NIH OTHER TRANSACTION AWARD POLICY GUIDE for the SPARC Program

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Introduction

The new program, Stimulating Peripheral Activity to Relieve Conditions or SPARC, is designed to revolutionize our understanding of the peripheral nervous system (PNS) by delivering detailed, integrated, functional and anatomical neural circuit maps in multiple organs. Modulation of autonomic and sensory nerve activity has been recognized as a powerful way to control organ function. Although devices that modulate neural activity have been developed and shown to be effective, the mechanisms through which they work are poorly understood, limiting our ability to employ neuromodulation broadly and effectively. The understanding of the control of organ function through autonomic and sensory innervation is hampered by the lack of high resolution neural circuit maps, which, in turn, are difficult to obtain because of inadequate neural stimulation and recording technologies. If these challenges could be overcome, neuromodulation therapies could benefit more patients.

The SPARC program intends to develop high resolution functional and anatomic neural circuit maps of the PNS by integrating ideas and expertise from several disciplines, including anatomy, surgery, neuroscience, engineering, biotechnology, neuromodulation and device design. Because no discipline possesses all the expertise required to generate fine circuit maps of the PNS, the SPARC program staff will aggregate the necessary expertise by using the Other Transaction Authority (OTA) to nimbly add or subtract specific expertise, tools, technologies, and approaches to the problem of mapping peripheral neural circuits in animals and human tissues. A significantly different baseline of knowledge is expected in various organs/organ systems and expertise gained on one organ could be flexibly combined with projects focused on less advanced areas to accelerate gains in knowledge across organs.

Some components of the overall SPARC Program have been designated for use of the Other Transaction Authority (OTA) described in the Consolidated and Further Continuing Appropriations Act of 2015 (P.L. 113-235). Under OTA, NIH can make research awards that are not grants, contracts or cooperative agreements. OTA has been used by NASA, DOD, DOE, and certain components of the HHS in the past but implementation has been quite different. This document describes flexible policies for implementing other transaction awards by the NIH SPARC Program.

PART I: SPARC OTHER TRANSACTION AWARDS —GENERAL INFORMATION

1. Definitions

Term	Definition
Acquisition cost	The cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices.
Additive alternative	A use of program income earned during or after the project period that permits income that is generated under an other transaction award to be added to funds committed to the project by the Federal awarding agency and recipient and used to further eligible project or program objectives.
Advance payment	A payment that a Federal awarding agency or pass-through entity makes by any appropriate payment mechanism, including a predetermined payment schedule, before the non-Federal entity disburses the funds for program purposes.
Award	The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.
Award date	The date when the award is signed by the authorized official of the Federal awarding agency.
Awarding IC	The NIH IC responsible for the award, administration, and monitoring of other transaction supported activities.
Budget	The financial plan for the project or program that the Federal awarding agency or pass-through entity approves during the award process or in subsequent amendments to the award. It may include the Federal and non-Federal share or only the Federal share, as determined by the Federal awarding agency or pass-through entity. The approved budget specified in the NoA may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the recipient in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.
Capital assets	Tangible or intangible assets used in operations having a useful life of more than one year which are capitalized in accordance with GAAP. Capital assets include: (1) Land, buildings (facilities), equipment, and intellectual property (including software) whether acquired by purchase, construction, manufacture, lease-purchase, exchange, or through capital leases; and (2) Additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations or alterations to capital assets that materially increase their value or useful life (not ordinary repairs and maintenance).
Capital expenditures	Expenditures to acquire capital assets or expenditures to make additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations, or alterations to capital assets that materially increase their value or useful life.

Term	Definition
Change of recipient organization	Transfer of the legal and administrative responsibility for a other transaction-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment).
Closeout	The process by which the Federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the award have been completed and the appropriate closeout actions have been taken.
Commercial organization	An organization, institution, corporation, or other legal entity, including, but not limited to, partnerships, sole proprietorships, and limited liability companies, that is organized or operated for the profit or benefit of its shareholders or other owners. The term includes small and large businesses and is used interchangeably with "for-profit organization."
Competitive segment	The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a renewal award.
Contract	A legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under an award. The term does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of an award or subaward. *See Subaward.*
Contractor	An entity that receives a contract. *See Contract*.
Disallowed costs	Those charges to an award that the Federal awarding agency or pass-through entity determines to be unallowable, in accordance with the applicable Federal statutes, regulations, or the terms and conditions of the award.
Equipment	Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000.
Expenditure report	(1) The SF-425 Federal Financial Report (FFR) (or other OMB-approved equivalent report).

Term	Definition
Expenditures	Charges made by a non-Federal entity to a project or program for which an award was received. (1) The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. (2) For reports prepared on a cash basis, expenditures are the sum of: (i) Cash disbursements for direct charges for property and services; (ii) The amount of indirect expense charged; (iii) The value of third-party in-kind contributions applied; and (iv) The amount of cash advance payments and payments made to subrecipients. (3) For reports prepared on an accrual basis, expenditures are the sum of: (i) Cash disbursements for direct charges for property and services; (ii) The amount of indirect expense incurred; (iii) The value of third-party in-kind contributions applied; and (iv) The net increase or decrease in the amounts owed by the non-Federal entity for: (A) Goods and other property received; (B) Services performed by employees, contractors, subrecipients, and other payees; and (C) Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments.
Federal awarding agency	The Federal agency that provides an award directly to another entity. *See also Awarding IC.*
Federal share	The portion of the total project costs that are paid by Federal funds.
General purpose equipment	Equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles.
Generally Accepted Accounting Principles (GAAP)	The meaning specified in accounting standards issued by the Government Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB).
Generally Accepted Government Auditing Standards (GAGAS)	Also known as the Yellow Book, generally accepted government auditing standards issued by the Comptroller General of the United States, which are applicable to financial audits.
Hospital	A facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state. Also includes a non-profit or for-profit hospital or a medical care provider component of a non-profit organization (for example, a foundation).
Institutions of Higher Education (IHEs)	*IHE* is defined at 20 U.S.C. 1001.

Term	Definition
Intangible property	Property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership (whether the property is tangible or intangible).
Internal controls	A process, implemented by a non-Federal entity, designed to provide reasonable assurance regarding the achievement of objectives in the following categories: (1) Effectiveness and efficiency of operations; (2) Reliability of reporting for internal and external use; and (3) Compliance with applicable laws and regulations.
Matching or cost sharing	The portion of project costs not paid by Federal funds (unless otherwise authorized by Federal statute). This may include the value of allowable third party in-kind contributions, as well as expenditures by the recipient. These costs are only required when identified in specific FOAs.
Non-Federal entity	A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out an award as a recipient or sub-recipient.
Notice of Award	The official, legally binding document, signed (or the electronic equivalent of signature) by an Agreement Officer that: (1) notifies the recipient of the other transaction award; (2) contains or references all the terms and conditions of the other transaction award and Federal funding limits and obligations; and, (3) provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system.
Obligations	When used in connection with a non- Federal entity's utilization of funds under a award, obligations means orders placed for property and services, contracts and subawards made, and similar transactions during a given period that require payment by the non- Federal entity during the same or a future period.
Other Transaction Award	Refers to the authority provided to the Director, NIH, to enter into transactions other than contracts, grants or cooperative agreements to carry out research identified pursuant to Section 402(b)(7) (pertaining to the Common Fund) or research and activities described in Section 402(b)(12) of the Public Health Service Act.
Pass-through entity	A non- Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program.
Payment Management System	The HHS centralized payment system operated by the Payment Management Service, Program Support Center. Most HHS (and some other Federal government agencies') recipients receive payments through this system.
Period of performance	The time during which the non-Federal entity may incur new obligations to carry out the work authorized under the award. The Federal awarding agency or pass-through entity must include start and end dates of the period of performance in the award.
Personal property	Property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities.

