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Managing Externally Funded Research Programs

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This guide may be used by institutions to help review their management systems and internal controls with regard to managing sponsored programs generally in the form of grants and contracts as distinguished from gifts and other supported activities at the institution

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COUNCIL ON GOVERNMENTAL RELATIONS

**MANAGING EXTERNALLY
FUNDED RESEARCH
PROGRAMS:**

**A GUIDE TO EFFECTIVE
MANAGEMENT PRACTICES**

JULY 2009

ABOUT THIS DOCUMENT

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

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

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 implies looking at compliance as a systemic enterprise rather than discrete practices in response to specific regulations. Thus, while compliance will take a different form in meeting financial, administration, or performance requirements, all these activities reflect a commitment to compliance across the organization.

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

The Guide is available in paper and web-based formats. The web-based format takes advantage of providing links at the end of each section to the principal regulatory documents and materials. 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. Paper copies of the Guide are available from COGR.

COGR appreciates the contribution of all its members in bringing new challenges and strategies for addressing them to the attention of their colleagues across the country. The members of the working group availed themselves of this general expertise and want to thank Patricia Greer, Peggy Lowry, Julie Norris, Judith Nowack and Mary Ellen Sheridan for their special assistance. 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, quality of life, 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 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 activities 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 reflect the highest code of conduct to guarantee the integrity and quality of the research whether it involves human participants, animals, or hazardous materials. An institution is responsible for developing policies and procedures addressing both general and specific issues in 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 demonstrate 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 describing those roles and responsibilities for all investigators and staff in the institution who have any contact with externally funded programs. Finally, a robust program of compliance provides for monitoring and oversight of individuals and the program itself to ensure it continues to meet the needs of the institution, its investigators and its sponsors.

A program of compliance is not the responsibility of any one individual or one group at the institution. Each individual, committee and/or office makes a contribution toward meeting the institution's obligations and, thus, providing invaluable service to the investigators and the institution.

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 or discrete actions or activities which assist in implementing crucial components in the attainment of each principle, but not necessarily all components.
- **Indicators** are suggested measures to use or elements to look for 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, regulations, policies and principles¹.

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

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

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

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

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

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

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

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

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.

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

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

Indicator 1. The institution has a senior-level administrative process to ensure sponsored programs compliance.

Indicator 2. The institution provides adequate resources and assigns appropriate authority to carry out such compliance program-related responsibilities 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 its implementation and effectiveness.

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.

Indicator 2. The institution has a training program addressing the responsible conduct of research for students and post-doctoral appointees².

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

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

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

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

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

²Some topics typically included in instruction in the responsible conduct of research may be mandatory for research staff supported in part or in whole with Public Health Service and National Science Foundation funds.

Indicator 1. The institution has auditing and monitoring systems.

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

Indicator 3. The institution describes disciplinary actions that may result from improper conduct or failure to take reasonable steps to prevent, detect, or report improper conduct to the institution.

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

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

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

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

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

Indicator 2. The institution notifies the sponsoring or regulatory entity, as required.

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

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

Indicator 1. The institution has a process for monitoring changes in federal, state and local regulations and coordinating changes in the institution's policies and procedures.

Indicator 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>

Federal Acquisition Regulations, 48 CFR Part 3.10
Contractor Code of Business Ethics and Conduct

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

PRINCIPLE II. SPONSORED PROGRAM MANAGEMENT

PRINCIPLE II-1. POLICY REQUIREMENTS

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

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

Indicator 1. Individuals have management responsibility for review of agency websites, publications, and other policy issuances which affect the conduct of sponsored programs.

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

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

Indicator 1. The policies comply with appropriate federal tax codes, Financial Accounting Standards Board (FASB), Governmental Accounting Standards Board (GASB) and OMB Circular A-21.

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

PRINCIPLE II-2. ADMINISTRATIVE REQUIREMENTS

The institution has trained personnel who are knowledgeable about sponsor regulations, 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 that participate in sponsored programs as well as central areas regarding the administrative, regulatory and financial requirements of awards (including the appropriate OMB Circulars and Federal Acquisition Regulations [FAR]).

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 and central levels are reviewed regularly and updated as required.

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

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

Indicator 2. 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 among offices in an emergency situation.

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

PRINCIPLE II-3. PREAWARD AND PROPOSAL REQUIREMENTS

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

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

Practice B. Assistance is available to investigators to understand sponsor requirements as well as to construct budgets and develop administrative sections of proposal documents.

Practice C. 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 in the proposal and certifies compliance with sponsor and institutional requirements.

Indicator 3. Institutional officials review proposal budgets (if required) 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 also III-3, Institutional Rate Agreements.]

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

Indicator 4. Qualified 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 also 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-6, Subrecipient Monitoring, below.]

Indicator 5a. The institution obtains information necessary for the reporting of the subaward to the federal government including but not limited to appropriate, unique identifiers, e.g., DUNS number.

Indicator 6. The institution has the ability to prepare and submit electronic proposals in a variety of acceptable formats to potential sponsors. [See also VII, Electronic Research Administration.]

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

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, animal use approvals, conflicts of interest management, 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 including but not limited to ownership of intellectual property rights, publication, data ownership, acceptance of classified material, indemnification, warranties, insurance, sponsor viability, 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 non-financial agreements such as confidential disclosure and non-disclosure agreements and material transfer agreements (MTA) that comply with all applicable laws and regulations and meet all institutional policies and practices.

Indicator 1. The institution has a process to identify other 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 its users.

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 of materials including importing and exporting materials including plants, animals, chemicals and/or biohazards.

Indicator 4. The institution has a process to determine and comply with export control regulations as related to the transfer of materials included deemed exports within the US. [See also XII-1. Export Control, Embargos, Trade Sanctions, and Executive Orders.]

Indicator 5. The institution has processes to identify and evaluate confidentiality or non-disclosure agreements. The process identifies when an investigator informs the sponsored programs office, or other assigned area of the institution, of a requirement for a confidential or non-disclosure agreement and the process for obtaining appropriate institutional approvals.

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

Practice D. The institution has procedures in place to determine the applicability of IRS revenue procedures 1997-14 (and 2007-47 clarification) to facilities financed with tax exempt bonds. Institutions with research programs utilizing space within a tax exempt financed facility have measures in place to determine if the proposed use is consistent with the tax exempt nature of the bonds. Any use of a tax exempt bonded facility that is not consistent with its tax exempt nature could be considered a private business use⁴.

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

⁴“Private business use” is defined by the IRS as “direct or indirect use in a trade or business carried on by any person other than a governmental unit.” In this context, it often refers to the use of tax-exempt bonded facilities by a for-profit business through a sponsored project. See the Internal Revenue Service, Revenue Procedure 2007-47 (June 26, 2007).

