COUNCIL ON GOVERNMENTAL RELATIONS

MANAGING EXTERNALLY FUNDED SPONSORED PROGRAMS:

A GUIDE TO EFFECTIVE MANAGEMENT PRACTICES

UPDATED MARCH 2016

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ABOUT THIS GUIDE

The Council on Governmental Relations (COGR) is an association of 190+ leading research universities and their affiliated academic medical centers and research institutes. One of COGR's important activities is helping to develop policies and practices in research and training that reflect the mutual interest and separate obligations of research institutions and federal and other sponsoring agencies. This guide is illustrative of such activity.

This guide may be used by institutions to help review their management systems and internal controls with regard to managing sponsored programs generally in the form of grants and contracts as distinguished from gifts and other supported activities at the institution. Readers must recognize that while general principles of effective management are stable and consistent and applicable to all externally-supported activities, rules and regulations imposed by external sponsors on grants and contracts obligate the institution to meet specific obligations and affects, among other things, the way the institution accounts for and reports on the use of the funds. The rules and regulations of external sponsors are subject to change requiring a different approach to management. This guide does not purport to set standards for sponsored program management; it only suggests effective management practices and indicators to test those practices.

This document was originally published in April 1989. This is its 7th edition. Each edition updates the information through additions and, as appropriate, deletions to reflect the current effective practices with some related indicators. Sometimes new principles are added as management practices expand in response to changes in research and sponsored programs and new regulations. COGR will periodically update this document via our website at www.cogr.edu. However, at any point in time, this document should be considered in the light of administrative and regulatory changes made subsequent to its latest revision date.

About this Guide (cont'd.)

The guide begins with a discussion of a comprehensive compliance system that sets the framework for all the principles that will follow. The discussion calls directly for an institutional commitment to compliance. A comprehensive compliance system implies looking at compliance as a systemic enterprise rather than discrete practices in response to specific regulations. Thus while compliance will take a different form in meeting financial, administration, or performance requirements, all these activities reflect a commitment to compliance across the organization.

Throughout this document, we use "sponsored research programs" or "sponsored programs" to be inclusive of sponsored project(s), except where the use of "project" is specifically called for by the context.

The Guide is available in paper and web-based formats. The web-based format takes advantage of providing links at the end of each section to the principal regulatory documents and materials. These external links will be checked periodically, and supplementary information and hyperlinks may be added from time to time as it becomes available. If a paper version is preferred, users may either print this document in its entirety or request a Guide from COGR.

COGR appreciates the contribution of all its members in bringing new challenges and strategies for addressing them to the attention of their colleagues across the country.

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Principle I. Institutional Program for Effective Compliance Practices

The institution has a comprehensive strategy in place that is designed to ensure compliance with federal, state and local laws, regulations, policies and principles[1].

Practice A. The institution has written policies, procedures, and practices covering the programmatic conduct of and the administrative and financial management for sponsored programs.

Indicator 1. The institution has a process for the initiation, preparation, review and approval of official institutional policies that ensures all affected parties have an opportunity for review and comment.

Indicator 1a. Periodic reviews are performed to ensure that institutional policies and procedures reflect current management practices of the institution and are sufficient to meet regulatory obligations. The process for revising and/or eliminating policies and procedures is defined.

Indicator 1b. The institution assesses on a regular basis compliance with its policies and procedures.

Indicator 2. The institution disseminates and makes known its policies and procedures at all levels of the institution including senior management, investigators, research personnel, and administrative staffs.

Indicator 3. The institution maintains a written code of business ethics and conduct that is communicated to all employees.

Practice B. The institution assumes overall responsibility for the programmatic, financial and administrative conduct; has clearly established lines of responsibility, i.e., a delineation of the roles and responsibilities, for all sponsored programs and administrative personnel involved in the conduct of and management for sponsored programs; and ensures that personnel understand and accept their specific roles and responsibilities.

Indicator 1. The institution obtains confirmation that the principal investigator understands and accepts their specific responsibilities for financial and administrative management of the proposed project.

Indicator 2. Within an operating unit, roles and responsibilities, along with appropriate internal controls, are clearly defined and understood.

Indicator 3. Where an institution-affiliated non-profit organization, such as a research or intellectual property development foundation, has responsibility for some institutional obligations, there are policies and procedures defining the roles and responsibilities of the institution and the affiliated organization.

Practice C. The institutional leadership is knowledgeable and supportive of an effective compliance program.

Indicator 1. The institution has assigned senior-level personnel with appropriate authority and responsibility for overseeing sponsored programs compliance.

Indicator 2. The institution provides adequate resources to carry out such compliance program-related responsibilities.

Indicator 3. The institution's governing authority is knowledgeable about the content and the operation of the compliance program and exercises reasonable oversight to ensure its implementation and effectiveness.

Indicator 4. The institution reports periodically to the governing authority, or an appropriate subgroup of the governing authority, on the compliance program.

Practice D. An educational process and training program is in place for both externally mandated and institutionally determined compliance requirements.

Indicator 1. The institution has a program of training in compliance for individuals involved in sponsored programs and has identified the specific training content necessary for each type of position.

Indicator 2. The institution has a training program for the responsible conduct of research as required and ensures that individuals for whom such training is mandated receive appropriate training.

Indicator 3. The institution provides required training to individuals in areas involving special research approaches including, but not limited to hazardous materials, radiation safety, select agents and toxins, recombinant DNA, animal use, and human subjects.

Indicator 4. If required by federal contract, the institution ensures employee awareness of and training in its business ethics and code of conduct policies.[2]

Indicator 5. There is a regular process for reviewing and updating training programs as necessary.

Indicator 6. The institution can document completion of required training programs for individuals involved in sponsored programs.

Practice E. The institution has programs to encourage compliance and systems and procedures designed to detect and report non-compliance with federal, state and local regulations including protections for employees who report non-compliance.

Indicator 1. The institution has audit monitoring processes and internal controls to detect compliance failures.

Indicator 2. The institution has a process in place to support the confidential or anonymous reporting of non-compliance, e.g., a hotline.

Indicator 3. The institution complies with the Whistleblower Protection Act and the Whistleblower Protection Enhancement Act.

Indicator 4. The institution describes disciplinary actions that may result from improper conduct or failure to take reasonable steps to prevent, detect, or report improper conduct to the institution.

Practice F. The institution has policies and procedures to address professional misconduct including failure to comply with federal, state and local laws, regulations, and policies, to meet pertinent professional standards, as appropriate.

Indicator 1. The processes and procedures for the identification, review and determination of professional misconduct or non-compliance are clearly delineated in institutional policies.

Indicator 2. Sanctions for failure to comply with institutional policies and procedures are clearly delineated in the appropriate policies.

Practice G. When instances of non-compliance are determined, the institution identifies and implements corrective actions and determines whether additional action is needed to mitigate the reoccurrence of similar problems.

Indicator 1. The institution takes appropriate and timely corrective action to remedy identified failures or deficiencies.

Indicator 2. The institution reviews and modifies as appropriate policies and practices to reduce the reoccurrence of compliance problems.

Indicator 3. The institution notifies the sponsoring or regulatory entity, as required.

Indicator 4. The institution has a process in place for timely disclosure of credible evidence of a violation of federal criminal law, violation of the civil False Claims Act, or a significant overpayment.[3]

Practice H. The institution conducts ongoing risk assessments as an essential component of the design, implementation, and modification of its compliance program.

Indicator 1. The institution is aware of and has implemented adequate internal controls consistent with national standards.[4]

Indicator 2. The institution has a process for monitoring changes in federal, state and local regulations and coordinating changes in the institution's policies and procedures.

Indicator 3. The institution periodically evaluates the effectiveness of its compliance program.

Internet Resources

US Sentencing Commission, Guidelines for Organizations

http://www.ussc.gov/guidelines-manual/organizational-guidelines

Federal Acquisition Regulations
http://www.acquisition.gov/far/

Federal Acquisition Regulations, 48 CFR Part 3.10 Contractor Code of Business Ethics and Conduct
http://www.gpo.gov/fdsys/granule/CFR-2011-title48-vol1/CFR-2011-title48-vol1-part3-subpart3-10

US Government Accountability Office, Standards for Internal Controls in the Federal Government
http://www.gao.gov/assets/670/665712.pdf

Committee of Sponsoring Organizations of the Treadway Commission (COSO)
http://www.coso.org/guidance.htm

Endnotes:

[1] The US Sentencing Commission Guidelines §8B2 describe the requirements for an Effective Compliance and Ethics Program that, if implemented, will mitigate the penalties imposed on an organization convicted and sentenced for a criminal offense. The Federal Acquisition Regulations (FAR) require a Contractor Code of Business Ethics and Conduct (48CFR Part 3.10) for certain contracts. Its requirements echo the US Sentencing Commission Guidelines.

[2] The Federal Acquisition Regulations (FAR) require a Contractor Code of Business Ethics and Conduct (48CFR Part 3.10) for certain contracts.

[3] As required by 48 CR Part 3.10, FAR Clause 52.203-13 & 14

[4] Such standards include "Standards for Internal Control in the Federal Government (GAO 14-704G; September 2014) and the "Internal Controls Integrated Framework (the "Greenbook") 2013" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Principle II. Sponsored Program Management

Principle II-1. Policy Requirements

The institution has clearly defined procedures for the review of sponsored programs management policies and for decision-making on implementation of such policies.

Practice A. Responsibility for reviewing externally imposed policy requirements related to general sponsored programs management is clearly defined.

> **Indicator 1.** The institution assigns responsibility to personnel for review of agency websites, publications, and other policy issuances which affect the conduct of sponsored programs.

Practice B. The institution considers policies, procedures, and practices related to the management of externally funded programs as a whole, i.e., integrated rather than a series of individual, unrelated parts, and prioritizes them as needed.

Practice C. The institution has appropriate policies and processes for defining and distinguishing sponsored programs from gifts and other sponsored activities.

> **Indicator 1.** The policies comply with appropriate federal tax codes, Financial Accounting Standards Board (FASB), Governmental Accounting Standards Board (GASB) and 2 CFR 200 "Uniform Guidance" (hereafter referred to as 2 CFR 200.).

> **Indicator 2.** The responsibility, criteria, and process for making a determination are clearly defined.

Principle II-2. Administrative Requirements

The institution has trained personnel who are knowledgeable about sponsor regulations, policies, and procedures.

Practice A. Roles and responsibilities are clearly delineated for research, administrative, and financial personnel involved in sponsored programs.

> **Indicator 1.** Principal investigators understand and accept their specific management responsibilities for the awards that the institution receives on their behalf and are aware of resources available to assist them in managing sponsored projects.

> **Indicator 2.** Training opportunities are available for all personnel that participate in sponsored programs regarding the administrative, regulatory, and financial requirements of awards (including the appropriate sections of 2 CFR 200 and Federal Acquisition Regulations [FAR]).

> **Indicator 3.** Personnel are cognizant of and exercise their appropriate responsibilities for the stewardship of external funds.

> **Indicator 4.** Procedures maintained at the unit and central levels are reviewed regularly and updated as required.

Practice B. Coordination among institutional offices responsible for various aspects of sponsored programs is evident.

Indicator 1. Timely notification is provided in advance when reports are due and when they are submitted.

Indicator 2. Offices are informed of appropriate policy changes relative to their role.

Indicator 3. A system is in place to coordinate responses and management among offices in an institutional emergency situation.

Practice C. The institution recognizes that personnel from the sponsored programs office and other institutional stakeholders should be involved in policy and procedural decisions affecting externally sponsored research activities.

Indicator 1. The institution has a process for seeking stakeholder input to policy and procedural changes for which the stakeholders have a shared responsibility.

Principle II-3. Pre-award and Proposal Requirements

The institution makes information available to personnel with pre-award responsibilities, including investigators, about prospective sponsors and their requirements, and processes proposals in compliance with institutional and sponsor guidelines and requirements.

Practice A. The institution provides resources for identification of funding opportunities for research and other scholarly activities.

Practice B. Assistance is available by central or departmental or shared services staff to assist investigators in understanding sponsor requirements including budget development, budget justification, determination of subrecipient vs. contractor determinations, and other administrative components of a proposal.

Practice C. The institution assigns personnel to conduct review of proposals prior to submission to the sponsor.

Indicator 1. The institution has written procedures delineating the approvals required for proposals to external sponsors.

Indicator 2. The principal investigator formally accepts responsibility for the content of the proposal and certifies compliance with sponsor and institutional requirements.

Indicator 3. Designated institutional personnel review proposal components prior to submission, including but not limited to budgets, budget justifications , documentation of effort or payroll certification, current and pending support, cost sharing (if applicable) and certify to the accuracy of institutionally-negotiated costs (e.g., fringe benefits, facilities and administrative costs, etc.). **[See also Principle III-3, Institutional Rate Agreements.]**

Indicator 3a. The institution has policies and procedures in place to ensure that proposal budgets prepared, developed or submitted in response to funding opportunities, performance based solicitations or other non-cost reimbursement solicitations account for all costs associated with the proposed projects. These procedures could include processes for the development of service center fees and other non-cost reimbursement based budget items. **[See also Principle III-9, Specialized Service/Recharge Centers.]**

Indicator 4. Designated institutional personnel review proposals for compliance with sponsor guidelines (e.g., required information, page limits), as well as other required reviews (e.g., animal care, human subjects, HIPAA Privacy Act, conflict of interest requirements, export controls, etc.), and call these to the attention of the principal investigator for correction, when necessary. **[See also Principle VI, Integrity & Protection Regulations.]**

Indicator 5. Sponsored programs personnel ensure receipt of completed and authorized proposals from proposed subrecipients prior to their inclusion in a proposal submission to a potential sponsor. [**See also Principle II-6, Subrecipient Monitoring.]**

Indicator 5a. The institution obtains information necessary for the reporting from the subrecipient to the Federal Government in compliance with Federal Funding Accountability & Transparency Act (FFATA) and conformance to 2 CFR 200.

Indicator 6. The institution has the ability to prepare and submit electronic proposals to potential sponsors in accordance with sponsor requirements.

Indicator 7. The institution has established internal timelines for submission to ensure adequate review and institutional endorsement.

Principle II-4. Award Acceptance and Negotiation

The institution has a process to review proposed award terms and conditions and to negotiate those terms in accordance with institutional standards prior to award acceptance.

Practice A. The institution has written procedures for review of award documents prior to acceptance.

Indicator 1. Award budgets are compared to proposal budgets. Revised scopes of work are submitted when awards have been significantly reduced from original requested amounts.

Indicator 2. The institution restricts funding as appropriate until compliance requirements are satisfied (e.g., human subjects protocol approvals, animal use protocol approvals, conflicts of interest management plans, etc.).

Practice B. The institution has staff trained to review and negotiate agreement terms and conditions.

Indicator 1. Institutional staff is cognizant of institutional and sponsoring agency policies and practices including but not limited to ownership of intellectual property rights, publication restrictions, data ownership, acceptance of classified material, indemnification, warranties, insurance, confidentiality, sponsor viability, etc.

Indicator 2. Staff is authorized to negotiate changes in award terms and conditions.

Indicator 2a. Institution has a process to document business decisions when non-standard terms and conditions are accepted in an award.

Indicator 3. Sponsored programs staff has access to legal assistance, either institutional or external counsel, when required during complex negotiations.

Indicator 4. Investigators and other concerned individuals are consulted and kept informed during the negotiation process.

Practice C. The institution has procedures for the review and negotiation of non-financial agreements such as teaming agreements, memoranda of understanding (MOUs) confidentiality/non-disclosure agreements(NDA), material transfer agreements (MTA) and Data Use Agreements (DUA) that comply with all applicable laws and regulations and meet all institutional policies and practices.

Indicator 1. The institution has a process to identify other related project funding sources and research relationships (i) to avoid creating conflicting obligations including as appropriate the rights of the Federal Government to any inventions and copyrighted materials; (ii) to ensure institutional compliance with prior award obligations to share or disseminate research resources; and (iii) to ensure compliance with the terms of an MTA, NDA or DUA by its users.

Indicator 2. The institution takes advantage, when appropriate, of standard agreements, e.g., the Uniform Biological Material Transfer Agreement. **[See also Principle VII, Intellectual Property Management.]**

Indicator 3. The institution has a process to determine and comply with necessary permits and/ or licensing requirements for the transfer of materials including importing and exporting materials including plants, animals, chemicals and/or biohazards.

Indicator 4. The institution has a process to determine and comply with export control regulations as related to the transfer of materials included deemed exports within the US. **[See also Principle VIII. Export Controls, Embargos, Trade Sanctions, and Executive Orders]**

Indicator 5. The institution has processes to review confidentiality or non-disclosure agreements. The process begins when sponsored programs office is notified, or other assigned area of the institution, of a requirement for a confidential or non-disclosure agreement. The process includes steps for obtaining appropriate institutional approvals.

