Managing Externally Funded Research Programs:
A Guide to Effective Management Practices

Council on Governmental Relations

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About This Document:

The Council on Governmental Relations (COGR) is an association of leading research institutions. 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 web-based guide is illustrative of such activity.

This guide may be used by institutions to help review their management systems and internal controls. Readers must recognize that while general principles of effective management are stable and consistent, rules and regulations imposed by external sponsors are subject to change. This guide does not purport to set standards; it only suggests effective management practices and indicators to test those practices. COGR periodically updates and revises this document. 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.

This document was originally published in April 1989. This is its fifth revision. 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 projects and new regulations. This edition includes a new principle addressing the challenges of international issues in sponsored projects. As sponsored projects become more collaborative and those collaborations involve the global community and questions of export controls, embargos, and visas affect the sponsored projects enterprise, international transactions have become more complex. A new principle bringing these various practices together is appropriate at this time.

This edition of the guide begins with a discussion of a comprehensive compliance system that sets the framework for all the principles that follow. The discussion calls directly for an institutional commitment to compliance. A comprehensive compliance system reflects new emphasis on the value of 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 culture of compliance. In this context, this edition is entirely reorganized within and among the basic principles.

All previous versions have been published on paper. In order to provide greater access and streamline the process of critical updates, the "publication" of this guide is online. This approach allows a listing at the end of each section of web links to the principal regulatory documents and materials. Generally the web links are to main or home pages and the user will need to search for a specific document. These external links will be checked periodically. Users may print each section individually, or the entire document as single file. If a user prints this document, the external links should be compared with the online version to ensure they are accurate. A companion, paper guide to the Principles (only) is available from COGR. It is intended to serve as an overview of effective management practices.

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. The members of the working group availed themselves of this expertise. The working group's dedication and commitment to a thoughtful and thorough revision benefits all the members.

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Preamble

The conduct of research and scholarly activities at the nation's colleges, universities, research hospitals, and specialized research institutes enhances the health, economic well-being, and creativity of the public. The advancement of our knowledge depends on the ability of individual scholars to pursue ideas in an open and collaborative environment conducive to innovation and exploration.

However, the support for these research activities comes from many sources which place obligations on investigators and their institutions for responsible stewardship to ensure full compliance with policies and regulations that govern the use of those funds to meet a common research goal.

Compliance has become a term of art in sponsored research activities. Compliance means meeting all the obligations associated with accepting funds to conduct research or perform an activity proposed to a sponsor. Compliance with a sponsor's requirements or, in the case of federal, state or local governments, regulations involves all aspects of the institution's operations and the research enterprise. Failure to meet these obligations simply wastes human, intellectual and financial resources. Financial and business systems need to be able to support and track purchases and hiring, operate the facilities and, maintain the infrastructure to conduct research. Administrative structures need to be available to offer advice and assistance in seeking funding, disseminating the results, and ensuring access to expertise and resources to complete the research. Performance standards must demand the highest code of conduct to guarantee the integrity and quality of the research whether it involves human participants, animals, or hazardous materials. Institutions are responsible for developing policies and procedures with regard to general and specific issues for the management of its research enterprise.

Research institutions seeking to assure the public of the strength of their stewardship of the public's funds and trust will demonstrates through a program of compliance an institutional commitment to adhere to the terms and conditions of a sponsored project and the broad regulatory framework that supports that project. Such a program begins with documentation of policies, practices, procedures, and controls and proceeds to the delineation of roles and responsibilities and educational programs for all investigators and staff in the institution who have contact with externally funded programs in any manner.

Managing Externally Funded Research Programs: A Guide to Effective Management Practices is intended to help institutions meet these compliance obligations. It has been formatted in such a way as to identify principles, practices, and indicators that may assist in assessing the performance of the systems designed to support research. These elements have been defined as follows:

- **Principles** state the general characteristics; i.e., they are overall statements of standards of quality management.
- **Practices** are measurable conditions which highlight crucial components in the attainment of each principle, but not necessarily all components.
- **Indicators** are suggested measures to use when examining whether effective practices are being employed or outcomes are being achieved.

Principle I. Institutional Program for Effective Compliance Practices

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

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

> **Indicator 1.** Periodic reviews are performed to ensure that institutional policies and procedures reflect current management of the institution and are accessible to all employees.
>
> **Indicator 2.** The institution disseminates and makes known its policies and procedures at all levels of the institution including senior management, administrative and research staffs.

Practice B. The institution has clearly established lines of responsibility, i.e., a delineation of the roles and responsibilities, for all sponsored projects and administrative personnel involved in the conduct and management of sponsored programs.

> **Indicator 1.** The institution obtains confirmation that the principal investigator accepts responsibility for financial and administrative management of the proposed project.
>
> **Indicator 2.** Within an operating unit, roles and responsibilities, along with an appropriate system of checks and balances, are clearly defined and understood.

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

> **Indicator 1.** The institution has a senior-level individual or individual with substantial authority within the institution assigned overall responsibility to oversee sponsored projects compliance.
>
> **Indicator 2.** The individual responsible for sponsored projects compliance has adequate resources and authority to carry out such responsibility and reports periodically to senior-level personnel and, as appropriate, to the governing authority, or an appropriate subgroup of the governing authority.
>
> **Indicator 3.** The institution's governing authority is knowledgeable about the content and the operation of the compliance program and exercises reasonable oversight with respect to the implementation and effectiveness of the compliance program.

Practice D. An education 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.

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[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 for an organization convicted and sentenced for a criminal offense.

Indicator 2. The institution has a training program addressing the responsible conduct of research for students and post-doctoral appointees[2].

Indicator 3. The institution mandates training for appropriate individuals in areas involving special research resources including hazardous materials, radiation safety, select agents and toxins, rDNA, animal use, and human subjects use.

Indicator 4. There is a regular process for reviewing and updating training programs as necessary.

Indicator 5. The institution can document completion of required training programs for each individual involved in sponsored programs.

Practice E. The institution has programs in place that create a climate that encourages compliance including appropriate incentives and protections for employees who report non-compliance.

Practice F. The institution has systems designed to detect non-compliance with Federal, state and local regulations.

Indicator 1. The institution uses auditing and monitoring systems.

Practice G. When instances of non-compliance are determined, the institution implements corrective actions to minimize the reoccurrence of similar problems.

Indicator 1. The institution modifies as appropriate policies and practices to reduce the reoccurrence of compliance problems.

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

Indicator 1. The institution assigns an individual to monitor changes in Federal, state and local regulations and to coordinate changes in the institution's policies and procedures.

Indicator 2. The institution periodically evaluates the effectiveness of its compliance program.

Internet Resources

US Sentencing Commission, Guidelines for Organizations
http://www.ussc.gov/orgguide.HTM

[2] Some topics typically included in instruction in the responsible conduct of research may become mandatory for research staff supported in part or in whole with Public Health Service funds.

Principle II. Sponsored Program Management

Principle II-1. Policy Requirements

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

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

> **Indicator 1.** Individuals carry management responsibility for review of agency websites, publications, and other policy issuances which affect the conduct of sponsored projects.

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

Principle II-2. Administrative Requirements

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

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

> **Indicator 1.** Principal investigators accept management responsibility for the awards which the institution receives on their behalf.
>
> **Indicator 2.** Training opportunities are available for administrative personnel in operating units as well as central areas regarding the administrative and financial requirements of awards (including the appropriate OMB circulars).

Practice B. The institution has assigned management responsibilities at all levels for sponsored programs.

> **Indicator 1.** Personnel are cognizant of and exercise their appropriate responsibilities for the stewardship of external funds.
>
> **Indicator 2.** Procedures maintained at the unit level are reviewed regularly and updated as required.

Practice C. Coordination between institutional offices responsible for varied 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.** Appropriate notification is provided to all offices affected by a new policy or procedural change.
>
> **Indicator 3.** A system is in place to coordinate responses and management between offices in an emergency situation.

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

Practice E. The institution uses reasonable efforts and due diligence not to include within the substantial authority personnel any individual whom the institution knows, or should know has engaged in conduct inconsistent with an effective program.

Principle II-3. Preaward and Proposal Requirements

The institution provides information on prospective sponsors and their requirements and processes proposals in compliance with institutional and sponsor guidelines and requirements.