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

PRINCIPLE II-5. 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 and programmatic management systems.

Indicator 1. The principal investigator formally accepts responsibility for the financial management of the program.

Practice B. The institution has a system for seeking prior approvals from sponsors, where required, and has developed procedures to implement the federal expanded authorities as provided in OMB Circular A-110/2CFR215⁵.

Indicator 1. The institution has policies and procedures for obtaining written prior approvals from sponsors, when 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 also III, Financial Administration.]

⁵In May 2004, the Office of Management and Budget (OMB) established 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, the related agency implementation regulations.

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 programs to appropriate offices.

PRINCIPLE II-6. SUBRECIPIENT MONITORING

The institution has policies and procedures for issuing subrecipient agreements and for monitoring the performance of subrecipients. [For international subrecipients, see also XII-4 International Transactions.]

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

Indicator 1. Adequate documentation for the selection and approval, if necessary, of the subrecipient when not named in the proposal, is prepared and maintained.

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

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

Indicator 1. The institution has mechanisms in place to conduct a risk assessment for its subrecipients to determine the level and type of on-going monitoring required based on the level of risk assigned by the institution. [See also XII-4 International Transaction.]

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

Practice D. Written agreements with subrecipients are prepared and executed by both parties. The agreements specify Code of Federal Domestic Assistance (CFDA) description and program number, where appropriate, and terms and conditions, including required flowdown clauses, and utilize federally endorsed models⁶ as appropriate.

Practice E. The institution ensures reporting of the subaward to the federal government in the manner designated by the federal government⁷.

Practice F. Compliance with all fiscal and administrative requirements and technical performance and reporting requirements is monitored.

⁶The Federal Demonstration Partnership (FDP) offers a model Subrecipient Agreement. Samples are available at: <http://thefdp.org/>

⁷The data elements and reporting requirements of the Federal Funding Accountability and Transparency Act of 2006 (FFATA) include reporting of all subawards (grants & contracts) of \$25,000 or more to a federalwide database, currently available at www.USASpending.gov

Indicator 1. Mechanisms are in place to communicate subrecipient requirements and relationships to appropriate individuals and committees within the institution including but not limited to the institutional human subjects and animal use committees and, if appropriate, a conflicts of interest committee to ensure appropriate reviews and approvals have been received and required reporting to the sponsoring agency is completed.

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

Practice H. Prior to final payment and closeout, the institution receives all final financial, property, patent and other sponsor-required reports from the subrecipient.

PRINCIPLE II-7. REPORTS, RECORDS, AND MANAGEMENT OF TECHNICAL DATA

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

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

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

Indicator 2. The investigator(s) is aware of sponsor requirements regarding access to peer-reviewed publications, as appropriate.

Indicator 3. At the time of account closeout, procedures are in place to confirm that technical reports and other technical deliverables have been submitted and receipt acknowledged by the sponsor.

Indicator 4. Reports and deliverables are submitted in a timely fashion in the format required by the sponsor.

Indicator 5. The institution has systems that are sufficiently flexible to allow for electronic reporting of technical, financial and administrative data as required by the sponsor. These systems are easily modified and/or linked to other institutional databases to allow for the addition of new information and/or the retrieval of institutional information to respond to unique sponsor reporting requirements.⁸

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

Indicator 1. Retention requirements for financial and administrative records are in accordance with the requirements of 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, retrieval and disposal of records.

⁸The reporting requirements proposed for the Federal Funding Accountability and Transparency Act (FFATA) and the American Recovery and Reinvestment Act of 2009 (ARRA) have specific and unique reporting requirements for subrecipients, in the former, and job creation and retention in the latter case. Flexible reporting systems can address these types of unique requirements.

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, retrieval 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, retrieval and/or disposition of electronically maintained records.

Practice C. The institution has policies and procedures regarding retention of and access to financial and administrative policies, both institutional and sponsor, in effect at the time of the award and incorporated as part of a sponsored program agreement.

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

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 the maintenance of research records by the project personnel subject to compliance with the institutional policy.

Indicator 3. Allowance is made in the written requirement for maintenance of research records when there is relocation of project personnel to allow for continued access by the original institution's personnel. [See also VI.E, Employment.]

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

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

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

Indicator 2. Ownership of patient medical records remains with the institution.

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

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

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

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

Practice F. 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 a policy and process 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 and A-133 compliance supplements, 45CFR A Subpart E,⁹ the Federal Acquisition Regulations and agency-specific regulations and the financial and technical terms and conditions of the specific award.

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. The institution has written roles and responsibilities for financial management and designates the individual ultimately accountable for external funding. Personnel involved in the administration of sponsored programs 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.

⁹Free-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 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.

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

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 (the DS-2) for cost accounting practices.

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 and approval 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.

PRINCIPLE III-3. INSTITUTIONAL RATE AGREEMENTS

The institution has systems, policies and procedures which enable it to prepare and submit required Facilities and Administrative (F&A)¹⁰ 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 F&A rates with the cognizant federal cost agency.

¹⁰Since 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 reimbursement continue to use the term "indirect" to refer to similar cost rates.

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.

Indicator 5. The institution has issued guidance on the application of F&A rates for non-federal programs.

Practice B. If required, fringe benefit rate proposals are 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 conformance with sponsor guidelines and the financial policy, procedures and current practices of the institution.

Practice B. The institution prepares and submits proposals based upon 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 or designee 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 any required or committed cost sharing, F&A rates and potential program income. [See also II-6, Subrecipient Monitoring.]

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 voluntary 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, administrative/clerical salaries, and other specialized cost items.

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.]

Indicator 7. The institution has processes in place to monitor financial commitments made in proposal narratives to ensure the commitments are consistent with the institution's intent and ability to meet the obligation.

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 program 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). When non-federal sponsors allow greater latitude in direct charging practices, the institution has processes in place to manage and monitor these differences.

Indicator 4. Costs normally allocable as 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 identifying and 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.

Indicator 3. The institution has a procedure whereby principal investigators may formally delegate authority for direct charging, if required or appropriate under institutional policies.

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

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.¹¹

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.

¹¹The National Institutes of Health's Grants Policy Statement (Part II, Subpart A: General, Cost Considerations) states that cost transfers "should be accomplished within 90 days of when the error was discovered," and describes the types of documentation required. Other agencies may have different requirements. The institution should consider procedures that meet all its sponsors.

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-110/2CFR215.¹²

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

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

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

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

Indicator 3. Salary for investigators, charged to or cost shared on sponsored programs reflects the level of effort commensurate with the proportional share of the institutional base salary for that period. Special attention is made to federal awards where the proportion of effort is "protected" for research (e.g., NIH career awards).

