typically for a specified period. Both aim to protect the government from fraud, waste, and abuse.

6. Lobbying

Applicant must certify the following:

No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment or modification of any Federal contract, grant, loan, or cooperative agreement.

7. Conflict of interest (COI)

Federal agencies including NIH and NSF have rules concerning FCOI.
Conflict of Interest is a cross-cutting issue that affects many policy areas such as peer review, financial conflict of interest, and responsible conduct of research. It generally means that a competing personal interest could affect, or could appear to affect, an individual's judgment or could cause the individual's impartiality to be questioned. Conflicts of Interest (actual or potential) may arise in the objective review process or in other activities or phases of the financial assistance process.

Types of Conflict of Interest

Financial

- Loyalty
- Objectivity

Personal

- Hiring and Supervision Conflicts
- Objectivity

Professional

- Time Conflicts

Organizational

- Institutional Interest

A financial conflict of interest (FCOI) exists when the grantee's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

An Investigator is defined as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

PHS / NIH Procedures:

When submitting a grant application, the signature of the AOR certifies the applicant Institution's compliance with the requirements of 42 CFR 50, Subpart F, including that:

1. There is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which NIH funding is sought or received;
2. The Institution shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests;

   Disclosure to the institution
   Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/ her known Significant Financial Interests (and those of his/her spouse and dependent children):
   (i) That would reasonably appear to be affected by the research for which PHS funding is sought; and
   (ii) In entities whose financial interests would reasonably appear to be affected by the research.

3. The Institution shall identify and manage financial conflicts of interest and provide initial and ongoing FCOI reports to the NIH consistent with this subpart;
4. When requested, the Institution will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a Financial Conflict of Interest;
5. The Institution shall fully comply with the requirements of the regulation.

When the Institution determines that a Financial Conflict of Interest exists (see #3 above), the Institution must report to the NIH awarding IC through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module.

Threshold

- De minimus threshold of $5,000 for disclosure of payments from publicly traded entities, or
- **Any** equity interest in non-publicly traded entities regardless of value
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 3rd Party paid Travel

Must disclose:

- Remuneration from external entities including salary and any payment for services – consulting fees, honoraria, paid authorship
- Equity interest, including stock, stock options, or ownership interest
- Royalties paid by non-university entities
- Travel paid for by outside entity if PHS investigator

Not included:

- Salary, royalties, remuneration, travel paid by university
- Income from investment vehicles, such as mutual funds and retirement accounts not directly controlled by investigator
- Income from seminars, lectures, teaching, or service on advisory committees or review panels sponsored by a federal, state, or local government agency, or institution of higher education (U.S. only)

Management Plan – to manage the FCOI may include

- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research

NSF Requirements

At proposal submission: An institutional conflict of interest policy should require that each investigator disclose to a responsible representative of the institution all significant financial interests of the investigator (including those of the investigator's spouse and dependent children): (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

•The term "significant financial interest" means **anything of monetary value**, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

•The institutional policy must include arrangements for keeping NSF's Office of the General Counsel appropriately informed if the institution finds that it is unable to satisfactorily manage a conflict of interest

NSF Threshold - similar to PHS requirements

- An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, **exceeds $10,000 in value** and/or **represents more than a 5% ownership interest** in any single entity;
- salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, exceed $10,000 during the prior twelve-month period

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Conflicts of Commitment

Conflicts of Commitment are generally situations in which a researcher is dedicating time to personal activities in excess of the time permitted by institutional policy, or to other activities that may detract from his or her primary responsibility to the institution. The issue is not necessarily financial or bias in one's judgment, but rather whether one's commitment of time and effort are inconsistent with one's commitment to the institution and its interest.

Some examples of conflicts of commitment:

1. A faculty member dedicating more that the permitted one day per week on personal consulting with a company or companies.
2. A faculty member accepting an unpaid position on a company's Scientific Board of Advisors and having access to and/or divulging confidential information when the company is sponsoring the faculty member's research.
3. A faculty member use institution resources, including office or laboratory space and secretarial services in support of his or her personal consulting.

A conflict of commitment also exists with a researcher's instructional and mentoring responsibilities f he/she uses graduate students on a personal consulting project.

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Questions

10. Dr. Smith has a full appointment with XYZ University and significant amount of his/her time consulting and conducting other external activities not related to the University. Colleagues and students have started to complain that Dr. Smith is not meeting his/her duties at the University. Which of the below *best* describes the type of conflict described in this scenario?
    a. Conflict of Conscience

b. Conflict of Interest
c. Conflict of Commitment
d. Significant Financial Interest

11. According to the 2011 Public Health Service Regulations titled Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is Sought 42 C.F.R. Part 50, Subpart F, which of the below activities require disclosure?
    a. The investigator's salary paid by the institution
    b. Income from investments vehicles such as mutual funds where the investigator does not have direct control.
    c. Ownership interest in a non-publicly traded entity that is reasonably related to the investigator's institutional responsibilities.
    d. Serving as a peer review panelists for the National Science Foundation.

74. According to the 2011 Public Health Service Regulations titled Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is Sought 42 C.F.R. Part 50, Subpart F, when should an investigator disclose a significant financial interest to their institution?

    a. No later than the time of proposal submission
    b. After proposal submission but before the award
    c. After the PI has posted expenditures to the grant
    d. When the notice of award is received by the institution

Answers: 72c, 73c, 74a,

8. Export controls (ITAR, EAR, OFAC)

Definition of "Export"
Any oral, written, electronic or visual disclosure, shipment, transfer or transmission outside the United States to anyone, including a U.S. citizen, of any commodity, technology (information, technical data, or assistance) or software/codes

"Export" also includes the concept of "Deemed Export"
The transfer of <u>controlled technology or technical data</u> to a <u>foreign national</u> <u>on campus</u> or <u>anywhere else.</u> Can involve release of information by:

- Tours of laboratories & visual inspection
- Published research

- Emails
- Oral conversations

- **Foreign Person:**
  - Any Person effectively owned or controlled by a foreign interest, whether located either inside or outside the U.S., (e.g., international oil companies)
  - Foreign businesses not incorporated in the U.S.
  - Individuals holding a work, business, or student visa (F1, J1, H1B), (e.g., Visiting Scholars or even short-term business visitors)
- **U.S. Person:**
  - U.S. Citizen
  - Green Card Holders
  - Asylum or Refugee Designations
  - U.S.-owned business incorporated under the laws of the U.S. to do business in the U.S.