Indicator 5a. The institution has sample language available to incorporate into confidential and non-disclosure agreements assuring compliance with related institutional policies and the obligations of the investigators.

Indicator 5b. The institution has training materials to make investigators and research staff aware of their obligations to these types of agreements.

Practice D. The institution has procedures in place to determine the applicability of IRS revenue procedures 1997-14 (and 2007-47 clarification) to facilities financed with tax exempt bonds. Institutions with research programs utilizing space within a tax exempt financed facility have measures in place to determine if the proposed use is consistent with the tax exempt nature of the bonds. Any use of a tax exempt bonded facility that is not consistent with its tax exempt nature could be considered a private business use.[1]

Indicator 1. For an industry sponsored program proposing to use tax exempt bonded facilities, the institution has processes and procedures for the review of the proposed use and the tax implications before signing an agreement.

Indicator 2. The institution has a method to track the use and value of private business sponsored use of tax exempt bonded space as necessary.

Principle II-5. Sponsored Program Management

The institution has a system to manage externally funded programs in accordance with the requirements of each sponsor.

Practice A. The institution has written procedures and standards for financial and programmatic management systems.

> **Indicator 1**. The principal investigator understands and accepts their specific responsibilities for the financial management of the program and is aware of resources available to assist them in carrying out their sponsored activities.

Practice B. The institution has a process for seeking prior approvals from sponsors, where required, and has developed procedures to implement any waivers to prior approvals implemented by the sponsoring federal agency and as provided for in 2 CFR 200.308.

> **Indicator 1.** The institution has procedures for obtaining prior approvals from sponsors, when required, and maintaining records of approvals granted.

> **Indicator 2**. The institution has procedures to document any waived prior approvals by the sponsoring federal agency and in accordance with 2 CFR 200.308. (e.g., pre-award costs, no-cost extensions).

Practice C. The institution has developed procedures to establish awards in its accounting system in a timely manner, including receipt of electronic awards. **[See also Principle III, Financial Administration.]**

> **Indicator 1.** Terms and conditions of awards are distributed to principal investigators and made available to other institutional personnel, as required, and resources available to assist in managing sponsored projects are identified.

Practice D. The institution has procedures regarding notification of upcoming termination dates for sponsored programs to principal investigators and appropriate offices.

> **Indicator 1.** Sponsored programs staff are assigned to review awards 90-60-30 days before the award period ends to ensure deliverables/reports, subrecipient deliverables/reports are progressing in accordance with the award requirements.

Principle II-6. Subrecipient Monitoring

The institution has policies and procedures for issuing subrecipient agreements and for monitoring the performance of subrecipients.

Practice A. The institution has policies and procedures for assigning roles and responsibilities for issuing and monitoring subrecipient agreements.

> **Indicator 1.** Adequate documentation for the selection (and approval, if necessary), of the subrecipient, is prepared and maintained. Adequate documentation is available to document the basis for subrecipient vs. contractor determination in accordance with agency requirements and 2 CFR 200.330, Subrecipient and Contractor Determinations.

Practice B. Policies and procedures are in place to determine whether subrecipients have established adequate management and financial systems prior to establishing subrecipient agreements. The procedures include a method for resolving subrecipient weaknesses in internal controls and noncompliance.

Practice C. The institution has procedures to ensure that its intended subrecipients have met the applicable federal audit requirements, exhibit no material weaknesses or material noncompliance with federal regulations, and are not subject to federal suspension or debarment or otherwise excluded from receipt of federal funds.

> **Indicator 1**. The institution has mechanisms in place to conduct a risk assessment for its subrecipients to determine the level and type of on-going monitoring required based on the level of risk assigned by the institution.
>
> **Indicator 2.** The institution has mechanisms in place to ensure compliance with any restrictions on transactions with foreign individuals or entities as required by federal law, e.g., Executive Order 13224 of September 23, 2001, Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism.

Practice D. Written agreements with subrecipients are prepared and executed by both parties. The agreements specify the appropriate required elements indicated in 2 CFR 200.331, Requirements for Pass-Through Entities, terms and conditions, including required flow-down clauses, and utilize standard agreements[2] as appropriate.

Practice E. The institution has guidance necessary to adequately train sponsored project personnel on the issuance and monitoring of international subrecipient agreements.

Practice F. The institution ensures reporting of the subaward to the Federal Government in the manner designated by the awarding agency.[3]

Practice G. Compliance with all financial and administrative requirements and performance reporting requirements by the subrecipient is monitored.

> **Indicator 1**. Mechanisms are in place to ensure any non-standard subrecipient requirements are communicated to appropriate individuals and committees within the institution, including but not limited to the institutional human subjects and animal use committees and, if appropriate, a conflicts of interest committee to ensure appropriate reviews and approvals have been received and required reporting to the sponsoring agency is completed.
>
> **Indicator 2.** Mechanisms are in place to ensure appropriate assurances, training requirements, compliance plans, etc., are collected and monitored, if necessary, in accordance with federal, state, and local requirements.

Practice H. The institution has procedures to ensure that prior to final payment and closeout, certification is received from the institution's principal investigator or project director and that all financial & performance requirements/reports from the subrecipient(s), have been completed and received.

Practice I. The institution has procedures to ensure that prior to final payment and closeout, the institution receives all final financial, property, patent, and other sponsor-required reports from the subrecipient, and verifies for accuracy.

Principle II-7. Reports, Records, and Management of Technical Data

The institution has policies and procedures in place to ensure adequate reporting of performance of sponsored programs as well as for the management of records and other technical data.

Practice A. The institution has policies and procedures regarding responsibility for, preparation of, and procedures for submission of required reports and other deliverables.

Indicator 1. There is consideration of the sponsor's requirements for acknowledgment of support and access to publications resulting from the sponsored programs.

Indicator 2. The investigator(s) complies with sponsor requirements regarding public access to the results of research, as appropriate. See OSTP's Policy on Public Access.

Indicator 3. Reports and deliverables are submitted in a timely fashion in the format required by the sponsor.

Indicator 4. At the time of account closeout, procedures are in place to confirm that the performance reports and other deliverables have been submitted and receipt acknowledged by the sponsor.

Indicator 5. Institution has systems that are sufficiently flexible to allow for electronic reporting of performance, financial and administrative data as required by the sponsor. These systems are easily modified and/or linked to other institutional databases to allow for the addition of new information and/or the retrieval of institutional information to respond to unique sponsor reporting requirements.

Practice B. The institution has policies and procedures regarding retention of and access to financial and administrative records including compliance records, e.g., human subjects protocols, financial conflicts of interest disclosures, etc., generated under sponsored programs.

Indicator 1. Retention requirements for financial and administrative records are in accordance with the requirements of 2 CFR 200 the Federal Acquisition Regulations (FAR), and sponsor policies and are clearly communicated within the institution.

Indicator 2. Responsibilities are assigned for retention, retrieval, and disposal of all records.

Indicator 3. There are written policies with respect to record retention schedules that adhere to sponsors and institutional requirements.

Indicator 4. Data imaging or other forms of electronic storage meet the appropriate federal standards.

Indicator 4a. Policies and procedures are in place for the retention, retrieval, and disposition of electronically maintained records.

Indicator 5. Internal controls are in place to ensure only authorized personnel can retrieve records, and records are contained in a secure and confidential manner.

Indicator 6. Procedures are in place for the secure retention, retrieval, and/or disposition of records containing information of a proprietary, confidential, or highly sensitive nature.

Practice C. The institution has policies regarding the retention of research records (e.g. samples, data, specimens, lab notebooks, etc.) derived from sponsored programs.

Indicator 1. There is a written requirement for retention and ownership of research records pertaining to all sponsored projects.

Indicator 2. Allowance is made in the written requirement for the maintenance of research records by the project personnel subject to compliance with the institutional policy.

Indicator 3. Allowance is made in the written requirement for maintenance of research records when there is relocation of project personnel to allow for continued access by the original institution's personnel.

Indicator 4. Procedures exist for the disposal of research records and materials, when appropriate, particularly when those items such as specimens and other samples are (or may become) toxic or hazardous when retained for long periods of time.

Practice D. The institution clearly communicates the policies and procedures for the ownership and management of research data to principal investigators, key personnel, post-doctoral fellows, students and others involved in the research process.

Indicator 1. Special processes are in place for the retention of data related to human subjects, biohazards, and other specialized regulatory requirements.

Indicator 2. Ownership of patient (human or animal) medical records remains with the institution.

Indicator 3. The institution has a policy that ensures investigators or other responsible staff members retain consent forms in accordance with applicable requirements.

Indicator 4. Access to medical and other personal records is strictly safeguarded pursuant to the parameters of the Institutional Review Board (IRB) approved protocol, the consent forms, and the HIPAA requirements.

Indicator 5. The institution has processes in place to ensure compliance with sponsor's rights in technical data provisions.

Indicator 6. The institution has policies and procedures in place to ensure adequate security and protection of third-party data subject to security and/or access restrictions.

Practice E. The institution has policies for responding to Freedom of Information Act (FOIA) and other open record requests.

Indicator 1. These policies and the name of an institutional official designated to respond to such requests have been communicated to researchers.

Indicator 2. The institution has a policy and process for compiling the cost of providing data requested under FOIA and other open record requests for securing approval and, subsequently, reimbursement for such costs, where allowable.

Principle II – 8. International Transactions

The institution has a process for structuring and pursuing international sponsored programs and relationships with foreign entities that brings the full range of required expertise to the undertaking and ensures that the sponsored programs and other activities can occur without the institution assuming unidentified and unreasonable financial burdens, and operational, legal, and reputational risks.

Practice A. The institutions' negotiators collaborate and draw upon specialized expertise to address a broad range of objectives and concerns.

Indicator 1. The sponsored program agreement specifies which nation's laws govern the agreement and asserts that, in any event, the institution is subject to US laws, regulations and requirements governing export controls and embargos and any activities undertaken in the United States.

Indicator 2. The institution identifies and complies with human subject research and institutional review board requirements of both US and foreign jurisdictions and cultural differences in informed consents and other requirements are addressed. Sponsored program agreements set out a process for compliance. In the case of biological materials, the agreement addresses compliance with international conventions as well as host country requirements.

Indicator 3. The sponsored program agreement reflects consideration of a formal collaboration or, in some cases, a new corporation rather than an actual or de facto legal partnership with a foreign institution to ensure that the US institution does not assume liability for the foreign institution or vice versa. New corporations, including foundations, are sometimes created to assemble and manage financial and other resources. Parties need to understand the source of such resources.

Indicator 4. The sponsored program agreement specifies the means, location, and jurisdiction for dispute resolution to ensure that a neutral and principled authority controls.

Indicator 5. The sponsored program agreement establishes English as the controlling language in the agreement and in any legal or administrative process relating to the sponsored programs or the agreement.

Indicator 6. The sponsored program agreement provides for payments of sponsored program costs to be made to the institution in or equated with US dollars. It may establish an up-front payment and a limitation on obligations based on adequacy of funding to guard against exchange rate fluctuations. In cases where the institute must accept foreign currency, the agreement should specify that the institute can adjust the scope of work where currency fluctuations cause the total funding amount to be reduced by 5%.

Indicator 7. The sponsored program agreement adequately addresses any visa or other clearances that need to be obtained from a foreign authority in order to undertake work in the foreign locale and how such costs are covered.

Indicator 8. Experts identify and appropriately address legal requirements that affect the sponsored programs including but not limited to US policies concerning human trafficking, prostitution, boycotts, and financing of terrorist organizations or individuals.

Indicator 9. Appropriate exit strategies are described in the agreement and other documents to facilitate the most politically acceptable termination of the undertaking when necessary.

Indicator 10. The institution ensures that the U.S. government enjoys "most favored nation" status in sponsored program agreement terms relating to recovery of facilities and administration costs regarding the awards and administration of the sponsored programs.

Practice B. Regardless of legal provisions, the potential of political influences (manifest in changes of government leadership or laws, interpretations of existing law by foreign authorities, or volatility of the

political and economic systems) are taken into account in identifying and managing risks to the sponsored program, and tax and other risks to the US institution.

> **Indicator 1.** Institution attempts to build broad relationships with a sponsor, not just an advocate for the project; Institution reports regularly to senior country officials on progress to date, seeks opportunities to address various government officials and other stakeholders; Institution seeks to build relationships with local universities in the area to help broaden the reach of the project.

Practice C. Prior to the travel, export or other activity occurring, heightened analysis is undertaken of the export controls and embargos issues related to (a) any export to or installation in a foreign locale of US origin equipment, software, computers, items, or materials, or related technical data/technology, (b) any teaching, lecturing, conducting of surveys, or any other advisory or non-public information conveyance activities in a foreign locale or involving foreign nationals, with any required licenses obtained, other requirements met, or prerequisites to exemptions or exclusions from controls satisfied.

> **Indicator 1.** US Treasury, Office of Foreign Assets Control (OFAC) lists are consulted to ensure that the transaction is not prohibited under Executive Orders or other regulations, taking into account both the entity and the individual participants.

Practice D. The institution establishes policies and processes related to the relationships of the institution, faculty, staff and students with foreign non-governmental organizations (NGO).

> **Indicator 1.** Whether the relationship involves a financial transaction or not, agreements with NGO should address the use of the institution's name, audits of NGO records and reporting of NGO activities.

Principle II-9. Electronic Research Administration

The institution has appropriate procedures and resources in place to access and utilize the electronic proposal, award, administrative, and financial management systems of the Federal Government or other sponsors.

Practice A. Electronic research administration is fully integrated into the institution's overall sponsored program administration processes.

> **Indicator 1**. Individuals have responsibility to periodically review the information provided through electronic government initiatives and incorporate that information into institutional planning and systems.

> **Indicator 2.** Individuals within Sponsored Programs are assigned to review annually stored electronic certifications and representations (e.g., System for Award Management (SAM) data) to ensure accuracy.

Practice B. The institution stays current with respect to the electronic research initiatives of sponsors.

> **Indicator 1.** Individuals are assigned responsibility for implementing mandatory electronic initiatives of sponsors, primarily the Federal government.

> **Indicator 2.** Principal investigators are made aware of the initiatives of sponsors so they can prepare proposals, reports, and other documentation in electronic formats, as required.

Indicator 3. Institution's record retention policies and procedures are made in accordance with 2 CFR 200.333-337 Record Retention and Access.

Practice C. The institution utilizes electronic systems available from federal agencies for proposal development and submission, award management and reporting (both fiscal and performance), and compliance.

Indicator 1. The institution has identified the personnel charged with institutional management of various systems utilized by federal agencies as they are implemented.

Indicator 2. The institution provides institutional training and guidance to principal investigators when sponsors require proposals to be submitted directly by the investigators and has processes to ensure institutional review of these proposals before their submission.

Practice D. The institution has clearly defined custodians for data and has established access controls to those data to ensure data integrity and retention.

Indicator 1. The institution has processes to collect and appropriately store data, at the inception of the project, and share the data across the enterprise, as appropriate.

Indicator 2. The institution has policies to assign responsibility for access to and modification of data within the system of record.

Indicator 3. Personnel responsible for Electronic Research Administration systems routinely back up all Electronic Research Administration related databases and other electronic files in accordance with generally acceptable backup procedures.

Internet Resources

US Office of Management and Budget (OMB) 2 CFR 200: Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards https://federalregister.gov/a/2013-30465

US Code of Federal Regulations (CFR)
http://www.ecfr.gov/cgi-bin/ECFR?page=browse

Federal Acquisition Regulations (including Cost Accounting Standards as Appendix)
https://www.acquisition.gov/?q=browsefar

Federal Electronic Grants.gov Portal
www.grants.gov

www.research.gov

www.USASpending.gov

System for Award Management
https://www.sam.gov/portal/SAM/##11

National Science Foundation (NSF) Electronic Research Administration (Fastlane)
https://www.fastlane.nsf.gov/fastlane.jsp

National Institutes of Health (NIH) Electronic Research Administration (eRA Commons)

https://commons.era.nih.gov/commons/ http://www.ott.nih.gov/forms-model-agreements

National Institutes of Health (NIH) Forms & Model Agreements
http://www.ott.nih.gov/forms-model-agreements

US Department of Treasury, Office of Foreign Assets Control
http://www.treas.gov/offices/enforcement/ofac/

US Department of State, Bureau of Consular Affairs (VISA)
http://travel.state.gov/index.html

US Department of Homeland Security,
US Immigration and Customs Enforcement (ICE)
http://www.ice.gov/

National Institutes of Health (NIH) Grants Policy Statement
http://grants.nih.gov/grants/policy/policy.htm

Endnotes:

[1] "Private business use" is defined by the IRS as "direct or indirect use in a trade or business carried on by any person other than a governmental unit." In this context, it often refers to the use of tax-exempt bonded facilities by a for-profit business through a sponsored project. See the Internal Revenue Service, Revenue Procedure 2007-47 (June 26, 2007).