¹²See COGR's *Policies and Practices: Compensation, Effort Commitments and Certification*, March 2007, for a more detailed discussion.

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 or functional activities.

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

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

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

Practice B. The institution has in place a 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 responsible 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, as specified in A-110/2CFR215, 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. The proportional share of payroll costs in excess of applicable caps is 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 the same manner that payroll charges are allocated.

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

PRINCIPLE III-7. COST SHARING

The institution has policies and procedures for properly monitoring and documenting cost sharing in the same manner as costs funded by the sponsor, 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 requirements of non-federal sponsors.

Indicator 4. Contributions and/or third party in-kind cost sharing of services and property are valued consistent with the requirements of OMB Circular A-110/2CFR215.23 and documentation of the basis for the determinations is maintained.

Indicator 5. Institutional systems provide for appropriate monitoring of cost sharing for timeliness and adequacy of expenditure or in-kind valuation documentation.

Indicator 6. The institution reports required cost sharing in accordance with the terms and conditions of awards.

Indicator 7. Voluntary uncommitted cost sharing (i.e. investigator-donated additional time above that agreed to as a condition of the award) is not considered for effort reporting and is excluded from the organized research base used for computing the F&A cost rates as specified in OMB's January 5, 2001 clarification memo.¹³

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 programs 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.

¹³The referenced memorandum is available on the OMB website as M-01-06, Clarification of OMB A-21 Treatment of Voluntary Uncommitted Cost Sharing and Tuition Remission Costs (January 5, 2001).

Indicator 2. Federally-funded research, including any no-cost time extension periods, 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 captured in the institution's financial systems, an estimated amount is computed by the university and included in the organized research base, consistent with the OMB January 2001 clarification memo.

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.D, 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 broad list of examples of program income.

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

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

PRINCIPLE III-9. SPECIALIZED SERVICE/RECHARGE CENTERS

The institution has policies and procedures to identify and manage Specialized Service Centers and Recharge Centers and charge the users for these services¹⁴.

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 specialized service and/or recharge centers.

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

¹⁴Specialized 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 has a mechanism to review rates to ensure that no unallowable costs according to A-21/A-110 are included in specialized service/recharge center rates.

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

Indicator 5. The institution establishes appropriate operating balances for each service center and is able to identify situations where excessive surpluses exist.

Indicator 6. The rate calculation is designed to take into consideration variances in calculating future rates and is reviewed and adjusted, if necessary, at least biennially as required by OMB Circular A-21.

PRINCIPLE III-10. CLINICAL RESEARCH BILLING COMPLIANCE

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

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

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

Indicator 2. The institution has analyzed the business processes related to research billing compliance and performed a gap analysis. This should include budget development and approval, determination of billing eligibility, registration of research participants, order entry for research services, documentation and coding, charge entry, patient billing and accounts receivable.

Indicator 3. The institution has determined the realistic process/workflow from the idea for a specific research study through the study's closure. This should be based on analysis of research billing models in like institutions and effective practices.

Indicator 4. The institution has evaluated the information technology infrastructure needed to support research billing compliance.

Indicator 5. The institution has provided ongoing educational opportunities for the clinical research community to inform them of their roles and responsibilities in research billing compliance. The institution has written and disseminated policies and procedures for research billing compliance. The institution has provided reference materials and tools to support and guide clinical research faculty and staff.

Indicator 6. The institution has a mechanism to measure the performance of its research billing compliance program to assure that it is accomplishing its goals.

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

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

Indicator 2. The institution has identified what types of studies need a prospective reimbursement analysis and communicates this widely to the clinical research faculty and staff.

Indicator 3. The institution performs a prospective reimbursement analysis to identify all items and services within the clinical research study and determine whether they are billable to the institution, sponsor or third-party payor.

Indicator 4. The institution has developed a process to verify the consistency of research billing language within the informed consent document, including but not limited to financial commitments made to subjects and coverage for research-related illness and injury, the budget, the clinical trial agreement and other documentation or guidance provided by the sponsor.

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

Indicator 1. The institution has developed a process to assure clinical research services are not billed inappropriately to third-party payors. The institution may perform a bill hold to verify clinical research services are charged appropriately.

Indicator 2. The institution has developed a process to respond to deficiencies in the research billing process whereby mis-billings may occur. The institution has a mechanism to perform charge and credit corrections.

Indicator 3. The institution has a process to track and trend issues related to research billing compliance. The institution provides a mechanism to re-educate clinical research faculty and staff on the research billing processes to promote compliance and prevent reoccurrence.

PRINCIPLE III-11. PROGRAM CLOSEOUT

The institution has policies and procedures for timely, complete and accurate program 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 to and monitors compliance with requirements for final technical report submissions by 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 compliance with sponsor guidelines and requirements as well as accurate, timely reporting and invoicing.

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

Indicator 2. The institution can document that all 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.

Indicator 5. The institution has mechanisms to accommodate and monitor exceptional reporting, audit and payment requirements including delays in final audits and payments.

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 programs are cognizant of the policies and procedures governing procurement of goods and services.

Indicator 2. Individuals involved in procurement adhere to the institutional written standards of conduct for procurement personnel and the 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 its 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) including regular monitoring and timely reconciliation of P-card reports and expenditures.

Practice B. The institution has a written procurement system that meets the requirements of OMB Circular A-110/2CFR 215 and the FARs 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 using 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 enterprises (DBE) are available. When required, the institution has a plan and monitors the implementation of the plan for encouraging DBE procurements. 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 program 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 programs. [See also, II-6, Subrecipient Monitoring¹⁵.]

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>

¹⁵The meaning of "subrecipient" may vary. As defined to meet reporting requirements for the federal USASpending.gov database, subawards are issued "to provide support for the performance of any portion of the substantive project or program." "Procurement" generally refers to the purchase of goods and services needed to carry out the project or program. OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations, Section __.210 provides guidance on Subrecipient and vendor determinations.

PRINCIPLE V. MANAGEMENT OF EQUIPMENT

The institution has a management system for equipment acquired from both federal and non-federal sources.¹⁶

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, Embargos, Trade Sanctions and Executive Orders.]

Indicator 3. Receiving procedures are in place to ensure that all purchases are inspected upon receipt for condition and completeness.

¹⁶See 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 4. Equipment acquisitions on sponsored accounts are reviewed for allowability, ownership, and taxes.

Indicator 5. 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.

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. EMPLOYMENT

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

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

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

Indicator 1. The institution collects Employee Eligibility Verification (I-9) forms from all employees.