Fundamental Research Exclusion

- Basic and applied research at Universities is generally exempt from Export License requirements due to a Fundamental Research Exclusion. (NSDD-189. September 21, 1985 National Policy on the Transfer of Scientific, Technical and Engineering Information)

- The Fundamental Research Exclusion only applies to technical data. It does not exempt the University from license requirements on any physical items.
- The Fundamental Research Exclusion is void if the institution accepts a contract with any
  - publication restrictions, or
  - restrictions on the participation of foreign nationals

Export Controls

- Apply to projects that do not meet the test of research being in the public domain.
- Restrict the export of goods and technologies that could contribute to the military or economic potential of US adversaries- "dual use" technologies.
- Prevent the proliferation of nuclear, chemical and biological weapons.
- Prevent terrorism and other illicit activities.
- Relevant regulations
  - **EAR (Export Administration Regulations)**

- **ITAR (International Traffic in Arms Regulations)**
- **OFAC (Office of Foreign Assets Controls)**

EAR Regulates items designed for commercial purpose but which could have military applications (computers, civilian aircraft, pathogens). Covers both the goods and the technology

- Department of Commerce is responsible for EAR
- Commerce Control List (CCL) list that includes "items" -- i.e., "commodities," "software," and "technology" -- subject to the authority of BIS
- Bureau of Industry and Security (BIS) - maintains the Commerce Control List (CCL)
- **Deemed exports** (It is the release to a foreign national located in United States, of technology or a source code that is subject to EAR
- **"Dual-use"** items (potential military use e.g. missile, avionics, GPS)
- May also apply to solely civil use items depending on the end use/end user)
- EAR regulates exports and re-exports of dual use commodities, software, equipment and technology.

ITAR

- Department of State
- Directorate of Defense Trade Controls (DDTC)
- Controls export and import of defense-related activities and services on US Munitions List (USML)
- Regulates goods and technology designed to kill or defend against death in a military setting, as well as defense services
- Includes space related technology because of application to missile technology
- Dictates what info and material pertaining to defense and military technologies may be shared

OFAC

- Department of Treasury
- Administers and enforces economic sanctions programs
- Prohibited transactions with countries, entities and persons subject to boycotts, trade sanctions and embargoes.
- Prohibits payments or providing "value" to nationals of sanctioned countries and certain entities

Technology Control Plans (TCP) helps ensure that **controlled** materials will not be accessed by unauthorized persons. ... It includes **plans** for storing / housing the items and procedures for guarding against unauthorized access to the restricted items or information. **-**

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Questions

12. International Traffic in Arm regulations (ITAR) are administered by which federal agency?
    a. Department of State correct
    b. Department of Energy
    c. Department of Treasury
    d. National Science Foundation

13. Which of the below are ways in which university personnel can "export" in violation of EAR?
    a. Physical Export
    b. Transmitting export controlled information or software electronically or digitally to a foreign country or foreign person
    c. Use of export controlled technology on behalf or for the benefit of a foreign person or foreign country (Defense Service)
    d. All of the above

14. Administers and enforces economic sanctions programs
    a. Department of State
    b. Department of Energy
    c. Department of Treasury
    d. National Science Foundation

Answers: 69a, 70d, 71c

9. Other – See Regulations and Compliance Handout for list of additional regulations.

G. Research Compliance (institutional committees, regulations, training)

1. Human subjects (IRB, CITI training)

1. Human Subjects (IRB, CITI Training)

a. *Verify Institutional Review Board training* –CITI offers IRB Administration courses.
b. *Attend Institutional Review Board meetings* - Except when an expedited review procedure is used, the IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (nonscientist). In order for the research to be approved, it must receive the approval of a majority of those members present at the meeting (45 CFR 46.108(b); 21 CFR 56.108(c)).
c. *Prepare Institutional Review Board reports* - Both the HHS regulations at 45 CFR 46.115(a)(2) and the FDA regulations at 21 CFR 56.115(a)(2) specifically require that an institution, or when appropriate, an IRB, prepare and maintain adequate documentation of IRB activities, including minutes in sufficient detail to show:
    - Attendance at the Meetings
    - Actions taken by the IRB
    - The vote on these actions, including the number of members voting for, against, and abstaining;
    - The basis for requiring changes in or disapproving research; and
    - A written summary of the discussion of controverted issues and their resolution
d. *Maintain Institutional Review Board records* - A copy of all documentation reviewed is to be maintained for at least three years after completion of the research at that institution [21 CFR 56.115(b)].

Research Involving Human Subjects

Definitions:

- Research
    - Defined as "a systematic investigation, including research development testing and evaluation designed to develop or contribute to generalizable knowledge." (45CFR46.102(d))
- Human subject
    - 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 or identifiable biospecimens.**." (45 CFR 46.102(f)(1),(2))

Three ways to involve Humans in Research

1. **Intervention** - using either physical or psychological procedures or manipulations of the subject or the subject's environment.

Commons Examples:

- Testing biomedical or behavioral processes:
    - drugs
    - dietary supplements
    - weight loss strategies
    - performance strategies
    - behavioral therapies and testing
    - cognitive therapies and testing
    - treatment or prevention strategies
- Testing new or revised educational or instructional methods:
    - students or teachers in classrooms
    - children or adults in special programs or general public
- Human factors evaluation - human experience with:
    - equipment
    - systems
    - technologies

2. **Interaction** through communication or interpersonal contact between the investigator and the subject.

Common Examples

- Face to face, phone, remote or online communications for:
    - Focus Groups
    - Interviews
    - Surveys

3. **Private Information** observing or recording behavior that is considered private or using private information that is identifiable.

Common Examples

- Obtaining identifiable data from:
    - medical records
    - student records
    - research records
    - repositories
- Obtaining identifiable human specimens (blood or tissue):
    - directly from human
    - repositories

Human Subject Protection: Historical Perspective

Relevant Regulations

- **1906 - Pure Food and Drug Act** – first consumer protection law that led to the creation of the FDA

- **1938 – Food, Drug & Cosmetic Act** – Set of laws that gave authority to the FDA to oversee the safety of food, drugs and cosmetics.