Term	Definition
Personally Identifiable Information (PII)	Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public Web sites, and university listings. This type of information is considered to be Public PII and includes, for example, first and last name, address, work telephone number, E-mail address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual.
Pre-award costs	Any cost incurred prior to the beginning date of the project period or the initial budget period of a competitive segment (under a multi-year award), in anticipation of the award and at the applicant's own risk. Under other transaction awards these costs are not allowable.
Prior approval	Written approval by an authorized HHS official, e.g., a designated Agreement Officer, evidencing prior consent before a recipient undertakes certain activities or incurs specific costs.
Program income	Gross income earned by the non-Federal entity that is directly generated by a supported activity or earned as a result of the other transaction award during the period of performance. Program income includes but is not limited to income from fees for services performed, the use or rental of real or personal property acquired under an award, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and principal and interest on loans made with award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, or the terms and conditions of the other transaction award, program income does not include rebates, credits, discounts, and interest earned on any of them.
Project period	The total time for which Federal support of a project has been programmatically approved as shown in the NoA; however, it does not constitute a commitment by the Federal government to fund the entire period. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a renewal award(s), and extensions.
Property	Real property or personal property.
Protected Personally Identifiable Information (Protected PII)	An individual's first name or first initial and last name in combination with any one or more of types of information, including, but not limited to, social security number, passport number, credit card numbers, clearances, bank numbers, biometrics, date and place of birth, mother's maiden name, criminal, medical and financial records, educational transcripts. This does not include PII that is required by law to be disclosed.
Questioned cost	A cost that is questioned by the auditor because of an audit finding: (1) Which resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of an award, including for funds used to match Federal funds; (2) Where the costs, at the time of the audit, are not supported by adequate documentation; or (3) Where the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances.

Term	Definition
Real property	Land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment.
Recipient	An entity, usually but not limited to non-Federal entities, that receives an award directly from a Federal awarding agency to carry out an activity under a Federal program. The term may also include an Individual. The term recipient does not include subrecipients, except as indicated below.
Research & Development (R&D)	All research activities, both basic and applied, and all development activities that are performed by HHS award recipients. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. ''Research'' is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. ''Development'' is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.
Special purpose equipment	Equipment which is used only for research, medical, scientific, or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments, and spectrometers.
Subaward	An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of an award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.
Subrecipient	A non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other awards directly from a Federal awarding agency. The term includes consortium participants.
Supplies	All tangible personal property other than those described in Equipment. A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-Federal entity for financial statement purposes or $5,000, regardless of the length of its useful life. *See Computing devices and Equipment*.
Suspension of award activities	An action by NIH requiring the recipient to cease all activities on the award pending corrective action by the recipient. It is a separate action from suspension under HHS regulations (2 CFR 376) implementing Executive Orders 12549 and 12689. *See Section 2.1 Debarment and Suspension and Section 9 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support.*
Termination	The ending of an award, in whole or in part at any time prior to the planned end of period of performance.
Third-party in-kind contributions	The value of non-cash contributions (i.e., property or services) that: (1) Benefit a federally assisted project or program; and (2) Are contributed by non-Federal third parties, without charge, to a non- Federal entity under a Federal award.

Term	Definition
Unliquidated obligations	For financial reports prepared on a cash basis, obligations incurred by the non- Federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the non-Federal entity for which an expenditure has not been recorded.
Unobligated balance	The amount of funds authorized under an award that the non-Federal entity has not obligated. The amount is computed by subtracting the cumulative amount of the non-Federal entity's unliquidated obligations and expenditures of funds under the award from the cumulative amount of the funds that the Federal awarding agency or pass-through entity authorized the non-Federal entity to obligate.

2. Roles and Responsibilities

NIH, as a Federal awarding agency, is responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively and in compliance with applicable rules and regulations. NIH seeks to ensure integrity and accountability in its other transaction award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for recipient organizations.

The following subsections highlight the major functions and areas of responsibility of Federal and recipient staffs. NIH recognizes that additional staff members in a number of different organizations may be involved in other transaction-related activities; however, this section details only the major participants representing the Federal government and the recipient.

2.1 NIH Staff

The roles and responsibilities of NIH participants are as follows:

- **Agreement Officer.** The AO whose name appears on the NoA is the individual responsible for the business management and other non-programmatic aspects of the other transaction award. These activities include, but are not limited to, evaluating other transaction applications for administrative content and compliance with statutes and guidelines; negotiating other transaction awards; providing consultation and technical assistance to applicants and recipients, including interpretation of other transaction administration policies and provisions; and administering and closing out other transaction awards. The AO works closely with his or her counterparts in other NIH ICs and with the designated Program Manager. The AO is the focal point for receiving and acting on requests for NIH prior approval or for changes in the terms and conditions of award, and is the only NIH official authorized to obligate NIH to the expenditure of Federal funds or to change the funding, duration, or other terms and conditions of award.

- **Program Manager.** The PM is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and OTA awards. The PM's responsibilities include, but are not limited to, development of research programs to meet the IC's mission; oversight of the objective review; and post-award administration, including review of progress reports, participation in site visits, and other activities complementary to those of the AO. The PM and the AO work as a team on many of these activities. The PM reviews applications for completeness and conformity to requirements, ensures that adequate numbers of reviewers with appropriate expertise are available for application review, assigns applications to individual reviewers as discussion leaders and for preparation of written critiques, and serves as the overall point of contact with applicants during the initial phase of the peer review process.

2.2 Recipient Staff

Overall responsibility for successfully implementing an NIH other transaction award is a shared responsibility of the PD/PI(s), the Authorized Organizational Representative (AOR), and the Research Administrator. As key members of the other transaction team, they respectively lead the scientific and administrative aspects of the other transaction award. While communications can be conducted with Research Administrators and other institutional staff, NIH staff members conduct official business only with the designated PD/PI(s) and AORs. The roles and responsibilities of recipient participants are as follows:

- **Authorized Organization Representative.** The AOR is the designated representative of the recipient organization in matters related to the award and administration of its NIH other transactions, including those that require NIH approval. The AOR should ascertain and assure that the materials the applicant organization are submitting on behalf of the PD/PI are the original work of the PD/PI and have not been used by other individuals in the preparation and submission of a similar other transaction application. In signing an other transaction application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual's signature on the other transaction application further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the other transaction-supported project or activities resulting from the application. This individual also is responsible to NIH for ensuring that the organization complies with applicable Federal laws and regulations, including required certifications and assurances, its application, and the terms and conditions of individual awards. For applications sub-mitted electronically through Grants.gov, the signature of the AOR is documented as part of the electronic submission process and is authenticated through the Grants.gov registration process. In the eRA Commons, this individual holds the Signing Official role. Although NIH requires that the recipient organization designate such an official, NIH does not specify the organizational location or full set of responsibilities for this official.

- **Program Director/Principal Investigator.** A PD/PI is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award. When a PD/PI is designated, that individual is not required to be an employee of the applicant organization. However, because the other transaction, if awarded, is usually made to the organization, the applicant organization must have a formal written agreement with the PD/PI that specifies an official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PD/PI is not an employee of the applicant organization, NIH will assess whether the arrangement will result in the organization or individual being able to fulfill its responsibilities under the other transaction, if awarded.

  PD/PIs are members of the recipient team responsible for ensuring compliance with the financial and administrative aspects of the award. They work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support of research findings in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. NIH encourages PD/PIs to maintain contact with the NIH PM with respect to the scientific aspects of the project and the AO concerning the business and administrative aspects of the award.

- **Research Administrator.** The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day other transaction-related support. Depending on the structure of the organization, this individual can be located centrally or within an organizational component such as a Department.

3. ERA Commons

eRA Commons is an online interface where other transaction applicants, recipients and Federal staff at NIH are able to conduct their research administration business electronically as well as access and share administrative information relating to research other transaction awards. While applicants use Grants.gov to find and apply for other transaction awards; the eRA Commons retrieves the application or proposal information from Grants.gov, compiles it into a consistent application format and then makes it available to applicants and NIH staff for electronic research administration purposes.

Access to the eRA Commons is vital for all steps in the SPARC program's other transaction administration process. Following application submission, the eRA Commons becomes the primary site for accessing other transaction information such as IC assignments, review outcomes, Summary Statements, and NoAs. The eRA Commons also provides electronic business processes such as Internet Assisted Review (IAR), submission of Financial Reports (FFRs), and submission of Closeout documents. Appropriate user roles are assigned to registered individuals depending on the responsibilities assigned to them by the recipient organization.

3.1 eRA Commons Registration

In order to participate in the SPARC program, an organization and PD/PI(s) must complete a **one-time** registration in the Commons. Institutional/organizational officials are responsible for registering PD/PI(s) in the eRA Commons. PD/PI(s) should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: Organizations registering in the eRA Commons for the first time should allow 2-4 weeks to complete the registration process.

