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Managing Externally Funded Programs at Colleges and Universities

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Managing Externally Funded Programs at Colleges and Universities

A Guideline to
Good Management
Practices

COGR
COUNCIL ON
GOVERNMENTAL
RELATIONS

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COUNCIL ON GOVERNMENTAL RELATIONS

The Council on Governmental Relations is an association of leading research-intensive universities. One of COGR's important functions consists of helping to develop policies and practices in research and training that fairly reflect the mutual interest and separate obligations of universities and federal and other sponsoring agencies. COGR seeks to serve the needs of its member universities by addressing compliance issues associated with the administration of sponsored programs. This document is illustrative of such activity.

This guideline may be used by colleges and universities to review their management systems and internal controls. Readers must recognize that general principles of good management are stable and consistent; rules and regulations imposed by external sponsors are subject to change. This guideline does not purport to set standards; it only suggests good management practices and indicators to test those practices.

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PREAMBLE

Colleges and universities are responsible for the management of significant amounts of money for research and training from a variety of sources. In like manner, they are responsible for developing policies and procedures with regard to issues such as the management of intellectual property and integrity in research. Criteria available to all members of the university community aid in ensuring appropriate management of research funds, the research process and research outcomes. By necessity, good practices entail that colleges and universities comply with rules established by the federal government, when those colleges and universities accept federal requirements as a condition of receiving federal funds. In instances where federal regulations require specific forms of implementation other than those set forth as good practices, they have been identified as such. Where state or local governmental entities have applicable laws or regulations more restrictive than these good practices, those laws and regulations may govern.

Managing Externally Funded Programs at Colleges and Universities: A Guideline to Good Management Practices, has been formatted in such a way as to identify principles, practices, and indicators, which have been defined as follows:

Principles state the general characteristics; i.e., they are overall statements of measures of quality management.

Practices are measurable conditions which highlight crucial components in the attainment of each principle, but not necessarily all components.

Indicators are suggested measures to use when examining whether good practices are being employed.

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. The COGR website (cogr.edu) is a useful source of information as to such changes.

Compliance has become a term of art in federally funded activities. As such, it means many different things to many college, university and academic medical center offices, faculty, and research staff. It can mean tracking Medicare physician reimbursement and discriminating between patient care and research subject billings; adherence to the Civil Rights Act; keeping of records in accordance with the Student Privacy Act; disclosing financial conflicts of interest in research; and spending award funds appropriately.

Historically for extramurally funded research programs, 'compliance' has traditionally been considered synonymous with good business practices assuring fiscal and administrative accountability. Compliance with the terms and conditions of an award, beginning with proposal development, presumed the investigator's conduct of research in accordance with ethical principles and professional standards. Adherence to the federal requirements governing regulated research activities such as the use of human and animal subjects were 'compliance' but implemented and enforced through, generally, faculty/academic committees. Academic oversight assured that research staff carried out their technical responsibilities.

In current parlance, compliance requirements apply to both the conduct of the science (research) and the management of funds used for research. A program of compliance demonstrates a college or university's institutional commitment to comply with the broadly construed terms and conditions of a sponsored project. A program of compliance begins with documentation of existing policies, practices, procedures, and controls but includes delineation of roles and responsibilities and education programs for all faculty and staff in the institution who touch externally funded programs in any manner.

Generally, compliance can be viewed in discrete, identifiable areas:

- Regulated research areas: human and animal subjects, biosafety, radioisotopes used in animals and humans
- Conflict of interest: individual and institutional financial interests that could bias the integrity of the research process
- Scientific misconduct
- Intellectual property
- Administrative compliance: terms and conditions of award, technical and fiscal reporting, property, procurement

Compliance is a theme that weaves its way through all the principles enunciated in this document and the reader will see references to specific compliance requirements throughout. Principle I itself addresses practices and indicators addressing general quality management.

PRINCIPLE I COMPLIANCE

The college or university has a comprehensive system in place that provides for written policies and practices covering the scientific conduct and the administrative and financial management of sponsored programs.

PRACTICE A.

The college or university has clearly established lines of responsibility, i.e., delineation of the roles and responsibilities, for all scientific and administrative personnel involved in the conduct and management of sponsored programs.

Indicator 1.

The institution obtains confirmation that the principal investigator accepts responsibility for financial management of the proposed project.

Indicator 2.

Within an operating unit, roles and responsibilities, along with an appropriate system of checks and balances, are clearly defined and understood.

PRACTICE B.

An education program is in place for both externally mandated and internal training.