- **1946 - Nuremberg Code** - resulted from criminal proceedings against German physicians and scientists for their part in crimes against humanity for their experiments that killed or permanently crippled their subjects.

    1. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
    2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
    3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.
    4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
    5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
    6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
    7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
    8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
    9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.
    10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

- **1964 - Declaration of Helsinki** - set of ethical principles regarding human experimentation developed for medical community by World Medical Association

Basic principles

The fundamental principle is respect for the individual (Article 8), his right to self-determination and the right to make informed decisions (Articles 20, 21 and 22) regarding participation in research, both initially and during the course of the research. The investigator's duty is solely to the patient (Articles 2, 3 and 10) or volunteer (Articles 16, 18), and while there is always a need for research (Article 6), the subject's welfare must always take precedence over the interests of science and society (Article 5), and ethical considerations must always take precedence over laws and regulations (Article 9).

The recognition of the increased vulnerability of individuals and groups calls for special vigilance (Article 8). It is recognized that when the research participant is incompetent, physically or mentally incapable of giving consent, or is a minor (Articles 23, 24), then allowance should be considered for surrogate consent by an individual acting in the subject's best interest, although his or her consent should still be obtained if at all possible (Article 25).

- **1974 - National Research Act** - Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in response to the Tuskegee Syphilis Study which was terminated in 1974. The act established the need for Institutional Review Boards. The Commission drafted the Belmont Report to identify the basic ethical principles that should underlie the conduct of human research.

- **1979 Belmont Report** - Summarizes ethical principles and guidelines for research involving human subjects. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects. This document provides the basis for Common Rule's criteria for approval followed by IRB's. The three guiding principles of the Belmont Report are (1) Respect for Persons, (2) Beneficence, and (3) Justice.

Basic Underlying Principles

- **Respect for Persons -** demands that subjects enter into the research voluntarily and with adequate information
    - **Informed Consent - i**nformation, comprehension, and voluntariness
        - Disclose procedures, purposes, risk, benefits, alternative methods, compensation, the opportunity to ask questions and withdraw at any time from research, conflict of interest

        - Comprehension
        - Time to read
        - 8th grade reading level
        - Seeking permission
        - Voluntariness (direct vs. environmental pressure)
    - **Privacy and confidentiality**

- **Beneficence**
    - **Do no harm**
    - **Risk vs. Benefits maximize benefits, minimize risk of harm**

- **Justice -** Who ought to receive the benefits of research and bear its burdens?
    - **Equitable selection of subjects so that benefits and risk are distributed fairly**
        - each person an equal share
        - to each person according to individual need,
        - to each person according to individual need
        - to each person according to individual effort
        - to each person according to societal contribution, and
        - to each person according to merit.

DHHS Regulations

The U.S. Department of Health and Human Services (DHHS) regulations require that all human subjects research supported by DHHS be reviewed and approved by a local institutional review board (IRB). With few exceptions, investigators may not involve human subjects in research without their informed consent, and additional safeguards are required when subjects are likely to be vulnerable to coercion or undue influence.

The Office for Human Research Protections (OHRP) was created in June 2000 to lead the Department of Health and Human Services' efforts to protect human subjects in biomedical and behavioral research and to provide leadership for all federal agencies that conduct or support human subjects research under the Federal Policy for the Protection of Human Subjects, also known as the Common Rule.

Federal-wide Assurance (FWA)

- HHS human subject protection regulations and policies require that any institution engaged in non-exempt human subjects research conducted or supported by HHS must submit a written assurance of compliance to OHRP. The Federal-wide

Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP. *Renewal is every 5 years.* FWAs also are approved by the Office for Human Research Protections (OHRP) for federal-wide use, which means that other federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely on the FWA for the research that they conduct or support. Assurances are of a contract nature in that they formally commit the institutions to adherence to the regulations and the ethics standards relevant to research on human subjects. It is not project specific.

The Office for Human Research Protections (OHRP) receives reports from institutions holding a Federal-wide Assurance (FWA) of:

1. unanticipated problems involving risks to subjects or others;
2. serious or continuing noncompliance with the Common Rule or the requirements or determinations of the IRB; or
3. suspension or termination of IRB approval.

Common Rule

- **1991 DHHs issued CFR Title 45 Part 46**
    - **Also known as the Common rule**
    - Adopted by 20 federal agencies
    - Special protection for vulnerable populations in Subparts B, C and D.

    - **Subpart B** - Additional Protections for **Pregnant Women**, **Human Fetuses** and **Neonates** involved in Research
    - **Subpart C** – Additional Protections Pertaining to Biomedical and Behavioral Research involving **Prisoners**
    - **Subpart D** – Additional Protections for **Children** Involved as Subjects in Research
    - **Subpart E-** Registration of Institutional Review Boards

    Additional safeguards are required for other vulnerable groups that are not mentioned in the subparts:

    - Economically disadvantaged
    - Socially disadvantaged
    - Educationally disadvantaged
    - Cognitively impaired
    - Disabled

IRB Membership

- Must have at least five voting members

- Membership must include at least one member:
  - At least one scientist
  - At least one non-scientist
  - A least one health care professional
  - At least one community member who (or his/her immediate family) has no employment or contractual relationship with the entity
  - -If regularly going to be reviewing vulnerable populations (At least one member who has knowledge and experience on at least one or more vulnerable categories if regularly reviewed