[2] The Federal Demonstration Partnership (FDP) offers a model Subrecipient Agreement. Samples are available at: http://sites.nationalacademies.org/PGA/fdp/PGA_063626

[3] The data elements and reporting requirements of the Federal Funding Accountability and Transparency Act of 2006 (FFATA) include reporting of all subawards (grants & contracts) of $25,000 or more to a federal-wide database, currently available at www.USASpending.gov

Principle III. Financial Administration

The institution's cost estimating, accumulating, and reporting as well as its budget administration systems are designed in accordance with generally accepted accounting principles. Appropriate internal controls must be in place to monitor performance against institutional standards; the applicable costing provisions of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR 200); OMB Circulars (as they remain applicable to selected awards); the Federal Acquisition Regulations; agency-specific regulations; and the financial and technical terms and conditions of the specific award. The institution is responsible for the efficient and effective administration of federal awards through the application of sound management practices and in a manner consistent with underlying agreements and program objectives.

Principle III-1. Financial Accounting and Reporting

The institution has an established financial management system that complies with generally accepted accounting principles, federal and state regulations, and institutional policies.

Practice A. The institution has published policies and procedures for its financial management.

Indicator 1. The institution has published roles and responsibilities for financial management. Personnel involved in the administration of sponsored programs are knowledgeable about and follow the institution's policies and procedures.

Indicator 2. The institution has published guidelines on standards of business conduct regarding the stewardship of external sponsor and university resources and provides training on financial policies and procedures.

Indicator 3. Advice and assistance on the financial management policies and procedures of the institution are available to the institution's investigators and staff.

Indicator 4. Policies and procedures are reviewed and updated periodically for appropriateness and applicability.

Practice B. The institution has an accounting system for the identification and control of all sponsored programs.

Indicator 1. Claims for reimbursement are made in a timely fashion.

Indicator 2. Financial reports are accurate and submitted in a timely fashion.

Indicator 3. General ledgers, source documentation and other required accounting records for recording research fund activity are maintained and retained pursuant to record retention requirements and established policies and procedures and available to persons responsible for financial oversight of sponsored programs. **[See also, Principle II-5, Sponsored Program Management.]**

Indicator 4. Appropriate payroll and personnel reporting systems are in place**. [See also Principle III-6, Compensation]**

Indicator 5. There is a system to record and document both mandatory and voluntary committed cost sharing on awards, if applicable. **[See also Principle III-7, Cost Sharing]**

Indicator 6. There is an adequate system of internal controls, as well as procedures for timely changes to policies, dissemination of policy changes, and staff training.

Practice C. The institution can manage required financial and other post award matters electronically, in compliance with Federal government requirements.

Principle III-2. Cost Accounting Standards and Disclosure Statement (DS-2)

The institution has systems to ensure compliance with the cost accounting standards (CAS) and DS-2 requirements mandated by the Federal government at 2 CFR 200.419, and has a system to update cost accounting practices, as appropriate.

Practice A. The institution has established policies and practices that ensure compliance with the mandated cost accounting standards (48 CFR 9905. 501, 502, 505, 506). Institutions that receive aggregate Federal awards totaling $50 million and more must comply.

Indicator 1. The institution has practices in place to ensure that there is consistency among the proposing of costs, the accumulation of costs, and the reporting of costs to the sponsor.

Indicator 2. The institution has appropriate review procedures to ensure that like costs are treated in a like manner in like circumstances, and that like costs are not treated both as direct and as indirect costs in like circumstances.

Indicator 3. The institution has practices in place to identify unallowable costs and exclude them from any billing, claim, or proposal (including the F&A rate proposal) applicable to a sponsored agreement.

Indicator 4. The institution's CAS period conforms to its institutional fiscal year.

Practice B. The institution has established policies and practices that ensure compliance with the DS-2 requirement. Institutions that receive aggregate Federal awards totaling $50 million and more must comply.

Indicator 1. When required, the institution has filed with the cognizant agency for indirect cost the required disclosure statement (the DS-2) of cost accounting practices. When not required to be filed per 2 CFR 200, still maintain an up-to-date, internal version of the DS-2, as required under 2 CFR 200.

Indicator 2. Institutional officials have provided adequate and appropriate training to ensure that affected units are adhering to the standards described in the DS-2.

Indicator 3. The institution has designated clear responsibility for maintaining the DS-2 and for completion of necessary revisions to the institution's DS-2 when required.

Principle III-3. Institutional Rate Agreements

The institution has in place systems, policies and procedures which enable it to correctly prepare and submit required indirect[1] cost rate proposals and, when appropriate, fringe benefit rate proposals.

Practice A. The institution's indirect cost rate proposal is based on applicable federal regulations contained in 2 CFR 200 Subpart E Appendix III. .

Indicator 1. The institution provides timely and properly prepared proposals for the negotiation and settlement of indirect cost rates with the cognizant federal cost agency.

Indicator 2. The institution has a process in place to identify for inclusion only allowable costs in the indirect cost pools.

Indicator 3. Costs unallowable by federal cost principles are separately identifiable in the accounting records of the institution and segregated in the direct and indirect cost calculations.

Indicator 4. The accuracy of all indirect cost calculations is reviewed at the appropriate levels of the institution.

Indicator 5. The institution has issued guidance on the application of indirect rates to be consistent with the terms of the negotiated rates agreement.

Practice B. If required, fringe benefit rate proposals are properly prepared and submitted in a timely manner to the cognizant federal agency for cost.

Indicator 1. The institution has published policies regarding the composition and allocation of negotiated fringe benefit rates.

Indicator 2. The negotiated fringe benefit rate is applied to proposed salaries and wages in the proposal budget consistent with the terms of the rate agreement.

Indicator 3. The negotiated fringe benefit rate is applied to all salary and wage expenses consistent with the terms of the negotiated rate agreement.

Indicator 4. Federal pools in the fringe benefit rate are reviewed to ensure they do not contain unallowable costs (e.g., dependent tuition expenses).

Principle III-4. Proposal Costing

The institution has a proposal cost estimating and budget administration process. Costs are included in proposal budgets and charged to awards consistent with the institution's financial practices. [See also Principle II-3, Pre-Award and Proposal Requirements]

Practice A. The institution has policies and procedures for proposal costing and budget administration that are disseminated and made known to the appropriate individuals within the institution.

Indicator 1. The institution has a process for periodic review of its policies and procedures for proposal costing and budget administration to ensure they are in conformance with sponsor guidelines and the financial policies, procedures, and current practices of the institution.

Practice B. The institution prepares and submits proposals based upon consistently applied direct and F&A financial practices which are reviewed and updated as appropriate. The institution has the ability to align proposal budgets with its accounting and financial reporting systems.

Indicator 1. Proposals are reviewed by an official(s) who is empowered to approve submission. The official verifies that appropriate costs have been determined and included.

Indicator 2. The institution has processes in place to monitor financial commitments made in proposal narratives to ensure the commitments are consistent with the institution's intent and ability to meet the obligation.

Indicator 3. Budgets for subrecipients are reviewed prior to proposal submission for verification based on receipt of adequate documentation including any mandatory or voluntary committed cost sharing, F&A rates, and potential program income. **[See also Principle II-6, Subrecipient Monitoring.]**

Indicator 4. Exceptions to the use of standard cost and fringe rates and other conventions for estimating costs are made only upon proper justification that is reviewed and approved by an institutional official empowered to approve such exceptions.

Indicator 5. Budget justifications are prepared and reflect the institution's financial practices in areas such as personnel salary, travel costs, equipment, materials and supplies, participant costs, subawards, mandatory and voluntary committed cost sharing, and appropriately applied escalation factors.

Indicator 6. The institution reviews proposal budgets to verify that budget categories and specific costs proposed are consistent with the institution's ability to account for and report such costs, including cost-sharing commitments and program income **[See also Principle III-7, Cost Sharing; and Principle III-8., Cash Management]** and that the proposed budget costs are allowable, allocable, and reasonable in accordance with federal regulations, if applicable.

Principle III-5. Allowable Costs

The institution has in place a financial control system that limits costs charged to accounts funded by a sponsor to costs allowable by that sponsor, in amounts that are properly allocable, and reasonable.

Practice A. The institution has published policies and procedures defining allowability of costs that are consistent with federal cost principles or applicable standards of other sponsors.

Indicator 1. Sponsored program accounts are easily and uniquely identifiable.

Indicator 2. Where there are multiple standards of allowability of costs the applicable standard is identified.

Indicator 3. The accounting policies include a centrally maintained list of costs that are expressly unallowable under federal cost principles or by the funding agency (whether federal or non-federal). When non-federal sponsors allow greater latitude in direct charging practices, the institution has processes in place to manage and monitor these differences.

Indicator 4. Costs normally allocable as indirect costs are accounted for in a way that ensures that similar costs in like circumstances are not budgeted or charged as direct costs to sponsored agreements absent a documented and approved exception and, if required, prior written approval of the sponsor.

Indicator 5. The accounting procedures include policies to ensure that cost sharing expenditures are allowable in accordance with federal cost principles (2 CFR 200.306) and sponsor guidelines.

Indicator 6. The accounting procedures include processes for identifying and recording program income and utilizing it in accordance with federal cost principles (2 CFR 200.307) and sponsor requirements.

Practice B. Persons responsible for the initiation of direct charges to programs and persons responsible for the approval and payment of those charges are knowledgeable of and follow the policies regarding allowability of costs and differentiation of types of costs into direct or indirect cost categories.

Indicator 1. A source of expertise is readily available to judge questions of allowability.

Indicator 2. The institution has a proactive program of investigator and staff training on its costing policies, including allowability, allocability, consistency, reasonableness and verifiability or auditability.

Indicator 3. The institution has a procedure to formally document a delegation of authority for direct charging costs that are allowable, allocable and reasonable.

Indicator 4. The institution has policies and procedures for allocating allowable direct costs across multiple benefitting awards in an appropriate manner.

Practice C. Cost transfers are made only with adequate, documented justification and in a reasonable period of time.[2]

Indicator 1. The institution has appropriate institutional systems and processes to implement the allocation, documentation, and allowability standards of 2 CFR 200, Subpart E including appropriate review and approval, and specific agency guidelines as they relate to cost transfers.

Indicator 2. Transfers of costs which represent corrections of all errors are made promptly in accordance with institutional policies.

Indicator 3. Documentation is retained by the awardee for the period stipulated by the funding source and the institution's record retention regulations and available for verification during the course of an audit or other review.

Principle III-6. Compensation

The institution has compensation and documentation policies that are consistently applied to all employees and a system for documenting compensation, including supplemental payments, into the financial management system of the institution. These systems must comply with federal requirements at 2 CFR 200.430.[3]

Practice A. The institution has policies and procedures in place to ensure that compensation costs are consistently applied in proposing, accumulating, and reporting these costs to external sponsors or within the institution.

Indicator 1. The institution has written compensation policies that include guidelines for salary increases, overload pay, and extra compensation.

Indicator 2. Institutional Base Salary is defined in the institution's policies and procedures and is applied to sponsored programs in accordance with federal and/or other sponsor requirements.

Indicator 2a. Compensation from outside entities such as clinical practice plans, the Department of Veterans Affairs, or other organization are treated in accordance with federal guidelines and institutional requirements.

Indicator 3. Salary for investigators, charged to or cost shared on sponsored programs reflects the distribution of the employee's salary or wages among specific activities or cost objectives. Special attention is made to federal awards where specific requirements are established for the proportion of the individual's activities that are"protected" for research (e.g., NIH career awards).

Indicator 4. The institution maintains a payroll distribution system capable of verifying the Institutional Base Salary and apportioning an employee's compensation to more than one sponsored agreement or other cost objectives or functional activities and the IBS is verifiable.

Indicator 5. The distribution of salaries and wages, whether as direct costs or indirect costs, is based on a reasonable estimate of the employee's total activity and the costs are captured in the institution's official payroll distribution system.

Indicator 6. The institution's payroll distribution system provides for modification of an individual's compensation or compensation distribution commensurate with a significant change in the individual's workload distribution.

Indicator 7. The institution has written procedures for the treatment and reporting of tuition remission and other forms of compensation paid as, or in lieu of, wages to students performing necessary work on sponsored agreements.

Practice B. The institution has in place a process to confirm that the salaries and wages charged to each sponsored agreement as well as other work allocable as F&A cost activities as stated at 2 CFR 200 are reasonable in relation to the actual work performed.

Indicator 1. The distribution of salaries and wages paid is supported by a system of internal controls which provides reasonable assurance that the charges are accurate, allowable, and properly allocated. Internal controls include processes to review after the fact interim charges made to federal awards based on budget estimates.

Indicator 2. The payroll records reasonably reflect the total activity for which the employee is compensated by the institution.

Indicator 3. Significant changes in the corresponding work activity must be identified in a timely manner and entered into the payroll distribution system to reallocate payroll costs.

Indicator 4. Changes in the committed level of effort that require sponsor approval, as specified at 2 CFR 200.308, are identified and action is taken to ensure compliance with sponsor requirements.

Indicator 5. The salary and wage documents/data are retained in accordance with the record retention guidelines at 2 CFR 200.333.

Indicator 6. The documentation of salaries charged to federal awards must be in compliance with the Standards for Documentation of Personnel Expenses as specified in 2 CFR 200.430(i).

Practice C. The institution has policies and procedures in place to ensure compliance with sponsor-imposed salary caps.

Indicator 1. The proportional share of payroll costs in excess of applicable caps is charged to institutional funds.

Indicator 2. Costs in excess of applicable caps are accounted for in accordance with federal, sponsor and institutional policy.

Practice D. The institution has policies and procedures governing fringe benefits and the method used to account for these costs.

Indicator 1. Fringe benefit costs are treated consistently and distributed to all institutional activities in the same manner that payroll charges are allocated.

Indicator 2. The institution includes only allowable fringe benefits in charges to sponsored agreements.

Principle III-7. Cost Sharing

The institution has policies and procedures for properly monitoring and documenting cost sharing in the same manner as costs funded by the sponsor. These policies and procedures comply with federal requirements at 2 CFR 200.306.

Practice A. The institution has written policies and procedures for cost sharing that are consistently applied in proposing, accumulating, and reporting costs to both external sponsors and within the institution.

Indicator 1. The institution should be aware of voluntary committed cost sharing expectations, as defined in 2 CFR 200: 2 CFR 200.306(a) specifies that voluntary committed cost sharing is not expected and 2 CFR 200 Appendix I states if an applicant's proposed cost sharing will be considered in the review process (as opposed to being an eligibility criterion), the announcement must specifically address how it will be considered.

Indicator 2. Cost sharing included in proposal budgets, accepted by the sponsoring agency, and made a condition of the award is appropriately treated as an obligation of the institution.

Indicator 3. The providing of investigator and staff effort as well as non-labor costs of the institution included as cost sharing obligations are appropriately recorded in the institution's accounting records.

Indicator 4. Cost sharing expenditures meet the standards of allowability, allocability, consistent treatment and reasonableness consistent with federal cost principles and requirements of non-federal sponsors.

Indicator 5. Contributions and/or third party in-kind cost sharing of services and/or property are valued consistent with the requirements at 2 CFR 200.306 (d) – (j) and documentation of the contribution, including the basis for the value determination is maintained.

Indicator 6. Institutional systems provide for appropriate monitoring of cost sharing for timeliness and adequacy of expenditure or in-kind valuation documentation.

Indicator 7. The institution reports required cost sharing in accordance with the terms and conditions of awards.

Practice B. Where cost sharing is a requirement of subawards, such commitment is included in subaward documents, monitored and appropriately reported to the pass-thru entity and sponsor.

> **Indicator 1**. Institutional policies and procedures clearly identify who is responsible for monitoring subrecipient compliance with cost sharing requirements.

Practice C. The institution's cost sharing, including investigator and staff effort and non-labor cost sharing, dedicated to organized sponsored programs is appropriately classified for the calculation of an institution's F&A cost rate.

> **Indicator 1.** Cost sharing is included in the appropriate base (e.g. reclassified to organized research if for research activity) for indirect cost calculation purposes.

> **Indicator 2.** Consistent with the OMB January 2001 clarification memo, federally-funded research, including any no-cost time extension periods, should reflect some level of committed senior investigator effort whether or not supported by the federal sponsor, except where the particular research program does not require committed investigator effort. If no effort is captured in the institution's financial systems and there is no exception, an estimated amount is computed by the university and included in the organized research base.

Principle III-8. Cash Management

The institution has a cash management system that complies with generally accepted accounting principles, federal and, if necessary, state regulations. The system provides adequate control and necessary flexibility to make timely deposits and disbursements.

Practice A. The institution has cash management policies and procedures to receive and deposit all monies on a timely basis and to invest in accordance with its policies and federal regulations. The institutional system provides for careful monitoring of cash flow.

