

Listing of Regulations and Certifications Applicable to Sponsored Programs

CREATE Act Cooperative Research & Technology Enhancement Act of 2004: Act purpose was to promote cooperative research among universities, the public sector, and private companies by treating joint inventions as if they had a single owner, but only if the collaborators had a written agreement before the invention was created. The following conditions must be met:

- Joint research agreement must be in effect prior to the date the claimed invention was made.
- Claimed invention was within the scope of the joint research agreement.
- Application for patent discloses the name of the parties to the joint research agreement.

Paperwork Reduction Act: To reduce the burden of federal paperwork on the public. The Office of Information and regulatory Affairs (OIRA) is required to review every agency's information management activities and approve all data collection activities.

The Coordinated Review Act: Executive Order 12372: entitled Intergovernmental Review of Federal Programs. States can choose which CFDA# to review. Requires submission of the proposal to the State single point of contact (SPOC) prior to submission to the federal sponsor.

Assurances, Representations Certifications, and Warranties

- accompanies a proposal submission
- may be incorporated by reference by signing the proposal
- may be incorporated either specifically or by reference in the award document
- Online Representation and Certifications (ORCA) that is a part of System for Award Management (SAM) registration

Assurance: An assurance is a written guarantee or pledge that one will act in a certain way or comply with the terms and conditions of an award.

Representation: A representation is an account or statement of fact concerning an offeror and its capabilities and its abilities to perform. It can be viewed legally as an inducement to parties to enter into a contract.

Certification: A certification is the submission of documents that serve as guarantee the award applicant meets certain standards or will comply with certain governmental acts. False certification may make the individual subject to criminal sanctions.

Warranty: A warranty is a promise the goods and/or services described within the terms of a contract will be delivered as represented or promised.

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Acts Prohibiting Discrimination

Civil Rights Act of 1964: Bars recipients of federal funds from excluding persons due to

- ☐ race
- ☐ sex
- ☐ color
- ☐ national origin

Rehabilitation Act of 1973: Employment of the Handicapped: No discrimination in employment based on person's handicap

American with Disabilities Act: Extends civil rights protection to those persons with disabilities.

Title IX Sex Discrimination: Prohibits the exclusion of a person on the basis of sex from any education program or activity receiving federal support or assistance

Age Discrimination Act of 1975: Prohibits unreasonable discrimination on the basis of age in any program receiving federal assistance.

Equal Employment Opportunity: Requires that awardees take positive affirmative action to provide equal opportunity without regard to race, color, religion, sex, or nationality to persons employed or seeking employment.

Applicable to

- ☐ any grant providing construction funds
- ☐ to all nonconstruction grants
- ☐ to contractor or subs with 50 employees or more and the contract is in excess of \$50,000
- ☐ to all construction contracts in excess of \$10,000

Equal Opportunity for Veterans: To take affirmative action to employ and advance in employment qualified special disabled veterans and veterans of the Vietnam era without discrimination based on disability or veterans' status.

Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation

Act of 1970: Cannot discriminate in treatment or admission because of alcohol abuse by any private or public general hospital that receives federal funding

Drug Abuse and Treatment Act of 1972: Private or public hospital that receives federal support shall not discriminate against person because of their drug abuse.

Utilization of Small and Small Disadvantaged Business Concerns: FAR 52.219-8 Utilization of Small Business Concerns is used in government contracts in excess of simplified acquisition threshold of \$250,000.

- Give maximum practical opportunity for small business to participate.
- Not applicable if work will be performed outside of any U.S. state, territory, or possession.
- Small Business subcontracting Plan FAR 52.219-9 is required for awards for more than \$750,000 (\$1.5M for construction)

Types of Disadvantaged Businesses

- Women-owned Small Businesses.
- Small Businesses in Hubzones.
- Veteran-owned Small Businesses.
- Service Disabled Veteran-owned Small Businesses.