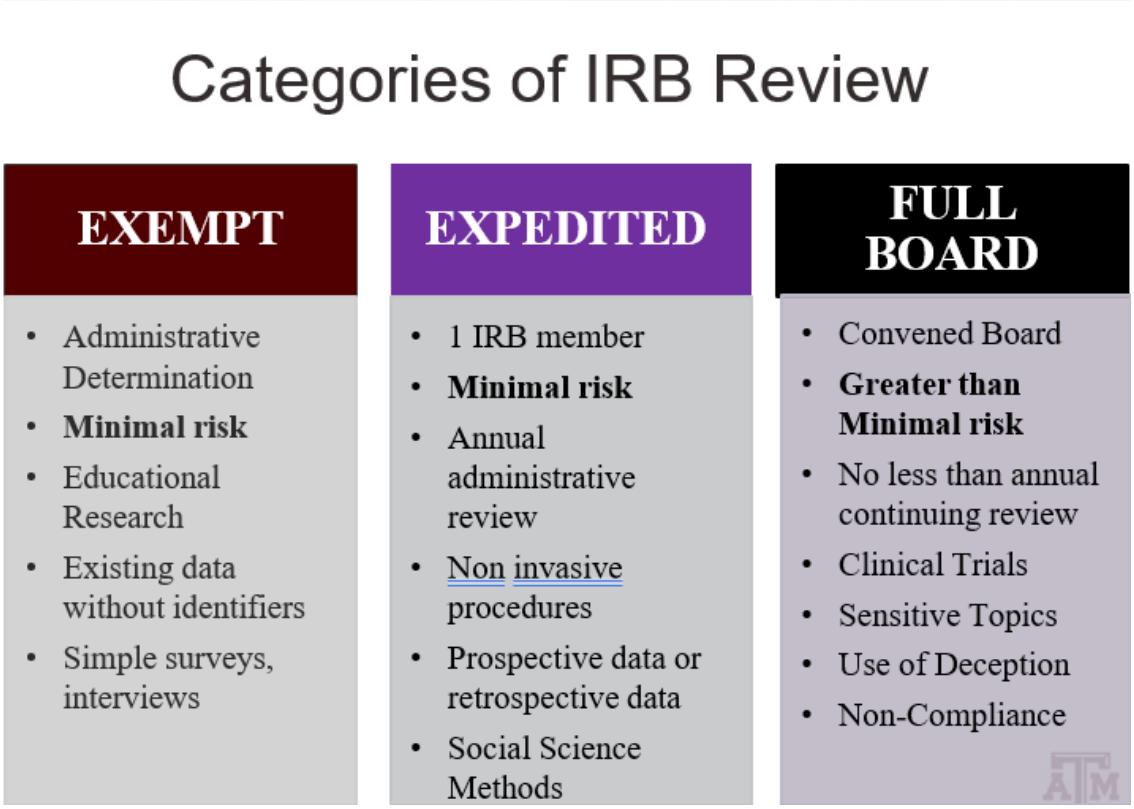
Registrations & Assurances

- IRB must register with Office of Human Research Protections (OHRP-HHS)
- IRB must register with Food and Drug Administration (FDA)

Authority of the IRB given to it by the regulations

- Approve research
- Require modifications to research
- Disapprove research
- Suspend or terminate approval of research
- Observe the consent process
  Observe the research (audit)

- **IRB Reviews & Approvals**
  - Initial
  - Continuation
  - Amendment/Modification
  - Unanticipated problems or adverse reactions
  - Non-compliance



Exemptions

Exemption 1: conducted in an educational setting using normal educational practices
Exemption 2: uses educational tests, surveys, interviews, or observations of public behavior
Exemption 3: uses benign behavioral interventions
Exemption 4: involves the collection or study of data or specimens if publicly available or recorded such that subjects cannot be identified
Exemption 5: public service program or demonstration project
Exemption 6: taste and food quality
Exemption 7: storage of identifiable information or biospecimens for secondary research use.
Exemption 8: secondary research use of identifiable information or biospecimens.

Criteria for Approval of Research

- Risks are minimized; sound procedures
- Risks are reasonable in relation to benefits
- Subject Selection is equitable

- Participation is voluntary and informed consent is obtained, documented or qualifies for a waiver
- Monitor the Data for Safety
- Adequate procedures for
- Privacy and Confidentiality
- Additional safeguard for Vulnerable Populations

Investigator Obligations

- *Follow the approved protocol*
- *Amendments*: Submit any changes to the protocol or study documents to the IRB for review and approval prior to implementation
- Submit a *Continuing Review no less than annually*
- *Report* any unanticipated problems, deviations, complaints and other reportable items.
- Keep Records of all study activity including:
  - IRB correspondence
  - consent and study documents
  - Keep track of participation numbers, reasons for withdrawals, complaints, unanticipated problems. Be audit ready at all times.
- Close –out by submitting a *completion report* when all study procedures including data analysis are done.

FDA Regulated Products

- Drugs, devices, biologics or other treatments (test articles) that are designed to work with the human body.
  - **Drug or biologic** – any article intended for use in the diagnosis, cure, mitigation, cure, treatment of prevention of disease in a human.
  - **Medical Device** – an instrument, apparatus, implement, machine contrivance, implant, reagent, or similar article, part or accessory intended for use in diagnosis, cure, mitigation, treatment or prevention of disease or other conditions in a human.
- **IND - Investigational New Drug Application (21 CFR Part 312)**
- **IDE - Investigational Device Exemptions (21 CFR Part 812)**

Definition of Clinical Trial

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes.

Clinical Trial Phases

Regulated by the FDA

Phase	Definition
I	First use with human – usually very small number of healthy subjects; looking at how absorbed, distributed, metabolized
II	First study to focus on clinical effectiveness in patients with the targeted condition; looking at short term side effects, safety risks;
III	Large number of subjects comparing to known effective treatments; application request for license to market
IV	Post marketing studies after approval on thousands of subjects to determine long term safety & efficacy in real world conditions.

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)

An independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection. To earn accreditation, organizations must provide tangible evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement.

As the "gold seal," AAHRPP accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that an HRPP is focused first and foremost on excellence.

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Questions:

15. According to federal regulations, institutional review boards must include:
    a. An ethicist
    b. An attorney
    c. A member of the clergy
    d. A member not otherwise affiliated with the institution

16. For which of the following population groups do special guidelines for their protection as research subjects apply?
    a. Prisoners
    b. The elderly
    c. College Students
    d. Persons diagnosed as HIV positive

17. Underlying principles of the Belmont report
    a. Respect for persons
    b. Beneficence
    c. Justice
    d. All of the above

18. An agreement between the institution and the Federal government certifying that all research supported by federal funds will be reviewed and approved by Institutional Review Board registered with OHRP.
    a. Human subjects protocol
    b. Federal compliance statement
    c. Federal-wide Assurance
    d. IRB declaration of compliance

19. Categories of IRB review.
    a. Exempt
    b. Expedited
    c. Full board
    d. All of the above

20. Defined as a systematic investigation, including research development testing and evaluation designed to develop or contribute to generalizable knowledge.
    a. Research
    b. Internally funded research
    c. Sponsored research
    d. Clinical trials

Answers: 48d, 49a, 50d, 51c, 52d, 53a

2. Animal subjects (IACUC, animal laboratory training requirements)

Use of Animals in Research, Teaching & Training

Overview - To provide for the humane care and use of live vertebrate animals in biomedical and behavioral research, teaching and testing