Practice A. The institution provides access to information for principal investigators on sources of support for research and other scholarly activities and advises investigators in preparation of compliant proposals.

> **Indicator 1**. The institution provides resources for identification of funding opportunities.
>
> **Indicator 2.** Assistance is available to investigators to understand sponsor requirements as well as to construct budgets and develop administrative sections of proposal documents.

Practice B. The institution provides adequate review of proposals prior to their submission to a sponsor.

> **Indicator 1**. The institution has written procedures defining the approvals required for proposals to external sponsors.
>
> **Indicator 2**. The principal investigator formally accepts responsibility for the content of in the proposal and certifies compliance with sponsor and institutional requirements.
>
> **Indicator 3.** Institutional officials review proposal budgets prior to submission including documentation of effort, current and pending support and cost sharing and certify to the accuracy of institutionally-negotiated costs (e.g., fringe benefits, facilities and administrative, etc.) [See III-3, Institutional Rate Agreements].
>
> **Indicator 4.** Staff in an institutional office 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, etc.), and call these to the attention of the principal investigator for correction, when necessary. [See IX, Protection Regulations and X, Research Integrity]
>
> **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 II-5.E, Award Management, below]
>
> **Indicator 6**. The institution has the ability to prepare and submit electronic proposals in a variety of formats to potential sponsors. [See also VII, Electronic Research Administration.]

Principle II-4. Award Acceptance and Negotiation

The institution has a system 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 and amended budgets or scopes of work are submitted when awards have been significantly reduced from requested amounts.
>
> **Indicator 2.** The institution does not make funds available until compliance requirements are satisfied (e.g., human subjects committee approvals, conflicts of interest disclosures, etc.).

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

> **Indicator 1**. Institutional staff is cognizant of institutional policies and practices with respect to ownership of intellectual property rights, publication, acceptance of classified material, etc.
>
> **Indicator 2.** Staff is authorized to negotiate changes in award terms and conditions.
>
> **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/informed during the negotiation.

Practice C. The institution has procedures for the review and negotiation of material transfer agreements (MTA) that meet all institutional policies and practices.

> **Indicator 1.** The institution has a process to identify other sources of funding 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 the MTA by subreceipients.
>
> **Indicator 2.** The institution takes advantage, when appropriate, of standard agreements, e.g., the Uniform Biological Material Transfer Agreement or the National Institutes of Health Simple Letter Agreement. [See also XI. Intellectual Property]
>
> **Indicator 3.** The institution has a process to determine and comply with necessary permits and/or licensing requirements for the transfer within the US and import or export of materials, including US export control laws, outside the US, including notification of transferees. [See also XII-1. Export Control and Embargos Compliance]

Principle II-5. Award 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 management systems.

Practice B. The institution has a system for seeking required sponsor prior approvals, where required, and has developed procedures to implement the federal expanded authorities as provided in OMB Circular A-110/2CFR215[3].

> **Indicator 1.** The institution has policies and procedures for obtaining written prior approvals from sponsors, where required, and maintaining records of approvals granted.
>
> **Indicator 2**. The institution has policies and procedures to document actions taken under the federal expanded authorities, (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 III, Fiscal Administration].

> **Indicator 1.** Terms and conditions of awards are distributed to principal investigators and made available to other institutional personnel, as required.

Practice D. The institution has procedures regarding notification of upcoming termination dates for sponsored projects to appropriate offices.

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

> **Indicator 1.** Policies and procedures are in place to determine whether subrecipients have established adequate management and financial systems prior to receiving subrecipient agreements.
>
> **Indicator 2**. Written agreements with subrecipients specifying terms and conditions, including required flowdown clauses, utilize federally endorsed models as appropriate and are prepared and executed by both parties thereto.
>
> **Indicator 3**. Compliance with both fiscal and technical reporting requirements is monitored.
>
> **Indicator 4**. The institution can ensure itself 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.

---

[3] In May 2004, the Office of Management and Budget (OMB) established a new Title 2 of the Code of Federal Regulations (2CFR) for policy guidance for grants and other financial assistance and non-procurement agreements. OMB Circular A-110 is located at 2CFR 215. Subtitle A includes government-wide guidance to Federal agencies for grants and agreements; subtitle B will include related agency implementation regulations.

Indicator 5. Adequate documentation for the selection and approval if necessary, of the subrecipient when not named in the proposal, is prepared and maintained.

Indicator 6. Ongoing monitoring of technical performance is documented by the principal investigator and of administrative requirements by the sponsored programs, financial or other responsible office.

Indicator 7. Prior to final payment and closeout, certification is received from the institution's principal investigator or project director that all performance requirements, including reports from the subrecipient(s) have been completed.

Indicator 8. Prior to final payment and closeout, final technical, financial, property and patent reports are obtained from the subcontractor.

Principle II-6. 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 receipt of copies of publications resulting from the sponsored projects.

Indicator 2. At the time of account closeout, procedures are in place to confirm that technical reports and other technical deliverables have been submitted and accepted by the sponsor.

Indicator 3. Reports and deliverables are submitted in a timely fashion in the format required by the sponsor. Institutions have systems that allow for electronic reporting of both technical and administrative data as required by the sponsor.

Practice B. The institution has policies and procedures regarding retention of and access to financial and administrative records generated under sponsored programs.

Indicator 1. Retention requirements for financial and administrative records are in accordance with the requirements of Circular A-110/2CFR215, the Federal Acquisition Regulations (FAR), and sponsor policies and are clearly communicated within the institution.

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

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

Indicator 4. Filing and storage facilities are adequate and accessible.

Indicator 5. Where data imaging or other forms of electronic storage are used, appropriate approval of governmental agencies has been received and guidelines are followed for electronic imaging.

Indicator 6. Controls are in place to ensure only authorized retrieval of records.

Indicator 7. Procedures are in place for the retention and/or disposition of records containing information of a proprietary, confidential, or highly sensitive nature.

Indicator 8. Policies and procedures are in place for the retention and/or disposition of electronically maintained records.

Practice C. The institution has policies regarding the retention of research records (e.g. samples, data, specimens, lab books, etc.) pertaining to a sponsored project.

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

Indicator 2. Allowance is made in the written requirement for 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 [See also VI.E, Human Resources].

Indicator 4. Procedures exist for the disposal of research records when appropriate, particularly when those records 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 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 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 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.

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

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

Indicator 2. The institution has identified an individual responsible for compiling the cost of providing data requested under FOIA for securing approval and, subsequently, reimbursement for such costs.

Internet Resources

US Office of Management and Budget (OMB) Circulars
http://www.whitehouse.gov/omb/circulars/index.html

US Code of Federal Regulations (CFR)
http://www.gpoaccess.gov/cfr/index.html

Federal Acquisition Regulations (including Cost Accounting Standards as Appendix)
http://www.acqnet.gov/far/

Federal Electronic Grants Portal
www.grants.gov

Principle III. Financial Administration

The institution's cost estimating, recording, accumulating, and reporting as well as its budget administration systems are designed in accordance with generally accepted accounting principles, the applicable costing provisions of Circulars A-21/A-122, A-110 [2CFR215], A-133 or 45CFR A Subpart E[4] and the financial and technical terms and conditions of the funding agency award. They are designed to ensure that the federal government and other sponsors bear their fair share of total project costs.

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 written policies and procedures for its financial management.

> **Indicator 1**. Personnel involved in the administration of sponsored projects are knowledgeable about and follow these policies and procedures.
>
> **Indicator 2**. Advice and assistance on the financial management policies and procedures of the institution are available to the institution's investigators and staff as needed.
>
> **Indicator 3**. 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 external funding.

> **Indicator 1**. Claims for reimbursement are made in a timely fashion.
>
> **Indicator 2**. Financial reports are accurate and distributed in a timely fashion.
>
> **Indicator 3**. General ledgers and other required accounting records for recording research fund activity are maintained and retained pursuant to record retention requirements and disseminated to persons responsible for financial oversight of external funding. [See also, II-6.B, Sponsored Program Management]
>
> **Indicator 4**. Appropriate payroll and personnel reporting systems are in place, including payroll certification. [See also III-6, Compensation, below]
>
> **Indicator 5.** There is a system to record and document both mandatory and voluntary committed cost sharing on awards. [See also III-7, Cost Sharing, below]
>
> **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.