Notification of Employee /Rights Under Federal Labor Laws: Physical posting of notice outlining employee rights under the National Labor Relations Act must be posted in a conspicuous place.

Health Information Privacy Act

HIPPA: Health Insurance Portability & Accountability Act, 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.

Transparency in Government

FFATA - Federal Funding Accountability and Transparency Act of 2006: Part of an openness in government initiative, the intent of this act is to provide citizens a way to hold government accountable for spending decisions, with a desired end result of less wasteful government spending. Recipients of grants, cooperative agreements, and contracts must

report subawards made in excess of \$30,000, at www.fsrs.gov. Information accessible on USAspending.gov.

System for Award Management (SAM): Entity registration for entities that want to submit proposal for federal funding. Applicant completes On-line certifications. Can search for Excluded Parties List - debarred or suspended parties.

Freedom of Information Act (FOIA): Stipulates information is made available to the public by, publication in the Federal Register, providing opportunity to read & copy records, and copying record upon request. FOIA Information the Government Typically Releases Proposal information after award has been made.

- Notice of grant awards or information included in those notices.
- Interim and final progress reports.
- Financial reports.
- Final reports of audits, surveys, or evaluation of awardee performance.

FOIA Access is Usually Denied to the Following:

- Pending or disapproved applications.
- Financial information pertaining to specific individual.
- Information subject to Privacy Act of 1974.
- Confidential information.
- Opinions expressed in interagency correspondence.
- Information that, if released, would adversely affect patent or other valuable commercial rights.

Data Access (Shelby Amendment): Applicable to source data produced with federal funds and cited publicly and officially by a federal agency in support of an action that has the force and effect of law (including regulations and administrative orders) available under FOIA request.

Open Access to Research Results: Purpose is to increase public access to the results of federally funded research. Applicable to all report of research included peer-reviewed scholarly publications

Environmental Protection Regulations

Clean Air Act: Established national standards for air quality. Offeror must certify if any facilities to be used in the work are listed by the EPA.

Clean Water Act: Offeror must certify if any facilities to be used in the work are listed by the EPA

National Environmental Policy Acts of 1969: Recipients may be required to prepare an Environmental Impact Statement.

Aquatic Nuisance Prevention: Purpose is to ensure that research does not result in the introduction or dispersal of nonindigenous species into U.S. waters. Prior to submitting a proposal that contains nonindigenous species, PI must submit protocol to institutional committee.

Protection of Wetlands: Applicable to any contracts for construction using federal funds. Determination that all practical measures to protect wetlands have been taken.

Compliance Protection – Human, Animal and Recombinant DNA

Human Subjects Protection: DHHS 45CFR 46.101-.409 Federal wide Common Rule; FDA CFR 21 Part 50, Protection of Human Subjects: Applicability: to all research involving Human Subjects. Compliance: Institutions provide an assurance that they will comply with requirements (Federal wide assurance FWA); Internal Review Board to review protocols; Investigators and staff receive training

Use of Animals in Research: Animal welfare Act; Public Health Service Policy on Humane Care and Use of Laboratory Animals. Requirements; Provide assurance to the NIH Office for Protection from Research Risks (OPRR) that institution will: Maintain a committee to provide oversight of its animal care program; and Comply with the provisions of the USDA/APHIS and the PHS

Research involving Recombinant DNA: responsible for ensuring that rDNA activities comply with the guidelines. Establish an institutional Biosafety Committee (IBC) to review and approve all rDNA research.

Human Embryonic Stem Cells in Research: Only human embryonic stem cells that have been approved pursuant to NIH guidelines can be used in research funded by NIH

Security

U.S. Patriot Act – 2001: Direct result of events of September 11, 2001. The intent of bioterrorism provisions are to help secure the nation from acts of terrorism with criminal penalties for violations. The obligation to comply concerning biological materials and their delivery systems, and, if violated, the criminal penalties that fall on the institution as well as the individual(s). Individuals and institutions will not produce, acquire, retain (stockpile), or possess types and quantities of any biological materials and/or delivery systems that are not “reasonable justified” for peaceful and prophylactic purposes, including bona fide research.