Indicator 2. The institution has mechanisms in place to comply with federal employment verification procedures as required.

Indicator 2a. The institution has mechanisms in place to ensure compliance with any restrictions on transactions with foreign individuals or entities as required by federal law, e.g., Executive Order 13224 of September 23, 2001 Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism.¹⁷

¹⁷The US Department of the Treasury's Office of Foreign Assets Control (OFAC) maintains Sanction Countries and Specially Designated Nationals Lists to meet the requirements of EO 13224. See also Principle XII, Export, Global Activities and Relationships with Foreign Entities.

Indicator 3. The institution recognizes and complies with the visa requirements for employees and students who are foreign nationals and coordinates the institution's sponsored program with other campus programs (e.g., deans, registrar, bursar, payroll, human resources) affecting or affected by visa status of individuals.

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

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

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

Indicator 4. The institution has a procedure for identifying and notifying federal sponsors if international graduate research assistants are engaged in sponsored programs activities under applicable awards, if required by the award.

Indicator 4a. The institution ensures that foreign nationals understand 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.

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

Practice D. The institution has procedures in place to ensure that any access to or use of controlled materials or information (e.g., select agents 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. When employment requires background checks and other extra conditions, potential employees are fully informed of these employment conditions.

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

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

Indicator 1. Mechanisms are in place to ensure that the institution and investigators leaving the institution engage in a comprehensive close-out process, e.g., lab inventory and clean out, closure or transfer to another investigator of regulatory approvals (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 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](http://www.aphis.usda.gov/programs/ag_selectagent/index.html)**

Executive Order 13224 of September 23, 2001

**Blocking Property and Prohibiting Transactions With
Persons Who Commit, Threaten To Commit, or Support
Terrorism**

PRINCIPLE VII. ELECTRONIC RESEARCH ADMINISTRATION

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

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

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

Indicator 2. The institution has sufficient and adequately trained personnel to support electronic sponsored programs administration, including information technology (IT) support, central administrative staff and in the operating units.

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

Indicator 1. Individuals are identified with responsibility to implement mandatory electronic initiatives of sponsors, primarily the federal government.

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

Practice C. 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 or agency specific grants submission programs when mandated by the federal agency and advises investigators and other staff of those requirements.

Indicator 1a. 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 forms or through the system-to-system interface provided by Grants.gov.

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 D. 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 1a. The institution has provided the necessary Central Contractor Registry (CCR) registration to allow it to receive payments electronically and to bid on certain programs from the mission agencies. [See also III-4, Proposal Costing; and III-8, Cash Management.]

Indicator 2. The institution has processes and procedures to ensure electronic reporting as required in areas including but not limited to inventions, financial conflicts of interest, etc.

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

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

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

Indicator 3. Personnel responsible for 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.gov Portal

www.grants.gov

www.research.gov

www.USASpending.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 drawn from appropriate professional auditing standards for performing compliance assessments, formal audits, and for reporting the results to the appropriate, responsible official. These policies and procedures are distributed to the appropriate institutional officials.

Indicator 1. The institution demonstrates a knowledge of and commitment to compliance by performing risk-based compliance assessments in areas of sponsored program activity and reports the results of such assessment to the appropriate responsible official.

Indicator 2. The institution develops a risk-based assessment/audit plan on a regular basis.

Indicator 3. The institution initiates formal risk-based audits of administrative and financial systems that support the sponsored program enterprise and reports the results of such audits to the appropriate responsible official. [See also, II-6, Subrecipient Monitoring.]

Indicator 4. The results of financial and compliance audits are communicated to all affected individuals and corrective action plans, as may be appropriate and developed in response to compliance assessments, are monitored for implementation.

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

Indicator 1. There are policies in place to ensure the institution's auditor has the appropriate reporting relationship to ensure independence within the organization.

Indicator 2. Procedures are in place to ensure that external auditors are selected in accordance with a process that complies with the requirements of OMB Circular A-133.

Indicator 3. The institution has an internal audit charter that states the internal auditors' responsibilities and authority.

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

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

Indicator 1. Audits of systems and operations are developed and maintained on a regularly scheduled basis.

Indicator 2. Financial objectives, goals and control procedures are established and maintained.

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

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

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

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

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

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

Practice E. 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 the institution.

Indicator 5. The institution's audit program includes tests for internal controls and compliance with administrative requirements, such as the compliance supplement to 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 sponsor requirements and all federal, state and local government regulations including the areas of protection of human subjects and of animals, the use of stem cells, the environment, and in the operation of its facilities.¹⁸

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

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

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

PRINCIPLE 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.

¹⁸This section deals with five specific areas of compliance in the conduct of research: human subjects, animals, stem cell research, the environment, and facilities. The reader should be cognizant that these regulations are under continuous review by agencies and subject to change.

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.¹⁹

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 protections program covered by the federal assurance.

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

Indicator 4. The institution provides educational resources to ensure that individuals engaged in the review and conduct of human 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 protections program.

¹⁹The filing of the Federal-Wide Assurance includes an institutional determination of whether to apply the Common Rule (45CFR46 Subpart A) to all research (federally funded and non-funded) and whether to apply vulnerable population rules (45CFR46, Subparts B-D) to research funded by federal agencies whose regulations do not require application of those process standards.

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 and types 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 eligible for expedited and requiring 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 of federally supported non-exempt research at intervals no greater than one year and for the timely review and consideration of unanticipated problems or reportable serious adverse events, depending on the governing regulations, 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 program. Assistance is available to investigators to develop compliant informed consent documents.

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

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

Indicator 13. For multi-site studies, the IRB reviews the plan for communication of unanticipated problems or interim results to ensure adequate protection for human subjects.

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

Indicator 1. Mechanisms exist within the institution to identify sponsored projects that involve human subjects and ensure approval of a research protocol or protocols 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 or a portion thereof when/if the protocol(s) expires or is terminated or suspended by the IRB.

Indicator 4. Contracting mechanisms ensure that consortium agreements require appropriate IRB assurances and reviews at collaborating sites. Institution requires appropriate documentation of those approvals.

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

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

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

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

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

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

Indicator 5. The institution monitors the performance of FDA sponsor functions when an investigator holds an IND or IDE.

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

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

Indicator 2. The IRB ensures that all data collected are 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.

Practice F. The institution has coordination between its IRB and other regulatory units.

Indicator 1. Conflicts of interest disclosure and management information is provided to the IRB as a part of the protocol review process. [See also, X-2 Financial Conflicts of Interest.]

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

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

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>

PRINCIPLE IX-2. ANIMAL CARE

The institution has 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 programs covered by such regulations.