Indicator 1.

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

Indicator 2.

The institution has a timeline for development and implementation of education and training programs pertinent to all individuals involved in sponsored programs.

Indicator 3.

The institution has an education program in place for ethical use of human subjects.

Indicator 4.

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

Indicator 5.

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

PRACTICE C.

Research compliance is a component of a college or university's risk assessment evaluation.

Indicator 1.

The institution's audit function provides oversight of the research compliance activities of the institution.

Indicator 2.

Risk assessment in the area of research compliance is an ongoing activity of the institution.

Indicator 3.

Senior management reviews the risks and benefits inherent in the research enterprise and sets parameters for the management of risk.

PRINCIPLE II. FISCAL ADMINISTRATION

The college or university cost estimating, recording, accumulating, and reporting as well as its budget administration systems are designed in accordance with generally accepted accounting principles, the costing provisions of OMB Circular A-21, and the financial and technical terms and conditions of the funding agency. They are designed to assure that the federal government and other research sponsors bear their fair share of total project costs.

Note: *In this document the term "facilities and administrative costs" is used interchangeably with its former designator, "indirect costs."*

PRINCIPLE II-1 ALLOWABLE COSTS

The college or university has in place a financial control system that limits costs charged to accounts funded by a sponsor to costs allowable by that sponsor, in amounts that are properly allocable, and that do not exceed the sponsor's fair share of total project costs.

PRACTICE A.

The college or university 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. Other 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 unallowable costs that are expressly unallowable by federal cost principles or the funding agency (whether federal or non-federal).

Indicator 4.

The accounting procedures include policies for the commitment of cost sharing, and the tracking of committed cost sharing.

PRACTICE B.

The college or university has policies regarding the differentiation of costs allocable as direct costs, and those allocable as indirect costs (facilities and administrative costs) which are based on applicable federal regulations, such as OMB Circular A-21, and the terms of the F&A Rates Negotiation Agreement.

Indicator 1.

Costs normally allocable as indirect are accounted for in a way that assures that similar costs in like circumstances are not budgeted or charged as direct costs to sponsored agreements, except with approval of the sponsor, and where the costs are associated with a major project as described by section F.6.b.(2) (and Exhibit C) of Circular A-21.

Indicator 2.

The college or university provides timely and properly prepared proposals for the negotiation and settlement of facilities and administrative cost rates with the cognizant federal cost agency.

Indicator 3.

The college or university has a system in place to include only allowable costs in the facilities and administrative cost pools.

Indicator 4.

Costs unallowable by federal cost principles are segregated in the direct and facilities/administrative cost calculations.

Indicator 5.

Review at appropriate levels is made to ensure the accuracy of all facilities/administrative cost calculations.

PRACTICE C.

Persons responsible for the initiation of direct charges to programs and persons responsible for the approval and payment of those charges are aware of and follow the policies regarding allowability of costs and the types of costs chargeable/allocable as direct costs or recovered as facilities or administrative costs.

Indicator 1.

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

Indicator 2.

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

PRACTICE D.

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

Indicator 1.

The college or university has appropriate internal systems to implement the documentation and allocation standards of OMB Circular A-21 as they relate to cost transfers.

PRACTICE E.

The college or university has established practices for monitoring, updating, and disseminating its policies and procedures to be in compliance with current government laws, regulations and practices.

Indicator 1.

The institution has a system to periodically update its Disclosure Statement (DS-2) when required to reflect changes made to the institutional practices, and if necessary communicate the changes to the institution's cognizant federal cost agency to determine whether a cost impact analysis is deemed necessary.

PRINCIPLE II-2. PROPOSAL COSTING

The college or university has a proposal cost estimating and budget administration system. Costs are included in proposal budgets and charged to awards consistent with the institution's cost accounting practices. The system used in proposing, recording, accumulating and reporting costs assures that research sponsors bear only their fair share of total project costs.

PRACTICE A.

The college or university has written policies and procedures for proposal costing and budget administration which are disseminated and made known at all levels of the institution including senior management and administrative officials and faculty.

PRACTICE B.

The college or university prepares and submits proposals based upon both consistently applied direct and indirect cost accounting practices which are reviewed and updated as appropriate, and has the ability to coordinate proposal budgets with its accounting and financial reporting systems.

Indicator 1.

Proposals that are prepared at the departmental level are forwarded to a central office which 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 of appropriate rates based on receipt of adequate documentation including cost and price analysis for direct costs.

Indicator 3.

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

Indicator 4.