Select Agents: Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Applies to all uses of identified agents/toxins and is applicable to both individuals and the entities. Institution must meet the requirements for compliance at 42CFR 73 or 7CFR 331.

Foreign Nationals: Background: Certain government agencies view the participation of foreign nationals as a potential risk. As a result they restrict the participation of foreign nationals. Compliance: Provide reporting or obtain permission as required. Implement technology control protocols and obtain export licenses when required.

Dual Use Research of Concern (DURC): is life sciences **research** that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety.

Data Security

Federal Information Security Management Act of 2002 (FISMA): Authority – E-Government Act of 2002. NIST is charged with implementing FISMA at the federal level. Application: For the basic safeguarding of contractor information systems that process, store or transmit Federal contract information. Requirement: Awardee must include a detailed plan of its present and proposed IT security systems

Export Administration Regulation (EAR) and International Traffic in Arms Regulation (ITAR): EAR and ITAR govern the export and release of certain commodities, services and technologies. These may not be exported or shared with a non-U.S. person except as authorized by the appropriate federal agency. The disclosing of this information to a non-U.S. person located in the U.S. is referred to as a “deemed export”.

Foreign Assets Control Regulations OFAC: are administered by the Department of Treasury's Office of Foreign Assets and Control (OFAC). Restricts trade or travel to certain embargoed countries. Prohibits unlicensed transactions with persons and organizations appearing on the Specially Designated Nationals and Blocked Persons List (SDN List)

Rights in Data: Copyright is a protection provided to authors of "original works of authorship". Applicability: Applies to grants, cooperative agreements and contracts. For contracts the government generally mandates the inclusion of FAR clause 52.227-14. Institutions of Higher Education should request Alternate IV in agreements for basic or applied research.

Publication Restrictions: Authority: Primarily contract clauses, DFAR 252.204-7000 Disclosure of information and ARL 52.005-4401 Release of Information. Requirements: Seek approval from sponsor for publications, oral presentation, thesis, dissertations and the dissemination of such information.

Workforce Related Acts

Drug Free Workplace: - No federal funding available if institution or individual does not have a drug-free workplace policy. Act provides an institution certify it will provide a drug-free workplace by Publishing a statement notifying employees the unlawful use of a controlled substance is prohibited in the workplace and specifying the action that will be taken against employees for violation. Establishing a drug-free awareness program. Notifying the employee that, as a condition of employment on a grant or contract, the employee agrees to abide by the terms of the institutional policy; and notify the employer of any criminal drug statute conviction occurring in the workplace no later than five days after such conviction.

Drug Free Schools and Communities Act: Amendments of 1989; Requires schools, colleges and universities to implement and enforce strict drug prevention programs and policies as a condition of eligibility to receive federal financial assistance. Institution must adopt and implement drug prevention program to prevent the unlawful possession, use or distribution of illicit drugs and alcohol by all students and employees on institutional premises. Annual distribution in writing to each employee and student

Drug Free Work Force: Affected Agency: Department of Defense. The Drug-Free Work Force requirements are contained in the Department of Defense Federal Acquisition Regulation Supplement (DFARS), Subpart 223.57, with the required clause at 252.223-7004. Drug-Free Work Force requirement addresses employee involvement with controlled substances, regardless of

where such involvement takes place. Drug testing requirements are applicable to persons employed directly as a result of the contract and those employees must be in a sensitive position.

Lobbying: Sometimes referred to as Byrd amendment. No appropriated funds may be expended to pay a person to lobby the federal government.

Lobbying Disclosure Act of 1995: Sometimes referred to as LDA or Simpson-Craig amendment. Intended to reach professional lobbyists or lobbying firms that are compensated by an institution to engage in direct lobbying activities. Any organization that is tax-exempt under section 501(c)(4) IRS code, is ineligible to receive federal funds if the organization has engaged directly in lobbying associated with the award

Hatch Act: This legislation was enacted to limit the political activities of employees whose principal employment activities are funded in whole or in part with federal funds. Is not applicable to institutions of higher education or employees of such institutions.