Practice A. The institution has filed a written assurance with the US Department of Health and Human Services (through the National Institutes of Health Office of Laboratory Animal Welfare) 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 number and composition 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 programs 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, as appropriate, sponsors of the outcome of IACUC protocol reviews.

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

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

Practice D. Adequate systems are in place to track, report, and maintain compliance with the Animal Welfare Act, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the *Guide for the Care and Use of Laboratory Animals*²⁰, and applicable occupational health regulations.

²⁰PHS 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 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 coordination between its IACUC and other regulatory units.

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

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

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

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

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

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

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

Indicator 2. Appropriate environmental alarms are 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 OVERSIGHT OF DERIVATION AND USE OF HUMAN PLURIPOTENT STEM CELLS

The derivation and use of human pluripotent stem cells in research is governed by a number of related and unrelated federal, state and local laws, regulations and guidance as well as international laws and regulations. On March 9, 2009, Executive Order 13505 Removed Barriers to Responsible Scientific Research Involving Human Stem Cells and President Barack Obama directed the HHS Secretary, through the National Institutes of Health (NIH) Director, to review existing NIH and other widely-recognized guidelines on human stem cell research and issue new NIH guidance. The National Institutes of Health *Guidelines for Human Stem Cell Research* was published on July 7, 2009. On July 30, 2009, President Obama issued a Memorandum directing all federal agencies to adopt the NIH Guidelines to the fullest extent practicable. As a consequence, the NIH Guidelines will be applicable to all federal funding of human embryonic stem cell research.

The NIH Guidelines address only the circumstances under which human embryonic stem cells (hESC) are eligible for use in research supported by the federal government. The NIH Guidelines will fund certain research using human embryonic stem cells (hESC) that are derived from embryos created by *in vitro* fertilization (IVF) for reproductive purposes and are no longer needed for that purpose. Federal funding continues to be available for human stem cell research using adult stem cells and induced pluripotent stem cells. There are some uses of these pluripotent cells lines (from embryos or induced) that, although they may come from allowable sources, are nevertheless ineligible for federal funding, including: research in which human embryonic stem cells or human induced pluripotent stem cells are introduced into non-human primate blastocysts; and research involving the breeding of animals where the introduction of human embryonic stem cells or human induced pluripotent stem cells may contribute to the germ line.

Federal funding is not available for research using hESC derived from other sources including somatic cell nuclear transfer, parthenogenesis and/or IVF embryos created for research purposes. The federal government will not fund the derivation of human pluripotent stem cell lines from embryos. The funding of the derivation of stem cells from human embryos is prohibited by the appropriations ban on funding of human embryo research (Consolidated Appropriations Act, 2009, Pub. L. 110-161, 3/11/09), otherwise known as the Dickey-Wicker Amendment.

At the end of this section, we provide information about other guidelines and recommendations offered by professional societies and organizations including the National Academies of Science, the International Society for Stem Cell Research and others. It is important that investigators and institutions recognize that there are a number of other factors or drivers to consider in determining if and how the institution will address research using human pluripotent stem cells that go beyond the very limited scope of the NIH Guidelines.

Practice A. The institution has policies and procedures in place that comply with state law concerning the derivation and use of human pluripotent stem cells, if applicable.

Practice B. The institution has policies and procedures in place to assure that federal funds are not used to derive human embryonic stem cell lines.

Practice C. The institution has policies and procedures in place to ensure that hESC cells used in federal research are listed on the NIH Registry or establishes the eligibility of hESC before expending federal funds.

Practice D. Institutions deriving hESC for potential use in federally supported research have policies and procedures in place to ensure the embryos used meet the criteria for eligibility for federal research support and can assure and document compliance with those criteria.

Indicator 1. The institution has a process in place to affirm that hESCs to be used in federally sponsored research are derived from human embryos that were created for reproductive purposes, were no longer needed for this purpose, were donated for research purposes, and for which required documentation of the source and conditions of donation are clearly met.

Indicator 2. The institution has a process in place to affirm written informed consent was obtained from individual(s) who sought reproductive services and who elected to donate human embryos for research purposes and that the written consent form was discussed with potential donor(s) at the time of the donation and that donor(s) were informed that they retained the right to withdraw consent until the embryos were actually used for research.

Indicator 2a. The institution has a process in place to affirm that the facility where the embryos were donated has necessary policies and procedures to meet the NIH Guideline requirements including a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes. Whenever practicable, the attending physician responsible for reproductive clinical care and the researcher deriving and/or proposing to utilize human embryonic stem cells should not be the same person.

Indicator 2b. If the institution derives stem cells from embryos, with the expectation that the stem cell lines will be used in federally-funded research, the institution has policies and procedures in place to obtain all necessary written consents to meet the NIH Guidelines.

Indicator 3. For embryos donated outside the US, the institution has processes and procedures in place to submit an assurance to determine eligibility, presenting documentation using the criteria for eligibility for embryos donated within the US or supporting alternative procedural standards of the foreign country at least equivalent to those for US-donated embryos.

Practice E. The institution's use of hESC is reviewed or has been reviewed by an Institutional Review Board (IRB) in those cases concerning hESC that include individually identifiable personal information.

Indicator 1. The institution has a process in place to manage identifiable hESC consistent with Federal regulations including 45 CFR 46, 21 CFR Parts 50 and 56 and HIPAA Privacy regulations.

Practice F. At the time of application, prior to the use of federal funds and at the time of progress reports, the institution has a process in place to ensure that only hESC that are on the NIH Registry have been or will be used in federally-supported research.

Practice G. The institution ensures that investigators do not use identifiable hESCs, de-identified hESCs or induced human pluripotent stem cell lines in prohibited categories of research.

Additional Considerations

Institutions may want to address the derivation, procurement, banking and use of hESC lines through policies or processes that meet the institution's research goals. The NIH Guidelines describe those hESC that are eligible for federal funding; the guidelines do not describe policies and procedures for derivation, banking or storing, etc. as well as cell lines derived from other sources including somatic cell nuclear transfer, parthenogenesis and/or embryos created for research – sources prohibited for use in federally supported research.

The National Academies of Sciences (NAS) published, “*Guidelines for Human Embryonic Stem Cell Research*” (2005) offering recommendation for institutions conducting human embryonic stem cell (hESC) research, including establishment of an institutional Embryonic Stem Cell Research Oversight (ESCRO) committee. The NAS recommendations were constructed in a manner to ensure that all then-current applicable regulatory requirements were met. NAS issued amendments to the Guidelines in 2007 and 2008. The 2008 amendments include, in part, guidance in response to the recent scientific advances enabling the derivation of human stem cells from non-embryonic tissues, including cells known as “induced pluripotent stem cells.”