3.2 eRA Commons Registration for the Organization

Organizations may verify their current registration status by accessing the "List of Recipient Organizations Registered in eRA Commons" at http://era.nih.gov/commons/quick_queries/index.cfm#commons.This listing can be accessed without logging into the Commons.

To register an Organization in the eRA Commons an AOR should follow the procedures found on the eRA Commons homepage at https://commons.era.nih.gov/commons/ under the link "Recipient Organization Registration."

During this registration process, NIH may make a preliminary assessment of applicant organization eligibility. Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH may deny registration if an organization is determined ineligible. Note, acceptance of an organization's registration in the Commons does not mean an organization is an acceptable recipient for a particular program. That assessment will be made by the NIH awarding component prior as part of the pre-award process.

3.3 eRA Commons Registration for the PD/PI

The individual designated as the PD/PI on the application must also be registered in the Commons. The PD/PI must hold a PD/PI eRA Commons role **and** be affiliated with the applicant organization. **The initial registration must be done by an AOR who has the SO role in the Commons or other authorized accounts administrators at the organization**. However, after the initial registration process is complete, it becomes the responsibility of the individual to maintain the information in his/her personal profile.

Designating the PD/PI role in the eRA Commons provides the individual with the administrative authority needed to see pertinent information regarding an application (e.g., electronic submission status, review assignment, etc.). The PD/PI role within the eRA Commons is necessary to complete the other transaction application process, and if an award is made, to complete required post-award actions such as submission of a progress report. The PD/PI may delegate certain authorities to other individuals.

Users should only have one PD/PI eRA Commons account. If the PD/PI has already been registered in eRA Commons by an organization other than the organization submitting an application, a separate eRA Commons registration with the submitting organization is not necessary. However, the submitting organization must take steps to affiliate the individual with that organization so that the individual can view and access data records for those applications.

Individual applicants not affiliated with an organization or who want to submit an application independently must complete all the required registrations as though they are an organization (http://grants.nih.gov/grants/ElectronicReceipt/UnaffiliatedUserRegistration.pdf). In eRA Commons, they will be registered as "independent scholars" and also be the Signing Official, with the same authority in eRA Commons that the AOR has in Grants.gov.

3.4 eRA Commons Registration for Other Individuals Participating in NIH Progress Reports

Any individual with an Undergraduate, Graduate Student, and/or Postdoctoral role who participates in a NIH-funded project for at least one person month or more should also be registered in the eRA Commons and should verify that all Personal Information located within the Personal Pro-file tab in the eRA Commons System is accurate. This is required regardless of whether salary is actually charged to the project. For graduate students supported on a particular other transaction award, this could include project roles of graduate research assistant or graduate student. For postdoctoral individuals supported on a particular other transaction award, this could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

When an individual is assigned the Undergraduate, Graduate Student, or Postdoctoral Role in the Commons, responses to certain data items in the Personal Profile tab will be required to meet NIH reporting requirements to Congress included in the NIH Reform Act, P.L. 109-482. The Commons user name ID for those with an Undergraduate, Graduate Student, or Postdoctoral Role is not required at the time of application submission, but will be required as part of the Research Performance Progress Report (RPPR).

A Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

4. Applications Information and Processes

This section provides an overview of types of entities eligible to receive other transaction awards, funding opportunities, and the legal implications of applications.

4.1 Eligibility

In general, NIH other transactions may be awarded to organizations that are domestic, foreign, public, private, non-profit or for-profit. Eligible organizations include governments, including Federal institutions, institutions of higher education, other non-profit organizations, hospitals, and, in rare occasions, individuals. Any special criteria for applicant eligibility or requirements concerning the qualifications of the PD/PI or other staff or participants will be specified in the FOA, program guidelines, or other publicly available documents.

As indicated, individuals unaffiliated with an institution may receive other transaction awards. These awards will be made to promising applicants who have the ability to be productive, independent investigators in fields related to the SPARC mission. The eligibility of these individuals to complete the project will be evaluated during the objective review process and by the AO and PM.

4.2 Funding Opportunity Announcement (FOA)

A FOA is a publicly available document in which a Federal agency makes known its intentions to make awards (e.g., other transactions), usually as a result of competition for funds. All SPARC applications must be submitted in response to a FOA. FOAs include information to allow prospective applicants to determine whether to apply.

FOAs pertaining to other transactions for the SPARC program are published in the *NIH Guide for Grants and Contracts* (http://-grants.nih.gov/grants/guide/index.html) and on Grants.gov under Find Grant Opportunities (http://www.grants.gov/applicants/find_grant_opportunities.jsp). Although these grants-related resources are being used for SPARC Other Transaction announcements, the awards are not grants or contracts.

4.3 Legal Implications of Applications

An applicant must be an eligible entity and must submit a complete application in accordance with established receipt (deadline) dates in order to be considered for support. The signature of an AOR on the application certifies that the applicant will comply with all applicable assurances and certifications referenced in the application. The applicant is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application. The AOR's signature further certifies that the applicant has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the other transaction-supported project or activities resulting from the application.

4.4 Policies Affecting Applications

Application information to be submitted typically includes a project description, budget and budget justification, biographical sketches of senior/key personnel, and other information specified in the

application instructions, in the announcement, and/or in program guidelines, if any. Specific details on application content are addressed in application instructions and specific FOAs. Any significant change to the application post-submission must be reported immediately to the appropriate NIH official.

4.5 DUNS Number and SAM Registration Requirements

All applicant organizations **must have** a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal other transaction awards. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual PD/PIs do not need to register for a DUNS number unless they are unaffiliated.

Additionally, all applicants must register in the System for Award Management (SAM) (formerly the Central Contractor Registry (CCR)) and maintain the registration with current information at all times during which it has an application under consideration for funding by NIH. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient.

If an award is issued, the recipient must notify potential subrecipients that they may not receive a subaward under the other transaction award unless they have provided their DUNS number to the recipient.

5. The Objective Review Process

Division G, Title II, Section 213 of the Consolidated and Further Continuing Appropriations Act of 2015 (P.L. 113-235) allows the NIH Director to enter into transactions other than contracts, grants or cooperative agreements to carry out Common Fund research. This authority additionally allows the Director to use nonstandard peer review procedures to obtain assessments of scientific and technical merit:

SEC. 213. (a) AUTHORITY.—Notwithstanding any other provision of law, the Director of NIH (‘‘Director’’) may use funds available under Section 402(b)(7) or 402(b)(12) of the Public Health Service (PHS) Act to enter into transactions (other than contracts, cooperative agreements, or grants) to carry out research identified pursuant to such Section 402(b)(7) (pertaining to the Common Fund) or research and activities described in such Section 402(b)(12). (b) PEER REVIEW.—In entering into transactions under subsection (a), the Director may utilize such peer review procedures (including consultation with appropriate scientific experts) as the Director determines to be appropriate to obtain assessments of scientific and technical merit. Such procedures shall apply to such transactions in lieu of the peer review and advisory

council review procedures that would otherwise be required under Sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494 of the PHS Act.

Objective review is an assessment of scientific or technical merit of applications by individuals with knowledge and expertise equivalent (peer) to that of the individuals whose applications of support they are reviewing, i.e., reviewers who are the professional equals of the principal investigator (PI) or program/project director (PD) for the proposed project and who often are engaged or were previously engaged in comparable activities.

Objective review is essential to ensuring selection of applications that best meet the needs of the program consistent with established criteria and providing assurance to the public that the evaluation and selection process was impartial and fair. To achieve this result, NIH strives to conduct reviews under the highest ethical standards. The review process should be viewed by practitioners, participants, and the public as credible and fair. Any circumstance that might introduce any conflict of interest, or appearance thereof, prejudices, biases, or predispositions into the process must be avoided.

The review process and criteria will be specified in each FOA. Only the review criteria described in the FOA will be considered in the review process. All applications submitted in response to the FOA will be evaluated by an appropriate review group.

Reviewers will individually provide an assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the review criteria.

PART II: TERMS AND CONDITIONS OF SPARC OTHER TRANSACTION AWARDS

1. Overview of Terms and Conditions

Part II includes the terms and conditions of SPARC other transaction awards and is incorporated by reference in all SPARC other transaction awards. These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts.