Davis-Bacon Act: This act was enacted in 1931, requires contractors to pay wages to laborers and mechanics at a rate no less than a minimum wage specified in a wage determination made by the Secretary of Labor. In addition, contracts are required to pay wages not less than once a week. It is a required flow down to contractors and subcontractors. Each contract over \$2,000 funded by the government must contain a clause setting forth the minimum wages to be paid to various classes of laborers and mechanics employed under the contract.

- Contractors must pay workers no less than the locally prevailing wages.
- Contractors must provide fringe benefits paid on similar projects.
- The Secretary of Labor determines the prevailing wage rates.

Walsh-Healey Public Contracts Act: The act stipulates the contractor comply with the government's minimum wage and hour requirement, child and convict labor restrictions, and work safety provisions.

Service Contract Act of 1965: The purpose of the act is to provide labor standards for certain persons employed by federal contractors to furnish services to federal agencies.

Contract Work Hours and Safety Standards Act of 1962: This act prescribes the 40-hour work week with overtime to be paid at not less than one-half times the basic rate of pay. Employees are not required to work under unsafe, dangerous, and unsanitary conditions.

Fair Labor Standards Act: The Fair Labor Standards Act was enacted to establish a minimum hourly wage, overtime pay, and regulate child labor. Employers must pay the

prevailing minimum wage to all employees with certain exceptions for employers with under 20 employees, students, apprentices, and workers with disabilities. There are specific limitations on child labor both in age and in hours worked.

Copeland (Anti-Kickback) Act: The law makes it unlawful to induce, by force, intimidation, threat of procuring dismissal from employment, or otherwise, any person employed in the construction or repair of public buildings or public works, financed in whole or in part by the United States, to give up any of the compensation to which that person is entitled under a contract of employment.

Combating Trafficking in Persons: Allows award in agency to terminate agreement if awardee or any subawardee is engaged in human trafficking or forced labor.

Contractor Code of Business Ethics and Conduct: Application: to all contracts expected to exceed \$5,000,000 and the performance period is 120 days or more. Minimum Compliance: Have a written code of conduct in place, appropriate training is provided to employees and internal controls exist.

Whistleblower Protection: Minimum Compliance: Notification to employees of appropriate policy concerning protection of whistleblowers. Prohibits reprisal against any employee for disclosing information related to gross mismanagement of a federal funds, or violation of law, rule or regulation related to the award.

Misconduct and Fraud

Misconduct in Science; Initial regulations of the National Science Foundation and the Public Health Service were developed as a result of congressional and public pressure to assure award recipients that the agencies had procedures in place to deal with misconduct allegations. Office of Science and Technology definition: fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results. Regardless of agency, the misconduct regulations adopted have generally contained the following requirements of institutions:

1. Development of policies and procedures to ensure an impartial process for receipt and disposition of allegations of scientific misconduct;
2. Notification of the funding agency;
3. Protection of the integrity of the research, research subjects, and the public;
4. Observation of legal requirements and responsibilities;
5. Protection of the person(s) bringing the allegation; and
6. Maintenance of records.

Procurement Integrity: The act specifies that no competing contractor or any officer, employee, representative, agency, or consultant of such competing contractor shall knowingly:

1. make, directly or indirectly, any offer or promise of future employment with any procurement officer of such agency;
2. offer or give, directly or indirectly, any money; gratuity, or other thing of value to any procurement officer of such agency; or
3. solicit or obtain, directly or indirectly, any proprietary or source selection information regarding such procurement.

The responsible institutional official must certify, concurrent with submission of the proposal and/or the award, that, to the best of his/her knowledge and belief, the institution has abided by the requirements of the regulations.