> **Indicator 1**. Cash withdrawals and deposits under governmental advance payment systems are made timely and accurately.

> **Indicator 2**. The institution has in place a system for calculating, recording, allocating, and/or remitting interest earned on federal cash balances in excess of what is permitted to be retained by the institution.

> **Indicator 3**. The institution limits requests for advance payment to amounts permissible under federal requirements.

> **Indicator 4.** The institution has a system in place that reconciles advance payment accounts/letters of credit on a regular basis to ensure cash is appropriately accounted for and reported.

Practice B. The institution has policies and procedures to bill sponsors, record the receipt of revenue and accounts receivable, and to disburse cash in a timely manner.

> **Indicator 1**. Procedures are established for the monitoring of financial transactions to maintain conformance with institutional and sponsor policies and/or regulations.

> **Indicator 2**. A credit, refund, and rebate system to make appropriate allocations and remittances is in place.

Indicator 3. The institution has an accounts receivable system that provides for timely application of funds from invoiced sponsors and enables follow-up in the event of non-payment.

Indicator 4. The institution has appropriate relationships with banking institutions to send and receive domestic and international electronic funds transfer payments.

Indicator 5. The institution has appropriate procedures in place to identify and appropriately credit payments made through electronic funds transfer as well as other methods.

Indicator 6. The institution ensures separation of duties and other appropriate internal controls in its cash handling processes.

Indicator 7. The institution has appropriate processes in place to make cash requests on a per award basis, as necessary, and to assure that payments are properly credited to the benefitting award.

Practice C. The institution has processes to properly identify, record, manage, and report program income in accordance with federal regulations at 2 CFR 200.307.

Indicator 1. The institution has established a broad list of examples of program income.

Indicator 2. There are clearly defined accounting procedures for identifying and recording program income and accounting for program income expenditures in conformance with institutional and sponsor policies and/or regulations and these procedures are communicated to units to ensure proper recording and accounting.

Indicator 3. The institution has a procedure to report program income to sponsors in accordance with the terms and conditions of awards.

Principle III–9. Specialized Service/Recharge Centers

The institution has in place a policy to identify and manage Specialized Service Centers and Recharge Centers and charge the users for these services[4].

Practice A. The institution has established policies and practices that ensure compliance with the provisions of 2 CFR 200 Subpart E where specialized service/recharge costs are material.

Indicator 1. The institution has policies and procedures for establishing specialized service and/or recharge centers.

Indicator 2. The institution can demonstrate that the costs of specialized service/recharge centers' services charged directly to sponsored agreements are based on actual costs and use, and recover only aggregate costs (less applicable credits) including direct costs and applicable F&A costs.

Indicator 3. The institution has a mechanism to review rates to ensure that no unallowable costs according 2 CFR 200 Subpart E are included in specialized service/recharge center rates.

Indicator 4. The institution can demonstrate that the charges do not discriminate against federally supported activities of the institution.

Indicator 5. The institution establishes appropriate operating balances for each service center and is able to identify surplus and/or deficit for adjustments in the future year.

Indicator 6. The rate calculation for each service center is designed to take into consideration variances in calculating future rates and is reviewed at least once every two years and adjusted if necessary.

Principle III-10. Clinical Research Billing Compliance

The institution has a system that complies with federal, state and local government regulations for appropriately billing Medicare/third-party payers for clinical research services.

Practice A. The institution conducts a needs assessment to identify compliance with clinical research billing in research programs involving clinical procedures or services.

Indicator 1. The institution is knowledgeable of the federal regulations related to research billing compliance and has conducted a risk/legal assessment of its billing system and current practices.

Indicator 2. The institution has published processes for research billing compliance.

Indicator 3. The institution provides ongoing educational opportunities for the clinical research community to inform them of their roles and responsibilities in research billing compliance.

Practice B. The institution has created a pre-award process to manage budget development, budget negotiation, and prospective reimbursement analysis.

Indicator 1. The institution has a process to develop and negotiate comprehensive budgets for clinical research studies to assure all costs are identified.

Indicator 2. The institution is responsible for determining if each cost is standard of care or eligible for reimbursement by the sponsor.

Indicator 3. The institution has a process to reconcile the informed consent document with the sponsor's award terms related to the financial obligations of the subjects and their coverage for research-related injuries or illness.

Practice C. The institution has created a post-award process to assure the research participants and third parties are billed as planned.

Indicator 1. The institution has developed a process to assure clinical research services are not billed inappropriately to third-party payers.

Indicator 2. The institution has developed a process to respond to deficiencies in the research billing process whereby erroneous billings may occur

Principle III-11. Program Closeout

The institution has policies and procedures for timely, complete and accurate program closeout in accordance with 2 CFR 200.343.

Practice A. The institution has procedures in place to ensure timely closeout of sponsored programs including the submission of all sponsor required deliverables in accordance with the requirements of each sponsoring agency.

Indicator 1. The institution clearly communicates to its principal investigators the importance of meeting the compliance obligations of final technical report submissions. **[See also, Principle II-7 Sponsored Program Management, Reports, Records, and Management of Technical Data.]**

Indicator 2. The institution clearly communicates requirements for final non-technical report submissions to responsible parties.

Indicator 3. The institution clearly communicates its policies and procedures regarding record retention and access to financial and administrative records generated under sponsored programs.

Indicator 4. The institution has a process to manage variations across agencies of closeout deadlines and expectations.

Practice B. The institution has mechanisms in place to ensure compliance with sponsor guidelines and requirements as well as accurate, timely reporting, and invoicing.

Indicator 1. The institution can document that all transactions are incurred within the allowable period of the sponsored agreement.

Indicator 2. The institution can document that all obligations under the award have been liquidated, within the period allowed by the award terms.

Indicator 3. The institution has mechanisms in place to ensure timely final invoicing and reporting.

Indicator 4. The institution has mechanisms to accommodate and monitor exceptional reporting, audit and payment requirements including delays in final audits and payments.

Principle III-12. Procurement

The institution has a procurement system for acquiring goods and services used in research and other sponsored activities in a competitive, fair, and timely manner. Special attention should be paid to the new requirements defined in 2 CFR 200.317-326, which are scheduled to be implemented at the beginning of the institution's FY2018.

Practice A. The institution has written policies and procedures for the purchase of goods and services used in sponsored programs.

Indicator 1. Personnel involved in the administration of sponsored programs are cognizant of the policies and procedures governing procurement of goods and services.

Indicator 2. Individuals involved in procurement adhere to the institutional written standards of conduct for procurement personnel, and the procurement procedures described by OMB Circular A-110 and 2 CFR 200.317-326 and the Federal Acquisition Regulations with individual agency supplements, as applicable.

Indicator 3. Individuals involved with any part of the procurement process (central or departmental) receive appropriate training in the institution's procurement policies and in the requirements imposed by external sponsors.

Indicator 4. The institution maintains written standards of conduct covering conflicts of interest, including financial, that govern the actions of its employees engaged in the selection, award and administration of contracts. The institution has a procedure to review contractor relationships, if any, with its employees to mitigate conflicts of interest in the selection process.

Indicator 5. The institution has a program in place for the detection, prevention, and reporting of kickbacks as required by federal regulations, including programs to monitor purchasing patterns and training programs for employees.

Indicator 6. The institution maintains records sufficient to substantiate that sponsor's requirements and institutional policies have been met (e.g., rationale for the method of procurement, contractor selection or rejection, contract type, and the basis for the contract price).

Indicator 7. The institution has written policies for the issuance and use of procurement cards (P-cards) including regular monitoring and timely reconciliation of P-card reports and expenditures.

Practice B. The institution has a procurement system that meets the requirements OMB Circular A-110 and 2 CFR 200.317-326 and the Federal Acquisition Regulations with individual agency supplements, as applicable.

Indicator 1. Methods of procurement such as Request for Proposal (RFP) and Request for Quotations (RFQ) are in place for the acquisition of goods and services in accordance with institutional and sponsor requirements.

Indicator 2. The institution has a process to award contracts to contractors that can demonstrate their ability to perform successfully under the terms and conditions of a proposed procurement. The institution has a process to demonstrate compliance with institutional policies and sponsor requirements.

Indicator 3. Criteria for selecting a single source for procurement acquisitions are made available and written justifications are prepared and documented.

Indicator 4. The institution has a process that includes all necessary affirmative steps to assure that minority businesses, women's business enterprises, and labor surplus area firms are used when possible. When required, the institution has a plan and monitors the implementation of the plan for encouraging Disadvantaged Business Enterprise (DBE) procurements. The institution has developed appropriate procedures to provide reports to agencies as required.

Indicator 5. Policies and procedures are in place to preclude purchases from contractors who are debarred or suspended.

Indicator 6. Documentation of certified cost or pricing data on contractor acquisitions is maintained and complies with federal requirements as applicable.

Indicator 7. Documentation of cost or price analysis is conducted in connection with every procurement action in excess of the designated federal thresholds, including contract modifications, and is maintained in compliance with applicable requirements.

Indicator 8. Institution-wide contracts and agreements serving the needs of the most frequently purchased items and services are developed to reduce errors in pricing or lost opportunity costs, to improve services and reduce re-order cycle times through better vendor relationships, and to provide for automated ordering and billing functions that remove administrative burden and improve efficiencies. The institution has a process to ensure that all prequalified lists of persons, firms, or products which are used in acquiring goods and services are current and include enough qualified sources to ensure fair competition.

Indicator 9. The institution has procedures to avoid the acquisition of unnecessary or duplicative items. Where appropriate, the institution considers lease versus purchase alternatives, and any other appropriate analysis to determine the most economical approach.

Practice C. The institution's procurement procedures distinguish between acquisition of goods and services and subrecipient agreements for sponsored programs. **[See also, Principle II-6 Subrecipient Monitoring.]**

Indicator 1. The institution has a process to ensure that contractors perform in accordance with the terms, conditions, and specifications of their contracts or purchase orders.

Practice D. The institution has processes in place to close out purchases in a timely manner in accordance with sponsors requirements.

Principle III-13. Equipment

The institution has a management system for equipment acquired from both federal and non-federal sources.[5]

Practice A. The institution has written policies and procedures that address the acquisition, use, and disposition of equipment.

Indicator 1. The institution has clearly defined the types of property for which it has responsibility and has established an institutional dollar threshold for items to qualify as equipment.

Practice B. The institution has adopted a system for appropriate acquisition and protection of equipment.

Indicator 1. Proposed purchases of equipment are reviewed to avoid acquisition of unnecessary items.

Indicator 2. The institution has implemented procedures to ascertain whether equipment shipped outside the US is export/embargo controlled and, if so, that the institution has secured appropriate licenses, as well as adequately tracks equipment in need of a technology control plan. **[See also, Principle VIII. Export Controls and Embargos, Trade Sanctions, and Executive Orders.]**

Indicator 3. Equipment acquisitions on sponsored accounts are reviewed for allowability, ownership, and taxes.

Indicator 4. When equipment is charged to more than one funding source, documentation supports the allocation of costs to each of the projects.

Practice C. The institution has an equipment inventory system.

Indicator 1. Equipment inventories are performed and records updated at least every two years.

Indicator 2. The inventory provides a description of the equipment (including serial number or other identifier), its acquisition cost, its current value, its location, its acquisition date, its condition, and the amount or percent of federal funding in the item, if applicable.

Indicator 3. Inventories reflect with whom title to equipment resides, the original source(s) of funds for the purchase, the percent of federal participation in the purchase, and the use of the equipment.

Indicator 4. The inventory system tracks all equipment, including that purchased on sponsored funds, by donations, or furnished by the government and is updated at the time of acquisition and de-acquisition.

Indicator 5. Items of accountable inventory and all items of federal equipment are properly tagged and safeguarded.

Practice D. The institution has a system for reporting of equipment to external sponsors, when required.

Indicator 1. Equipment residual to an externally sponsored award and not titled to the institution is reported on a timely basis to the sponsoring agency for disposition instructions.

Indicator 2. The institution has a process for determining the conditions under which equipment can be transferred, sold, or loaned to another institution and the methods for handling such transactions.

Practice E. The institution has a system for managing loaned equipment according to the agreement or federal guidelines (2 CFR 200.312).

Indicator 1. The inventory system can identify and submit an inventory of federally-owned property at least annually and at the completion of an award.

Indicator 2. The institution has a process to ensure meeting the instructions for disposal of federally owned equipment declared excess by the federal awarding agency.

Principle III-14. International Transactions

Practice A. The institution and all its personnel, agents, contractors, and collaborators are aware of the US anti-bribery laws. Contract provisions should foster compliance even in the context of other cultures that may not proscribe, and may even encourage, what US law characterizes as bribery.

Indicator 1. The institution shows particular sensitivity to, and confers with legal experts with respect to any payments or value proposed to be given by or on behalf of the institution to a foreign government, entity, or person to obtain a contract or other discretionary benefit, other than providing services or sponsored research in exchange for customary sponsored programs compensation and support.

Practice B. The institution establishes policies and processes that assess the risks associated with subawards to foreign entities. **[See also Principle II-6. Subrecipient Monitoring.]**

Indicator 1. Pre-award assessment of the subawardee addresses its capacity both financial and non-financial to meet the terms and conditions of the agreement.

Indicator 2. The institution develops mechanisms for monitoring the subrecipient's compliance with the terms and conditions of the agreement.

Principle III-15. International Taxation [See also Principle II-6. Subrecipient Monitoring]

The institution develops strategies to address taxation and manages tax related requirements for all jurisdictions where necessary.

Practice A. International tax experts (legal and accounting) determine the foreign laws and international treaties that govern taxation.

Indicator 1. The institution files tax documents in all jurisdictions where necessary.

Practice B. The institution has established a reasonable system of compliance with Internal Revenue Code requirements and Internal Revenue Service guidance concerning withholding taxes for travel reimbursements to non-resident aliens, employees, contractors and visitors.

Practice C. When negotiating new agreements, the institution considers appropriate objectives with regard to payment of associated tax burdens.

Indicator 1. The institution considers whether the creation of a "permanent establishment" (e.g., offices, bank accounts, contract execution, repeated or long personal visits or domiciles) in a foreign locale, which may lead to taxation of the US institution, should be avoided or whether such permanent establishments are essential for the success of the endeavor.

Indicator 2. The institution considers the following negotiation objectives: (i) the sponsored program agreement provides that the foreign government or entity assumes the US institution's and its personnel's individual, tax obligations to the foreign jurisdiction; or (ii) the sponsored program support to the US institution is adequate to both cover the sponsored program and the tax burden; or (iii) the cost to the institution and its personnel of filing foreign tax returns is addressed along with the tax burden.

Internet Resources

OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl

US Code of Federal Regulations (CFR)
http://www.ecfr.gov/cgi-bin/ECFR?page=browse

Federal Acquisition Regulations
https://www.acquisition.gov/?q=browsefar

Internal Revenue Service (IRS)
http://www.irs.gov/

American Institute of CPAs
http://www.aicpa.org/Research/ExternalLinks/Pages/TaxesStatesDepartmentsofRevenue.aspx

Endnotes:

[1] Since 1996, the Federal government uses the term "facilities and administrative" costs (F&A) rather than "indirect" costs to refer to costs that are not separately assigned to an individual project but are charged as a percentage of the direct costs to cover institutional costs like electricity, sponsored project administration, etc. In this document, we use F&A rather than "indirect" while recognizing that hospitals that work through their intermediaries to establish Medicare cost reimbursement continue to use the term "indirect" to refer to similar cost rates.

[2] In the case of the National Institutes of Health Grants Policy Statement (Part II, Subpart A: General, Cost Considerations section 7.5) states that cost transfers "should be accomplished within 90 days of when the error was discovered," and describes the types of documentation required. Other agencies may have different requirements. The institution should consider procedures that meet all its sponsors' requirements. NOTE: The NIH GPS is currently under revision and the expected release date was November 2015. As of the date of this publication the GPS had not yet been published. A summary of significant changes can be found at http://grants.nih.gov/grants/policy/nihgps/Significant_Changes_NIHGPS_Oct2015.pdf.

[3] See COGR's *Policies and Practices: Compensation, Effort Commitments and Certification*, March 2007, for a more detailed discussion. For additional information, see COGR's Guide to 2 CFR 200.430 Compensation-Personal Services located here: http://cogr.sitefpo.com/COGR/files/ccLibraryFiles/Filename/000000000207/Guide%20to%202%20CFR%20200%20430%20Compensation_Personal%20Services.pdf.

[4] Specialized Service Centers are highly complex facilities often with unique instrumentation and technical support. Recharge Centers are organizational units of activities that provide goods and services primarily to internal institutional operations and secondarily to external users.