---

[4] Free-standing hospitals follow the additional cost principles outlined in 45 CFR Subtitle A, 74.80-83 [Subpart E] (formerly OASC-3). These cost principles address awards to commercial organizations and deal specifically with questions of profit, program income, and intangible property. In this document, references to A-21/A-122 include, by reference and as appropriate, Subpart E.

Indicator 7. Source documentation is maintained for all financial transactions at central and/or departmental levels, in accordance with established policies and procedures.

Principle III-2. Cost Accounting Standards

Where appropriate, the institution has systems to ensure compliance with the cost accounting standards mandated by the federal government in OMB Circular A-21 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 (CAS 501, 502, 504, 505).

Indicator 1. When required, the institution has filed with the cognizant audit agency the required disclosure statement for cost accounting practices, the DS-2.

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

Practice B. The institution demonstrates on-going compliance with the requirements of the CAS standards whether a DS-2 is filed, or not.

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.

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 compliance period conforms to its institutional fiscal year.

Practice C. The institution has an ongoing review program to ensure that revisions to the DS-2 are filed as required and that changes in cost accounting practices are made after submission of the revised disclosure statement.

Indicator 1. 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.

Indicator 2. The institution can demonstrate that changes in cost accounting practices are adequately documented in DS-2 revisions submitted to the cognizant federal agency.

Principal III-3. Institutional Rate Agreements

The institution has in place systems, policies and procedures which enable it to correctly prepare and submit required Facilities and Administrative (F&A)[5] or indirect and, when appropriate, fringe benefit rate proposals.

Practice A. The institution's F&A rate proposal is based on applicable federal regulations contained in OMB Circular A-21/A-122.

> **Indicator 1**. The institution provides timely and properly prepared proposals for the negotiation and settlement of facilities and administrative rates with the cognizant federal cost agency.
>
> **Indicator 2**. The institution has a system in place to identify for inclusion only allowable costs in the F&A 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 F&A cost calculations.
>
> **Indicator 4**. Review at appropriate levels is made to ensure the accuracy of all F&A cost calculations.

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

> **Indicator 1.** The institution has written 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.

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 II-3, Sponsored Programs Management]

Practice A. The institution has written policies and procedures for proposal costing and budget administration which are disseminated and made known at all levels of the institution.

> **Indicator 1**. The institution has a system for periodic review of its policies and procedures for proposal costing and budget administration to ensure they are in

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[5] Since 1996, A-21 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 issues continue to use the term "indirect" to refer to similar cost rates.

conformance with sponsor guidelines and the financial policy and procedures of the institution.

Practice B. The institution prepares and submits proposals based upon both consistently applied direct and indirect 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 institutional official who is empowered to approve submission. The official verifies that appropriate costs have been determined and included and that resource commitments have been received.

Indicator 2. Budgets for known subrecipients are reviewed prior to proposal submission for verification based on receipt of adequate documentation including cost and price analysis for direct costs, any required or committed cost sharing, facilities and administration rates and potential program income. [See also II-5.E, Award Management]

Indicator 3. Exceptions to the use of standard rates are made only upon proper justification that is reviewed and approved by an institutional official empowered to approve such exceptions.

Indicator 4. If required, detailed cost justifications are prepared and reflect the institution's financial practices in areas like individual salary rates, detailed travel costs, equipment and supply details, cost of subawards, required and committed cost sharing, potential program income and appropriately applied escalation factors.

Indicator 5. Budgets recognize and provide justification for specialized elements of cost, such as including the cost of compliance with federal regulations (e.g. environmental or ADA renovations/construction projects financed with federal funds), where appropriate, or administrative/clerical salaries.

Indicator 6. Institutions review 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 III-7, Costs Sharing; and III-8.C, Cash Management, below].

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 that do not exceed the sponsor's fair share of total project costs.

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

Indicator 1. Externally sponsored program accounts are easily and uniquely identifiable. Institutional accounts are easily and uniquely identifiable.

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

Indicator 3. The accounting procedures include a list of costs that are expressly unallowable under federal cost principles (OMB Circular A-21/A-122) or by the funding agency (whether federal or non-federal).

Indicator 4. Costs normally allocable as F & A 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, except with written approval of the sponsor, and where the costs are associated with a major project as described by section F.6.b.(2 & 3) (and Exhibit C) of OMB Circular A-21 or section D.3.b.(4) of OMB Circular A-122.

Indicator 5. The accounting procedures include policies to ensure that cost sharing expenditures are allowable in accordance with federal cost principles and sponsor guidelines. (OMB Circular A-110, subpart C.23/2CFR215.23)

Indicator 6. The accounting procedures include guidance for recording program income and utilizing it in accordance with sponsor requirements. (OMB Circular A-110, subpart C.24/2CFR215.24)

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 F&A cost categories.

Indicator 1. A source of expertise is readily available to judge questions of allowability for accounts that are exceptions to established standards of allowability, allocability, accountability, and reasonableness.

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

Practice C. Cost transfers are made only with adequate justification and in a reasonable period of time with the reasons for the transfers explained and documented.

Indicator 1. The institution has appropriate institutional systems to implement the allocation, documentation, and allowability standard of OMB Circular A-21/A-122, including appropriate review and approval, and specific agency guidelines as they relate to cost transfers.

Indicator 2. Transfers of costs which represent corrections of clerical or bookkeeping errors are made promptly after the errors are discovered.

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

Principle III-6. Compensation

The institution has compensation 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 comply with federal requirements of OMB Circulars A-21/A-122 and A-110/2CFR215.

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 3. Salary for investigators, charged to sponsored programs reflects the level of effort commensurate with the proportional share of the institutional base salary for that period.

Indicator 4. The institution maintains a payroll distribution system capable of apportioning an employee's compensation to more than one sponsored agreement or other cost objectives.

Indicator 5. The distribution of salaries and wages, whether as direct costs or F&A costs, is based on a reasonable estimate of the employees' 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 system 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 in OMB Circular A-21/A-122 (and any related clarifications) are reasonable in relation to the actual work performed.

Indicator 1. The distribution of salaries and wages paid is confirmed by the employee or by a person who has suitable means of verification of the total compensated activity performed by the individual.

Indicator 2. Confirmation of an individual's activity must occur at the frequency indicated in OMB Circular A-21 J.10/A-122 Attachment B.8.

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

Indicator 4. Changes in the committed level of effort that require sponsor approval are identified and action is taken to ensure compliance with sponsor requirements.

Indicator 5. The confirmed salary and wage documents/data are retained in accordance with the record retention guidelines in OMB Circular A-110/2CFR215.

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

> **Indicator 1.** Payroll costs in excess of applicable caps are not charged to federal funds.
>
> **Indicator 2.** Costs in excess of applicable caps are accounted for in accordance with 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 proportion to the relative amount of time or effort actually devoted by the employee.
>
> **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, including mandatory and voluntary committed investigator effort. These policies and procedures comply with federal requirements of OMB Circulars A-21/A-122 and A-110/2CFR215.

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

> **Indicator 1.** Cost sharing included in proposal budgets, accepted by the sponsoring agency, and made a condition of the award is considered to be an obligation of the institution.
>
> **Indicator 2.** Investigator and staff effort as well as non-labor costs included as cost sharing obligations are appropriately recorded in the institution's accounting records.
>
> **Indicator 3**. Cost sharing expenditures meet the standards of allowability, allocability, and reasonableness consistent with federal cost principles and standards of sponsors.
>
> **Indicator 4**. Institutional systems provide for appropriate monitoring of cost sharing for timeliness and adequacy of expenditure or in-kind valuation documentation.
>
> **Indicator 5.** The institution reports required cost sharing in accordance with the terms and conditions of awards.
>
> **Indicator 6.** Voluntary uncommitted cost sharing (i.e. investigator-donated additional time above that agreed to as a condition of the award) is excluded from the organized sponsored projects base used for computing the F&A cost rates.

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

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

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

Indicator 1. Cost sharing is transferred to the organized research base for F&A cost calculation purposes.

Indicator 2. Institutional payroll systems identify significant changes in the corresponding work activity properly included in the "organized research" base. When an institution reduces an investigator's level of activities dedicated to other institutional responsibilities in order to shift his/her activities to organized research activities, the reduction is properly reflected in the payroll distribution system and in F&A cost rate proposals.