Institutions can provide detailed cost justification such as individual salary rates, detailed travel costs, equipment and supply details, cost of subawards, 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).

Indicator 6.

Institutions review the 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.

**PRINCIPLE II-3.
FINANCIAL ACCOUNTING
AND REPORTING**

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

PRACTICE A.

The college or university has written policies and procedures for its financial management.

Indicator 1.

Personnel involved in the administration of research 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 faculty and staff as needed.

Indicator 3.

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

PRACTICE B.

The college or university has an accounting system for the identification and control of all extramural funding.

Indicator 1.

Claims for reimbursement are made in a timely fashion.

Indicator 2.

Financial reports are accurate, easy to read, and distributed in a timely fashion.

Indicator 3.

General ledgers and other required accounting records for recording fund activity are maintained and retained pursuant to record retention requirements and disseminated to persons responsible for financial oversight of extramural funding.

Indicator 4.

Appropriate payroll and personnel reporting systems are in place, including salary certification.

Indicator 5.

There is a system to record and document committed cost sharing on awards, including both mandatory and voluntary committed cost sharing.

Indicator 6.

There is an adequate system of internal controls, as well as procedures for timely corrective policy actions, dissemination of policy changes, and staff training.

Indicator 7.

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

PRINCIPLE II-4.

CASH MANAGEMENT

The college or university has a cash management system that complies with federal, internal, and, if necessary, state regulations and which provides adequate control and necessary flexibility to make timely deposits and disbursements.

PRACTICE A.

The college or university 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 college or university system provides for careful monitoring of cash flow.

Indicator 1.

A treasurer/cashier system is available.

Indicator 2.

Cash withdrawals and deposits under governmental advance payment systems are made in a timely fashion.

Indicator 3.

The college or university has in place a system for recording, allocating, and remitting interest earned.

Indicator 4.

The college or university limits requests for advance payment to amounts as provided by federal requirements.

PRACTICE B.

The college or university has policies and procedures to record the receipt of income and to disburse cash, to bill agencies for receivables, and to report its cash management activities to sponsoring agencies.

Indicator 1.

The college or university maintains a current list of individuals who are authorized by the institution to disburse funds for all goods and services.

Indicator 2.

There is monitoring of financial and budgetary transactions to maintain conformance with institutional and extramural agency regulations.

Indicator 3.

A credit, refund, and rebate system to make appropriate remittances is in place.

Indicator 4.

An accounts receivable system provides for timely billing and payment for monies due.

Indicator 5.

The management and reporting of program income is in accordance with the appropriate regulations.

Indicator 6.

There is appropriate monitoring and remitting of interest earned on federal funds in excess of what is permitted to be retained by the college or university.

Indicator 7.

The institution has appropriate relationships with banking institutions to effect and receive electronic funds transfer payments.

Indicator 8.

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

Indicator 9.

The institution ensures separation of duties between receipt of checks and deposits.

PRINCIPLE II-5. COMPENSATION

The college or university 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 and A-110.

PRACTICE A.

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

Indicator 1.

The institution has written compensation policies that include uniform guidelines for salary increases.

Indicator 2.

Salary rates charged to sponsored programs must not exceed the proportional share of the base salary for that period.

Indicator 3.

The distribution of salaries and wages, whether as direct costs or facilities and administrative costs, should be based on a reasonable estimate of all the employees' activity and the costs captured in the institution's official payroll distribution system.

PRACTICE B.

The college or university must be able to reflect the activity (more commonly known as effort) applicable to each sponsored agreement as well as facilities and administrative cost activities as stated in OMB Circular A-21 (and any related clarifications).

Indicator 1.

Confirmation of an individual's activity that represents a reasonable estimate of work performed must be done by the employee or a person having direct knowledge of the employee's work.

Indicator 2.

Confirmation of an individual's activity must occur at the frequency indicated in Circular A-21.

PRACTICE C.

The college or university has policies and procedures in place to ensure compliance with sponsor-imposed salary caps.

PRACTICE D.

Institutional fringe benefit rates and method for distributing these costs conform to the requirements of Circular A-21.

PRINCIPLE II-6. COST SHARING

The college or university has policies and procedures for properly documenting cost sharing in the same manner as costs funded by the sponsor, including mandatory and voluntary committed faculty effort. These policies and procedures comply with federal requirements of OMB Circulars A-21 and A-110.

PRACTICE A.

The college or university 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.

Committed faculty and staff effort included as cost sharing is appropriately recorded in the institution's accounting records.