[5] See OMB 2 CFR 200 for the definition of equipment (l), exempt property (n), and property (aa). It is important to note that property is defined as real property, equipment, intangible property (including intellectual property), and unused supplies over a specified threshold. However, this section covers only the management of equipment that is defined at 2 CFR 200.33 as tangible nonexpendable property having a useful life of more than one year and an acquisition cost of $5000 or more per unit. However, institutional policy may set lower limits. Intellectual property is addressed in Principle VII. The reader should consult OMB 2 CFR 200 for a discussion of other types of property.

The institution provides the infrastructure to adequately support its sponsored programs and to support a culture of compliance necessary to adhere to regulations and policies applicable to the use of federal funds and has processes to ensure compliance.

Practice A. The institution has mechanisms to document compliance with federal policy requirements that affect in part or in whole the conduct of research as a part of regular business practice.

Practice B. The institution has mechanisms to respond to specific requests or requirements applicable to an individual federal and non-federal award as a part of its regular business practices.

Practice C. The institution fosters a collaborative environment that encourages investigators, departments, and central offices to work together and pro-actively ensure the proper stewardship of externally sponsored programs.

> **Indicator 1**. Roles and responsibilities are sufficiently defined and available to guide individuals requesting documentation of compliance or the recipient of a request to the appropriate institutional authority.

Principle IV- 1. Employment

The institution has a human resources management program including written policies and procedures available to all employees and practices that provide safeguards to ensure that the institution complies with laws and regulations regarding recruitment, hiring, compensation, terms, conditions and termination of employment.

Practice A. The institution's human resource policies and procedures address relevant state and federal laws and regulations governing employment.

> **Indicator 1.** The human resources policies provide for a prompt and diligent investigation and resolution of allegations relating to discrimination, harassment, retribution or retaliation, and other workplace issues.
>
> **Indicator 2.** The institution has procedures in place to periodically review and modify its programs for effectiveness, compliance with applicable laws, and consistent application of sanctions.

Practice B. The institution has human resources policies that provide procedures for consistency in classifying (e.g., exempt vs non-exempt), recruiting, hiring, evaluating, compensating, disciplining, and terminating employees.

> **Indicator 1.** The institution uses reasonable efforts and due diligence to determine whether an individual with substantial authority, defined as those who within the scope of their responsibilities exercise a substantial level of discretion to act for the institution, has engaged in conduct inconsistent with an effective sponsored research compliance program.

Practice C. The institution has policies and procedures to ensure compliance with U.S. laws governing immigration and the employment of foreign nationals.

> **Indicator 1.** The institution collects Employee Eligibility Verification (I-9) forms from all employees.
>
> **Indicator 2.** The institution has mechanisms in place to comply with federal employment verification procedures as required.

Indicator 2a. The institution has mechanisms in place to ensure compliance with any restrictions on transactions with foreign individuals or entities as required by federal law, e.g., Executive Order 13224 of September 23, 2001 Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism.[1]

Indicator 3. The institution recognizes and complies with the visa requirements for employees and students who are foreign nationals.

Indicator 3a. The institution has processes and procedures that maximize the likelihood that foreign participants in research and support staff will have the appropriate visas in a timely manner to commence and continue sponsored programs and to travel to and from international conferences and meetings.

Indicator 3b. The institution has mechanisms to identify the countries and disciplines of concern that are likely to require extra visa processing time (e.g., for security reviews) and have systems and practices in place to initiate the earliest applications possible.

Indicator 3c. The institution has mechanisms in place to ensure that sponsored funds are not spent during periods of delay in securing visas if the foreign researcher may not pursue the sponsored programs activities during such period.

Indicator 4. The institution has a procedure for identifying and notifying federal sponsors if international employees, consultants or other personnel are engaged in sponsored programs activities under applicable awards, if required by the award.

Indicator 4a. The institution has processes in place that foreign nationals understand the effects of changes in research or study areas on the institution's immigration reporting obligations and on the visa status of the individual researcher, staff or student.

Indicator 5. The institution has mechanisms in place to comply with federal program requirements that have citizenship or residence requirements.

Practice D. The institution has procedures in place to ensure that any access to or use of controlled materials or information (e.g., select agents, export-controlled technologies) by employees (both U.S. citizens and foreign nationals as applicable) is in accordance with relevant laws and regulations.

Indicator 1. The institution's human resources process has the capacity to condition employment on the individual's (whether U.S. citizen or foreign national) ability to legally have access to and work with all materials (e.g., select agents and toxins, export controlled materials) that are necessary or for the work of the position. When employment requires background checks and other extra conditions, potential employees are fully informed of these employment conditions.

Indicator 2. The institution has controls in place to ensure compliance with export controls. **[See also, Principle VIII. Export Controls, Embargos, Trade Sanctions and Executive Orders]**

Practice E. The institution has policies and procedures to deal with changes in employment status.

Indicator 1. Mechanisms are in place to ensure investigators transferring to a new institution have obtained necessary approvals from regulatory agencies and the prior employer for the transfer of any restricted laboratory materials (e.g., select agents and toxins, export controlled materials) in compliance with sponsor and regulatory requirements.

Indicator 2. Mechanisms are in place to ensure that the institution and investigators leaving the institution engage in a comprehensive close-out process, e.g., lab inventory and clean out, closure or transfer to another investigator of regulatory approvals (e.g., IRB, IACUC, IBC), termination of access to secured areas (e.g., where select agents and toxins are used or stored), filing final reports, and proper disposition of laboratory notebooks, data, sample archives, equipment, etc. and that all hazardous materials (e.g. chemicals, radionuclides, biological materials) are properly transferred or disposed of. To address export controlled items, Technology Control Plans are appropriately closed out including proper disposition of controlled materials, data and equipment.

Indicator 3. Human resource policy and procedures ensure that student and staff employees are provided appropriate orientation and access to services (e.g., procedures for transferring sponsored programs, regulatory training) related to their job duties.

Practice F. The institution has appropriate training programs available as required by institutional policies.

Indicator 1. The institution has mechanisms to identify the training needed to meet the obligations of a specific job and duties assigned.

Indicator 2. The institution documents the delivery of the training determined to be necessary for employment.

Indicator 2a. The documentation of training is accessible by those individuals in the institution that require such access.

Indicator 3. The institution has a process for reviewing and updating training materials regularly.

Principle IV-2 Environmental Health and Safety

The institution has a comprehensive and integrated systems approach to environmental health and safety (EHS) that is appropriate for the size and scope of the institution's sponsored research activity. The institution ensures compliance with federal, state and local government regulations governing the conduct and effects of sponsored programs activities, materials, and equipment on the environment and on the health, safety and security of researchers and the public[2].

Practice A. The institution has established an EHS Management System or other coordinated approach and published processes that include adequate program components for the scope and complexity of regular activities at the institution.

Indicator 1. The institution identifies all EHS regulations that are applicable to the institution and its activities and assigns responsibility for compliance to appropriate individuals and/or units.

Indicator 2. The institution has a mechanism to assess the training needs for individuals involved in the use or management of regulated materials.

Indicator 2a. The institution has processes to develop and deliver specialized training consistent with regulations and policies governing unique research activities.

Indicator 2b. The institution has a process to document training required by statute and/or regulations.

Indicator 2c. The documentation of training is accessible by those individuals in the institution that require such access.

Indicator 3. The institution includes appropriate periodic compliance monitoring and assessments through inspections or reviews at the local laboratory, whole research unit, and institution-wide levels.

Indicator 4. The institution conducts appropriate periodic EHS system audits covering system implementation, controls, and effectiveness to identify and rectify system and performance deficiencies.

Indicator 5. The institution maintains an inventory or utilizes an alternate approach for identifying, classifying and managing possession of, access to, use of, and disposal of regulated materials, regulated wastes, regulated activities and equipment, as well as hazards to health and safety, down to the local lab level. For Department of Homeland Security Chemicals of Interest and select agents, the process includes risk assessment and registration as required.

Indicator 5a. The institution has a means for identifying all locations where chemicals including chemicals of interest; biological agents including select agents and toxins; radioactive materials including radionuclides of concern are used and stored and has provisions for appropriate security and access restrictions.

Indicator 6. The institution provides special access controls, security risk assessment, background checks of employees as appropriate and/or required by governing regulations, purchasing, transfer, and disposal protocols for materials to whose access and whose acquisition, transfer and/or disposal are regulated (e.g., radioactive materials, select biological agents and toxins and biological and hazardous wastes) to ensure compliance.

Indicator 6a. The institution has a means of identifying all individuals working with chemicals including chemicals of interest; biological agents including select agents and toxins; radioactive materials including radionuclides of concern and ensuring that the individuals have appropriate security clearances before working with such materials.

Indicator 7. The institution provides compliance resource materials and tools that are easily accessible to the regulated community.

Indicator 8. The institution monitors changes in regulatory requirements and incorporates such changes in the EHS system programs.

Indicator 9. The institution has a communications program concerning all aspects of the EHS system and all affected people centrally and locally.

Indicator 10. The institution has record-keeping and reporting procedures that meet regulatory requirements.

Indicator 11. The institution has emergency preparedness and response systems to meet environmental or safety events.

Indicator 12. The institution has mechanisms for measuring, preventing, responding to and mitigating occupational injuries and illnesses.

Indicator 13. The institution may include an approach for minimizing, if practical without interfering with sponsored program objectives, the use of materials and equipment that trigger regulation, and for reducing pollution from and toxicity of research.

Practice B. Regulations pertaining to compliance requirements for health and safety standards in the workplace, including compliance with Occupational Safety and Health Administration (OSHA) regulations and all state and local laws and regulations, where appropriate, are published and disseminated to employees.

Indicator 1. Information, procedures, and requirements on industrial insurance and accident protection and reporting exist and are disseminated as required to affected employees.

Indicator 2. Appropriate safety personnel provide advice on storage of flammable materials, conduct fire investigations and fire safety inspections, and provide maintenance and information on fire extinguishers, fire alarms, and fire sprinklers.

Indicator 3. The institution has an occupational safety and health program for investigators, research staff, and students involved in sponsored program activities, including ongoing training as required for employees.

Principle IV-3. Facilities

The institution has a system to ensure security for campus buildings, other institution facilities, and equipment.

Practice A. The institution has policies and procedures for maintaining the security of its buildings, grounds, restricted materials, e.g., select agents and toxins, facilities, and animals to provide protection from loss or disruption of institutional and/or sponsor investments in its sponsored programs.

Indicator 1. Fire protection and other emergency preparedness programs exist and are disseminated within the institution.

Indicator 2. The institution has procedures for authorized access to its buildings and laboratories. The authorization procedures are capable of restricting access to certain areas as necessary because of the materials used or stored in the area.

Practice B. The institution reviews building construction and renovation design drawings to ensure that security, safety and health requirements are met and that the institution complies with federal requirements for the construction of research facilities. The review includes assessment of risks associated with the storage and use of chemicals, radioactive materials and/or select agents and toxins that require specialized security measures including restricted access.

Practice C. The institution has insurance and/or liability coverage which complies with federal and, where necessary, state and local regulations and provide a reasonable level of protection against unanticipated property loss, injury and liability exposure.

Indicator 1. The institution has a system to identify and evaluate potential injury, property loss, and liability exposure.

Indicator 2. The institution has policies regarding the property loss and liability exposures that will be assumed by the institution and those that will be transferred.

Indicator 3. A process exists to confirm that purchased insurance policies provide the nature and scope of intended coverage.

Indicator 4. Appropriate indemnification and hold harmless provisions are inserted into award documents.

Indicator 5. Appropriate insurance and bonding provisions are incorporated into award documents.

Indicator 6. Contractual insurance and bonding provisions are monitored for contractor compliance.

Indicator 7. The institution has a record keeping system for its risk management programs.

Indicator 8. If self-insured, the institution has a system for responding to property loss and liability claims.

Practice D. The institution has a disaster recovery plan and emergency procedures for dealing with catastrophic events that could affect facilities, equipment, and other institutional systems and materials including research, financial and other administrative records.

Indicator 1. The institution has mechanisms to establish, monitor and evaluate plans and procedures.

Indicator 2. The institution has considered and, as appropriate, has a plan for protection of losses to research activity that result from natural disasters or other catastrophic events, disruption in business continuity limiting access to resources and other adverse events.

Indicator 2a. The institution has a plan for recovery from the loss of research materials including archived documents, bio-specimens, etc.

Principle IV-4. Information Management/Security

The institution has appropriate mechanisms to ensure compliance with sponsor and other applicable requirements related to data security and safeguarding of information systems.

Practice A. The institution has methods in place to identify categories of information including, sensitive but unclassified information, controlled unclassified information, covered defense information, and classified information.

Indicator 1. The institution has procedures in place to identify and evaluate data security requirements before acceptance of an award.

Indicator 2. The Principal Investigator and Sponsored Programs Office collaborate, as needed, with the Information Technology Office to ensure compliance with rules, regulations, policies and procedures pertaining both to categories of information and information system requirements.

Indicator 3. The institution assigns responsibility to an individual(s) or an office to identify compliance risks, monitor, investigate and report instances of noncompliance.

Indicator 4. The institution has a process to develop, submit and maintain System Security Plans and other cybersecurity measures for classified and unclassified projects and systems.

Indicator 5. The institution has the proper resources to secure, store, and destroy business documents to minimize the risk of access by unauthorized personnel. Institution is aware of certain categories of restricted documents such as:

- **Sensitive but Unclassified Information**
- **Controlled But Unclassified Information**[3]
- **Classified Information**

and has policies in place to address the handling, storage, and destruction of such documents.

Indicator 6. The institution has a clear policy on the acceptance (or prohibition) of classified research.

Principle IV-5. International Activities

The institution has mechanisms to coordinate international activities.

Practice A. The institution has methods for collecting and sharing information on international activities and relationships.

Indicator 1 . Internal communication mechanisms are created which focus on international activities and relationships. Such mechanisms may offer members of the institution a tool for self-reporting international activities.

Practice B. The institution has processes for addressing requirements related to foreign visitors to the institution, including dignitaries, laboratory visitors and conference attendees.

Indicator 1. The institution has a mechanism for coordinating visits of dignitaries and delegations from abroad to the institution and visits from the institution abroad.

Indicator 2. The institution has a mechanism for coordinating laboratory visitors from aboard including management of deemed export issues as appropriate.

Indicator 3. The institution has resources available to complete necessary screenings prior to the visit.

Practice C. The institution has a travel risk policy which addresses health, security and other safety concerns.

Indicator 1. The policy addresses faculty, staff and student travel in relation to different categories of risk.

Indicator 2. The institution may require registration of travel plans and documented acknowledgement of travel risk by the traveler.

Indicator 3. The policy includes a clear process for appeal of decisions.

Practice D. The institution secures, as appropriate, assistance and insurance for travelers.

Indicator 1. The institution may provide 24/7 access to emergency services for travelers.

Indicator 2. The institution provides information to travelers regarding accident-emergency medical travel insurance for proposed destinations.

Practice E. Communication mechanisms are created for clear and timely dissemination of information regarding travel procedures and health and security advisories.

Indicator 1. Travel websites provide important summary information and links to travel resources.

Indicator 2. Emergency contact information is provided to travelers.

Practice F. The institution's compliance program includes systems that are integrated with the institution's travel programs to identify Office of Foreign Asset Control (OFAC) embargo issues and licensing requirements prior to making international travel arrangements.

Internet Resources

US Office of Management and Budget (OMB), 2 CFR 200, UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS
http://www.ecfr.gov/cgi-bin/text-idx?SID=6026081d9cb1d2f569fe651a888c8f6f&mc=true&node=pt2.1.200&rgn=div5

Federal Acquisition Regulations (FARs)
http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title48/48cfr52_main_02.tpl

US Department of Labor (FMLA, FLSA)
http://www.dol.gov/opa/aboutdol/lawsprog.htm

US Equal Employment Opportunity Commission
http://www.eeoc.gov/

US Federal Trade Commission (Fair Credit Reporting Act)
http://www.ftc.gov/credit/

U.S. Food and Drug Administration
http://www.fda.gov/

HHS Centers for Disease Control and US Department of Agriculture, Animal and Plant Health Inspection Service
http://www.selectagents.gov/

U.S. DHHS, Office of the Assistant Secretary for Preparedness and Response
http://www.phe.gov/s3/legal/Pages/laws.aspx

Environmental Protection Agency
Resources Conservation and Recovery Act (RCRA) – Office of Solid Waste
http://www.epa.gov/osw/

Major Laws and Regulations (Clean Air, Water, RCRA)
http://www.epa.gov/epahome/laws.htm

National Institutes of Health (NIH) Office of Biotechnology Activities (Biosafety and Recombinant DNA Research)
http://www4.od.nih.gov/oba/

US Nuclear Regulatory Commission – State and Tribal Programs
http://www.nrc.gov/about-nrc/state-tribal.html

U.S. Nuclear Regulatory Commission, Assuring the Security of Radioactive Material
http://www.nrc.gov/security/byproduct.html

US Department of Labor Occupational Safety and Health Administration
http://www.osha.gov/

Department of Homeland Security
Chemical Facility Anti-Terrorism Standards
http://www.dhs.gov/chemical-facility-anti-terrorism-standards

US Department of Homeland Security
http://www.dhs.gov/dhspublic/

US Department of Homeland Security, Federal Emergency Management Agency
http://www.fema.gov/

United States Government
Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

United States Government
Executive Order 13556, Controlled Unclassified Information
https://www.whitehouse.gov/the-press-office/2010/11/04/executive-order-13556-controlled-unclassified-information

Department of Justice
http://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption7_0.pdf

Endnotes:

[1] The US Department of the Treasury's Office of Foreign Assets Control (OFAC) maintains Sanction Countries and Specially Designated Nationals Lists to meet the requirements of EO 13224. See also, Check Reference Export, Global Activities and Relationships with Foreign Entities.
[2] Materials can include chemicals, radionuclides, biologicals including select agents, toxins, blood borne pathogens and infectious agents, recombinant DNA (rDNA) and other specially regulated materials. Environmental impacts include effects on the air, water, and soil as well as indoor environments.
[3] See also Federal Register 5/8/15 on Proposed Rule on Controlled Unclassified Information.