Indicator 3. Federally-funded research reflects 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 shown, an estimated amount is computed by the university and included in the organized research base, consistent with OMB Circular A-21.

Principle III-8. Cash Management

The institution has a cash management system that complies with generally accepted accounting principles and 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 them when permitted 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 in a timely and accurate fashion. [See also, VII.F.3, Electronic Research Administration]

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 record the receipt of revenue, to disburse cash, and to bill agencies in a timely manner.

Indicator 1. Procedures are established for 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 remittances is in place.

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

Indicator 4. The institution has appropriate relationships with banking institutions to send and receive 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.

Practice C. The institution has policies and procedures to properly identify, record, manage, and report program income in accordance with regulations.

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

Indicator 2. There are clearly defined accounting procedures for 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 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[6].

Practice A. The institution has established policies and practices that ensure compliance with the provisions of OMB Circular A-21/A-122 where specialized service/recharge costs are material.

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

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

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[6] 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.

Indicator 3. The institution can demonstrate that the charges do not discriminate against federally supported activities of the institution.

Indicator 4. The rate calculation is designed to take into consideration variances in calculating future rates and is reviewed on a regular basis.

Principle III-10. Project Closeout

The institution has policies and procedures for timely, complete and accurate project closeout in accordance with OMB Circulars A-21/A-122 and A-110/2CFR215.

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

Indicator 1. The institution clearly communicates requirements for final technical report submissions to principal investigators. [See also, II-6.A, Sponsored Program Management]

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.

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

Indicator 1. The institution can document that all financial transactions are incurred (or encumbered if appropriate) within the period of performance of the sponsored agreement.

Indicator 2. The institution can document that all financial transactions are allowable, allocable, reasonable, and consistently applied.

Indicator 3. The institution can document that all obligations under the award have been liquidated, generally within 90 days after the funding period or per award terms.

Indicator 4. The institution has mechanisms in place to ensure timely final invoicing and reporting.

Internet Resources

US Office of Management and Budget (OMB) Circulars
http://www.whitehouse.gov/omb/circulars/index.html

US Code of Federal Regulations (CFR)
http://www.gpoaccess.gov/cfr/index.html

Federal Acquisition Regulations (including Cost Accounting Standards as Appendix)
http://www.acqnet.gov/far/

Principle IV. 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.

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

> **Indicator 1.** Personnel involved in the administration of sponsored projects 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 cost principles governing expenditure of federal funds (i.e., OMB Circular A-21/A-122) and the procurement procedures described by federal regulations (i.e., OMB Circular A-110/2CFR 215 and the Federal Acquisition Regulations with individual agency supplements).
>
> **Indicator 3.** Individuals in central administrative offices and the institution's operating units receive appropriate training in the institution's procurement policies and in the requirements imposed by external sponsors.
>
> **Indicator 4.** The institution has a procedure to review vendor relationships, if any, with institution employees to prevent 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 has written policies for the issuance and use of procurement cards (P-cards).

Practice B. The institution has a written procurement system that meets the requirements of OMB Circular A-110/2CFR 215 and the Federal Acquisition Regulations with agency supplements, as applicable.

> **Indicator 1.** A Request for Proposal (RFP), Request for Quotations (RFQ), or other bid system is in place for the acquisition of goods and services (at levels specified by sponsor and institutional policy) that provides for competitive procurement and justification for accepting other than the low bid.
>
> **Indicator 2.** Criteria for utilizing sole source acquisitions are available and written justification is prepared for sole source procurements.
>
> **Indicator 3.** Policies and procedures that encourage procurement from small, minority, disadvantaged, and/or woman-owned businesses are available and the institution has developed appropriate procedures to provide reports to agencies as required.
>
> **Indicator 4.** Policies and procedures are in place to preclude purchases from vendors who are debarred or suspended.
>
> **Indicator 5.** Documentation is maintained on vendor acquisitions which comply with federal requirements as applicable for certified cost or pricing data.

Indicator 6. Documentation indicating that cost analysis was performed on procurements, where necessary, is maintained.

Indicator 7. The institution has procedures in place to determine, prior to acquisition, that no equipment is available to meet project needs that would make a purchase unnecessary.

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.

Practice C. The institution's procurement system allows for expedited purchase.

Indicator 1. A small and/or micro order purchasing system is available which complies with the dollar thresholds in the federal regulations.

Indicator 2. A petty cash system is available.

Indicator 3. Emergency purchase orders are processed when needed.

Indicator 4. Blanket purchase orders are used, where appropriate.

Indicator 5. The use of P-cards is restricted to purchases that comply with sponsor and institutional dollar limits for purchases using those cards.

Practice D. The institution's procurement procedures distinguish between acquisition of goods and services and subrecipient agreements for sponsored projects [See also, II-5.E, Awards management].

Practice E. The institution has processes in place to close out purchases in a timely manner, including closeouts within 60 days of the termination date of an award.

Internet Resources

US Office of Management and Budget (OMB) Circulars
http://www.whitehouse.gov/omb/circulars/index.html

Federal Acquisition Regulations (including Cost Accounting Standards as Appendix)
http://www.acqnet.gov/far/

National Contract Management Association (Code of Ethics)
http://www.ncmahq.org/membership/profession.asp#vision

Principle V. Management of Equipment

The institution has a management system for equipment acquired from both federal and non-federal sources.[7]

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. [See also XII-1, Export Controls and Embargos]
>
> **Indicator 3.** Receiving procedures are in place to ensure that all purchases are inspected upon receipt for condition and completeness.
>
> **Indicator 4.** Only authorized personnel are allowed to place purchase orders.
>
> **Indicator 5.** Equipment acquisitions on sponsored accounts are reviewed for allowability, ownership, and taxes.
>
> **Indicator 6.** 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.

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[7] See OMB Circular A-110/2CFR 215,__.2 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 in the circulars 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 XI. The reader should consult OMB A-110/2CFR215, __.30-.37 for a discussion of other types of property.

Indicator 3. Inventories reflect with whom title to equipment resides, as well as the original source(s) of funds for the purchase.

Indicator 4. The inventory system tracks all equipment, including that purchased on sponsored funds, by donations, or furnished by the government.

Indicator 5. A system is in place for the timely and accurate updating of equipment records upon acquisition or deletion of items.

Indicator 6. Reconciliation of inventory records with financial records is performed at least biennially.

Indicator 7. 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. Disposing of equipment is done through the Surplus Sales Department or similar responsible department in accordance with institutional policy.

Indicator 3. 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.

Internet Resources

US Office of Management and Budget (OMB) Circulars
http://www.whitehouse.gov/omb/circulars/index.html

Federal Acquisition Regulations (including Cost Accounting Standards as Appendix)
http://www.acqnet.gov/far/

Principle VI. Human Resources

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, terms, conditions and termination of employment.

Practice A. The institution's human resource policies and procedures address relevant laws and regulations such as equal employment opportunity and anti-discrimination regulations, Family Medical Leave (FMLA), Fair Labor Standards Act (FLSA), Fair Credit Reporting Act, USA PATRIOT Act Section 817 (2), Public Health Security and Bioterrorism Preparedness and Response Act, nondiscrimination, prevention of sexual harassment, reasonable accommodation of recognized disabilities under federal or state law, and drug and alcohol abuse.

> **Indicator 1.** There is documentation that such policies have been published and disseminated.
>
> **Indicator 2.** The human resources policies provide for a prompt and diligent investigation and resolution of allegations relating to discrimination, harassment, and other workplace issues.
>
> **Indicator 3.** There are programs that provide employee assistance in identification and treatment of alcohol and/or drug abuse.
>
> **Indicator 4.** 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 recruiting, hiring, evaluating, compensating, disciplining, and terminating employees.

Practice C. The institution has policies and procedures to ensure compliance with U.S. laws governing immigrants and foreign nationals.

> **Indicator 1.** The institution collects Employee Eligibility Verification (I-9) forms from all employees.
>
> **Indicator 2.** The institution recognizes and complies with the visa requirements for employees and students who are foreign nationals.
>
> **Indicator 3.** The institution has a procedure for identifying and notifying federal sponsors if international graduate research assistants are engaged in sponsored projects activities under applicable awards, if required by the award.