The International Society for Stem Cell Research (ISSCR) produced guidelines in 2006 that cover all stem cell research including human totipotent, pluripotent or multipotent stem cells. Like NAS, the ISSCR recommends a Stem Cell Research Oversight (SCRO) body and the review and approval of the use of cells. Both the NAS and ISSCR guidelines address the introduction of human stem cells into non-humans.

If appropriate for the institution’s research portfolio, the institution should consider the creation of a process to guide and advise the institution and researchers working with human embryonic germ (EG) cells, human adult stem (AS) cells, human umbilical cord blood (UCB) stem cells, and/or human/non-human chimeras. Such a process of oversight may include a separate institutional committee and institutional policies. The NAS recommended ESCRO policies and review are intended to provide local oversight of all issues related to derivation and research use of hESC lines, and to facilitate education of investigators involved in hESC research.

Please Note: Policies and regulations vary greatly across jurisdictions, and because they are continually changing, institutions and investigators should contact their **General Counsel** prior to beginning and approving any stem cell research that might be governed by the **policies of other jurisdictions**. Consult the regulations and guidelines for each location of human embryonic stem cell specimen collection, each institutional location of research using such hESC, each research staff member's and research participant/donor's country of citizenship and the funding source(s) restrictions for the research.

Internet Resources

National Academies' Guidelines for Human Embryonic Stem Cell Research

<http://books.nap.edu/openbook.php?isbn=0309096537>

National Institutes of Health - Resource for Stem Cell Research

<http://stemcells.nih.gov/info>

International Society for Stem Cell Research

<http://www.isscr.org/about/index.htm>

State and International Regulations and Guidelines: The International Society for Stem Cell Research, a nonprofit organization established to promote and foster the exchange and dissemination of information and ideas relating to stem cells, maintains information on its website concerning state and international laws and regulations concerning the use of stem cells in research.

<http://isscr.org/public/regions/states.cfm#About>

PRINCIPLE IX-4. 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 institution ensures compliance with federal, state and local government regulations governing the conduct and effects of sponsored programs activities, materials, and equipment on the environment and on the health, safety and security of researchers and the public²¹.

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 programs activities. The institution ensures that the policy is implemented locally at all levels of the institution's sponsored programs endeavor, as well as centrally in an EHS Office and/or institutional oversight committees.

Indicator 1. The institution has policies identifying the roles and responsibilities of individuals and offices and outlining basic practices and procedures including emergency procedures.

Indicator 2. Training is provided in general health and safety practices as well as job-specific practices and hazards.

Indicator 3. The institution has a process to document training required by statute and/or regulations.

²¹Materials 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.

Practice B. The institution has developed a risk assessment system to identify all potential environment, health and safety/security risks associated with its sponsored programs activities. These risks cover the range of possible activities from the use of hazardous materials to research-related physical activities, e.g., diving.

Indicator 1. The results of risk assessments are communicated to all affected individuals and corrective actions plans, as may be appropriate and developed in response to compliance assessments, are monitored for implementation.

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

Practice D. The institution has created a functional organization, either centrally in an EHS office and/or through institutional oversight committees that report to a high level of the institution and/or 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. As required by applicable regulations, 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 and the Department of Homeland Security Chemicals of Interest²²). The committees may also oversee the effectiveness and evolution of the institution's EHS system as institutional activities and applicable laws change.

Indicator 1a. The committees meet regularly and maintain a record of their decisions and determinations.

Indicator 2. The roles and responsibilities and reporting lines for 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, other administrative units (e.g., facilities management, occupational health, etc.) 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.

²²The Department of Homeland Security has established Chemical Facility Anti-Terrorism Standards (6CFR Part 27) that require site security vulnerability assessments and plans to control access to Chemicals of Interest. The list of chemicals and the screening threshold quantities are included as Appendix A to the regulations. Some universities will be required to meet these regulations depending on the types and quantities of those chemicals housed on the campus.

Indicator 2c. The institution either through a central EHS office or other organized operation 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 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 programs and regulations, 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 official to arrange for and manifest hazardous waste for disposal, its radiation protection officer, and its chemical hygiene officers.

Indicator 2f. The institution has appointed individuals responsible for compliance with the provisions of the select agent regulations, Chemical Facility Anti-Terrorism Standards (CFATS) and Nuclear Regulatory Commission (NRC) or NRC Agreement State's requirements.

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 program awards is coordinated with the institution's EHS system, as necessary, to ensure early identification of compliance issues (e.g., those for rDNA or select agents and toxins or hazardous waste).

Practice E. The institution has established an EHS Management System or other coordinated 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 institution identifies all EHS regulations that are applicable to the institution and its activities and assigns responsibility for compliance to appropriate individuals and/or units.

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

Indicator 2a. The institution 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 programs needs.

Indicator 3. The institution 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 4. The institution conducts appropriate periodic EHS system audits covering system implementation, controls, and effectiveness to identify and rectify system and performance deficiencies.

Indicator 5. The institution maintains an inventory or 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. For Department of Homeland Security Chemicals of Interest and select agents, the process includes risk assessment and registration.

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

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

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

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

Indicator 10. The institution has record-keeping and reporting procedures that 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 10a. The institution has a means of identifying all individuals working with chemicals including chemicals of interest; biological agents including select agents and toxins; radioactive materials including radionuclides of concern and ensuring that the individuals have appropriate security clearances before working with such materials.

Indicator 10b. The institution has a means for identifying all locations where chemicals including chemicals of interest; biological agents including select agents and toxins; radioactive materials including radionuclides of concern are used and stored and has provisions for appropriate security and access restrictions.

Indicator 11. The institution has emergency preparedness and response systems.

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

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

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](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.hsr.d.ornl.gov/nrc/home.html>

**US Department of Labor Occupational Health and Safety
Administration**

<http://www.osha.gov/>

Department of Homeland Security

Chemical Facility Anti-Terrorism Standards

**[http://www.dhs.gov/xprevprot/programs/gc_116950148617
9.shtm](http://www.dhs.gov/xprevprot/programs/gc_1169501486179.shtm)**

PRINCIPLE IX-5. 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, restricted materials, e.g., select agents and toxins, facilities, and animals to provide protection from loss or disruption of institutional and/or sponsor investments in its sponsored programs.

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

Indicator 1a. The institution holds regular fire and evacuation drills and tests fire safety and protection equipment in accordance with state and uniform fire codes.

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

Indicator 3. Individuals with appropriate authority have been assigned the positions of facility and information systems security officers to oversee the security systems, including classified research activities, if applicable.

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

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

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

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

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

Practice 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 record keeping system for its risk management programs.