Principle V. Assessments and Audits

The institution has a formal system for institution initiated compliance assessment, monitoring and audit that demonstrates that the institution complies with federal regulations, institutional and other sponsor policies.

Practice A. The institution has published processes drawn from appropriate professional auditing standards for performing compliance assessments, formal audits, and for reporting the results to the appropriate, responsible official. These policies and procedures are distributed to the appropriate institutional officials.

> **Indicator 1.** The institution demonstrates a knowledge of and commitment to compliance by performing risk-based compliance assessments in areas of sponsored program activity and reports the results of such assessment to the appropriate responsible official.
>
> **Indicator 2.** The institution develops a risk-based assessment/audit plan on a regular basis.
>
> **Indicator 3.** The institution initiates formal risk-based audits of administrative and financial systems that support the sponsored program enterprise and reports the results of such audits to the appropriate responsible official. **[See also, Principle II-6 Subrecipient Monitoring.]**
>
> **Indicator 4.** The results of financial and compliance audits are communicated to all affected individuals and corrective action plans, as may be appropriate and developed in response to compliance assessments, are monitored for implementation.
>
> **Indicator 5.** The institution develops a monitoring program for high risk areas that enables identification of systematic issues across campus.

Practice B. The institution has published processes for both its external audit and its internal audit responsibilities.

> **Indicator 1**. There are policies in place to ensure the institution's auditor has the appropriate reporting relationship to ensure independence within the organization.
>
> **Indicator 2.** Procedures are in place to ensure that external auditors are selected in accordance with a process that complies with the requirements of 2 CFR 200 Subpart F Audit Requirements.
>
> **Indicator 3.** The institution has an internal audit charter that states the internal auditors' responsibilities and authority.

Practice C. The institution's auditors and external auditors under appropriate circumstances have unrestricted access to the institution's records, properties, and personnel as those relate to any given subject under review.

Practice D. The institution has procedures for ongoing review of its finances, compliance with its administrative directives, and conformance with governmental laws and regulations.

> **Indicator 1**. Audits of systems and operations are developed and maintained on a regularly scheduled basis.
>
> **Indicator 2**. Financial objectives, goals, and control procedures are established and maintained.

Indicator 3. Systems of controls adequately ensure the reliability and integrity of financial and operating information.

Indicator 4. Systems of controls adequately safeguard and account for the assets of the institution.

Indicator 5. Operations or programs are being conducted and their performance measured consistent with established goals and objectives.

Indicator 6. Systems of controls adequately measure and ensure that resources are used economically and efficiently.

Indicator 7. Reports are prepared for management stating findings and recommendations, and significant audit matters are reported directly to appropriate officials.

Indicator 8. Adequate follow-up exists to determine that appropriate actions are taken to resolve audit findings, including those of subrecipients.

Indicator 9. Systems of controls adequately safeguard protected personally identifiable and sensitive information.

Practice E. The institution complies with government auditing requirements with respect to its federally-supported programs.

Indicator 1. Controls are in place to ensure external audits are performed in accordance with and submitted as required by federal regulations.

Indicator 2. Mechanisms exist to coordinate and manage the activities of internal and external auditors.

Indicator 3. Controls are in place to ensure that nonprofit subrecipients have met respective audit requirements and, in cases of noncompliance, that corrective action is taken.

Indicator 4. There is periodic verification by internal and/or external auditors of the subrecipient process instituted at the institution.

Indicator 5. The institution's audit program includes tests for internal controls and compliance with administrative requirements, such as the compliance supplement to 2 CFR 200.

Internet Resources

US Office of Management and Budget (OMB) 2CFR 200, Uniform Guidance: Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
https://federalregister.gov/a/2013-30465

US Sentencing Commission, Guidelines for Organizations
http://www.ussc.gov/guidelines-manual/organizational-guidelines

Standards for Internal Control in the Federal Government
GAO-14-704G: Published: Sep 10, 2014.
http://www.gao.gov/assets/670/665712.pdf

Internal Control - Integrated Framework: Internal Control Over External Financial Reporting: A Compendium of Approaches and Examples, Committee of Sponsoring Organizations' (COSO)
http://www.coso.org/ic.htm

Principle VI. Integrity and Protection Regulations

The institution is in compliance with all federal regulations and institutional policies designed to ensure the responsible conduct of research, including deterring research misconduct, managing financial conflicts of interest, protecting the welfare of vertebrate animals used in research, and protecting the rights and welfare of human research subjects.

Principle VI-1. Research Integrity

The institution has a formal system, embodied in policies and procedures that commit the institution and its investigators, students and research staff to design, conduct, and report their scholarly activities in accordance with accepted standards of integrity and ethical behavior.

Practice A. The institution has policies or statements that demonstrate a commitment to the integrity of its scholarly activities and provide procedures for raising and resolving questions about professional or ethical standards.

> **Indicator 1**. The institution provides an environment in which responsible conduct is a fundamental requirement in the design, conduct and reporting of research data and results.
>
> **Indicator 2**. The institution has policies that encourage unimpeded public dissemination of research results, such as those that protect investigators, students, and research staff from requirements for prior approval of publications by parties external to the institution.
>
> **Indicator 3**. The institution requires investigators to abide by standards, appropriate to the discipline, for data management and reporting to the research community and to ensure that such reported work will meet peer review standards of the discipline.
>
> **Indicator 4**. The institution provides programs to meet educational requirements for all applicable research personnel as specified in sponsoring agency requirements for instruction in the responsible conduct of research, including mandatory instruction on scientific integrity and ethical principles.[1]
>
> **Indicator 5.** The institution has easily accessible and diverse means for educating investigators, students, and research staff about research ethics and responsible conduct standards.

Principle VI-1A. Research Misconduct

The institution has a policy that addresses the handling of allegations of research misconduct in a manner that meets appropriate sponsor requirements. [See also, Principle I-Practice F.]

Practice A. The institution has policies and procedures that allow it to meet the requirements of sponsoring agencies for responding to allegations of research misconduct, including but not limited to conducting timely and fair inquiries and investigations, maintaining confidentiality, and reporting to the sponsoring agency.[2]

> **Indicator 1**. The institution has an Assurance of Compliance with PHS Policy on Research Misconduct, and the institution's definition of research misconduct is adequate to satisfy PHS requirements.

Indicator 2. The institution has designated a Research Integrity Officer who has primary responsibility for handling allegations of research misconduct, and has provided the RIO with adequate resources (time, staff, etc.) to conduct these responsibilities.

Indicator 3. The institution's policy clearly delineates points of contact and confidential lines of communication for persons making allegations of research misconduct.

Indicator 4. The institution's policy provides for a separation of phases in which adjudication is separated organizationally from inquiry and investigation.

Practice B. The institution has individuals who are assigned the responsibilities to respond to an allegation of research misconduct, including securing and protecting (sequestering) source data, laboratory notebooks, and other relevant materials.

Practice C. The institution is committed to the protection of the rights of the complainant who raises the allegation and the respondent(s) against whom the allegation is made. The rights and reputations of all parties involved in any inquiry or investigation are fully protected by the institution and strict confidentiality of the proceedings is observed to the maximum extent possible.

Practice D. The institution's policy provides guidance for assessing whether an allegation is sufficiently credible and specific that it warrants an inquiry and, if so, that the respondent is notified.

Practice E. The institution has procedures for conducting, in a timely manner, an inquiry for the narrow and specific purpose of conducting an initial review of the evidence to determine whether to conduct an investigation.

Practice F. If, after an inquiry, an allegation of research misconduct is deemed to be of sufficient merit to warrant a formal investigation, a designated institutional official or body is charged with investigating the allegation and documenting their findings.

Practice G. When required by the sponsor, the institution provides notification that the institution is undertaking a formal investigation into allegations of misconduct and subsequently, the institution reports the outcome of the formal investigation to the sponsor.

Practice H. In the case of a finding of research misconduct, the institution has a clearly defined process of adjudication.

Practice I. The institution has a mechanism in place to monitor compliance with sanctions or corrective action imposed after a finding of research misconduct.

Practice J. The institution complies with sponsor requirements for retention and custody of research misconduct proceeding records.

Practice K. The institution complies with the Federal Whistleblower Protection Act and the Federal Whistleblower Enhancement Protection Act.

Principle VI-1B. Financial Conflicts of Interest

The institution has a policy to assist investigators, postdoctoral fellows, students and research staff, including study coordinators, in determining whether and to what extent outside financial relationships and interests may conflict with their research and academic activities or other institutional responsibilities.[3]

Practice A. The institution provides guidance and examples to investigators regarding the types of financial interests that must be reported to the institution, conflict avoidance and conflict management, including disengagement from research activities and decision-making. The institution's policy identifies an entity that is responsible for responding to questions on the policy.

Practice B. The institution provides educational opportunities for investigators to familiarize themselves with the institution's conflicts of interest policies, which may include web-based tutorials, regular reminders during administrative processes and/or individualized training, as appropriate or required.

Practice C. The institution clearly defines the individuals who are required to report/disclose personal financial interests. These individuals will include all members of a research team that have an independent role in the design, conduct or reporting of the research.

Practice D. The institution clearly defines the activities that are subject to reporting the level of financial interest that must be reported, and the timing of such reports (e.g., annual, transactional, when interests change, ad hoc, etc.).

Practice E. The institution's policy complies with sponsor and institutional requirements for identifying, reporting, and managing, reducing or eliminating financial conflicts of interest, and any other requirements imposed by the government (federal, state and local) regarding financial conflicts of interest. This includes designating an individual or entity responsible for soliciting, collecting, and reviewing reports. (For example, the 2011 Revised PHS FCOI Regulation).

Practice F. The institution's policy has designated enforcement mechanisms and/or sanctions if an individual fails to report accurate information to the responsible official or is in non-compliance with other aspects of the requirements.

Practice G. The institution's policy specifically addresses financial conflicts of interest issues that pertain to student-faculty relationships to ensure that a student's degree-oriented research does not conflict with an investigator's outside financial interests, that such interests do not impede student's progress toward degree or their related financial support, and does not restrict students' communication with each other and or/their right to publish their dissertation/thesis.

> **Indicator 1.** In addition to a senior investigator mentor, students—both graduate and undergraduate—are provided access to resources and individuals who can advise students with respect to specific financial conflicts of interest concerns.

Practice H. The institution has procedures for managing, reducing, or eliminating individual financial conflicts of interest.

> **Indicator 1**.The institution has clear lines of responsibility and authority for the review of disclosed potential conflicts, the determination that a real or potential conflict exists, and the determination of what action(s) should be taken by the institution to eliminate, reduce or manage such conflicts of interest.
>
> > If the institution chooses to establish a conflicts of interest committee, the committee membership includes academic and administrative personnel (with seniority) who are knowledgeable about institutional policies and processes with respect to conflicts of interest and about the academic issues and the research under discussion. The institution assesses any committee members' potential conflicts of interest in matters under consideration by the committee.

Indicator 2. If the institution determines that an actual or potential conflict can be managed, the institution designates an entity responsible for developing a specific, individualized conflicts of interest management plan. The management plan summarizes the financial interests or relationship, the relatedness of the interest/relationship to the research programs and the strategies to assist in managing or reducing the potential conflicts.

Indicator 3. The institution employs a range of strategies in its individual management plans and seeks uniformity in the implementation of these strategies. The institution ensures the timely and informed communication of required management practices to investigators with disclosed conflicts.

Indicator 4. The institution has processes for monitoring to ensure that management plans are being adhered to.

Indicator 5. The institution informs investigators of its enforcement mechanisms and/or sanctions if investigators fail to comply with conflicts of interest management plans.

Practice I. The institution has policies and procedures for the reporting of individual financial conflicts of interest.

Indicator 1. The institution informs external sponsors, as required, when it confirms the existence of a conflict of interest related to the sponsor's current or potential supported activity.

Indicator 2. The institution ensures public accessibility via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest (SFI) disclosed to the institution that meets the criteria in the PHS regulations.

Indicator 3. The institution requires disclosure of conflicts of interest to human subjects when appropriate.

Indicator 4. The institution is compliant with 2 CFR 200.318 "General Procurement Standards" that requires the grantee to "maintain written standards of conduct covering conflicts of interest and governing the performance of its employees engaged in the selection, award and administration of federal awards."

Practice J. The institution has policies and procedures to ensure that subrecipients comply with federal or other sponsor requirements regarding conflicts of interest. **[See Also Principle II-6, Subrecipient Monitoring.]**

Indicator 1. The institution has procedures that flow-down conflicts of interest requirements to its subrecipients. If the subrecipients cannot comply with the sponsor's requirements, the institution will seek assurance that the subrecipient will comply with the institution's conflicts of interest policy.

Indicator 2. The institution reports, as necessary, to the sponsor upon notification that a subrecipient has managed, reduced, or eliminated a conflict of interest. The institution seeks additional information as necessary for this notification.

Practice K. The institution has processes that identify potential or actual financial conflicts of interest of the institution, its senior management, a sub-unit, or related organizations (such as an institution-related philanthropic foundation), and has mechanisms in place for managing them.

Indicator 1. The institution has in place an institutional financial conflicts of interest process—for both conflicts related to the institution's financial interests and relationships and those involving senior officers—that follow a three-fold approach: disclose the conflict, manage the conflict, and eliminate the activity when necessary to protect the public interest or the interest of the institution.

Indicator 2. The institution has policies and procedures that recognize the heightened level of concern regarding institutional conflicts of interest in research involving human subjects, use of students, involvement members of its governing board, and significant equity or royalty positions.

Indicator 3. The institution has established procedural firewalls between the administrative functions related to research from those related to investments of institutional endowment and financial funds, and to institutional purchasing.

Indicator 4. If the institution chooses to establish an institutional conflicts of interest committee, this committee's membership includes individuals that are knowledgeable, by training or experience, regarding conflicts of interest issues. The institution has considered whether a non-affiliated individual is included in the committee's composition. The institution assesses any committee members' potential conflicts of interest in matters under consideration by the committee.

Principle VI-2. Protection Regulations

The institution complies with sponsor requirements and all federal, state and local government regulations for protection of human research subjects and use of animals in research.

Practice A. The institution's compliance systems accommodate multiple and integrated compliance obligations and are coordinated so that oversight and approval responsibilities are linked in an effective and timely manner.

Indicator 1. A process is in place to provide coordination between and among the appropriate oversight committees.

Indicator 2. The institution has a system in place to ensure that appropriate reviews and approvals are completed before the research begins when multiple committees share responsibilities for various aspects of compliance.

Principle VI-2A. Human Subjects

The institution has a system that complies with federal, state and local government regulations and with the requirements of sponsors to protect the rights and, welfare of human research subjects.

Practice A. If receiving federal funds, the institution has filed a Federal-Wide Assurance (FWA) with the US Department of Health and Human Services and as required by other federal agencies, and received approval in accordance with federal regulations.[4]

Indicator 1. The institution has processes consistent with the approved FWA that describe the specific review procedures required when human subjects are used in research.

Indicator 2. A senior institutional official, as specified by federal regulations, is responsible for the entire human research protections program covered by the federal-wide assurance.

Indicator 3. The institution has a mechanism by which it regularly reviews the nature of its human research protections program, evaluates resources, and has mechanisms to adjust resources to accommodate the operation of its program in compliance with applicable laws and regulations.

Indicator 4. The institution provides educational resources to ensure that individuals engaged in the review and conduct of human subjects research are adequately trained, and institutional records are maintained which document such training.

Practice B. The institution has established at least one Institutional Review Board (IRB) in accordance with federal regulations to review, approve, require modifications in, disapprove, suspend, or terminate research activities involving humans as research subjects.