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 or 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 conditions employment on the individual's (whether U.S. citizen or foreign national) ability legally to have access to and

work with all materials (e.g., select agents and toxins) that are necessary or convenient for the work of the position.

Indicator 2. The institution has controls in place to ensure compliance with export controls. [See also XIII-1, Export Controls and Embargos].

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

Indicator 1. Mechanisms are in place to ensure that the institution and investigators leaving the institution engage in a comprehensive close-out process, e.g., lab clean out, closure or transfer to another investigator of regulatory approvals (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.

Indicator 2. Mechanisms are in place to ensure that investigators entering an institution and the new institution have obtained necessary approvals from the prior employer and from regulatory agencies regarding the transfer of data, sample archives, equipment, etc. and regarding access to and use of regulated materials (e.g., select agents and toxins), as needed for research at the new institution.

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 projects programs, regulatory training) related to their job duties.

Practice F. The institution has appropriate training programs available as required by external sponsors and laws and regulations.

Practice G. The institution has in place appropriate policies and practices to guard against unauthorized disclosure of personally identifiable non-public information (e.g., social security numbers) about employees and to respond appropriately to inadvertent unauthorized disclosures according to institutional policy and state and local laws.

Internet Resources

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/

Public Health Security & Bioterrorism Preparedness Act (Bioterrorism Act of 2002) and USA Patriot Act Restrictions
HHS Food and Drug Administration
http://www.fda.gov/oc/bioterrorism/bioact.html
HHS Centers for Disease Control
http://www.cdc.gov/od/sap/ (CDC Select Agent Program)

US Department of Agriculture, Animal and Plant Health Inspection Service (AHPIS Select Agents)
http://www.aphis.usda.gov/programs/ag_selectagent/index.html

Principle VII. Electronic Research Administration

The institution has appropriate procedures in place to allow it 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 (eRA) is fully integrated into the institution's overall strategy for e-business and is recognized as a significant element in the development of approaches to e-commerce.

> **Indicator 1**. Institutional personnel periodically review the information provided through electronic government initiatives and incorporate that information into institutional planning.
>
> **Indicator 2**. There is evidence that an institution has adequately trained personnel to support e-commerce initiatives, including electronic sponsored projects administration, both in central administration and in the operating units.

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

> **Indicator 1**. The institution maintains strategies to be able to submit proposals, receive awards, and provide financial reports to agencies in an electronic format for utilization in electronic commerce where mandated by the agency.
>
> **Indicator 2.** Individuals are identified with responsibility to recognize and implement mandatory electronic initiatives of sponsors, primarily the federal government.
>
> **Indicator 3.** Principal investigators are made aware of the initiatives of sponsors so they can prepare proposals, reports, and other documentation in electronic formats, where required.

Practice C. The institution takes advantage, when practicable, of on-line training programs for both mandatory and voluntary sponsored projects regulatory requirements, e.g., use of human or animal research subjects, conflicts of interest, and export controls, etc.

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

> **Indicator 1.** The institution has the ability to submit electronic proposals to grants.gov when mandated by the federal agency and advises investigators and other staff of those requirements.
>
> **Indicator 2**. The institution has identified the personnel charged with institutional management of various systems utilized by federal agencies as they are implemented.
>
> **Indicator 3.** 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 E. The institution has electronic systems to take advantage of opportunities for the submission of applications to potential sponsors as required.

> **Indicator 1**. Procedures are in place to allow for electronic creation of proposals in a prescribed format, such as the approved SF 424 Research and Related (R&R) and agency specific PureEdge forms or through the system-to-system interface provided by grants.gov.

Practice F. The institution can manage required financial and other post award matters electronically, when required by the federal government.

> **Indicator 1.** Electronic funds transfers are utilized where possible to affect rapid financial billing and reporting and to receive funds and payments on federal awards.
>
> **Indicator 2.** The institution complies with electronic funds transfer requirements of all federal agencies.
>
> **Indicator 3.** The institution has provided the necessary Central Contractor Registry (CCR) registration to allow it to receive payments electronically and to bid on certain projects from the mission agencies. [See also III-4, Proposal Costing; and III-8, Cash Management]

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

> **Indicator 1.** Sponsored projects data should be collected once, at the inception of the project, and shared across the enterprise.
>
> **Indicator 2.** A system of rights and roles exists to prohibit unauthorized access to and modification of data within the system of record.
>
> **Indicator 3**. Personnel responsible for eRA systems routinely back up all eRA related databases and other electronic files in accordance with generally acceptable backup procedures.

Internet Resources:

Federal Electronic Grants Portal
www.grants.gov

Central Contractor Registration
http://www.ccr.gov/

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/

Principle VIII. Assessments and Audits

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

Practice A. The institution has written policies and procedures for performing compliance assessments and formal audits and for reporting the results of such reviews to management.

> **Indicator 1.** The institution demonstrates a knowledge of and commitment to compliance by performing compliance assessments in areas of sponsored project activity.
>
> **Indicator 2.** The institution initiates formal audits of administrative and financial systems that support the sponsored project enterprise and reports the results of such audits to management.

Practice B. The institution has written policies and procedures for both its external independent audit and its internal audit responsibilities.

> **Indicator 1**. There are policies in place to ensure the independence of auditors and the institution's auditor reports directly to its governing body.
>
> **Indicator 2.** Procedures are in place to ensure that external auditors are selected in accordance with a process that complies with the requirements of OMB Circular A-133.

Practice C. Policies and procedures for the institution's audit system are distributed to its responsible officials.

> **Indicator 1.** Compliance assessments adhere to the same audit standards that apply to formal audits.
>
> **Indicator 2.** The results of financial and compliance audits are communicated to all affected individuals and corrective action plans, developed in response to compliance assessments, are acknowledged.

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

Practice E. 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.

Practice F. Assessments supporting the institution's program of compliance are performed on a regular basis.

Practice G. The institution complies with government auditing requirements with respect to its federal 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 an institution.

Indicator 5. The institution's audit program includes tests for internal controls and compliance with administrative requirements, such as the compliance supplement to OMB Circular A-133.

Internet Resources

US Office of Management and Budget (OMB) Circulars
http://www.whitehouse.gov/omb/circulars/index.html

US Sentencing Commission, Guidelines for Organizations
http://www.ussc.gov/orgguide.HTM

Principle IX. Protection Regulations

The institution has systems that comply with federal, state and local government regulations and with requirements of non-federal sponsors in the areas of protection of human subjects and of animals, the environment, and in the operation of its facilities.[8]

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.** An office or individual is identified 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 IX-1. Human Subjects

The institution has a system that complies with federal, state and local government regulations and with the requirements of non-federal sponsors to protect the rights, well-being, and personal privacy of human subjects in research.

Practice A. The institution has filed a written Federal-Wide Assurance (FWA) with the US Department of Health and Human Services and received approval in accordance with federal regulations.

> **Indicator 1.** The institution has written and disseminated policies and procedures consistent with the approved FWA that describe the specific review procedures 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 review program covered by the federal assurance.
>
> **Indicator 3.** The institution has a mechanism by which it regularly reviews the nature of its human 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 individuals engaged in the review and conduct of human subject research are adequately trained, and institutional records are maintained which document such training.
>
> **Indicator 5.** The institution has a mechanism for the review, implementation and dissemination of new policies and procedures related to its human research program.

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[8] This section deals with four specific areas of compliance in the conduct of research: human subjects, animals, the environment, and facilities. The reader should be cognizant that these regulations are under continuous review by agencies and subject to change.

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

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

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

Indicator 3. The IRB has representation 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 protocol review procedures and mechanisms to determine which studies meet the federal definition for exemption as well as those requiring expedited and full-board review.

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

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

Indicator 7. A system exists for monitoring of protocols as approved.

Indicator 8. When proposed research involves subjects that are likely to be vulnerable to coercion or 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 incorporates additional protection regulations in its review.

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 concerns of risk-benefit and 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 project.

Indicator 11. Where appropriate, the IRB considers investigator and institutional financial conflicts of interest in its protocol review process.

Practice C. The institution has a system of coordination between its IRB and sponsored projects administration.