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

Practice 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 including research records.

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/>

US Department of Homeland Security, Chemical Facility Anti-Terrorism Standards

http://www.dhs.gov/xprevprot/laws/gc_1166796969417.shtm

Centers for Disease Control and Prevention (CDC) and Select Agent Programs

<http://www.cdc.gov/od/sap/>

US Department of Agriculture Select Agent Program

http://www.aphis.usda.gov/programs/ag_selectagent/

U.S. Nuclear Regulatory Commission, Assuring the Security of Radioactive Material

<http://www.nrc.gov/security/byproduct.html>

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 programs 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 policies or statements that demonstrate a commitment to the integrity of its scholarly activities and provide procedures for raising and resolving questions of what professional or ethical standards in conducting sponsored programs 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 programs 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 available to meet education requirements for all applicable research personnel as specified in sponsoring agency requirements for instruction in the responsible conduct of research and research integrity, including mandatory instruction on scientific integrity and ethical principles.²³

Indicator 6. The institution has easily accessible and diverse means, including web-based tools, for educating investigators, students and employees about research ethics and responsible conduct standards.

PRINCIPLE X-1. RESEARCH MISCONDUCT

The institution has a written policy that defines research misconduct and addresses the management of allegations of research misconduct that meets appropriate sponsor requirements. (See also, I-F. Professional Misconduct.)

Practice A. The institution has policies and procedures that allow it to meet the requirements of sponsoring agencies to address allegations of research misconduct including but not limited to requirements for reporting and joint inquires and investigations.²⁴

Indicator 1. The institution has an Assurance of Compliance with PHS Policy on Research Misconduct.

²³Training in the responsible conduct of research is currently required for Public Health Service/National Institute trainees and undergraduate and graduate students and post-doctoral fellows who are supported by the National Science Foundation to conduct research as required by the America COMPETES Act of 2007.

²⁴The US Office of Science and Technology Policy (OSTP) issued a Federal Policy on Research Misconduct in December 2000. Federal agencies were directed to implement the Federal Policy within one year. The Federal Policy includes definitions, grounds for a finding of misconduct, the responsibilities of federal agencies and research institutions, guidelines for fair and timely procedures and agency administrative actions. Institutions will want to review the implementation policies of the specific federal agency sponsor.

Indicator 2. The institution's policy clearly delineates points of contact and lines of communication for persons making allegations of research misconduct.

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

Practice C. The institution is committed to the protection of the rights of the 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.

Practice D. The institution has a procedure for assessing whether concerns advanced constitute allegations of misconduct in research to be further pursued under established procedures.

Practice E. The institution uses a procedure for conducting, in a timely manner, an 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.

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

Practice G. 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 H. In the case of a finding of research misconduct, the institution has a clearly defined process of adjudication that provides for an appeal of the finding by the respondent.

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

PRINCIPLE X-2. FINANCIAL CONFLICTS OF INTEREST

The institution has a written policy to assist investigators, postdoctoral fellows, students and research staff, including study coordinators, in determining whether and to what extent outside financial relationships and interests may conflict with their primary research and academic activities or other institutional responsibilities.²⁵

Practice A. 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 disengagement from research activities and decision-making. The policy distinguishes between conflicts of interest and conflicts of commitment. The policy identifies an individual or office that is responsible for responding to questions on the policy.

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

²⁵The institution has considered the final guidance document issued by HHS regarding "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" ("Guidance Document") and association guidance, such as the Association of American Medical Colleges and Association of American Universities "Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research" (February 2008) in establishing its policies and procedures related to human subjects research activities.

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

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

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

Practice F. The institution has established lines of communication that identify to the designated responsible official potential conflicts of interest that result from the operation of the technology transfer offices, sponsored programs, and/or the identification of conflicts in human subject research protocols.

Practice G. The institution's policy has a process that ensures that the individual is in compliance with the financial conflicts of interest policies of the institution and his/her external sponsor and has designated enforcement mechanisms and/or sanctions when the individual does not report accurate information to the responsible official or is in non-compliance with other aspects of the requirements.

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

Indicator 1. In addition to a senior investigator mentor, students—both graduate and undergraduate—are provided access to resources and individuals who can advise students with respect to specific financial conflicts of interest concerns. These resources and individuals are available for research staff of a potentially conflicted investigator.

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

Indicator 1. The institution has clear lines of responsibility and authority for the review of disclosed potential conflicts, the determination that a real or potential conflict exists and the determination of what action(s) should be taken by the institution to eliminate, reduce or manage such conflicts of interest. The institution has considered establishing a conflicts of interest committee(s) to assist the designated official with these determinations.

Indicator 1a. If the institution chooses to establish a conflicts of interest committee, the committee membership includes academic and administrative personnel (with seniority) and knowledge of institutional policies and processes with respect to conflicts of interest in addition to knowledge about the academic issues and the research under discussion. The institution assesses any committee members' potential conflicts of interest in matters under consideration by the committee.

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

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

Indicator 4. The institution has regular follow-up and institutional monitoring to ensure that management plans are being complied with.

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

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

Indicator 1. The institution informs external sponsors, as required, when an investigator has disclosed a financial conflict related to the sponsor's current or potential supported activity.

Indicator 2. The institution discloses conflicts of interest to human subjects as appropriate.

Practice K. The institution has policies and procedures that outline its responsibility to ensure that subawardees comply with federal or other sponsor requirements regarding conflicts of interest. [See Also II-6, Subrecipient Monitoring.]

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

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

Practice L. 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 conflicts of interest process—for both conflicts related to the institution's financial interests and relationships and those involving senior officers—that follow a three-fold approach: disclose the conflict; manage the conflict; and eliminate the activity when necessary to protect the public interest or the interest of the institution.

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

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

Indicator 4. Institutional conflicts of interest management plans are signed by parties that have responsibility for management strategies, the institutional official that has been designated to approve the plans (e.g., Provost, President, or Board Chair) and distributed to parties that have a need to know of management strategies.

Indicator 5. If the institution chooses to establish an institutional conflicts of interest committee, this committee's membership includes individuals that are knowledgeable, by training or experience, regarding conflicts of interest issues. The institution has considered whether a non-affiliated individual is included in the committee's composition. The institution assesses any committee members' potential conflicts of interest in matters under consideration by the committee.

Note: Research institutions and the federal government continue to consider how to address institutional financial conflicts of interest, and the reader should ascertain whether there are any developments in this area subsequent to the date of this revision.

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)
<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>

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

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 including the Bayh-Dole Act, 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 programs 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 programs 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 commercialize intellectual property and facilitate the distribution of tangible research materials created at the institution.