SPARC other transaction awards are based on the application submitted to, and approved by, the NIH and are subject to the terms and conditions incorporated either directly or by reference in the following:

- The other transaction program legislation and program regulation cited in the NoA.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts. This also includes any recent legislation.
- The NIH Other Transaction Award Policy Guide for the SPARC Program, including any revisions in effect as of the beginning date of the next budget period.
- The NoA including all terms and conditions cited on the document or attachments.

Notice of requirements not specified in the NIH Other Transaction Award Policy Guide for the SPARC Program generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations. An individual award also may contain award-specific terms and conditions. For example, the AO may include terms or conditions necessary to address concerns about an applicant's management systems.

Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of the NIH Other Transaction Award Policy Guide for the SPARC program apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the policy.

This NIH Other Transaction Award Policy Guide for the SPARC program is an aid to the interpretation of statutory requirements. These terms and conditions are intended to be compliant with governing statutes.

1.2 SPARC Program Standard Terms of Award for Other Transactions

In general, NIH recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities. The recipient-initiated changes that may be made under the recipient's authority and the changes that require NIH approval are outlined below:

Recipient Authorities as SPARC Program Standard Terms of Award

1.2.1 Cost-Related Prior Approvals

Other transaction awards use the cost principles at 45 CFR Part 75, Subpart E as a guide for negotiating the award amount. However, NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope.

1.2.2 Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement

Prior approval by the NIH awarding IC is not required to transfer the performance of already approved programmatic work unless the activity constitutes a change in scope or results in the transfer of substantive programmatic work to a foreign component.

NIH prior approval is required for:

1.2.3 Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period

Recipients should be aware that there is a difference between unliquidated obligations and unobligated balances. Unliquidated obligations are commitments of the recipient and are considered to be obligations and, therefore, should not be reported as unobligated balances.

For other transaction awards, the NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority or if prior approval is required to carryover unobligated balances from one budget period to any subsequent budget period. Recipients will be required to indicate, as part of the other transaction's progress report, whether any estimated unobligated balance (including prior-year carryover) is expected to be greater than 25 percent of the current year's total approved budget. The total approved budget amount includes current year and any carryover from prior years of the project period. If the unobligated balance is greater than 25 percent of the total approved budget, the recipient must provide an explanation and indicate plans for expenditure of those funds within the current budget year.

When a recipient reports a balance of unobligated funds in excess of 25 percent of the total amount awarded for the budget period, plus any approved carryover of funds from a prior year(s), the AO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project, and may request additional information from the recipient, including a revised budget, as part of the review.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit the availability of funds for carryover.

1.2.4 No-cost Extensions

For other transaction awards, any project period extension beyond the initial project period requires NIH prior approval. The request should include a description of the project activities that require support during the extension and a statement about the funds available to support the extension.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period.

1.2.5 Change in Scope

In general, the PD/PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the recipient must obtain prior approval from the NIH awarding IC for a change in scope. The recipient must make the initial determination of the significance of a change and should consult with the AO as necessary.

Potential indicators of a change in scope include, but are not limited to, the following:

- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded. For example, if the award budget for total costs is $200,000, any rebudgeting that would result in an increase or decrease of more than $50,000 in a budget category is considered significant rebudgeting. The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements.

1.2.6 Change of Recipient Organization

NIH prior approval is required for the transfer of the legal and administrative responsibility for an other transaction-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment).

1.2.7 Deviation from Award Terms and Conditions, including Restrictions in the NoA

NIH prior approval is required for any deviation from terms or conditions stated or referenced in the NoA, including those in the NIH Other Transaction Award Policy Guide for the SPARC Program. This includes undertaking any activities disapproved or restricted as a condition of the award.

1.3 Requests for Prior Approval

All requests for NIH prior approval must be made in writing (including submission by E-mail) to the AO no later than 30 days before the proposed change, and signed by the AOR. If the request is E-mailed, it must provide evidence of the AOR's approval; a cc to the AOR is not acceptable. A request by a subrecipient for prior approval will be addressed in writing to the recipient. The recipient will promptly review such request and shall approve or disapprove the request in writing. A recipient will not approve any budget or project revision which is inconsistent with the purpose or terms and conditions of the other transaction award to the recipient.

2. Public Policy Requirements and Objectives

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its recipients. The public policy requirements specified in this section set many of those standards. The signature of the AOR on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances referenced (and, in some cases, included) in the application instructions. The policies, certifications and

assurances listed in this section may or may not be applicable to the project, program, or type of applicant organization. This list is not intended to be comprehensive and other laws may be determined to apply generally to all NIH OT awards, or specifically to a particular award depending on the terms of the OTA.

2.1 Debarment and Suspension

HHS regulations published in 2 CFR 376 implement the government-wide debarment and suspension system guidance (2 CFR 180) for HHS' non-procurement programs and activities. "Non-procurement transactions" include, among other things, grants, cooperative agreements, scholarships, fellowships, and loans. NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, recipients of NIH other transaction awards are required to determine whether it or any of its principals (as defined in 2 CFR 180.995 and 2 CFR 376.995) is excluded or disqualified from participating in a covered transaction prior to entering into the covered transaction, i.e., prior to the drawdown of funds which signals acceptance of the other transaction award. Recipients may decide the method and frequency by which this determination is made and may check excluded parties in SAM, although checking SAM is not required.

2.2 Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible. These circumstances are outlined below:

1. Airline "Open Skies" Agreement. A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an "Open Skies" Agreement with the European Union (EU). This Agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States.

   The U.S.-EU Open Skies Agreement was amended effective June 24, 2010. GSA issued Guidance October 6, 2010. Pursuant to the amendment, federal contractors and recipients (not U.S. Government employees) need not be concerned about city-pair contract fares. However, contractors and recipients must check with the airline to ensure that the airline is covered by the U.S.-EU Open Skies agreement which may change periodically.

   Additionally, pursuant to the amendment, EU airlines are no longer limited to flying passengers between points in the United States and points in the EU. Instead, EU airlines are authorized to

transport passengers between points in the United States and points outside the EU if the EU airline is authorized to serve the route under the U.S.-EU Open Skies Agreement. This includes flights that originate, arrive, or stop in the European Union. For additional information, please see the text of the Amendment and GSA Bulletin FTR 11-02. For information on other "open skies" agreements in which the United States has entered, refer to GSA's Web site: http://www.gsa.gov/portal/content/103191.

2. Involuntary Rerouting. Travel on a foreign-flag carrier is permitted if a U.S.-flag air carrier involuntarily reroutes the traveler via a foreign-flag air carrier, notwithstanding the availability of alternative U.S.-flag air carrier service.
3. Travel To and From the U.S. Use of a foreign-flag air carrier is permissible if the airport abroad is: (a) the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or (b) an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by two or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
4. Travel Between Points Outside the U.S. Use of a foreign-flag air carrier is permissible if: (a) travel by a foreign-flag air carrier would eliminate two or more aircraft changes en route; (b) travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or (c) the travel is not part of the trip to or from the U.S., and use of a U.S.-flag air carrier would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
5. Short Distance Travel. For all short distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag air carrier would double the travel time.

2.3 Metric System

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, measurement values in applications and recipient-prepared reports, publications, and other transaction award-related documents should be in metric.

2.4 National Environmental Policy Act

All NIH other transaction awards, whether or not they include construction or major A&R activities, are subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended. This Act requires Federal agencies to consider the reasonably foreseeable environmental consequences of all other transaction-supported activities. As part of NIH's implementation of this Act, recipients are required to promptly notify NIH of any reasonably foreseeable impacts on the environment from other

transaction-supported activities, or certify that no such impacts will arise upon receipt of an other transaction award. In addition, NIH has determined that most NIH other transaction awards are not expected to individually or cumulatively have a significant effect on the environment unless any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below:

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the pro-posed research.

2.5 Pro-Children Act of 1994

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children's services are provided. NIH other transaction awards are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development (Head Start) services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient drug or alcohol treatment, or facilities where Women, Infants and Children (WIC) coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the AOR will indicate the intent to

comply. Any questions concerning the applicability of these provisions to an NIH other transaction award should be directed to the AO.

2.6 Research Misconduct

Title 42 CFR 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions" specifies recipient responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity, and take all reasonable and practical steps to foster research integrity. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The HHS Office of Research Integrity (ORI) has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities (http://www.ori.dhhs.gov).

2.7 Research Involving Recombinant or Synthetic Nucleic Acid Molecules

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (November 2013 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of the *NIH Guidelines* is available at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines.