Indicator 1. Mechanisms exist within the institution to identify sponsored projects that involve human subjects and ensure approval of a research protocol before initiation of the 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 terminate sponsored research activities when/if the protocol expires.

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

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

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

Indicator 2. The IRB has a process for determining whether an IDE is a significant or non-significant risk device.

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

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

Indicator 1. Subject confidentiality is a component of IRB approval deliberations and is addressed in informed consent documents.

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

Indicator 3. When patient 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 an ethics board.

Internet Resources

Office for Human Research Protections (OHRP), Department of Health and Human Services (HHS)
http://www.hhs.gov/ohrp/

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

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/

National Institutes of Health (NIH) Office of Biotechnology Activities
Secretary's Advisory Committee on Xenotransplantation
http://www4.od.nih.gov/oba/Sacx.htm

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/www.aspx

Partnership for Human Research Protection
http://www.phrp.org/

Principle IX-2. Animal Care

The institution has a system to ensure the existence of policies and procedures which 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 sponsored projects covered by such regulations.

Practice A. The institution has filed a written assurance with the US Department of Health and Human Services and received approval thereof, and has also secured US Department of Agriculture registration.

> **Indicator 1.** The institution has written and disseminated policies and procedures 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, and institutional records are maintained which 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 research program.

Practice B. 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, or disapprove, suspend or terminate activities involving animals used in research.

> **Indicator 1.** The size and number of IACUCs are appropriate for the volume of animal research conducted by the institution.
>
> **Indicator 2.** IACUC membership includes appropriate expertise for the nature of research conducted at the institution, and includes 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 determines that:
>
> - The use of the proposed animal model is appropriate for the scientific question being asked.
> - The number of animals requested is scientifically justified.
> - Alternative models have been appropriately considered in the justification of animal model.
> - Discomfort, pain and distress are minimized.
> - Investigators are appropriately trained for the procedures to be performed.
> - Euthanasia techniques are consistent with guidelines of the American Veterinary Medical Association unless a waiver is scientifically justified.

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

Indicator 5. The IACUC has authority to suspend a previously approved activity if it determines that the activity is not being conducted in accordance with applicable provisions.

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

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

Indicator 2. The institution has a mechanism to notify investigators and external 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*[9], 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), 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 as well as to identify new staff to the institution's occupational health program.

Indicator 3. A comprehensive veterinary medical care program is provided to all animal colonies, including diagnostic resources, preventative medicine, post-surgical care and mechanisms for emergency care.

Practice E. The institution has a security plan to protect against unauthorized entry into animal facilities.

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

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[9] 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 Academies' Press.

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

Practice F. 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 utilized to ensure the welfare of research animals on a 24-hour basis.

Internet Resources

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/ac/

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

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
http://www.ncrr.nih.gov/newspub/CARS.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/

Principle IX-3. Environment, Health and Safety/Security

The institution has a comprehensive and integrated systems approach to environment, health and safety (and related security) (EHS) that is appropriate for the size and scope of the institution's sponsored research activity. The systems ensure compliance with federal, state and local government regulations governing the conduct and effects of sponsored projects activities, materials, and equipment on the environment and on the health, safety and security of researchers and the public[10].

Practice A. The institution's governing board or appropriate senior policy-making committee has adopted an EHS policy for the institution that meets environmental, health and safety regulatory standards in sponsored projects activities. The institution ensures that the policy is implemented locally at all levels of the institution's sponsored projects endeavor, as well as centrally in an EHS Office and institutional oversight committees.

Practice B. The institution has devoted adequate staffing, funding and other resources to implement, manage and oversee its EHS system and performance.

Practice C. The institution has created a functional organization, both centrally in an EHS office and in institutional oversight committees that report to a high level of the institution and locally in each research unit. The organization has a clear allocation of roles, responsibilities and accountabilities for EHS regulatory compliance and permitting/licensing, and for institutional policy-making and oversight.

> **Indicator 1.** Institutional EHS oversight committees are responsible for compliance with (a) biosafety and security laws (including those for using recombinant DNA and for using select biological agents and toxins), (b) radiation safety and security laws (including those for safe research protocols and security measures for research using nuclear or radioactive materials), and (c) hazardous chemicals laws (including those for hazardous waste). The committees also oversee the effectiveness and evolution of the institution's EHS system as institutional activities and applicable laws change.
>
> **Indicator 2.** The roles and responsibilities of the institutional committees, central EHS office, local research units, each principal investigator, other research personnel, and outside contractors are allocated according to each component's expertise and areas of control, are clearly articulated in writing, and are known and acknowledged across the institution and by the institution's contractors.
>
> > **Indicator 2a.** The EHS office, committees and local research units work together and efficiently contribute resources to address all EHS requirements and needed services.
> >
> > **Indicator 2b.** The principal investigator and relevant local research unit assume appropriate responsibility for their EHS compliance and performance based on the size, organization and culture of the institution.

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[10] Materials can include chemicals, radioactives, 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.

Indicator 2c. The central EHS office provides EHS services to support local compliance, provides EHS technical expertise to the development and review of research and security protocols, contributes to EHS policy-making and supports the institutional EHS committees, and also oversees institutional performance and EHS contractors' performance.

Indicator 2d. A senior EHS officer has authority to ensure that appropriate remedial corrective actions are taken and consequences are imposed for inadequate institutional, local or individual EHS performance.

Indicator 2e. The institution has, to the extent applicable based on the scope and substance of its sponsored projects program, appropriately expert individuals who serve as its institutional biosafety officer, its authorized official to administer the institution's select agent and toxin compliance program, its authorized officials to arrange for and manifest hazardous waste for disposal, its radiation protection officer, and its chemical hygiene officers.

Indicator 3. The institutional committees have members, keep records, and act in accordance with regulatory requirements (e.g., NIH's rDNA committee requirements).

Indicator 4. The institution's process for administering applications for sponsored projects awards is coordinated with the institution's EHS system to ensure early identification of compliance issues (e.g., those for rDNA or select agents and toxins or hazardous waste).

Practice D. The institution has established an EHS Management System or other systems approach and written policies and procedures that include adequate program components for the scope and complexity of regular activities at the institution.

Indicator 1. The system identifies and classifies all EHS regulations that are applicable to the institution and its activities and links these to a position identified as accountable for overseeing compliance with each.

Indicator 2. The system includes a training needs assessment approach to determine minimum training requirements established by regulations and institutional policy for each individual.

Indicator 3. The system includes regulatory training for investigators, staff, students, visitors and contractors, at least satisfying minimum regulatory and institutional requirements and allowing for customization to meet unique sponsored projects needs.

Indicator 4. The system includes appropriate periodic compliance monitoring and measurements through inspections or reviews at the local laboratory, whole research unit, and institution-wide levels to reinforce training, track performance trends, and self-identify and remedy regulatory and policy/standard operating procedure violations and system or program deficiencies. The approach also tracks corrective actions and imposes consequences, as warranted, on individual units.

Indicator 5. The system includes appropriate periodic EHS system audits covering system implementation, controls, and effectiveness to identify and rectify system and performance deficiencies.

Indicator 6. The system includes an inventory or other 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.

Indicator 7. The system includes special access controls, security, 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 8. The system includes compliance resource materials and tools that are easily accessible to the regulated community.

Indicator 9. The system includes an approach to track changes in regulatory requirements and to incorporate such changes in the EHS system programs.

Indicator 10. The system includes a communications program concerning all aspects of the EHS system and all affected people centrally and locally.

Indicator 11. The system includes record-keeping and reporting procedures that are accessible to local research units and to the central EHS office and that both satisfy regulatory requirements and provide good and timely data for management of EHS performance.

Indicator 12. The system includes emergency preparedness and response systems.

Indicator 13. The system includes approaches for measuring, preventing, responding to and mitigating occupational injuries and illnesses.

Indicator 14. The system may include an approach for minimizing, if practical without interfering with sponsored projects objectives, the use of materials and equipment that trigger regulation, and for reducing pollution from and toxicity of research.