Indicator 3.

Cost sharing expenditures meet the standards of allowability, allocability, and reasonableness consistent with federal cost principles and standards of other sponsors.

Indicator 4.

Institutional systems provide for appropriate monitoring of cost sharing for timeliness and adequacy of documentation.

Indicator 5.

The institution has a policy whereby it reports required cost sharing in accordance with the terms and conditions of awards.

PRACTICE B.

Where cost sharing is a requirement of subawards, such activity is included in subaward documents, monitored by the prime and subrecipient institutions, and appropriately reported to the sponsor when required.

PRACTICE C.

Committed cost sharing including faculty and staff effort and other non-labor cost sharing, dedicated to organized research is appropriately classified for the calculation of a college or university's facilities and administrative cost proposal.

Indicator 1.

Committed cost sharing is transferred to the organized research base for facilities and administrative cost calculation purposes.

Indicator 2.

Voluntary uncommitted cost sharing (i.e. faculty-donated additional time above that agreed to as part of the award) is treated differently from committed effort and is excluded from payroll reporting requirements and not included in the organized research base for computing the facilities and administrative cost rates.

Indicator 3.

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

Indicator 4.

Federally-funded research programs reflect some level of committed faculty (or senior researcher) effort whether paid or unpaid by the federal sponsor, except where the particular research program does not require committed faculty effort. If no effort is shown, an estimated amount is computed by the university and included in the organized research base, consistent with OMB Circular A-21.

PRINCIPLE II-7.

COST ACCOUNTING STANDARDS

The college or university has appropriate 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 college or university has established policies and practices that ensure compliance with the mandated cost accounting standards (CAS 501, 502, 504, 505).

Indicator 1.

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

Indicator 2.

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

PRACTICE B.

The college or university demonstrates on-going compliance with the requirements of the cost accounting standards.

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, and that like costs are not treated both as direct and as indirect costs.

Indicator 3.

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

PRACTICE C.

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

Indicator 1.

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

Indicator 2.

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

PRINCIPLE III. PROCUREMENT

The college or university has a procurement system for acquiring goods and services in a competitive, fair, and timely manner.

PRACTICE A.

The college or university has written policies and procedures for the purchase of goods and services.

Indicator 1.

Personnel involved in the administration of research are cognizant of the policies and procedures governing procurement of goods and services.

Indicator 2.

Individuals involved in procurement adhere to a written code of ethics for procurement personnel and are familiar with the cost principles governing expenditure of federal funds (i.e., OMB Circular A-21) and the procurement procedures described by federal regulations (i.e., OMB Circular A-110 and the Federal Acquisition Regulations).

Indicator 3.

Individuals in central administrative offices and the organization's academic 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 college or university employees to prevent conflict 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.

PRACTICE B.

The college or university has a written procurement system that meets the requirements of OMB Circular A-110 and the Federal Acquisition Regulations, as applicable.

Indicator 1.

A Request for Proposal (RFP), Request for Quotations (RFQ), or bid system for the acquisition of goods and services is in place that provides for competitive procurement and justification for accepting other than the low bid.

Indicator 2.

Criteria for utilizing sole source acquisitions are available and written justification is on file for sole source procurements.

Indicator 3.

Policies and procedures that encourage procurement from small, minority, disadvantaged, and/or women-owned businesses are available and the institution has developed appropriate procedures to provide reports to agencies as required.

Indicator 4.

Policies and procedures are in place to determine if vendors 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 purchasing, that no unnecessarily duplicative equipment is available to meet project needs.

Indicator 8.

College or university-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, improve services and reduce re-order cycle times through better vendor relationships, and provide for automated ordering and billing functions that remove administrative burden and improve efficiencies.

PRACTICE C.

The college or university'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.

PRACTICE D.

The college or university's procurement procedures distinguish between acquisitions of goods and services and subrecipient agreements for research (see Principle VIII-2, Practice E).

PRINCIPLE IV. MANAGEMENT OF PERMANENT EQUIPMENT

Note: See OMB Circular A-110, __.2 Definitions 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 supplies over a specified threshold. However, this section covers only the management of permanent equipment. Intellectual property is addressed in Principle IX. The reader should consult OMB A-110, __.30-.37 for a discussion of other types of property.

The college or university has a management system governing permanent equipment acquired from both federal and non-federal sources.

PRACTICE A.

The college or university has written policies and procedures that address permanent equipment issues.

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 permanent equipment.

PRACTICE B.

The college or university has adopted a system for appropriate acquisition and protection of permanent equipment.