Indicator 1. The size and number of IRBs are appropriate for the volume and types of human subjects research conducted by the institution.

Indicator 2. The IRB(s) include appropriate expertise for the nature of research conducted at the institution, and each includes at least one non-scientist and at least one member otherwise not affiliated with the institution.

Indicator 3. The IRB(s) has representation or seeks expert consultation on a continuing or "ad hoc" basis, when special or vulnerable populations are being considered as research subjects (e.g., prisoners, children, etc.).

Indicator 4. The institution has review procedures and mechanisms to determine which studies meet the federal definition for exemption as well as those eligible for expedited review or requiring full-board review.

Indicator 5. The IRB maintains records that document its meetings, deliberations and actions as well as correspondence with investigators.

Indicator 6. The institution has a documented process to meet requirements for substantive continuing review of federally supported non-exempt research at intervals no greater than one year and for the timely review and consideration of reportable serious adverse events, unanticipated problems, and other new information that may affect the rights and welfare of research subjects.

Indicator 7. The institution conducts post-approval monitoring of approved human research.

Indicator 8. When proposed research involves subjects who are likely to be vulnerable to undue influence, the IRB's records include deliberations about the need for additional safeguards to protect the rights and welfare of the subjects. If applicable, the IRB requires additional protection provisions.

Indicator 9. When proposed research involves remote (including foreign) sites, the IRB's records include deliberations about the local research context, including local cultural values and practices to address risk-benefit concerns and to address the needs of vulnerable categories of human subjects.

Indicator 10. A process is in place to ensure that informed consent documents include all elements required under federal regulation as well as those optional elements appropriate for the specific program.

Indicator 11. The IRB has a process for determining when to waive consent, or elements of consent, or to waive the documentation of consent and/or assent if criteria in the federal regulations are met, and it documents that deliberation and determination.

Indicator 12. The IRB reviews the plan for data and safety monitoring, if needed, and determines that the plan is appropriate for the level of risk and provides adequate protection for the human subjects.

Practice C. The institution has a system of coordination between its IRB(s), compliance offices, and sponsored programs administration.

Indicator 1. Mechanisms exist within the institution to identify sponsored projects that involve human subjects and to ensure approval of a research protocol or protocols before initiation of the sponsored activity.

Indicator 2. The institution has a mechanism to notify investigators and external sponsors of the outcome of IRB protocol reviews.

Indicator 3. Mechanisms exist within the institution to suspend or terminate sponsored research activities, or a portion thereof, when/if the protocol(s) expires or is terminated or suspended by the IRB.

Indicator 4. The institution has contracting mechanisms to ensure that consortium agreements require appropriate IRB assurances and reviews at collaborating sites. The institution requires appropriate documentation of those approvals.

Indicator 5. The institution has a mechanism for ensuring that consent documents are consistent with sponsored research agreements, including but not limited to financial commitments made to subjects and coverage for research-related illness and injury.

Practice D. If the institution undertakes research programs involving investigational new drugs (IND) or devices (IDE), it has policies and mechanisms for handling such activities.

Indicator 1. The institution has a process for determining when an IND or IDE is required prior to the initiation of research.

Indicator 2. The institution has a process for determining whether an investigational device poses is a significant or non-significant risk.

Indicator 3. The institution has a process for assuring that appropriate data safety and monitoring programs are in place to assist in the protection of research subjects' rights and welfare.

Indicator 4. The institution has a program for training sponsor-investigators on the FDA requirements associated with assuming the sponsor role for an IND or IDE.

Practice E. The institution and IRB implement mechanisms to protect the confidentiality of human subject data.

Indicator 1. Subject privacy and data confidentiality are components of IRB approval deliberations and are addressed in informed consent documents.

Indicator 2. The IRB ensures that all data collected are reasonable and necessary for the conduct of the proposed research.

Indicator 3. When information protected under the Health Insurance Portability and Accountability Act (HIPAA) will be disclosed for research purposes, the institution has processes to ensure that information is disclosed through an appropriate authorization agreement or with a waiver from a privacy board.

Indicator 4. The institution has mechanisms in place to assess the data security needs of its research programs and to assist and advise investigators about appropriate data security methods and tools to protect study data.

Practice F: The institution fosters effective coordination between its IRB and other regulatory units.

Indicator 1. Financial conflict of interest disclosure and management information is provided to the IRB as a part of the review process. **[See also, VI-1B Financial Conflicts of Interest.]**

Indicator 2. The IRB has the authority to impose additional conflict of interest management mechanisms, if necessary, in order to protect the rights and welfare of human research subjects. The institution has mechanisms to convey IRB concerns and requirements to the appropriate officials.

Indicator 3. Reviews of other ancillary oversight bodies including Institutional Biosafety, Radiation Safety, and Pharmacy committees are coordinated with the IRB to ensure that the IRB has all necessary and relevant information to meet its review and oversight responsibilities.

Principle VI-2B. Animal Care

The institution has policies and procedures that comply with federal, state and local government regulations and with the requirements of non-federal sponsors to humanely, efficiently, effectively, and legally use live vertebrate animals in activities covered by such regulations.

Practice A. If receiving federal funding, the institution has filed an Animal Welfare Assurance with the US Department of Health and Human Services through the National Institutes of Health Office of Laboratory Animal Welfare (OLAW) and received approval thereof, and has also secured US Department of Agriculture (USDA) registration, if applicable.

Indicator 1. The institution has published processes consistent with the approved assurance, which describe the specific procurement and review procedures when animals are used in research.

Indicator 2. A senior institutional official, as specified by federal regulations, is responsible for the entire animal resource program covered by a specific assurance.

Indicator 3. The institution has a mechanism by which it regularly reviews the nature of its animal research program, evaluates resources, and has mechanisms to adjust resources to accommodate the operation of its program in compliance with applicable laws and regulations.

Indicator 4. The institution provides educational resources to ensure that personnel engaged in the review and conduct of animal research and animal husbandry are adequately trained in animal use ethics and in species-specific handling, and institutional records are maintained that document such training.

Indicator 5. The institution has a mechanism for the review, implementation and dissemination of new policies and procedures related to its animal care and use program.

Practice B. If federally funded, the institution has established at least one Institutional Animal Care and Use Committee (IACUC), in accordance with federal regulations to review, approve, require modifications to, disapprove, suspend, or terminate activities involving animals used in research.

Indicator 1. The number and composition of IACUCs are appropriate for the volume and types of animal research conducted by the institution.

Indicator 2. IACUC membership includes appropriate expertise for the nature of research conducted at the institution, and consists of not fewer than five members, including at least one veterinarian, one non-scientist, and one member otherwise not affiliated with the institution.

Indicator 3. During its review of protocols, the IACUC reviews and makes determinations concerning the use of animals consistent with regulations and institutional policies

Indicator 4. The institution maintains records that document its meetings, deliberations, and actions, as well as its correspondence with investigators.

Practice C. The institution has a system of coordination between its IACUC and sponsored programs administration.

Indicator 1. Mechanisms exist within the institution to identify sponsored projects that involve animal subjects and to ensure approval of a research protocol before initiation of the sponsored activity.

Indicator 2. The institution has a mechanism to notify investigators and, as appropriate, sponsors of the outcome of IACUC protocol reviews.

Indicator 3. The institution has a mechanism to ensure that the information the IACUC reviews and approves is consistent with that contained in the application/proposal submitted to an external sponsor.

Indicator 4. Contracting mechanisms ensure that consortium agreements require appropriate IACUC assurances and reviews at collaborating sites.

Practice D. Adequate systems are in place to track, report, and maintain compliance with the Animal Welfare Act, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the *Guide for the Care and Use of Laboratory Animals* [5], and applicable occupational health regulations.

Indicator 1. The IACUC conducts semi-annual evaluations of the animal care and use program, which includes the adequacy of facilities, husbandry (including veterinary care), occupational health and safety, and the administrative program.

Indicator 2. The animal care program includes a process for communicating mandatory and optional occupational health requirements to facility and research staff.

Indicator 2a. Access to animal facilities is restricted only to personnel registered with the institution's occupational health and safety program.

Indicator 3. A comprehensive veterinary medical care program is provided to animals housed at the institution, including diagnostic resources, preventative medicine, sentinel surveillance, post-surgical care, and mechanisms for emergency care.

Practice E: The institution has coordination between its IACUC, compliance offices, and other regulatory units.

Indicator 1: Reviews by any/all other ancillary review bodies including but not limited to Institutional Review Board (for human subjects research), Institutional Biosafety, Radiation Safety, Occupational Health and Safety, and Pharmacy committees are coordinated with the IACUC to ensure that the IACUC has all necessary and relevant information to meet its review responsibilities.

Practice F. The institution has a security plan to protect its research and animal care staff and its laboratory and animal facilities.

Indicator 1. The institution's security personnel are aware of the location of animal housing facilities and any security systems in operation.

Indicator 2. The institution has a process to regularly evaluate the security of its animal facilities.

Indicator 3. The institution has processes in place for reporting of and responding to threats or instances of violence against the research and animal care staff. The institution coordinates its response with local, state and federal authorities to ensure compliance with applicable laws and regulations.

Practice G. The institution has in place a disaster recovery plan and emergency procedures for dealing with catastrophic events that could affect animal facilities.

Indicator 1. The institution's emergency and security personnel have 24-hour contact information to alert husbandry staff.

Indicator 2. Appropriate environmental alarms are in place to ensure the welfare of research animals on a 24-hour basis.

Indicator 3. Specific plans for feeding, watering, and evacuating animals in case of emergency are documented and disseminated to relevant personnel.

Internet Resources

Department of Health and Human Services (HHS) Office of Research Integrity (ORI)
http://ori.dhhs.gov/

National Science Foundation (NSF)
http://www.nsf.gov/publications/pub_summ.jsp?ods_key=papp

White House Office of Science & Technology Policy (OSTP)
Federal Policy on Research Misconduct
http://www.gpo.gov/fdsys/pkg/FR-2000-12-06/pdf/00-30852.pdf

Association of American Universities (AAU)
http://www.aau.edu

Association of American Medical Colleges (AAMC)
https://www.aamc.org/

Council on Governmental Relations (COGR)
http://www.cogr.edu

Food and Drug Administration (FDA)
http://www.fda.gov/

Department of Defense, DoD Directive 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
http://www.dtic.mil/whs/directives/

DOD-Office of Naval Research
http://www.onr.navy.mil/en/About-ONR/compliance-protections/Research-Protections/Human-Subject-Research.aspx

Department of Health and Human Services
Public Health Service Policies on Research Misconduct (42 CFR Parts 50 and 93)
http://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf

National Science Foundation
http://www.nsf.gov/bfa/dias/policy/si/index.jsp

Guidance for Institutional Review Boards and Clinical Investigators, FDA
http://www.fda.gov/oc/ohrt/irbs/default.htm

HIPAA Privacy Rule Information for Researchers
http://privacyruleandresearch.nih.gov/

Secretary's Advisory Committee on Human Research Protections (SACHRP)
http://www.hhs.gov/ohrp/sachrp/index.html

Association for the Accreditation of Human Research Protection Programs (AAHRPP)
http://www.aahrpp.org/

Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH)
http://grants.nih.gov/grants/olaw/olaw.htm

Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA)
http://www.aphis.usda.gov/wps/portal/aphis/home/

Institute for Laboratory Animal Research (ILAR), National Academy of Sciences (NAS)
http://dels.nas.edu/ilar

Animal Welfare Act and Regulations, USDA
http://www.nal.usda.gov/awic/legislat/usdaleg1.htm

Cost Analysis and Rate Setting Manual for Animal Research Facilities, NIH
https://grants.nih.gov/grants/policy/air/rate_setting_manual_2000.pdf

Guide for the Care and Use of Laboratory Animals, ILAR
http://www.nap.edu/readingroom/books/labrats/

Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC)
http://www.aaalac.org/

Endnotes:

[1] Training in the responsible conduct of research is currently required for Public Health Service/National Institutes of Health trainees and for undergraduate and graduate students and post-doctoral researchers who are supported by the National Science Foundation to conduct research as required by the America COMPETES Act of 2007.

[2] The US Office of Science and Technology Policy (OSTP) issued a Federal Policy on Research Misconduct in December 2000. Federal agencies were directed to implement the Policy within one year. The Policy includes definitions, grounds for a finding of misconduct, the responsibilities of Federal agencies and research institutions, guidelines for fair and timely procedures and agency administrative actions. Institutions will want to review the implementation policies of the specific federal agency sponsor.

[3] The institution has considered the final guidance document issued by HHS regarding "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" ("Guidance Document") and association guidance, such as the Association of American Medical Colleges and Association of American Universities "Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research" (February 2008) in establishing its policies and procedures related to human subjects research activities.

[4] The filing of the Federal-Wide Assurance includes an institutional determination of whether to apply the Common Rule (45CFR46 Subpart A) to all research (federally funded and non-funded) and whether to apply vulnerable population rules (45CFR46, Subparts B-D) to research funded by federal agencies whose regulations do not require application of those process standards. The Department of Defense applies additional requirements according to DoD Directive 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research." The Office of Naval Research requires additional training.

[5] PHS requires institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* published by the Institute for Laboratory Animal Research (ILAR) of the National Academy of Sciences. The Guide is published by the National Academies Press and is currently in the Eighth Edition

Principle VII. Intellectual Property Management

The institution has an intellectual property management system adequate to comply with terms and conditions of its institutional policies, all pertinent laws and regulations including the Bayh-Dole Act, and agreements with external sponsors including the Federal Government as well as principles endorsed by groups such as the AAU and APLU.

Practice A. The institution's intellectual property management or technology transfer offices have the capability of properly managing the intellectual property produced during sponsored programs by investigators, research staff, students, and fellows. This may include patentable inventions, copyrightable works (including but not limited to scientific and technical writings and computer software), data, tangible research products over which control of distribution is maintained, mask works or plant varieties and data maintained as know-how, trade secrets, or confidential information provided by the external sponsor or as generated during sponsored programs if permitted by institutional policy.

> **Indicator 1**. Personnel trained in intellectual property management or technology transfer, supplemented as necessary by service arrangements with qualified external organizations or individuals, are employed by the institution. These employees advise and assist sponsored program staff, when necessary, in negotiating intellectual property terms in funding agreements and other agreements (e.g., material transfer agreements) as appropriate in accordance with institutional policy; receive disclosures; and seek to protect and commercialize intellectual property and facilitate the distribution of tangible research materials created at the institution.
>
> **Indicator 2.** The institution has sufficient management resources (i.e., databases, etc.) to track obligations to external sponsors to ensure that conflicting grant of rights to intellectual property do not occur.
>
> **Indicator 3.** The intellectual property staff recognize the impact of granting rights to external sponsors on the future freedom to operate of its investigators, research staff and students and other nonprofit organizations.

Practice B. The institution has written policies and procedures governing the operation and management of its intellectual property.

> **Indicator 1**. The institution has procedures to obtain disclosure and, where appropriate, assignment of intellectual property developed by its employees (i.e., investigators, research staff, students, visitors, consultants, etc.) to the extent required by institutional policy and/or for compliance with agreements of external sponsors.
>
> **Indicator 2**. The institution has procedures for the timely reporting within the institution of intellectual property created during the term of the sponsored project and for notifying external sponsors as needed.
>
> **Indicator 3**. The institution has procedures in place, which may include license agreement templates, to comply with the requirements of the federal patent, copyright, and data rights laws and regulations and institutional policies regarding licensing.
>
> **Indicator 4.** The institution has policies and procedures for royalty sharing with inventors/authors, as required by institutional policies, inter-institutional agreements and federal regulations.
>
> **Indicator 5**. The institution has personnel and procedures to ensure compliance with the Bayh-Dole Act, including but not limited to, designating the use of institutional royalty revenue (after

expenses) for scientific research or education purposes, reporting of federally-funded inventions, timely election of title to inventions, confirming a non-exclusive, royalty free license for government purposes, and other appropriate mechanisms to fully comply with government rights.

Indicator 6. The institution has mechanisms that ensure institutional dissemination of information to relevant offices and/or individuals regarding intellectual property.

Indicator 7. The institution, in its management of intellectual property and technical data, takes appropriate measures including, if appropriate, agreement terms to comply with national security requirements, including export control laws such as the International Trafficking in Arms Regulations (ITAR) and Export Administration Regulations (EAR), regardless of whether such laws are explicitly referenced in its agreements with external sponsors, as well as with the provisions of other relevant federal regulations and executive orders. [See also Principle VIII, Export Controls and Embargos, Trade Sanctions and Executive Orders].

Indicator 8. The institution has procedures, consistent with research practices, to share, track and manage tangible research materials or other research tools, including, as appropriate, data, in order to comply with federal requirements or other sponsor terms and conditions relative to the sharing or transfer of such materials, tools and data.

Indicator 9. The institution has established institutional procedures regarding background intellectual property rights and, if appropriate, mechanisms to identify background intellectual property to comply with the provisions of its agreements.