Internet Resources

Environmental Protection Agency
Resources Conservation and Recovery Act (RCRA) – Office of Solid Waste
http://www.epa.gov/osw/
National College and University Sector Program
http://www.epa.gov/sectors/colleges/index.html
Major Laws and Regulations (Clean Air, Water, RCRA)
http://www.epa.gov/epahome/laws.htm

Public Health Security & Bioterrorism Preparedness Act (Bioterrorism Act of 2002) and USA Patriot Act Restrictions
Food and Drug Administration
http://www.fda.gov/oc/bioterrorism/bioact.html
Centers for Disease Control
http://www.cdc.gov/od/sap/ (CDC Select Agent Program)
US Department of Agriculture, Animal and Plant Health Inspection Service (AHPIS Select Agents)
http://www.aphis.usda.gov/programs/ag_selectagent/index.html

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.hsrd.ornl.gov/nrc/home.html

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

Principle IX-4. Facilities

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

Practice A. The institution has policies and procedures for maintaining the security of its buildings, grounds, information systems, 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.
>
> **Indicator 3.** Individuals of sufficient rank have been assigned the positions of facility and information systems security officers to oversee the security systems, including classified research activities, if applicable.
>
> **Indicator 4.** The institution is committed to providing a safe and healthy environment for its employees, students, and visitors.

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, where appropriate, are published and disseminated to employees.

> **Indicator 1.** Information, procedures, and requirements on industrial insurance and accident protection and reporting exist.
>
> **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 projects activities, including ongoing training as required for employees.

Practice C. The institution reviews building construction and renovation design drawings to ensure that safety and health requirements are met and that the institution complies with federal requirements on the construction of research facilities.

Practice D. The institution has risk financing mechanisms which comply with federal and, where necessary, state 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 system for the management and resolution of liability claims.

Indicator 8. The institution has a record keeping system for its risk management programs.

Indicator 9. If self-insured, the institution has a system for responding to property loss and liability claims.

Practice E. 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.

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

Internet Resources

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

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

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

Principle X. Research Integrity

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

Practice A. The institution has written statements that demonstrate an understanding of ethical scholarship and provide procedures for raising and resolving questions of what professional or ethical standards in conducting sponsored projects entail.

> **Indicator 1**. The institution provides an environment where responsible conduct of research is a fundamental prerequisite in the design, conduct and reporting of research data and results.
>
> **Indicator 2**. The institution has policies that encourage unimpeded public dissemination of sponsored projects outcomes, such as protecting investigators, students and research staff from requirements for prior approval by parties external to the institution.
>
> **Indicator 3**. The institution encourages investigators to abide by or develop standards, appropriate to the discipline, for data management and reporting to the scientific community and to ensure that such reported work will meet peer review standards of the discipline.
>
> **Indicator 4**. The institution has guidelines and practices that recognize the need for senior investigators to mentor students and research staff in the understanding of ethical standards of research conduct.
>
> **Indicator 5**. Programs are in place that meets PHS education requirements for PHS-supported trainees for instruction in research integrity, including mandatory instruction on scientific integrity and ethical principles.
>
> **Indicator 6.** The institution has easily accessible means, including web-based tools, for educating investigators, students and employees about research ethics and responsible conduct standards.

Practice B. The institution has a written policy that addresses treatment of allegations of research misconduct and that meets sponsor requirements.

> **Indicator 1**. The institution has an Assurance of Compliance with PHS Policy on Research Misconduct accepted by the HHS Office of Research Integrity.
>
> **Indicator 2**. The institution's policy clearly delineates points of contact and lines of communication for persons making allegations of scientific misconduct.
>
> **Indicator 3**. The institution has designated Research Integrity Officer(s) and staff prepared to respond to an allegation with practical approaches for securing and protecting (sequestering) source data, laboratory notebooks, and other relevant materials.
>
> **Indicator 4.** The institution's policy contains commitment for protection of the rights of the whistleblower and any party 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.

Indicator 5. The institution uses a procedure for conducting in a timely manner, a preliminary inquiry for the narrow and specific purpose of discriminating between those allegations that are of substance and those that are not, and for documenting the procedure and its findings.

Indicator 6. If, after a preliminary 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 preparing written findings.

Indicator 7. Notice that the institution is undertaking a formal investigation into allegations of misconduct is reported to any directly affected sponsor, as appropriate, and the outcome of the formal investigation is subsequently reported by the institution to the sponsor, where required by sponsor regulation.

.

Practice C. The institution has a written policy to assist investigators, students and research staff in determining whether and to what extent outside financial relationships and interests may conflict with their primary research and academic activities or other institutional responsibilities.

Indicator 1. The institution provides written guidance and examples to research investigators regarding the types of financial interests that must be reported to the institution, conflict avoidance and conflict management, including disqualification from decision-making. The policy distinguishes between conflicts of interest and conflicts of commitment.

Indicator 2. The policy of the institution clearly assigns to the employee or research investigator the responsibility for disclosing to the institution a personal financial interest that might pose a conflict of interest (COI) as required by a sponsor.

Indicator 3. The institution's policy complies with sponsor requirements if applicable for identifying, disclosing, and managing financial conflicts of interest, and any other requirements imposed by the government regarding financial conflicts of interest.

Indicator 4. The institution's policy has a process that ensures that the investigator is in compliance with the COI policies of the external sponsor.

Indicator 5. The institution's policy specifically addresses conflict of interest issues that pertain to student-faculty relationships to ensure that a student's degree-oriented research does not become entangled with a investigator's outside commercial interests, that such interests do not impede the student's progress toward degree, and do not restrict students' communication with each other and or/their right to publish their dissertation/thesis.

Indicator 6. 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 conflict of interest concerns.

Practice D. The institution has procedures for managing or resolving 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 of specific management plans that eliminate, reduce or manage the disclosed conflict, and the timely and informed communication of required management practices to investigators with disclosed conflicts.
>
> **Indicator 2**. The institution has regular follow-up and institutional monitoring to ensure that management plans are being complied with.
>
> **Indicator 3**. The institution informs external sponsors, as required, when an investigator has disclosed a financial conflict related to the sponsor's current or potential supported activity.
>
> **Indicator 4**. Adequate enforcement mechanisms and/or sanctions exist.

Practice E. The institution has policies and procedures that recognize the heightened level of concern regarding conflict of interest in research involving human subjects. [See also IX-1, Human Subjects]

> **Indicator 1.** 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") in establishing its policies and procedures and has asked the questions and considered the actions set out in that document.

Practice F. The institution has policies and procedures that identify potential 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 conflict of interest process—for both financial holding-related conflicts and those involving senior officers—that follows a three-fold approach: always disclose the conflict; manage the conflict in most cases; and prohibit the activity when necessary to protect the public interest or the interest of the institution.

Note: Research institutions and the federal government are considering how to address institutional financial conflicts of interest, and the reader ascertain whether there are any developments in this area subsequent to the date of this revision. The Association of American Universities (AAU) and Association of American Medical Colleges (AAMC) have issued principles and recommendations for oversight of institutional financial interest in human subjects research.

Internet Resources

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

National Science Foundation (NSF) Grants Policy Manual
http://www.nsf.gov/funding/spo.jsp

HHS Office of Human Subjects Protection (Guidance on Financial Conflicts of Interest)
http://www.hhs.gov/ohrp/special/conflict.html

White House Office of Science & Technology Policy (OSTP)
Committee on Science (COS), Research Business Models Subcommittee (Federal Policy on Research Misconduct)
http://rbm.nih.gov/index.htm

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

Association of American Medical Colleges (AAMC)
http://www.aamc.org/members/coitf/start.htm

Principle XI. Intellectual Property

The institution has an intellectual property management system adequate to comply with terms and conditions of its institutional policies, all pertinent laws and regulations, and agreements with external sponsors including the federal government.

Practice A. The institution's intellectual property management system has the capability of properly managing the intellectual property produced during sponsored projects by investigators, research staff, and graduate students. This may include patentable inventions, copyrightable works (including but not limited to scientific and technical writings, 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 projects if permitted by institutional policy.

> **Indicator 1**. Personnel trained in intellectual property management, 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 in negotiating intellectual property terms in funding agreements and other agreements as appropriate (e.g., material transfer agreements); receive disclosure; and seek to protect and/or commercialize intellectual property and to distribute tangible research materials created at the institution.
>
> **Indicator 2.** The management system tracks obligations to external sponsors to ensure that conflicting grants of rights to intellectual property do not occur.
>
> **Indicator 3.** The management system recognizes the impact of granting rights to external sponsors on the future freedom to operate of its investigators, research staff and students.