Two set of laws and regulations – USDA and PHS

The primary difference is that **PHS Policy covers all live vertebrate animals in PHS-funded research**, including rats and mice, while

- **USDA regulations (Animal Welfare Act) currently covers all warm-blooded, vertebrate animals, except:**
  - **Farm animals used for agriculture (food or fiber research)**
  - **Birds bred for use in research**
  - **Mice and rats bred for use in research**

For an institution receiving PHS funding, the PHS Policy sets a broader standard by covering all vertebrates, while still requiring full compliance with the narrower USDA regulations for the species the AWA covers. Most institutions adopt a single, robust animal welfare program that meets the requirements of both to avoid dual standards and ensure comprehensive coverage

USDA AWA Requirements

- Housing locations to be inspected every six months **- Housing locations is anywhere animals are held for more than 12 hours**

- Requires that all protocols (with USDA covered animals) **have a review and approval by the IACUC at intervals not exceeding 3 years.**

- Requires USDA representatives to perform **unannounced inspections at least annually.**

- Requires an annual report that documents all animal numbers used from the previous year, documentation that alternatives were considered for procedures that cause more than momentary pain or distress, and any programmatic changes.

- USDA requires all records of animal activities to be maintained for a minimum of 3 years after the animal activity has concluded.

Public Health Service (PHS)

Congress passed the Health Research Extension Act in 1985

- The policy applies to all PHS supported or conducted activities. <u>The policy covers all live vertebrate species.</u>
- The policy is based on and requires adherence to the AWA and the Guide for the Care and Use of Laboratory Animals.
- All institutions and entities that accept PHS funds must provide a written assurance to the NIH Office for Laboratory Animal Welfare (OLAW).
- The Assurance is renewed a maximum of every 5 years. The expiration date is determined by OLAW.
- The Assurance must:
    - Describe the institution's program for the care and use of animals
    - List the IO (Institutional Official), Attending Veterinarian (AV), and IACUC Chair
    - Provide qualifications of the IACUC members
    - Describe the procedures that the IACUC will follow to fulfill the requirements of the Policy.

    - PHS requires all procedure and **housing locations to be inspected every six months. Housing locations is anywhere animals are held for more than 24 hours.**
    - PHS requires that all protocols have a 3 year *de novo* review.
    - PHS requires a semiannual program review to be conducted by a majority of IACUC members.
    - PHS requires an annual report that documents all programmatic changes, exemptions to the Guide as approved by the IACUC, inspection dates, semiannual program review dates, minority reports, and a list of all IACUC members.

Guide for the Care and Use of Laboratory Animals "**The Guide**".

- Primary guidance document for OLAW and AAALAC
- Provides standards for cage sizes, sanitation, environment, and enrichment
- Outlines standards for the animal care and use program
- Requires an Occupational Health Program for all personnel who work with or have contact with animals or their tissues

Each institution that receives PHS support for activities involving vertebrate animals or is subject to the authority of the Animal Welfare Act (AWA) must operate an animal care and use program with clear lines of authority and responsibility. The program must include:

- •a properly constituted and functioning Institutional Animal Care and Use Committee (IACUC);
- • procedures for self monitoring;
- • an adequate veterinary care program;
- • an occupational health and safety program (not required under the AWA);
- • a personnel training program;
- • an environment, housing and management program for animals; and
- • appropriately maintained facilities for housing and support.

Institutional Animal Care and Use Committees (IACUC)

- Required by Federal Law- Animal Welfare Act.
  - Requires a **minimum of 3 members**- Chair, Veterinarian, **Nonaffliated** member. Veterinarian must have training/experience in laboratory animal science.
  - No more than 3 members from any one unit.
  -
- Required by Institutional Assurance- Public Health Service/OLAW.
  - Requires a **minimum of 5 member**s- Chair, Veterinarian, Scientist, Nonscientist, and **Nonaffliated** member. Veterinarian must have training/experience in laboratory animal science.
  -
- Appointed by & report to the CEO
  - The president has delegated the Vice President for Research as the Institutional Official (IO) who appoints the IACUC and is responsible to the federal regulators.

IACUC Duties

- Review and approve, require modifications to gain approval, or withhold approval of animal activities that involve vertebrates used in research, testing, or teaching activities. (**AUP**)
- Review and approve, require modifications to gain approval, or withhold approval of significant changes to approved animal activities. (**Amendment**)
- Conduct semiannual inspections of all animal housing, holding, and surgery areas associated with those activities.
- Investigate all animal welfare concerns.
- Conduct semiannual reviews of the animal care and use program.

- Suspend an activity involving animals if that activity is not being conducted according to the approved protocol or is not in accordance with the AWA, Guide, PHS policy, or Institution's Assurance.
- Make recommendations to the IO regarding the animal program, facilities, or personnel training.

Protocol Review
Considerations:

- Health and welfare of the animals
- Rationale and purpose for the use of animals
- 3Rs (Reduction, Refinement, Replacement)
- Pain and Distress (lowest level possible)
- Justification for study species and animal numbers
- Assurance that the research is not duplicative

The **3 R's** (Russell & Birch, 1959) are guiding principles underpinning the ethical use of animals in Research:

- **Replacement** – The use of alternative techniques that do not involve animals. Can we replace the use of animals with a lower species or a non-animal model?

Reduction – involves using the fewest animals possible. Can we reduce the number of animals and still achieve statistically significant data?

Refinement – Sometimes called the most important R. Its purpose is to refine procedures and practices in order to minimize pain/distress and improve animal welfare.

AAALAC, International (**Association for Assessment and Accreditation of Laboratory Animal Care International)**

- Voluntary accreditation organization. "Gold Standard" for research organizations.
- Makes recommendations based on the results of site visits.
- Requires compliance with both the AWA and the Guide

Questions:

21. How often do approved animal protocols need to be reviewed by the Institutional Animals Care and Use Committee (IACUC)?
    a. Annually
    b. Semiannually
    c. every 2 years
    d. every 3 years

22. The Institutional Animal Care and Use Committee (IACUC) is required to inspect animal facilities a MINIMUM of
    a. once a month
    b. twice a year
    c. once a year
    d. once every three years

23. The PHS policy governing the use and care of animals covers
    a. live, vertebrate animals only
    b. any animal use in research and training
    c. animals involved in research only
    d. animals that might otherwise be kept as pets only.