According to the *NIH Guidelines*, recombinant and synthetic nucleic acid molecules are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3)molecules that result from the replication of those described in (1) or (2). The *NIH Guidelines* apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines*.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant or synthetic nucleic acid molecule research at the organization, or a requirement for NIH prior approval of any or all recombinant or synthetic nucleic acid molecule projects at the organization. Two specific requirements of the *NIH Guidelines* are discussed below, but the recipient should carefully review the *NIH Guidelines* in their entirety to ensure compliance with all of the requirements for projects involving recombinant or synthetic nucleic acid molecules.

Recombinant or synthetic nucleic acid research involving select agents also is subject to pertinent CDC and USDA regulations, 42 CFR 73, Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121, Possession, Use, and Transfer of Biological Agents and Toxins.

2.8 Select Agents

Domestic recipients who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR 73 and 9 CFR 121 and Section 3 of 7 CFR 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.

2.9 USA Patriot Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. Chapter 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. "Restricted persons," as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent.

2.10 Salary Cap/Salary Limitation

None of the funds appropriated in the governing appropriation Act for the NIH (the Act), shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of that prescribed in the Act. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of the rate prescribed in the Act will be adjusted in accordance with the legislative salary limitation.

2.11 Gun Control

The Consolidated and Further Continuing Appropriations Act, 2015, provides that NIH funds may not be used, in whole or in part, to advocate or promote gun control.

2.12 Lobbying Prohibition

(a) No part of any appropriation contained in the Consolidated and Further Continuing Appropriations Act, 2015, or transferred pursuant to Section 4002 of Public Law 111–148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

(b) No part of any appropriation contained in this Act or transferred pursuant to Section 4002 of Public Law 111–148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent

acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

(c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

2.13 Restriction on Abortion Funding

NIH appropriated funds and funds in any trust fund to which funds are appropriated in the governing appropriation Act may not be spent for any abortion. None of the funds appropriated in the governing appropriation Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion. The term ‘‘health benefits coverage’’ means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.

2.14 Exceptions to Restrictions on Abortions

(a) The limitations established in the preceding section shall not apply to an abortion— (1) if the pregnancy is the result of an act of rape or incest; or (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State’s or locality’s contribution of Medicaid matching funds).

(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State’s or locality’s contribution of Medicaid matching funds).

(d) (1) None of the funds appropriated to NIH may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions. (2) In this subsection, the term ‘‘health care entity’’ includes an individual physician or other health care professional, a hospital, a provider-sponsored

organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

2.15 ClinicalTrials.gov Requirement

Applicants and recipients should familiarize themselves with the requirements of Title VIII, Sec. 801 of Public Law 110-85 (also known as the FDA Amendments Act of 2007 or FDAAA), with respect to registration and results reporting requirements that may apply to certain studies. In particular, recipients should be aware that if an applicable clinical trial is funded in whole or in part by an NIH other transaction award, any application or progress report shall include a certification that the Responsible Party has made all required submissions to ClinicalTrials.gov. The NIH strongly encourages registration of all clinical trials, whether required by FDAAA or not. For additional information, see http://grants.nih.gov/clinicaltrials_fdaaa/index.htm and https://clinicaltrials.gov/.

2.16 Human Stem Cell Research

Under Executive Order 13505 NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. NIH Guidelines on Human Stem Cell Research, effective July 7, 2009, implement the Executive Order. The Guidelines apply to the expenditure of NIH funds for research using hESCs and certain uses of induced pluripotent stem cells.

For the purpose of the NIH Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. Induced pluripotent stem cells are human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.

NIH recipients may use hESCs that have been approved by NIH in accord with the NIH Guidelines and are posted on the NIH Human Embryonic Stem Cell Registry, or may establish eligibility of specific cell lines for NIH funding by submitting a Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (NIH Form 2890). Prior to the use of NIH funds, applicants and recipients must provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs to be used are listed on the NIH Registry and will be used in accordance with any restrictions associated with the line as cited on the Registry. If a specific line from the NIH Registry cannot be identified at the time of submission, the applicant/recipient must provide a strong justification why one cannot be identified at that time and a certification that one from the NIH Registry will be used.

2.17 Human Embryo Research and Cloning Ban

NIH funds may not be used to support human embryo research. NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)). The term “human embryo or embryos” includes any organism not protected as a human subject under 45 CFR 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

In addition to the statutory restrictions on human fetal research under subsection 498(b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

2.18 Human Fetal Tissue Research

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

Guidance for recipients conducting research on human fetal tissue and other information on the governing Federal statute is found in Sections 498A and 498B of the PHS Act, 42 U.S.C. 298g-2.

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements, particularly Section 498B. When an application involving human fetal tissue research is submitted to NIH, the AOR’s signature certifies that researchers using these tissues are in compliance with Section 498B of the PHS Act. The statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. The term “valuable consideration” is a concept similar to profit and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control, or transportation of these tissues. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire human fetal tissue.

2.19 Human Subjects Protections

The HHS regulations for the protection of human subjects, in 45 CFR 46, implement Section 491(a) of the PHS Act and provide a framework, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the NIH or other HHS components.

The HHS regulations stipulate that the recipient organization(s), whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in HHS-supported activities (46.101(a) and 46.103(a)). Recipient organization(s) "engaged" in human subjects research

must obtain a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP), and establish appropriate policies and procedures for the protection of human subjects.

2.20 Animal Welfare Requirements

The *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all recipient organizations receiving PHS support for research or related activities using live vertebrate animals. Recipient organizations must establish appropriate policies and procedures to ensure the humane care and use of animals, and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.

The PHS Policy incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495).

2.21 Promotion or Legalization of Controlled Substances

Recipients are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedules of controlled substances established by Section 202 of the Controlled Substances Act, 21 U.S.C. 812 except for normal and recognized executive-congressional communications. This limitation does not apply if the recipient notifies the AO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

2.22 Dissemination of False or Deliberately Misleading Information

None of the funds made available in the governing appropriations Act may be used to disseminate information that is deliberately false or misleading.

2.23 Restriction on Distribution of Sterile Needles

NIH appropriated funds may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

2.24 Restriction of Pornography on Computer Networks

The Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235) includes the following restriction:

(a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.
(b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities."

3. The Notice of Award

The NoA is the legal document issued to notify the recipient that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is issued for the initial budget period and each subsequent budget period in the approved project period. The NoA reflects any future-year commitments. A revised NoA may be issued during a budget period to effect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. NIH will not issue a revised NoA to reflect a recipient's post-award rebudgeting.

3.1 Notice of Award Notification

NIH notifies the recipient organization via E-mail when an award has been issued-i.e., on the award date. In order to allow for the E-mail notification of the NoA, recipient organizations must register a valid E-mail address in the NoA E-mail field in the eRA Commons Institutional Profile once the initial eRA Commons registration process is complete. Organizations are encouraged to use a unique E-mail address that is not specific to an individual in order to avoid communication problems when personnel change. It is the responsibility of the recipient organization to maintain a current and accurate E-mail address for NoAs. NIH will not distribute NoAs other than through this system-generated E-mail notification process. Recipients that do not maintain a current NoA notification E-mail address will be responsible for accessing NoAs via the eRA Common.

3.2 Funding

NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget periods. The length of an initial project period (competitive segment) or of any subsequent competitive segment is determined by the NIH awarding IC on the basis of:

- any statutory or regulatory requirements,
- the length of time requested by the applicant to complete the project,
- limitation on the length of the project period recommended by the peer reviewers,
- the awarding IC's programmatic determination of the frequency of competitive review desirable for managing the project, and
- NIH funding principles.

The total project period consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. NIH policy limits each competitive segment to a maximum of 5 years (exclusive of non-competing

extensions). A single award covering the entire period of support generally is used only if the project is solely for construction or modernization of real property, if the total planned period of support will be less than 18 months, or if the project is awarded under a special support mechanism.

The initial NoA provides funds for the project during the first budget period. Budget periods usually are 12 months long; however, shorter or longer budget periods may be established for compelling programmatic or administrative reasons. The NoA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Recipients are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period. A decision to fund the next budget period will be formalized by the issuance of the NoA indicating the new budget period and the amount of new funding. The NoA also will reflect any remaining future-year commitments. NIH may withhold support for failure to meet the terms and conditions of the award.