Debarment and Suspension: Generally, applicants are asked to certify to their best knowledge and belief that neither they, their principals, nor their researchers

1. are presently debarred, suspended, proposed for debarment, declared ineligible, or excluded from covered transactions by any federal agency;
2. have, within a three-year period preceding an application, been convicted of or had a civil judgment rendered against them for
 - --- commission of fraud;
 - --- violation of federal or state antitrust statutes; or
 - --- commission of embezzlement, theft, forgery, falsification, or destruction of records, making false statements, or receiving stolen property;
3. are presently indicted or charged by a government entity; or
4. have, within a three-year period preceding application, had one or more public transactions terminated for cause or default.

Covenant Against Contingent Fees: Representation and certification must be made at the time of proposal submission using form SF 119. The Reps and Certs indicates whether or not a person or company has been employed to solicit the contract under a commission, percentage or any other type fee.

Anti-Kickback Act of 1986: This act was passed to deter subcontractors from making payments and contractors from accepting payments for the purpose of obtaining favorable treatment in connection with a prime contract or a subcontract relating to a prime contract. Prohibits persons from soliciting, accepting, or attempting to accept any kickback.

Conflict of Interest: These regulations require a principal investigator to disclose the existence of certain financial interests, and require the institution to review these disclosures. The institution determines if any potential conflict of interest exists, and establish a way to manage, reduce or eliminate the conflict of interest.

Truth In Negotiations Act: The disclosure ensures that the government pays a fair price for the goods or services received by allowing open scrutiny of the cost and price details and methods. TINA requires the government to show three material elements:

- (1) The cost or pricing data at issue must fall within the threshold.
- (2) The data was not disclosed to a proper government representative.
- (3) The government relied on defective data and has a reasonable method of showing the amount of the overstatement by the provider.

False Claims Act: Any person or agency that commits fraud is subject to a fine equal to the amount of the original contract amount. Ensure neither an institution of higher education nor an employee of such institution submits false claims to the government. A FCA action contains four material elements:

- (1) The provider made, used, or caused to be made or used a record or statement to get a claim against the United States paid or approved.
- (2) The claim was false or fraudulent.
- (3) The provider knew the claim was false or fraudulent.
- (4) The government suffered damages as a result of reliance on the claim.

Miscellaneous Administrative Requirements

Buy American Act: A variety of policies favoring domestic sources adopted by the government. This act establishes a general preference for domestic articles, materials, and supplies. Passed in the 1930s, the act protects American workers by saving and creating jobs. The offeror certifies each end product is considered to have been substantially mined, produced, or manufactured in the United States. Exceptions to the Buy American Act must be identified in specification, and a public record must be made of findings that justify the exception.

Fly American Act: Designed to assure that federal funds are being spent to the benefit of American companies. The grantee or contractor and subcontractors agree that U.S. flag air carriers

will be used to transport personnel and property when costs are charged directly to the grant or contract.

Ship American Act: As with Fly America and Buy American Acts, this law protects domestic industry by establishing general preference for using domestic vessels. A shipper of personnel or goods within or without the United States shall take such steps as may be necessary and practical to assure the personnel and/or at least 50% of the gross tonnage of equipment, materials, and commodities are shipped on U.S.-flag commercial vessels to the extent such vessels are available at fair and reasonable rates.

Debt Delinquency: OMB Circular A-129, Managing Federal Credit Programs, issued November 25, 1988, last revised November 2000, under the authority of the Budget and Accounting Act of 1921, the Debt Collection Act of 1982, and the Deficit Reduction Act of 1984. The government was concerned individuals and organizations are benefiting from federal programs while delinquent in repayments to other programs. The circular, in part, addresses federal debt delinquency. Requires federal agencies to take appropriate steps to ensure those receiving federal financial assistance are not delinquent on loans or other accounts to the federal government. In the case of awards to institutions, the institution must certify it is not delinquent on federal debts. If the award is to an individual, only the individual need certify.