24. Members of an Institutional Animal Care and Use Committee (IACUC) must be appointed by
    a. funding agency program officer
    b. office of Human Research Protection
    c. responsible administrative official of the organization
    d. research administrator responsible for the committee

25. The Federal Animal Welfare Act applies to which of the following?
    a. vertebrate animals except rats, mice, and birds
    b. amphibians
    c. warm-blooded mammals
    d. non-human primates.

26. Responsible for enforcing the Animal Welfare Act.
    a. Office of Laboratory Animal Welfare
    b. Public Health Service
    c. Animal Plant and Health Inspection Service
    d. American Veterinary Society

Answers: 54d, 55b, 56a, 57c, 58a, 59c

3. Other (radiation safety, institutional biosafety, chemical safety committees)

Radiation Safety and Bio Safety

a. *Prepare and maintain biohazard report* - IBC is responsible for Reporting any significant violations of the NIH Guidelines. Reporting any research related accidents or illnesses to the appropriate institutional official and to NIH within 30 days.

b. *Attend meetings on biohazards* - The frequency of IBC meetings should be commensurate with the volume of protocols needing review, the nature and risks of the research, and the need for continuing oversight.

c. *Verify biohazard training* - PIs must also complete all training requirements set forth by the IBC, and ensure that their personnel have also completed the training requirements.- Most importantly, ALL PIs are responsible for providing training and supervision to students and staff in the lab, and this should be done on an ongoing basis.

d. Attend meetings on radiation – Many institutions have a separate Radiological Safety Office (RSO) that manages all aspects of the safe use of radioactive material (RAM), radiation producing devices (RPD) and lasers. RSO activities may include training, inventory of sources and machines, radioactive waste pickups, calibration services, personnel dosimetry to monitor radiation exposure, as well as technical support for all radiation safety concerns.

e. Prepare and maintain radiation report - The Radiation Exposure Information and Reporting System (REIRS) database contains reports of occupational radiation exposure experienced by individual employees monitored by the authorizing licensee. Certain licensees are required to submit such records on an annual basis in accordance with 10 CFR 20.2206. The U.S. Nuclear Regulatory Commission (NRC) then tracks the licensee exposure histories.

f. Verify radiation training - Most institutions that use radioactive materials will have required training for users.

Safety and Health Requirements and Procedures

The Principal Investigator of a laboratory has primary responsibility for promoting health and safety therein. All Laboratory Personnel are responsible for knowing and following the requirements set forth in their equivalent Environmental Health and Safety Manual, regarding laboratory safety and security. Items to be addressed:

- Radiation, lasers, power tools, welding equipment, or other devices or machinery with the potential for physical injury
- Toxins, pathogens, animals or other living organisms; or
- Chemicals, flammable substances or other hazardous materials

Security

Laboratories contain valuable research equipment, samples, work in progress, notes and data. They also contain potentially hazardous materials, such as chemicals, biological agents, and radioactive substances. All of these institutional assets must be protected from unauthorized access or removal, theft, or mishandling.

- Secure important research documents, equipment and experimental materials (e.g., lab notebooks, samples, hazardous substances) in locked areas.
- Secure devices capable of storing sensitive information or data (such as computer disks, magnetic tape, flash drives, smartphones, or tablets) in locked areas.

Renovation and Construction

Construction and building renovation sites are dynamic, ever changing work areas that offer unique safety challenges. Wear appropriate work clothing & personal protective equipment (PPE). Examples of PPE.

a. Hard hat and safety glasses
b. Protective gloves
c. Hearing protection
d. Full face shields when cutting, grinding, or chipping
e. Chemical splash goggles
f. Respiratory protection
g. Other equipment such as protective clothing, fall protection when working above 6 feet, or safety-toed shoes

The **Occupational Safety and Health Act of 1970 (OSH Act)** was passed to prevent workers from being killed or seriously harmed at work. This law created the Occupational Safety and Health Administration (OSHA), which sets and enforces protective workplace safety and health standards. OSHA also provides information, training, and assistance to employers and workers. Under the OSH Act, employers have the responsibility to provide a safe workplace.

Biohazards

Biohazard definition - An agent or material of biological origin that is potentially hazardous to humans, animals, plants or the environment.

Biohazarous Agents Examples:

- *Bacteria, viruses, parasites, fungi, protozoa and prions infectious to humans, animals or plants;*
- *Biologically active agents (e.g. toxins of biological origin);*
- *Human (and non-human primate) blood, cell lines, and tissues; and*
- *Recombinant DNA, RNA, or synthetic nucleic acids (as defined in the NIH Guidelines); transgenic animals; transgenic plants.*

Biosafety

- Addresses safe handling and containment of biohazardous materials
- Protects researchers, support staff, the environment, and the public
    - Work practices
    - Safety equipment
    - Personal protective equipment (PPE)
    - Facility design

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Risk Groups & Biosafety Levels

Risk Groups (RGs)

- Classification scheme for microbiological agents based on their association with /severity of human disease
- RGs are one factor among many used to determine the biosafety level at which work will be conducted with a given agent

Biosafety Levels (BSLs)

A **biosafety level** is a set of biocontainment precautions required to isolate dangerous **biological** agents in an enclosed laboratory facility. The **levels** of containment range from the lowest **biosafety level** 0 (BSL-0) to the highest at **level** 4 (BSL-4

- Combinations of lab practices/techniques, safety equipment, lab facility design and training geared to working safely with biohazards
- Applied to operations performed with a given agent, based on level of hazard; does not always correlate with the RG

Each biosafety level has its own specific containment controls that are required for the following:

- Laboratory practices
- Safety equipment
- Facility construction

Classification of Biohazards by Risk Group (RG) and Biosafety Level (BSL)				
RG1	Not associated with disease in healthy adult humans	No or low individual and community risk	BSL1	Work may be conducted on the open bench
RG2	•Associated with disease •Can be serious	Moderate individual risk	BSL2	•Personnel require specific training

	•Preventative measures or treatment often available	•Limited community risk •Most common for clinical research		•access to the lab is restricted •aerosol generating procedures are confined to a BSC
RG3	•Associated with serious or lethal disease through inhalation •Preventative measures or treatment may be available	•High individual risk •Low community risk	BSL3	•All procedures are confined to a BSC •Labs have special engineering and design features
RG4	•Likely to cause life threatening or lethal disease •Preventative measures or treatment are not usually available	High individual risk •High community risk	BLS4	•A cabinet laboratory • A suit laboratory • BSL-4 labs have special engineering and design features to prevent any release

BSL-1: BSL-1, the microbes there are not known to consistently cause disease in healthy adults and present minimal potential hazard to laboratorians and the environment. An example of a microbe that is typically worked with at a BSL-1 is a nonpathogenic strain of *E. coli*.