3.3 Budget

Each NoA sets forth the amount of funds awarded. The amount will be shown as a categorical (line item) budget. The recipient has certain rebudgeting flexibility within the overall amount awarded. The recipient may be required to provide matching funds under certain NIH programs or awards if specified in the FOA.

4. Payment

The Payment Management System (PMS) is a centralized payment and cash management system, operated by HHS PSC, PMS. HHS other transaction award payments may be made by one of several advance payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis, as specified in the NoA and as described in this section. Payments under SPARC other transaction awards generally are made as advance payments. SPARC other transaction award payments are made by PMS, operated by PSC, in accordance with Department of the Treasury requirements (31 CFR part 208). These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal government and disbursement by a recipient. Therefore, although the other transaction award may be financed by advance payments, the intent is that recipients draw funds on an as-needed basis—specifically, no more than 3 business days before the funds are needed.

All Federal funds deposited by PMS in a recipient's bank account as an unrestricted advance payment should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the next workday after receipt of the funds. The potential for excessive Federal cash on hand exists each time a recipient does not disburse Federal funds in this manner. The recipient is responsible for determining when the Federal funds have been deposited into its bank account for each drawdown, ensuring that the funds are fully disbursed by the close of business the next work day after they are received, and immediately returning all undisbursed Federal funds to PMS.

The Treasury and OMB policies also establish accountability for interest earned on advances of funds and provide for use of the reimbursement method if cash management requirements are not met. Advances made by recipients to consortium participants and contractors under other transaction awards must conform to substantially the same standards of timing and amount that govern advances to the recipient.

Operational guidance for recipients is provided through a training CD from PSC. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds through the Federal Financial Report (SF 425) should be directed to PSC/PMS.

4.1 SMARTLINK II/ACH

The SMARTLINK II/ACH method of advance payment makes direct deposit of funds to a recipient's bank account and requires recipients to have Internet access to submit a request for funds to PMS. SMARTLINK II/ACH provides funds the day following the request with direct deposit using the Federal Reserve Bank's (Richmond, Virginia) ACH process.

4.2 Cash Request

Recipients not eligible for an unrestricted advance of funds by SMARTLINK II/ACH must submit a cash request, usually monthly. The cash request may be on either an advance or reimbursement basis, as specified by the NIH awarding IC. Cash requests are used when a recipient's cash management must be closely monitored or under programs where reimbursement financing is appropriate. A recipient also may be converted from an unrestricted advance payment method to a cash request basis if, during post-award administration, the AO determines that a recipient is not complying with the cash management requirements or other requirements of the award, including the submission of complete and timely reports.

If the cash request is for an advance payment, the recipient may request funds from PMS monthly on the basis of expected disbursements during the succeeding month and the amount of Federal funds already on hand. A request for reimbursement may be submitted more often, if authorized. For timely receipt of cash, a recipient must submit the request through the awarding IC early enough for it to be forwarded to PMS at least 2 weeks before the cash is needed. PMS makes payment to the recipient electronically through the ACH process upon receipt of the approved payment request from the awarding IC.

4.3 Interest Earned on Advances of SPARC Other Transaction Award Funds

NIH recipients that receive advance payments must maintain those advances in an interest-bearing account. Recipients are expected to promptly return any funds not spent within three business days. Interest earned on Federal advance payments deposited in interest-bearing accounts must be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to $500 per year may be retained by the recipient for administrative expenses.

5. Cost Consideration

Cost considerations are critical throughout the life cycle of an other transaction award. An applicant's budget request is reviewed using the governing cost principles and other requirements and policies applicable to the type of recipient as a guide. Any resulting award will include a budget that is consistent with these requirements.

NIH anticipates that, because of the nature of research, the recipient may need to modify its award budget during performance to accomplish the award's programmatic objectives. Therefore, NIH provides some flexibility for recipients to deviate from the award budget, depending on the deviation's significance to the project or activity. More significant post-award changes require NIH prior approval.

During post-award administration, the AO monitors expenditures for conformance with cost policies. The AO's monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports.

5.1 The Cost Principles

In general, SPARC other transaction awards provide for reimbursement of actual, allowable costs incurred and are subject to the Federal cost principles. The cost principles establish standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or F&A costs, and set forth the allowability and allocability principles for selected items of cost. Applicability of a particular set of cost principles depends on the type of organization making the expenditure. For example, a for-profit organization collaborating with a university recipient would be subject to the cost principles for commercial organizations, while the university would be subject to the cost principles for Institutions of Higher Educations (IHEs). The cost principles are set forth in HHS regulations at 45 CFR 75, Subpart E and Appendix IX (hospitals) to Part 75. Commercial organizations are subject to the cost principles located at 48 CFR 31.2 Federal Acquisition Regulation.

5.2 Direct Costs and Facilities and Administrative Costs

A direct cost is any cost that can be specifically identified with a particular project, program, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the other transaction-supported project or activity.

Most organizations also incur costs for common or joint objectives that cannot be readily identified with an individual project or program. Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that usually are treated as F&A costs. The organization is responsible for the management and accounting of costs consistently and must not include costs associated with its F&A rate as direct costs. As a general policy NIH will reimburse F&A costs under other transaction awards using the applicants federal negotiated indirect cost rate. Any applicant that has never received a negotiated indirect cost rate, may elect to charge a de minimis rate of 10 percent of modified total direct costs.

F&A costs on foreign awards will be reimbursed at a rate of eight (8) percent of total direct cost, less only equipment.

NIH will not provide F&A reimbursement on awards to individuals.

6. Availability of Research Results: Publications, Invention Rights, and Sharing Research Resources

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. Depending on each SPARC program and as stated in the applicable FOA, the award issued may adopt the prescriptions and requirements of the Bayh-Dole Act (Act), as amended by the Technology Transfer Commercialization Act of 200 (P.L. 404) and 37 C.F.R. 401.14 in their entirety, portions thereof, or none at all.

6.1 Rights in Data (Publication and Copyrighting)

In general, recipients own the rights in data resulting from an other transaction-supported project. Special terms and conditions of the award may indicate alternative rights, e.g., based on specific programmatic considerations as stated in the applicable FOA. Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under a SPARC other transaction award may be copyrighted without NIH approval. For this purpose, “data” means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.

Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages recipients to arrange for publication of NIH-supported original research in primary scientific journals. Recipients also should assert copyright in

scientific and technical articles based on data produced under the other transaction award where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

Journal or other copyright practices are acceptable unless the copyright policy prevents the recipient from making copies for its own use. All recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Each publication, press release, or other document about research supported by an NIH other transaction award must include:

1) An acknowledgment of NIH other transaction award support such as:
   "Research reported in this [publication, release] was supported by [name of the Institute, Center, or other funding component] of the National Institutes of Health under other transaction award number [specific NIH other transaction award number in this format: OT2GM012345]."
2) A disclaimer that says:
   "The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

If the recipient plans to issue a press release about research supported by a SPARC other transaction award, it should notify the NIH funding component in advance to allow for coordination. Publications resulting from work performed under an NIH other transaction-supported project must be included as part of the annual or final progress report submitted to the NIH awarding IC. When publications are available electronically, the URL or the PMCID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report.

6.2 NIH Public Access Policy

The NIH Public Access Policy implements Division F, Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009). The policy ensures that the public has access to the published results of NIH-funded research at the NIH NLM PMC, a free digital archive of full-text biomedical and life sciences journal literature (http://www.pubmedcentral.nih.gov/).Under the policy NIH-funded investigators are required by Federal law to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication on or after 4/7/2008, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this policy. Applicants citing articles in NIH applications, proposals, and progress reports that fall under the policy, were authored or co-authored by the applicant and arose from NIH support must include the PMCID or NIHMS ID. The NIHMSID may be used to indicate compliance with the Public Access Policy in

applications and progress reports for up to three months after a paper is published. After that period, a PMCID must be provided to demonstrate compliance.

This policy applies to all peer-reviewed articles resulting from research supported in whole or in part with direct costs from NIH.

6.3 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of recipients and contractors to elect and retain title to subject inventions as may be set forth in the terms of the FOA.

Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans. To provide further clarification of the NIH policy on disseminating unique research resources, NIH published Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources (64 FR 72090, December 23, 1999; http://grants.nih.gov/grants/intell-property_64FR72090.pdf) and Best Practices for the Licensing of Genomic Inventions (70 FR 18413, April 11, 2005). These policy documents will assist recipients in determining reasonable terms and conditions for disseminating and acquiring research tools.