Indicator 10. If the institution utilizes tax exempt bond financing, written guidelines or other institutional processes exist for review and, as appropriate, consultation with bond counsel before acceptance of intellectual property provisions involving such facilities to ascertain that they are in accordance with financing covenants and regulations.

Indicator 11. The institution's intellectual property management organization has procedures in place to ensure consideration of industry standards such as the Association of University Technology Managers (AUTM) "Nine Points to Consider in Licensing University Technology" when licensing its intellectual property.

Practice C. The institution has policies and procedures for obtaining sufficient rights in intellectual property to satisfy any requirements of agreements with external sponsors and for transferring inventions to the marketplace.

Indicator 1. Procedures have been established to obtain written agreements with investigators, research staff, and students receiving support from sponsored agreements regarding reporting and assignment of intellectual property as required by federal laws and regulations or other agreements with external sponsors relating to intellectual property.

Indicator 2. Procedures have been established to identify and document the legal inventors, authors, or creators of all disclosed intellectual property.

Indicator 3. The institution has procedures to document compliance of its subrecipients with required flow down of intellectual property terms and conditions from external sponsors.

Indicator 4. Institutional policies ensure retention of agreements for a sufficient period of time to allow appropriate evaluation of the downstream intellectual property rights of sponsors.

Practice D. The institution has coordination between its intellectual property /technology transfer and other regulatory units and administrative offices.

> **Indicator 1.** Reviews by any/all other institutional review bodies, including but not limited to Institutional Review Board, Financial Conflicts of Interest, Institutional Biosafety, and Pharmacy committees or boards are coordinated with the intellectual property management system to ensure that the institution, in its management and dissemination of intellectual property and technical data, takes appropriate measures to comply with the provisions of federal regulations.

Practice E. The institution has policies and training programs in place to inform investigators, research staff, students and fellows about their rights and responsibilities with respect to intellectual property.

> **Indicator 1.** The institution has training and awareness programs to inform and train institutional faculty, staff, students and fellows with regard to their rights and responsibilities with respect to all aspects of the institution's intellectual property policy. This includes the obligation to disclose all inventions conceived or reduced to practice while conducting institutional research and awareness of any terms or conditions imposed by external sponsors or third-party material providers in the agreement (including individual agreements) before the sponsored program activity begins.
>
> **Indicator 2.** The institution has an established process for review and adjudication of disputes among investigators.
>
> **Indicator 3**. A training program is in place to acquaint students with the institution's intellectual property polices for independent work, classroom work, and sponsored programs.
>
> **Indicator 4.** The institution has implemented safeguards to protect the student's educational progress from potentially conflicting demands arising from intellectual property claims of third parties.

Internet Resources

US Government Publishing Office, Patents, Trademarks, & Copyrights
http://www.gpo.gov/fdsys/pkg/CFR-2002-title37-vol1/content-detail.html

US Department of Commerce, Patents & Trademarks
http://www.commerce.gov/patents.html

iEdison (Federal Interagency Invention Reporting)
https://s-edison.info.nih.gov/iEdison/

National Institutes of Health, Office of Technology Transfer Policies
http://ott.od.nih.gov/policy/Reports.html

Association of University Technology Managers (AUTM)
In the Public Interest: Nine Points to Consider in Licensing University technology
http://www.autm.net/aboutTT/Points_to_Consider.pdf

Principle VIII . Export Controls, Embargos, Trade Sanctions and Executive Orders

The institution has an export controls compliance program that enables to the maximum extent possible retention of an open, collaborative and international sponsored programs environment while ensuring compliance with federal laws and regulations governing export controls and embargoes.

Practice A. The institution, with senior management support, creates a culture of compliance relating to export controls and embargo regulations.

> **Indicator 1.** The institution either (i) does not accept publication or access restrictions in sponsored programs, but allows a short pre-publication sponsor review period **only** for purposes of the identification of sponsor-provided proprietary information or to seek patent protection, but **not** approval of sponsored programs results, or (ii) identifies, segregates and secures export-controlled sponsored programs from the otherwise open campus, and obtains necessary deemed export licenses for export-controlled sponsored programs.
>
> > **Indicator 1a.** Policies are consistently applied and the institution has a process to ensure appropriate, high-level institutional decision-making on whether and when to grant exceptions to policies.

Practice B. The institution has clearly assigned roles and responsibilities creating accountability for administering and overseeing export controls, embargo compliance. A central office and individual(s) who report at a high level of the institution and with whom the research staff routinely interacts (e.g., for research funding)are responsible for program management , export licensing, and recordkeeping.

> **Indicator 1**. The central office has adequate resources and expert staff supported by outside assistance as necessary to address day-to-day compliance and licensing.

Practice C. The institution has implemented a written and effective export control compliance program that assigns clear responsibilities and accountabilities to individual researchers, staff, and students, based on their expertise and the information in their control, as compared with those of the central office.

> **Indicator 1.** Effective training programs are implemented for export controls and embargoes throughout the research community which includes dissemination of user-friendly aides and resources to assist in adhering to the regulations.
>
> **Indicator 2.** Institutional controls are in place to identify export controlled sponsor-provided information, equipment and materials and to either comply with related export controls or to decline acceptance of such controlled information and items.
>
> **Indicator 3.** The researchers, technology transfer, procurement and shipping staff are aware of export and embargo issues when traveling abroad; carrying or transferring materials, equipment or other items abroad; conveying information beyond basic and general marketing information on use, development, production of shipment of materials, equipment or other items subject to export controls to anyone abroad or to foreign nationals in the US (including as part of international collaborations and

conferences); receiving sponsor-provided information, materials, equipment or items, and the licensing of institutional controlled technology for export.

Indicator 4. The compliance program includes record-keeping of determinations concerning controls and licensing actions, appropriate safeguarding of export controlled information through technology control plans and procedures to monitor compliance and to identify and respond appropriately to violations.

Practice D. The institution includes terms in its agreements where appropriate to require compliance with export controls and embargoes and discourages sponsors from sending export controlled information to anyone other than the individual designated in the agreement to receive such information. The terms provide for termination of agreements if they cannot be performed in compliance with applicable export control regulations.

Practice E. US Office of Foreign Asset Controls (OFAC) Specially Designated Nationals List (SDN) and other sanctions lists are reviewed by the institution's offices that enter into contracts, procure services, make payments, or enter into transactions of value to ensure that no payments or anything of value are transferred to, and no transactions are entered into with sanctioned countries, organizations, or individuals (foreigners and US citizens) where prohibited or that licenses, as may be required by OFAC, that approve the institution's activities in the sanctioned country have been obtained prior to initiating the activity.

Internet Resources:

US Department of Commerce, Bureau of Industry & Security (Export Controls)
http://www.bxa.doc.gov/

US Department of State, Directorate of Defense Trade Control (ITAR)
http://www.pmdtc.org/itar_index.htm

US Department of Treasury, Office of Foreign Assets Control
http://www.treas.gov/offices/enforcement/ofac/

US Department of State, Bureau of Consular Affairs (VISA)
http://travel.state.gov/index.html

US Department of Homeland Security,
US Immigration and Customs Enforcement (SEVIS)
http://www.ice.gov/graphics/sevis/index.htm

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Allocable Costs

As defined in §200.405 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200), Costs are allocable if 1) the costs are incurred specifically for the Federal award; (2) the costs benefit both the Federal award and other work of the non-Federal entity and can be distributed in proportions that may be approximated using reasonable methods; and (3) the costs are necessary to the overall operation of the non-Federal entity and is assignable in part to the Federal award in accordance with the principles in this subpart.

Authorized Organizational Representative (AOR)

An individual who is legally authorized to act on behalf of the institution, obligates the institution to grant applications, terms and conditions, and compliance assurances. Also referred to as the Authorized Official, Authorized Signatory, etc.

Business Ethics

Business ethics (also corporate ethics) is a form of **applied ethics** or professional ethics that examines ethical principles and moral or ethical problems that arise in a business environment. It applies to all aspects of business conduct and is relevant to the conduct of individuals and entire organizations.[1]

Closeout

Closeout means the process by which the federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the federal award have been completed and takes actions as described in 200.343 Closeout of the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards.

Code of Conduct

A set of rules outlining the social norms and rules and responsibilities of, or proper practices for, an individual, party or organization.[2]

Common Rule

The Federal Policy for the Protection of Human Subjects Research.

Corrective Action

Correction action means action taken by the auditee that:

a) Corrects identified deficiencies;
b) Produces recommended improvements; or
c) Demonstrations that audit findings are either invalid or do not warrant auditee action.

Direct Costs

As defined in §200.413 of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200), those costs that can be identified specifically with a particular final cost objective, such as a Federal award, or other internally or externally funded activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.

Effort Reporting

A process used to certify to granting agencies that the estimated time and effort proposed and included in a grant application/proposal has been provided. Other methods include planned confirmation and payroll certification.

Export Controls

Export Controls regulate the shipment or transfer, by whatever means, of controlled items, software, technology, or services out of U.S. (termed an "Export") including foreign nationals in the U.S. ("deemed exports").

Federal Acquisition Regulation (FAR)

The **Federal Acquisition Regulation** (**FAR**) is the primary regulation for use by all Federal Executive agencies in their acquisition of supplies and services with appropriated funds.

Federal Wide Assurance (FWA)

A written assurance of compliance required by the Office of Human Research Protections (OHRP) of institutions engaged in non-exempt human subjects research supported or conducted by Health and Human Services (HHS). The assurance may be used Federal-wide for any department or agency that adopts the Federal Policy for the Protection of Human Subjects, also known as the Common Rule.

Financial Accounting Standards Board

A seven member private sector board designated for establishing financial standards for accounting that governs the preparation of financial reports for nongovernmental entities. Officially recognized as authoritative by the Securities Exchange Commission and the American Institute of Certified Public Accountants.[3]

Financial Conflict of Interest (NIH definition)

A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

Governmental Accounting Standards Board (**GASB**) is the source of generally accepted **accounting** principles (GAAP) used by State and Local governments in the United States. (Wikipedia)

Indirect (facilities & administrative (F&A) costs

Costs incurred for a common or joint purpose benefiting more than one cost objective, and not readily assignable to the cost objectives specifically benefited, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of indirect (F&A) costs. Indirect (F&A) cost pools must be distributed to benefited cost objectives on bases that will produce an equitable result in consideration of relative benefits derived.

Institutional Animal Care and Use Committee (IACUC)

A committee responsible for oversight of the animal care and use program and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) and the *Guide for the Care and Use of Laboratory Animals* (*Guide*). Its oversight functions include an ongoing assessment of animal care and use.
http://grants.nih.gov/grants/olaw/tutorial/iacuc.htm

Institutional Official (IO)

The IO is responsible for ensuring that the Human Research Protection Program (HRPP) and animal research program functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human and animal subjects. The IO represents the institution named in the Federalwide Assurance (FWA).

Indirect Cost Rate Proposal

Indirect cost rate proposal means the documentation prepared by a non-Federal entity to substantiate its request for the establishment of an indirect cost rate as described in Appendix III to Part 200—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs) through Appendix VII to Part 200—States and Local Government and Indian Tribe Indirect Cost Proposals of this part, and Appendix IX to Part 200—Hospital Cost Principles.

Institutional Review Board (IRB)

Is a committee established to review and approve research involving human subjects. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines.

Investigator (PHS Definition)

"Investigator" means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants."

Material Transfer Agreement

A Material Transfer Agreement (MTA) is a contract that sets forth terms and conditions for the transfer of tangible research materials between the owner and the recipient of the materials for research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.

Modified Total Direct Costs

As described in §200.68 of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200), MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award).

Non-Disclosure Agreement

A Non-disclosure agreement (NDA), also known as a confidentiality agreement (CA), confidential disclosure agreement (CDA), proprietary information agreement (PIA), or secrecy agreement (SA), is a legal contract between at least two parties that sets forth the criteria for which designated confidential information may be shared or restricted.

Office of Management and Budget (OMB)

An Executive Office of the President responsible for assisting the President in overseeing the preparation of the Federal budget and in supervising its administration in Federal agencies. The OMB also oversees and coordinates the Administration's procurement, financial management, information, and regulatory policies.

Organizational Conflicts of Interest

Organizational conflicts of interest means that because of relationships with a parent company, affiliate, or subsidiary organization, the non-Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization.

Participant Support Costs

Participant Support Costs are direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects.

Peer Review

A process that is used to evaluate the research, scholarly works or ideas of a researcher by a peer group of experts in the same field.

Policy

A formal governance document for institution.

Prior Written Approval

As described in §200.407 of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200), under any given Federal award, the reasonableness and allocability of certain items of costs may be difficult to determine. In order to avoid subsequent disallowance or dispute based on unreasonableness or nonallocability, the non-Federal entity may seek the prior written approval of the cognizant agency for indirect costs or the Federal awarding agency in advance of the incurrence of special or unusual costs.

Principles

State the general characteristics; i.e., they are overall statements of standards of quality management.

Procedure

Formal steps taken to implement policies, e.g., Standard Operating Procedures (SOP).

Process

Process

The combination of various procedures including documentation, training, reporting, etc. to implement a policy (may be interchangeable with system).

Practices

Measurable conditions, discrete actions or activities which assist in implementing crucial components in the attainment of each principle, but not necessarily all components.

Preaward Costs

As defined in §200.458 of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200), pre-award costs are those incurred prior to the effective date of the Federal award directly pursuant to the negotiation and in anticipation of the Federal award where such costs are necessary for efficient and timely performance of the scope of work. Such costs are allowable only to the extent that they would have been allowable if incurred after the date of the Federal award and only with the written approval of the Federal awarding agency.

Program Income

Income earned by a University that is directly generated by a sponsored activity or earned as a result of an award.

Reasonable Costs

As defined §200.404 of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200), a cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost.

Research Misconduct

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, according to 42 CFR Part 93.

Risk assessment

According to 2 CFR Part 200, Subpart D, risk assessments and risk based monitoring must be conducted by pass-through entities. Risk assessments are used for the purposes of evaluating a pass-through entities or subrecipients eligibility to perform in accordance with rules, regulations and terms and conditions of an award. Factors to consider may include an entities financial stability, quality of management systems, history of past performance, policies and procedures, etc.

Specialized Service Facilities

Services of highly complex or specialized facilities that may be directly charged to applicable awards based on actual usage of the services on the basis of a schedule of rates or established methodology.

Sponsored Programs

For purposes of this guide, sponsored programs means extramural funds supporting research endeavors and scholarly activities of its students and faculty through sponsorship of contracts and grants from outside entities (federal, nonprofit, industry).

Sponsored Programs Management

Sponsored Programs Management encompasses a myriad of activities including but not limited to proposal review and processing, negotiation and award acceptance, account set-up, award monitoring in accordance with sponsors terms, policies, governmental regulations and University policies and procedures, subaward monitoring, and financial accounting.

Subaward

Subaward means an award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal 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.

Subrecipient

Subrecipient means 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 Federal awards directly from a Federal awarding agency.

Subrecipient Monitoring

OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR §200) ("Uniform Guidance"), sections §200.330 and §200.331, requires prime recipients of federal funds to monitor subawards and to ensure subrecipients meet the audit requirements in Subpart F of the Uniform Guidance. Subrecipient monitoring can include such activities as the review of a subrecipients financial status and management controls to mitigate the risk of entering into an agreement with a subrecipient organization.

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200)

A government wide framework for grants management applicable to non-Federal entities including state and local governments, Indian tribes, institutions of higher education, and nonprofit organizations. Parts of the framework may also apply to for-profit entities in limited circumstances and to foreign entities as described in the Uniform Guidance and the Federal Acquisition Regulation. The final guidance supersedes and streamlines requirements from eight existing OMB Circulars A-21, A-87, A-110, A-122, A-89, A-102, A-133 and Circular A-50 and relocates into one consolidated set of guidance, Title 2 of the Code of Federal Regulations.

Unliquidated Balance

Unobligated balance means the amount of funds under a Federal 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 Federal award from the cumulative amount

of the funds that the Federal awarding agency or pass-through entity authorized the non-Federal entity to obligate.

Unliquidated Obligations

Unliquidated Obligations means, 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.

Voluntary committed cost sharing

Cost sharing specifically pledged on a voluntary basis in the proposal's budget or the Federal award on the part of the non-Federal entity and that becomes a binding requirement of Federal award.

Voluntary uncommitted cost sharing

University faculty effort that is over and above that which is committed and budgeted for but not charged to the sponsored agreement.

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[1] See https://www.boundless.com/accounting/textbooks/boundless-accounting-textbook/introduction-to-accounting-1/overview-of-key-elements-of-the-business-19/ethical-considerations-120-11158/

[2] See https://en.wikipedia.org/wiki/Code_of_conduct

[3] See http://www.fasb.org/facts/