Specific considerations for a BSL-1 laboratory include the following:

Laboratory practices

- Standard microbiological practices are followed.
- Work can be performed on an open lab bench or table

Safety equipment

- Personal protective equipment (lab coats, gloves, eye protection) are worn as needed

Facility construction

- A sink must be available for hand washing.
- The lab should have doors to separate the working space with the rest of the facility.

BSL-2: Specific considerations for a BSL-2 laboratory include the following:

BSL-2 builds upon BSL-1. If you work in a lab that is designated a BSL-2, the microbes there pose moderate hazards to laboratorians and the environment. The microbes are typically indigenous and associated with diseases of varying severity. An example of a microbe that is typically worked with at a BSL-2 laboratory is *Staphylococcus aureus*.

BSL-3: Specific considerations for a BSL-3 laboratory include the following:

BSL-3 builds upon the containment requirements of BSL-2. If you work in a lab that is designated BSL-3, the microbes there can be either indigenous or exotic, and they can cause serious or potentially lethal disease through respiratory transmission. Respiratory transmission is the inhalation route of exposure. One example of a microbe that is typically worked with in a BSL-3 laboratory is *Mycobacterium tuberculosis*, the bacteria that causes tuberculosis.

In addition to BSL-2 considerations, BSL-3 laboratories have the following containment requirements:

Laboratory practices

- Laboratorians are under medical surveillance and might receive immunizations for microbes they work with.
- Access to the laboratory is restricted and controlled at all times.

Safety equipment

- Appropriate PPE must be worn, and respirators might be required.
- All work with microbes must be performed within an appropriate BSC

Facility construction

- A hands-free sink and eyewash are available near the exit.
- Exhaust air cannot be recirculated, and the laboratory must have sustained directional airflow by drawing air into the laboratory from clean areas towards potentially contaminated areas.
- Entrance to the lab is through two sets of self-closing and locking doors

BSL-4: Specific considerations for a BSL-4 laboratory include the following:

BSL-4 builds upon the containment requirements of BSL-3 and is the highest level of biological safety. There are a small number of BSL-4 labs in the United States and around the world. The microbes in a BSL-4 lab are dangerous and exotic, posing a high risk of aerosol-transmitted infections. Infections caused by these microbes are frequently fatal and without treatment or vaccines. Two examples of microbes worked with in a BSL-4 laboratory include Ebola and Marburg viruses.

In addition to BSL-3 considerations, BSL-4 laboratories have the following containment requirements:

Laboratory practices

- Change clothing before entering.
- Shower upon exiting.
- Decontaminate all materials before exiting.

Safety equipment - All work with the microbe must be performed within an appropriate Class III BSC , or by wearing a full body, air-supplied, positive pressure suit.

Facility construction

- The laboratory is in a separate building or in an isolated and restricted zone of the building.
- The laboratory has dedicated supply and exhaust air, as well as vacuum lines and decontamination systems.

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NIH Guidelines

The NIH Guidelines detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.

An institution must follow the NIH Guidelines if it receives **any funding** from the NIH for research involving recombinant or synthetic nucleic acid molecules. Even if only one research project involving recombinant or synthetic nucleic acid molecules at an institution benefits from NIH support, all such projects conducted at or sponsored by that institution must comply with the NIH Guidelines.

The NIH Guidelines require physical and biological containment for experiments involving the use of transgenic plants and animals, including insects. As with other research involving recombinant or synthetic nucleic acid molecules, the appropriate level of containment is graded according to the potential risks of the experiment.

Institutional Biosafety Committees (IBCs) were established under the NIH Guidelines to provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. Over time, many institutions have chosen to assign their IBCs the responsibility of reviewing a variety of experimentation that involves biological materials (e.g., infectious agents) and other potentially hazardous agents (e.g., carcinogens). This additional responsibility is assigned entirely at the discretion of the institution.

Each institution conducting or sponsoring research involving recombinant or synthetic nucleic acid molecules that is covered by the NIH Guidelines is responsible for:

1. Establishing an IBC;

2. Ensuring that the IBC has adequate expertise and training (using *ad hoc* consultants as necessary);
3. Providing appropriate training for the IBC chair and members, biological safety officer (BSO), principal investigators (PI), and laboratory staff;
    a. Filing an annual report with the NIH OSP that includes (1) a roster of IBC members clearly indicating the chair, contact person and, as applicable, the BSO, plant expert, animal expert, and human gene transfer expert or *ad hoc* consultant; and (2) biographical sketches of all IBC members, including community members; Establishing procedures that the IBC shall follow in its initial and continuing review and approval of applications, proposals, and activities; and making available to the public, upon request, all IBC meeting minutes and any documents submitted to or received from funding agencies that those agencies must make available to the public.

On behalf of the institution, IBCs review research involving recombinant or synthetic nucleic acid molecules for compliance with the NIH Guidelines. This entails examination of a number of matters, including:

- Containment levels
- Facilities;
- Institutional procedures and practices; and
- Training and expertise of personnel

Institutional Biosafety Committee criteria

- An IBC must consist of at <u>least five members</u>. There is no limit on the maximum number of members.
- <u>Every committee is required to have two members not affiliated with the institution who represent the interest of the surrounding community with respect to health and protection of the environment.</u>

Depending on the kind of research conducted at your institution, you may also be required to have:

<u>Biological Safety Officer (BSO):</u> If your institution is conducting any high containment research involving recombinant or synthetic nucleic acid molecules (BL 3 or 4) or research on a large scale (above 10 liters), you must have a BSO on your committee.