As specified in the SPARC FOA, the terms of the SPARC program other transaction awards may adopt the prescriptions and requirements of the Bayh-Dole Act to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH, the recipient also must provide a copy of documents or a sample of any material developed under an NIH other transaction award. The recipient may charge a nominal fee to cover shipping costs for providing this material.

To facilitate the availability of unique or novel materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories and should ensure that those entities distribute them in a way that is consistent with the above referenced *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and*

Disseminating Biomedical Research Resources. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

6.3.1 Data Sharing Policy

NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set.

NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, and local, State and Federal laws and regulations, including the HIPAA Privacy Rule. The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data sharing is limited, applicants should explain such limitations in their data sharing plans.

Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Organizations that believe they will be unable to meet these expectations should promptly contact the AO to discuss the circumstances, obtain information that might enable them to share data, and reach an understanding in advance of an award.

6.3.2 Sharing Model Organisms

All applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible. Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

This expectation is for **all** applications where the development of model organisms is anticipated, regardless of funding amount.

For additional information on this policy, see the NIH Model Organism for Biomedical Research Web site at: http://www.nih.gov/science/models/.

6.3.3 Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS)

The NIH Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports the NIH mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health.

The GDS Policy, an extension of the 2008 NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (the NIH GWAS Policy), applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. For the purposes of this Policy, the genome is the entire set of genetic instructions found in a cell and large-scale genomic data include GWAS, single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the GDS Policy (available at https://gds.nih.gov/pdf/supplemental_info_GDS_Policy.pdf) provides examples of genomic research projects that are subject to the Policy and the timeline for submission and sharing of data from such projects.

The GDS Policy became effective on January 25, 2015 for applications with due dates on or after that date. Research that was initiated prior to the effective date of the GDS Policy will continue to operate under the terms of the policies that were in effect when the research began, such as the NIH GWAS Policy, however, NIH strongly encourages investigators to comply with the expectations outlined in the GDS Policy. All applications, regardless of the amount requested, proposing research that will generate large-scale genomic data, are expected to include a genomic data sharing plan (see http://gds.nih.gov/pdf/NIH_guidance_developing_GDS_plans.pdf for guidance on developing a genomic data sharing). For additional information, see: http://gds.nih.gov/. Questions about the GDS policy can be E-mailed to GDS@mail.nih.gov.

6.3.4 Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212) and the related EO 12591 (April 10, 1987) provide incentives for the practical application of research supported through Federal grants, cooperative agreements, or contracts. For some SPARC other transaction awards, all or some of the prescriptions and requirements of the Bayh-Dole Act (http://grants.nih.gov/grants/bayh-dole.htm) will be adopted, as specified in the FOA and NoA. There may be circumstances where the scientific goals of

the SPARC program may require management of inventions made under a SPARC other transaction award to be managed consistent with NIH's policies for the dissemination and use of information and technologies without the adoption of the prescriptions and requirements of the Bayh-Dole Act in their entirety or at all.

Some of the adopted rights and obligations required by the Bayh-Dole statute and regulation for an award recipient to retain intellectual property rights to inventions and provide the Federal Government with all of its rights include:

- Report all subject inventions to NIH and annually report an OT award recipient of their efforts to transfer the invention for the public's use.
- For all inventions that the funding recipient retains ownership, the funding recipient is obligated to file and prosecute all patent applications in a manner that protects the government's rights worldwide.
- Make reasonable efforts to and take effective steps to achieve practical application of an invention.
- Protect the Federal government's rights in all filed patent applications and issued patents by: (1) conveying to the government a confirmatory license that evidences the government's rights in the invention; and, (2) include a statement of the Federal government's rights in each patent application or issued patent.

For all prescriptions and requirements of the Bayh-Dole Act that may be adopted as specified in the FOA and NoA, recipients should refer to 37 C.F.R. 401 (available at the NIH Interagency Edison site: http://grants.nih.gov/grants/intell-property.htm).

7. Management Systems and Procedures

Recipient organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Recipients may use their existing systems to manage NIH other transaction award funds and activities as long as they are consistently applied regardless of the source of funds.

NIH seeks to foster within recipient organizations an organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resources to underpin that research. Actions to achieve this result should include a clear delineation of the roles and responsibilities of the organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing.

7.1 Financial Management System Standards

The standards and requirements for a financial management system are essential to the other transaction relationship. NIH cannot support the research unless it has assurance that its funds will be used appropriately, adequate documentation of transactions will be maintained, and assets will be safeguarded.

Recipients must have in place accounting and internal control systems that provide for appropriate monitoring of other transaction accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. In addition, the systems must be able to identify large unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds, and recipients must notify NIH when problems are identified. A recipient's failure to establish adequate control systems constitutes a material violation of the terms of the award.

7.2 Program Income

Program income is gross income—earned by a recipient, a consortium participant, or a contractor under an other transaction award—that was directly generated by the other transaction-supported activity or earned as a result of the award. (Note: Program income from license fees and royalties from copyrighted material, patents, and inventions is exempt from reporting requirements unless otherwise specified in the terms and conditions of award.) Unless otherwise specified in the terms and conditions of the award, NIH recipients are not accountable for program income accrued after the period of other transaction support.

NIH applies the additive alternative to all recipients, including for-profit entities, unless there is a concern with the recipient, or the program requires a different program income alternative.

7.3 Reporting Program Income

The amount of program income earned must be reported in the non-competing continuation progress report (RPPR). Income resulting from royalties or licensing fees is generally exempt from reporting as program income.

7.4 Royalties and Licensing Fees from Copyrights, Inventions, and Patents

NIH recipients do not have to report program income resulting from royalties or licensing fees from sale of copyrighted material unless specific terms and conditions of the award provide otherwise. The NoA may include special terms and conditions if commercialization of an invention is an anticipated outcome of a research project.

7.5 Property Management System Standards

Generally, recipients may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using SPARC other transaction award funds. Recipients are required to be prudent in the acquisition of property under an other transaction-supported project. It is the recipient's responsibility to conduct a prior review of each proposed property acquisition to ensure that the property is needed and that the need cannot be met with property already in the possession of the organization.

7.6 Procurement System Standards and Requirements

Recipients may acquire a variety of goods or services in connection with an other transaction-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. Recipients must acquire goods and services under other transaction awards in compliance with the organizations established policies and procedures.

8. Monitoring

Recipients are responsible for managing the day-to-day operations of other transaction-supported activities using their established controls and policies, as long as they are consistent with NIH requirements. However, to fulfill their role in regard to the stewardship of Federal funds, NIH awarding ICs monitor their other transaction awards to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to NIH. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the recipient at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the other transaction award is administratively closed out and NIH is no longer providing active other transaction award support.

8.1 Reporting

NIH requires that recipients periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Recipients also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities.

The AO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and available for all closeout documents (final progress reports, final invention statements and certifications, and final financial status reports).

Recipients are allowed a specified period of time to submit required financial and final progress reports (**within 120 calendar days of the end of SPARC other transaction award support**). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions.

8.2 Progress Reports

Progress reports usually are required annually as part of the non-competing continuation award process and NIH requires use of the RPPR for all other transaction progress reports. NIH may require more frequent updates on research progress in a different format such as slides or oral presentations.

Recipients have an obligation to submit a complete and accurate progress report. NIH program or agreements management staff may require additional information to evaluate the project for continued funding. Failure to provide this information will result in a delayed award. Incomplete or inadequate progress reports may result in a delay of continued support.

The progress report for the final budget period of a competitive segment for which a competing continuation application is submitted will be part of that application; however, if an award is not made or the recipient does not submit an application for continued support, a final progress report is required.

8.3 Submitting Progress Reports

For SPARC other transaction awards, all progress reports are due the 15th of the month preceding the month in which the budget period ends (e.g., if the budget period ends 11/30, the due date is 10/15). If the 15th falls on a weekend or Federal holiday, the due date is automatically extended to the next business day.

The RPRR module in the eRA Commons allows recipients to electronically prepare and submit progress reports and supporting documentation. The RPPR module provides the user with dedicated screens to collect the required progress report information, including appropriate uploads for text documents. Data submitted through RPPR for Performance Sites and Participants is retained in the system to assist the recipient in completion of future progress reports.