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

> **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 of intellectual property within the institution and for notifying external sponsors as needed.
>
> **Indicator 3**. The institution has procedures in place, which may include license formats, to comply with the requirements of the federal patent, copyright, and data rights regulations and institutional policies regarding licensing.
>
> **Indicator 4.** The institution has a policy on and procedures for royalty sharing with inventors/authors, as required by institutional policies, interinstitutional agreements and federal regulations.
>
> **Indicator 5**. The institution has 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, licensing 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 XII-1, Export Controls and Embargos]

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 sponsor or provider terms and conditions relative to the sharing or transfer of such materials, tools and data.

Indicator 9. The institution has established and enforces institutional practices 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.

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 all technical and professional investigators and staff or with students receiving support from agreements with external sponsor regarding reporting and assignment of intellectual property as required by federal laws and regulations 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 policies and training programs in place to inform investigators, research staff, students and fellows on their rights and responsibilities with respect to intellectual property.

Indicator 1. The institution has training and awareness programs to inform and train institutional employees 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 employed by the institution and any terms or conditions imposed by external sponsors or third-party material providers in the agreement (including individual agreements) before the sponsored projects activity begins.

Indicator 2. 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 3. The institution has implemented safeguards to protect the student's educational progress from potentially conflicting demands of intellectual property claims of third parties.

Internet Resources

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

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

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

Principle XII – International Issues in Sponsored Projects

Principle XII -1. Export Controls and Embargos

The institution has an export controls and embargo compliance program that enables retention of an open, collaborative and international sponsored projects environment while ensuring compliance with federal laws and regulations governing export controls and embargoes.

Practice A. The institution has a policy relating to export controls and embargo compliance and senior officials support the uniform and consistent application of the policy in sponsored projects.

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

Practice B. The institution has clearly assigned responsibility and accountability for administering and overseeing export controls and embargo compliance and licensing to a central office and individual who report at a high level of the institution and with whom the research staff routinely interacts (e.g., for research funding).

> **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.** Export controls and embargo policies, institutional controls and exclusion pre-requisites, and the extent of licensing and oversight authority for the institution are known and uniformly implemented in the sponsored projects community. Possible control triggers are known and researchers confer with central office experts when controls may apply.
>
> **Indicator 2.** The investigators understand the basics of exports to US citizens or foreign nationals abroad, deemed exports to foreign nationals in the U.S. (including on campus) and how to handle information resulting from or arising during fundamental research on campus in the U.S. They also understand how to make information beyond basic and general marketing materials used or created in their sponsored projects available in the public domain, and respect the boundaries of the educational and fundamental research and publicly available exclusions.

Indicator 3. 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 4. The researchers and technology transfer and procurement 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 or production of materials, equipment or other items to anyone abroad or to foreign nationals in the U.S. (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 5. The compliance program includes record-keeping of determinations concerning controls and systems to monitor compliance and to identify and respond appropriately to violations.

Practice D. The institution includes terms in its agreements to require compliance with export controls and embargoes to the extent applicable. The terms provide for termination of agreements if they cannot be performed in compliance with applicable controls and embargoes, and avoid transfers of controlled materials, items and information when the recipient has not ensured compliance.

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

Practice F. OFAC 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 U.S. citizens) where prohibited.

Principle XII-2. Visas.

The institution has offices that administer visa programs for foreign researchers, research staff, and students (a) that are appropriately coordinated with the institution's sponsored projects program and with other campus programs (e.g., deans, registrar, bursar, payroll, human resources) affecting or affected by visa status of individuals; (b) 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 projects and to travel to international conferences and meetings and return to the U.S. smoothly; and (c) that foster controls ensuring that sponsored funds are not spent during periods of delay in securing visas if the foreign researcher may not pursue the sponsored projects activities during such period.

Practice A. The international scholars and students offices have communications and training programs for international members of the research community and other mechanisms for visa compliance, timely approvals and renewals.

Indicator 1. The international scholars and students offices 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.

Practice B. The international scholars and students' offices coordinate closely with the office of sponsored programs to ensure that both offices are aware of visa delays that may affect sponsored projects, that they coordinate schedules and solve problems.

Practice C. The international scholars and students' offices have systems, communications, and educational programs in place to support the ability of foreign researchers and students to travel to international conferences and return to the U.S. in a timely way.

Practice D. The international scholars and students offices are coordinated with other university offices (e.g., registrar, financial aid, disciplinary authorities, bursar, human resources, etc.), as well as with the international campus community, to ensure broad knowledge of the effects of their actions, including 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.

Principle XII-3. International Transactions and Taxation

The institution has a process for structuring and pursuing international sponsored projects and participation in campus activities by foreign visitors that brings the full range of required expertise to the undertaking and ensures that the sponsored projects and other activities can occur without the institution assuming unidentified and unreasonable financial (including international tax) burdens, and operational, legal and reputational risks.

Practice A. The sponsored programs office and counsel's office work together with the relevant research unit, and with the controller's office and outside experts as needed, to structure, design and pursue international sponsored projects and academic endeavors in a manner that will accomplish the program objectives and also manage institutional risk appropriately.

Indicator 1. The sponsored projects agreement specifies what nation's laws govern the agreement and asserts that, in any event, the institution is subject to U.S. 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 projects agreements set out a process for compliance.

Indicator 3. The sponsored projects agreement establishes a collaboration or a new corporation rather than an actual or de facto legal partnership to ensure that the US institution does not assume liability for the foreign institution or vice versa.

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

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

Indicator 6 The sponsored projects agreement requires payments of sponsored projects costs to be made the institution in or equated with U.S. dollars. It may establish an up-front payment and a limitation on obligations based on adequacy of funding to guard against exchange rate fluctuations.

Indicator 7. The sponsored projects 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. In the case of biological materials, it addresses compliance with international conventions as well as host country requirements.

Indicator 8. Experts identify and appropriately address legal requirements that affect the sponsored projects.

Indicator 9. Appropriate exit strategies are captured 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 projects agreement terms relating to recovery of facilities and administration costs regarding the awards and administration of the sponsored projects.

Practice B. The sponsored projects endeavor is designed to avoid, if possible, the creation of an "establishment" (e.g., offices, bank accounts, contract execution, repeated or long personal visits or domiciles) in a foreign locale may lead to taxation of the U.S. institution.

Indicator 1. International tax experts (legal and accounting) determine the foreign laws and international treaties that govern taxation to assess, quantify and ensure that the sponsored projects agreement appropriately allocates the excise, withholding and other tax burdens.

Indicator 1a. Either (i) the sponsored projects agreement provides that the foreign government or entity assumes the U.S. institution's, and its personnel's individual, tax obligations to the foreign jurisdiction or (ii) the sponsored projects support to the U.S. institution is adequate to both cover the sponsored projects program and the tax burden. The cost of filing foreign tax returns is taken into account.

Practice C. 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 projects program, and tax and other risks to the U.S. institution.

Practice D. Prior to the travel, transfer or other activity occurring, heightened analysis is undertaken of the export controls and embargos issues related to (a) any transfer to or installation in a foreign locale of U.S. 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. OFAC lists are consulted to ensure that the transaction is not prohibited, taking into account both the entity and the individual participants.

Practice E. The institution and all its personnel, agents, contractors and collaborators are aware of the U.S. anti-bribery laws. Its contract provisions foster compliance even in the context of other cultures that may not proscribe, and may even encourage, what U.S. 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 projects compensation and support.

Practice F. 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 providing for withholding. This applies except where business expenses are being reimbursed, are treated as being made under an "accountable plan," and are deductible to the aliens as a business expense.

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

Regulations:
Foreign Corrupt Practices Act (Prohibited Foreign Trade Practices)
15 USC §78dd 1-3
(Title 15 of the United States Code, Chapter 2B – Securities, Section 78 dd 1-3)

Internal Review (IRS) Code Sections:
26 USC sub A, Chap 1, Sub B Part I, §62. Adjusted gross income defined
26 USC Sub A, Chap 1, Sub B Part IX §274. Disallowance of certain entertainment, etc., expenses.
26 USC Sub A, Chap 3, Sub A, §1441. Withholding of tax on nonresident aliens
(Title 26 of the United States Code, Chapters 1 and 3, etc.)