Indicator 2. The institution has sufficient management resources (e.g. databases, etc.) to track 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 (e.g., investigators, research staff, students, visitors, consultants, etc.) to the extent required by institutional policy and/or for compliance with agreements of external sponsors.

Indicator 2. The institution has procedures for the timely reporting within the institution of intellectual property created during sponsored programs 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 policies and procedures for royalty sharing with inventors/authors, as required by institutional policies, interinstitutional agreements and federal regulations.

Indicator 5. The institution has personnel and procedures to ensure compliance with the Bayh-Dole Act, including but not limited to, designating the use of institutional royalty revenue (after expenses) for scientific research or education purposes, reporting of federally-funded inventions, timely election of title to inventions, confirming a non-exclusive, royalty free license for government purposes, and other appropriate mechanisms to fully comply with government rights.

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

Indicator 7. The institution, in its management of intellectual property and technical data, takes appropriate measures including, if appropriate, 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, Embargos, Trade Sanctions and Executive Orders.]

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

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

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

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

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

Indicator 1. Procedures have been established to obtain written agreements with 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 or other agreements with external sponsors relating to intellectual property.

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

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

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

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

Indicator 1. The institution has training and awareness programs to inform and train institutional faculty, students and staff with regard to their rights and responsibilities with respect to all aspects of the institution's intellectual property policy. This includes the obligation to disclose all inventions conceived or reduced to practice while conducting institutional research and awareness of any terms or conditions imposed by external sponsors or third-party material providers in the agreement (including individual agreements) before the sponsored program activity begins.

Indicator 2. The institution has an established process for review and adjudication of disputes among investigators.

Indicator 3. A training program is in place to acquaint students with the institution's intellectual property policies for independent work, classroom work, and sponsored programs.

Indicator 4. The institution has implemented safeguards to protect the student's educational progress from potentially conflicting demands arising from intellectual property claims of third parties.

Internet Resources

US 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

National Institutes of Health, Office of Technology Transfer Policies

<http://ott.od.nih.gov/policy/Reports.html>

**Association of University Technology Managers (AUTM)
In the Public Interest: Nine Points to Consider in
Licensing University technology**

[http://www.autm.net/aboutTT/Points to Consider.pdf](http://www.autm.net/aboutTT/Points_to_Consider.pdf)

PRINCIPLE XII. EXPORT, GLOBAL ACTIVITIES AND RELATIONSHIPS WITH FOREIGN ENTITIES

The institution builds its international relationships and activities on the foundation of policies, practices, procedures and controls forming its comprehensive compliance system, including those systems supporting compliance with visa and export control regulations, embargos, sanctions and sponsor restrictions. The institution enhances its management practices to provide necessary additional support to its global activities and relationships with foreign entities.

PRINCIPLE XII-1. EXPORT CONTROLS, EMBARGOS, TRADE SANCTIONS AND EXECUTIVE ORDERS

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

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

Indicator 1. The institution either (i) does not accept publication or access restrictions in sponsored programs, 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 programs results, or (ii) identifies, segregates and secures export-controlled sponsored programs from the otherwise open campus, and obtains necessary deemed export licenses or excludes foreign nationals from participation in export-controlled sponsored programs.

Indicator 1a. Policies are consistently applied and the institution has a process to ensure appropriate, high-level institutional decision-making on 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 programs 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 programs 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 an education and awareness program, record-keeping of determinations concerning controls and licensing actions, 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. US Office of Foreign Asset Control (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 or that licenses, as may be required by OFAC, that approve the institution's activities in the sanctioned country have been obtained prior to initiating the activity.

PRINCIPLE XII-2. INTERNATIONAL RELATIONSHIPS

The institution develops strategies to focus its resources to international activities which match the institution's core mission.

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

Indicator 1. The institution has mechanisms to collect and report information on international activities and relationships in which they are involved.

Indicator 2. Internal communication mechanisms are created which focus on international activities and relationships. Such mechanisms may offer members of the institution a tool for self reporting international activities.

Practice B. The institution develops a mechanism for special advance review and monitoring of major institution initiatives.

Indicator 1. The institution has a mechanism for reviewing, approving and monitoring all international sites.

Indicator 2. The institution has a mechanism for reviewing, approving and monitoring international programs of a significant size and duration.

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

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

Indicator 2. The institution develops a mechanism for coordinating laboratory visitors from abroad including deemed export issues as appropriate.

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

PRINCIPLE XII-3. INTERNATIONAL TRAVEL

The institution addresses the risks and requirements of international travel for its faculty, students and staff.

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

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

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

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

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

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

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

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

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

Indicator 2. Emergency contact information is provided to travelers.

Practice D. The institution's compliance program includes systems that are integrated with the institution's travel programs to identify OFAC embargo issues and licensing requirements prior to making international travel arrangements.

PRINCIPLE XII-4. INTERNATIONAL TRANSACTIONS

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

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

Indicator 1. The sponsored program agreement specifies 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 program agreements set out a process for compliance. In the case of biological materials, the agreement addresses compliance with international conventions as well as host country requirements.

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

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

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

Indicator 6. The sponsored program agreement requires payments of sponsored program costs to be made to 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 program agreement adequately addresses any visa or other clearances that need to be obtained from a foreign authority in order to undertake work in the foreign locale.

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

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

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

Practice B. Regardless of legal provisions, the potential of political influences (manifest in changes of government leadership or laws, interpretations of existing law by foreign authorities, or volatility of the political and economic systems) are taken into account in identifying and managing risks to the sponsored program, and tax and other risks to the U.S. institution.

Practice C. 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 under Executive Orders or other regulations, taking into account both the entity and the individual participants.

Practice D. The institution and all its personnel, agents, contractors and collaborators are aware of the U.S. anti-bribery laws. Contract provisions should 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 programs compensation and support.

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

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

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

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

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

PRINCIPLE XII-5. INTERNATIONAL TAXATION

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

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

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

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

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

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

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

PRINCIPLE XII-6 ESTABLISHING INTERNATIONAL SITES

The institution develops strategies for establishing sites in foreign locations.

Practice A. The institution addresses both employee needs while in foreign locations and the return of employees to campus.

Indicator 1. The institution researches and addresses local labor and employment laws including but not limited to laws governing retirement.

Indicator 2. The institution implements additional practices to comply with US and sponsor regulations, for example, regulations prohibiting trafficking in persons and regulation prohibiting bribery.

Practice B. The institution researches and addresses all applicable local laws for operating a business in a foreign location.

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.)

Re: Taxation, see:

<http://www.taxworld.org/OtherSites/International/international.htm>

<http://tax.aicpa.org/Resources/International>

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