The RPRR may be routed to authorizing officials at the applicant institution for review and approval prior to submission to NIH. The RPPR module provides recipients with the option to delegate to the PD/PI the

authority to submit the progress report directly to NIH. This optional authority is managed on a PD/PI basis in the eRA Commons; such authority can be rescinded at any time.

Guidance on RPPR submission is documented in the RPPR Instruction Guide found at: http://grants.nih.gov/grants/rppr/index.htm.

8.4 Final Progress Reports

A final progress report is required for any SPARC other transaction award that is terminated and any award that will not be extended through award of a new competitive segment.

8.5 Financial Reports

For SPARC other transaction awards, there is one type of financial report used. Cash transaction data is submitted on a quarterly basis directly to PMS. Expenditure data which is submitted directly to the NIH will not be required.

8.6 Cash Transaction Reports

The FFR has a dedicated section to report Federal cash receipts and disbursements. For domestic recipients this information is submitted quarterly directly to the PMS using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

8.7 Revised Financial Reports and Expenditures

Revised Expenditure Reports. NIH requires all financial expenditure reports to be submitted using the electronic FSR/FFR system located in eRA Commons. This includes the initial FFR and any FSR/FFR revisions being submitted or resubmitted to NIH. In some cases the recipient may have to revise or amend a previously submitted FSR/FFR. The revised report should be submitted in the same format as the original; e.g., if the original was an FSR, the revision will also be submitted using the FSR format. When the revision results in a balance due to NIH, the recipient must submit a revised report whenever the overcharge is discovered, no matter how long the lapse of time since the original due date of the report. Revised expenditure reports representing additional expenditures by the recipient that were not reported to NIH within the 90-day time frame may be submitted electronically through the eFSR/FFR system to OFM with an explanation for the revision. The explanation also should indicate why the revision is necessary and describe what action is being taken by the recipient to preclude similar situations in the future. This should be done as promptly as possible, but no later than 1 year from the due date of the original report for annual FFRs and no later than 60 calendar days from the due date of

the original report for final FFRs (i.e., 180 days from the project end date). If an adjustment is to be made, the NIH awarding IC will advise the recipient of actions it will take to reflect the adjustment.

8.8 Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the award. Using the principle of "first in-first out," unobligated funds carried over are expected to be used before newly awarded funds.

8.9 Invention Reporting

Each SPARC NoA will identify the funding recipients' obligations to report inventions, which may include filing for appropriate patent protection as well as how to report any inventions made under the NoA. If awards issued under the FOA will adopt the prescriptions and requirements of the Bayh-Dole Act (37 C.F.R. 401.14), all invention reporting requirements are set forth. In addition NIH requires awardees to provide an annual invention utilization report on their efforts to achieve practical application of all inventions. Each annual and final progress report must include a listing of all subject inventions. If the prescriptions and requirements of the Bayh-Dole Act are not adopted in their entirety or at all, each SPARC award will set forth how and when inventions are to be reported to NIH.

A recipient's failure to comply with invention reporting requirements and/or associated NIH policies on intellectual property and resource sharing may result in the loss of patent rights or a withholding of other transaction award funds or other enforcement actions, including the imposition of special terms and conditions.

If the NoA includes invention reporting requirements, and unless stated otherwise, NIH strongly supports electronic reporting through an Internet-based system, Interagency Edison (http://iEdison.gov). The system supports confidential transmission of required information and provides a utility for generating reports and reminders of pending reporting deadlines. Further information about the system, including instructions for creating an account needed to submit reports electronically, are on the iEdison site. Recipients also may contact the Division of Extramural Inventions and Technology Resources Branch, OPERA, OER.

8.10 Financial Conflict of Interest Reports

NIH requires recipients of SPARC other transaction awards and their investigators to comply with requirements consistent with 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." A Final Rule amending the 1995 PHS regulation (and the companion regulation at 45 CFR 94, "Responsible Prospective Contractors," imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf).

When submitting an other transaction application, the signature of the AOR certifies the applicant Institution's compliance with requirements consistent with 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;
3. The Institution shall identify and manage FCOIs 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 an FCOI;
5. The Institution shall fully comply with the requirements of the regulation.

When the Institution determines that an FCOI 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. The initial FCOI report will include the following information:

- Other transaction award number and PD/PI;
- Name of Investigator (if different from the PD/PI) with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests);
- Value of the financial interest $0-4,999; $5,000-9,999; $10,000-19,999; amounts between $20,000-100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000 or a statement that a value cannot be readily determined;
- A description how the financial interest relates to the NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's management plan, including:
    1. Role and principal duties of the conflicted Investigator in the research project;
    2. Conditions of the management plan;
    3. How the management plan is designed to safeguard objectivity in the research project;
    4. Confirmation of the Investigator's agreement to the management plan;
    5. How the management plan will be monitored to ensure Investigator compliance; and
    6. Other information as needed.

For other transaction awards an annual FCOI report is due only when there are changes to the previous report. When changes occur, the FCOI report will include the following information:

- Status of the FCOI

- Changes to the management plan, if applicable

The Institution will incorporate, as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified Financial Conflicts of Interest to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the NIH to meet its reporting obligations.

The Institution will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the regulation.

The Institution will require each Investigator (including subrecipient Investigators, if applicable) to complete training prior to engaging in NIH-supported research and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds an Investigator noncompliant with the Institution's FCOI policy or management plan.

As described in the regulation, examples of how FCOIs might be addressed include but are not limited to, the following:

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- Disclosure of FCOI directly to human subjects research participants;
- Monitoring of research by independent reviewer(s);
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of Significant Financial Interests (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts.

The information above is only a sample of the regulatory requirements found in 42 CFR 50, Subpart F, and applicants and recipients must comply with standards equivalent to these requirements. Applicants and recipients must review the regulation in its entirety to ensure compliance with all of the requirements. Resources applicable to FCOI, including Frequently Asked Questions, etc. can be found on OER's Conflict of Interest Web site at http://grants.nih.gov/grants/policy/coi/.

8.11 Record Retention and Access

For awards under other transactions authority, the 3-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Therefore, recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.

These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.

8.12 Audit

NIH recipients are subject to the audit requirements of OMB 2 CFR 200, Subpart F-Audit Requirements, as implemented by HHS 45 CFR Subpart F. In general, 45 CFR 75, Subpart F-Audit Requirements requires a State government, local government, or non-profit organization (including institutions of higher education) that expends $750,000 or more per year under Federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions in Subpart F.

A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of $750,000 or more in HHS awards. For-profit organizations have two options regarding the type of audit that will satisfy the audit requirements. The recipient either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the “Yellow Book”), GPO stock 020-000-00-265-4, of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one HHS program, or (2) an audit that meets the requirements of 45 CFR 75, Subpart F—Audit Requirements.

For-profit organizations expending less than $750,000 a year are not required to have an annual audit for that year but must make their award-related records available to NIH or other designated officials for review or audit.

9. Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

If a recipient has failed to materially comply with the terms and conditions of award, NIH may take one or more enforcement actions which include disallowing costs, withholding of further awards, or wholly or partly suspending the other transaction award, pending corrective action. NIH may also terminate the award for cause.

NIH generally will suspend (rather than immediately terminate) an other transaction award and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

decision. However, NIH may decide to terminate the award if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate an other transaction award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

An other transaction award also may be terminated, partially or totally, by the recipient. If the recipient decides to terminate a portion of an other transaction award, NIH may determine that the remaining portion of the award will not accomplish the purposes for which the other transaction award was originally awarded. In any such case, NIH will advise the recipient of the possibility of termination of the entire other transaction award and allow the recipient to withdraw its termination request. If the recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire award for cause.

10. Termination

If the NIH decides to terminate an other transaction award, the termination of the award will be considered a unilateral change and the recipient will not have the right to appeal. Although a decision is made to terminate an award, the recipient must continue to comply with the Record Retention and Access requirements contained in Section 8.11.

11. Recovery of Funds

NIH may identify and administratively recover funds paid to a recipient at any time during the life cycle of an other transaction award. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances.

12. Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L.104-134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for HHS in 45 CFR 30. NIH is required to collect debts due to the Federal government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by recipients.

13. Closeout

The requirement for timely closeout is generally a recipient responsibility. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due to the recipient or NIH. Therefore, recipients must submit the last quarterly FFR (FCTR portion), final progress report, and Final Invention Statement and Certification within 120 calendar days of the end of other transaction award support. The reports become overdue the day after the 120 day period ends.