<u>Plant Expert: If your institution is conducting research subject to Appendix P you must have a plant expert on your committee.</u>

Animal Expert: If your institution is conducting research subject to Appendix Q you must have an animal expert on your committee.
It is also recommended that IBCs include:

- Experts in biosafety and containment
- Persons knowledgeable in institutional policies and applicable laws
- Individuals reflecting community attitudes
- At least one representative member from the laboratory staff

Nature of the research defines the level of review and containment required

- Nonexempt research requires registration
- CDC list of select agents
- Safety & Health Requirements
    - Community Notification
    - Containment
    - Emergency preparedness
    - Security

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Select Agents

Biological Select Agents or Toxins" (BSATs) — or simply **select agents** for short — are bio-agents which since 1997[1] have been declared by the U.S. Department of Health and Human Services (HHS) or by the U.S. Department of Agriculture (USDA) to have the "potential to pose a severe threat to public health and safety". The agents are divided into (1) **HHS select agents and toxins** affecting humans; (2) **USDA select agents and toxins** affecting agriculture; and (3) **overlap select agents and toxins** affecting both.

The U.S. Centers for Disease Control and Prevention (CDC) regulates the laboratories which may possess, use, or transfer select agents within the United States

- Entities must
    - Designate a responsible official (RO)
    - Develop…
        - A safety plan and laboratory compliance program
        - An emergency response plan
        - A security risk assessment
        - A record management system
        - A theft, loss, or release notification procedure

- Applies to ALL use of identified agents/toxins and is applicable both to individuals and entities

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Radiation Safety

- Only licensed use of radiation sources, radioisotopes, radio labeled compounds
- Regulated by the Nuclear Regulatory Commission and States
- Radiation Safety Committee reviews and approves use and protocols
- Training required

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Chemical Safety: OSHA Lab Standard

- Affects all facilities using hazardous chemicals (even those using small quantities)
- Institutional Chemical Hygiene Plan must minimize employee exposure
- Information and training
- Medical exam for persons showing symptoms of chemical exposure

Hazard Communication Safety Data Sheets. The Hazard Communication Standard (HCS) requires chemical manufacturers, distributors, or importers to provide Safety Data Sheets (SDSs) (formerly known as **Material Safety Data Sheets** or **MSDSs**) to communicate the hazards of hazardous chemical products. SDS contains information on the potential hazards (health, fire, reactivity and environmental) and how to work safely with the chemical product.

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Questions

27. How many members are required on the Institutional Biosafety Committee?
    a. 2
    b. 3
    c. 4
    d. 5

28. Which of the following best describes essential laboratory biosafety levels in medical research?
    a. special microbiological practices used to conduct procedures with high aerosol potential
    b. basic and containment procedures designed to protect personnel and the environment
    c. degrees of protection provided to human subjects

d. biological safety cabinets class I, II or II according to the agent under study

29. An agent or material of biological origin that is potentially hazardous to humans, animals, plants or the environment.
    a. Biosecurity
    b. Biohazard
    c. Biosafety
    d. BSL1

30. Addresses safe handling and containment of biohazardous materials
    a. Biosecurity
    b. Biohazard
    c. Biosafety
    d. BSL1

31. Classification scheme for microbiological agents based on their association with severity of human disease
    a. Risk Groups (RGs)
    b. Biosafety Levels (BSLs)
    c. NIH rDNA classification level
    d. Centers for Disease Control levels

32. Reviews and approves recombinant (and non-recombinant) research utilizing biohazards
    a. Institutional Biosafety Committee (IBC)
    b. Institutional Biohazards Committee (IBC)
    c. Institutional Review Committee (IRC)
    d. Centers for Disease Control

33. Not associated with disease in healthy adult humans would be in which Risk Group?
    a. RG-1
    b. RG-2
    c. RG-3
    d. RG-4

34. The following are examples of Biohazardous agents
    a. Bacteria, viruses, parasites, fungi, protozoa and prions infectious to humans, animals or plants
    b. Human (and non-human primate) blood, cell lines, and tissues
    c. Recombinant DNA, RNA, or synthetic nucleic acids
    d. All of the above

35. Contains information on the potential hazards (health, fire, reactivity and environmental) and how to work safely with the chemical product.
    a. Hazard Communication Safety Data Sheets
    b. Biosafety protocols
    c. Manufacturer's warranty information card
    d. Product application manual

Answers: 60d, 61b, 62b, 63c, 64a, 65a, 66a, 67d, 68a

H. Health Information Portability and Accountability Act (HIPAA)

Health Information Portability and Accountability Act (HIPAA)

- Administered by Department of Health & Human Services (DHHS).
- Limits use of identifiable health information identified as "Protected Health Information" (PHI).
- For research, this has meant additional language in HS consent forms and increased scrutiny from IRB.

I. Responsible Conduct of Research (RCR) (required institutional policy, relevant regulations, required documentation, agency oversight)

NSF

Amended to have a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to faculty and other senior personnel who will be supported by NSF to conduct research will go into effect for new proposals submitted or due on or after July 31, 2023.

Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act (42 USC 1862o–1), as amended, requires that each institution that applies for financial assistance from the Foundation for science and engineering research or education describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, postdoctoral researchers, faculty, and other senior personnel supported by the proposed research project. Such training must include mentor training and mentorship.

- While training plans are not required to be included in proposals submitted to NSF, institutions are advised that they are subject to review, upon request.
- An institution must designate one or more persons to oversee compliance with the RCR training requirement.
- Institutions are responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers, faculty, and other senior personnel supported by NSF to conduct research have received training in the responsible and ethical conduct of research.

NIH

- NIH mandates that trainees on an NIH institutional research training grant, individual fellowship, career development award (institutional or individual), research education grant, dissertation research grant, or other grant programs that have a significant training component have a minimum of eight hours of formal instruction at least once during each career stage and at least every four years.
- Research faculty of the institution should participate in instruction in responsible conduct of research in ways that allow them to serve as effective role models for their trainees, fellows, and scholars.
- Instruction should include face-to-face discussions by course participants and faculty; i.e., on-line instruction may be a component of instruction in responsible conduct of research but is not sufficient to meet the NIH requirement for such instruction, except in special or unusual circumstances.

Subject Matter: While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

a. conflict of interest – personal, professional, and financial
b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
c. mentor/mentee responsibilities and relationships
d. collaborative research including collaborations with industry
e. peer review
f. data acquisition and laboratory tools; management, sharing and ownership
g. research misconduct and policies for handling misconduct
h. responsible authorship and publication
i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research