Smoke-Free Workplace: Requires that smoking not be permitted in any portion of any indoor facility owned, leased, or controlled by an entity and used routinely for the provision of health, day care, early childhood development services, library services to children under the age of 18.

Use of Seat Belts: Encourages federal contractors, subcontractors and grantees to adopt and enforce on the job seat belt use policies and programs.

Military Recruiting Solomon Amendment: No federal funds if institution has policy that effectively bars:

- military recruiting on campus,
- Military access to student directory information
- Operation of a Senior ROTC unit on campus

Metric Conversion Act: Offerors are encouraged to prepare proposals using the metric systems of measurement

Acknowledgment of Federal Grant Support (Stevens Amendment): When issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds, including but not limited to State and local governments, shall clearly state (1) the percentage of the total costs of the program or project which will be

financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources."

Constitution and Citizenship Day: Educational institutions receiving federal funding are required to hold an educational program pertaining to the United States Constitution on September 17 of each year. A notice published in the Federal Register outlined the requirements for such a program.

Open Skies: Exception to the Fly America Act that allows for bilateral or multilateral transportation agreements between the USA and governments of foreign countries. Under these, flag carriers of member countries may transport passengers or cargo on flights, using federal funds, from a point in US to any point in an agreement country. Agreements with EU, Australia, Switzerland and Japan.

Certificate of Current Cost and Pricing Data: Cost and pricing data enable the contracting agency to perform cost and price analysis in negotiating a fair and reasonable price of a contract to the government. A certificate of current cost and pricing data is required for any contract or contract modification exceeding \$500,000. Contractors are required to execute the certificate of current cost and pricing prior to the award of a contract. The certification must state that, "to the best of my knowledge and belief", the prices are accurate and current. The certification should not be made until the contract price has been fully negotiated. If it is determined the quoted prices are not appropriate, the contract may be reduced.

FAPIS - Federal Awardee Performance and Integrity Information System: A gov't-wide database meant to compile integrity and performance information on federal grant and/or contract recipients in excess of \$500K. FAPIS goal is to provide information to gov't officials for evaluating business ethics and past performance of prospective awardees, and to protect gov't from making awards to non-responsible entities.

America Competes Act: Purpose was to invest in innovation through research and development and to improve competitiveness of the US. Portion with most impact to college and university sponsored research and education compliance activities is Title VII, which imposed new NSF (National Science Foundation) award requirements in areas of training, mentoring, reporting, research results, and responsible research conduct. Requirements:

- § 7008 requires all NSF grant applications, that include funding to postdoctoral researchers, must describe mentoring activities to be provided to these individuals.
- § 7009 requires proposals to include a plan for training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will participate in research project.
- § 7010 requires all final project reports and citations of published research, which results in whole or in part from research funded by NSF, to be made available to the public in a timely manner, as well as electronically through NFS's website.

Disclosures of Foreign Gifts: The requirement to disclose foreign gifts or contracts was most likely the result of congressional concern of involvement of institutions of higher education with foreign countries or companies

Reducing Text Messaging While Driving (Executive Order 13513): The government requires federal employees not text message, email, or any other form of electronic data retrieval or communication, while driving a government- owned or privately-owned vehicle while on official government business, or when using electronic equipment supplied by the government while driving. Applies to all federal fund recipients.

Prompt Payment: Requires federal agencies to pay invoice within a certain time period or incur an interest penalty

Employment Eligibility Verification (E-Verify) (E.O. 12989): Requires contractors to use E-Verify to verify the employment eligibility of employees

Acts Related to Student

Higher Education Act of 1965: Contains many requirements related to student financial aid Includes requirements for Pell Grants, work study and student loans

Family Education Rights and Privacy Act (FERPA): Known as the Buckley Amendment. Protects the privacy of students education record Institutions must have policy to prohibit disclosure of a student's protected information to a third party. Student can opt out of having directory information: name, address, & phone # disclosed

Crime Awareness and Campus Security Act (Clery Act): Institutions must publish and distribute Annual Campus Security report to current and prospective students.