Indicator 1.

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

Indicator 2.

Receiving procedures are in place to assure that all purchases are inspected upon receipt.

Indicator 3.

Only authorized personnel are allowed to place purchase orders.

Indicator 4.

Permanent equipment acquisitions on sponsored accounts are reviewed for allowability, ownership, and taxes.

PRACTICE C.

The college or university has a permanent equipment inventory system.

Indicator 1.

Permanent 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 of funds for the purchase.

Indicator 4.

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

Indicator 5.

Reconciliation of inventory records to financial records is performed at least biennially.

Indicator 6.

Items of accountable inventory and all items of federal property are properly tagged and safeguarded.

PRACTICE D.

The college or university has a system for reporting of capital equipment to external sponsors, when required.

PRACTICE E.

The college or university has a system to determine whether permanent equipment should be transferred, retained on inventory, disposed of or salvaged.

Indicator 1.

Permanent 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 permanent equipment is done through the Surplus Sales Department or similar responsibility area in accordance with institutional policy.

Indicator 3.

The institution has a process for determining the conditions under which permanent equipment can be transferred or loaned to another institution and the methods for handling such transfers/loans.

PRINCIPLE V. HUMAN RESOURCES

The college or university has a human resources management program including written personnel policies and procedures available to all employees that provides safeguards to assure that the institution complies with laws and regulations regarding recruitment, hiring, terms, conditions and termination of employment.

PRACTICE A.

The college or university's personnel policies address public policy issues such as equal employment opportunity, 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 openly and knowingly discussed.

Indicator 2.

The personnel 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 to aid in resolving violations of such policies.

Indicator 4.

There are programs that provide employee assistance in identification and treatment of alcohol and/or drug abuse.

Indicator 5.

The institution periodically reviews and modifies its programs for effectiveness, compliance with applicable laws, and consistent application of sanctions.

PRACTICE B.

The college or university has personnel policies that provide procedures for consistency in the recruiting, hiring, evaluating, compensating, disciplining, and terminating of employees.

PRACTICE C.

The college or university has appropriate available education programs as required by external sponsors.

Indicator 1.

The institution mandates training in the areas of hazardous materials, animal use, and human subjects use for appropriate individuals.

PRACTICE D.

The college or university has policies and procedures to ensure compliance with U.S. immigration laws.

Indicator 1.

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

Indicator 2.

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

PRINCIPLE VI. COMPLIANCE ASSESSMENTS AND AUDITS

The college or university has a formal system for compliance assessment and audit that demonstrates that the institution complies with both internal policies and federal regulations.

PRACTICE A.

The college or university has written policies and procedures for performing compliance assessments and formal audits and for reporting the results of such reviews to management.

Indicator 1.

The institution demonstrates a knowledge of and commitment to compliance by performing compliance assessments in areas of research activity.

Indicator 2.

The institution initiates formal audits of administrative and financial systems that support the research enterprise and reports results of such audits to management.

PRACTICE B.

The college or university has written policies and procedures for both its external independent audit and its internal audit responsibilities.

Indicator 1.

There are policies in place to assure the independence of auditors and the institution's auditor reports directly to a board of regents or equivalent structure.

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-110.

PRACTICE C.

Policies and procedures for the college or university's audit system are distributed to its responsible officials.

Indicator 1.

Compliance assessments adhere to the same audit standards that apply to formal audits.

Indicator 2.

The results of financial and compliance audits are communicated to all affected individuals.

PRACTICE D.

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

PRACTICE E.

The college or university has procedures for recurring 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.

Results of operations or programs are consistent with established goals and objectives, and operations or programs are being carried out as planned.

Indicator 6.

Systems of controls adequately measure and assure that resources are used economically and efficiently.

Indicator 7.

Reports are prepared for management stating findings and recommendations, and matters of audit significance are reported directly to appropriate officials.

Indicator 8.

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

PRACTICE F.

Compliance assessments supporting the college or university's program of compliance are performed on a regular basis.

PRACTICE G.

The college or university complies with government auditing requirements with respect to its federal programs.

Indicator 1.

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

Indicator 4.

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

Indicator 5.

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

PRINCIPLE VII. COMPLIANCE WITH PROTECTION REGULATIONS

Note: Compliance is incorporated throughout this document as appropriate to the topic. This section, however, deals with four specific areas of compliance in the conduct of research: human subjects, animals, the environment, and facilities. It should be noted that the federal government is in the process of revising regulations which impact these areas (for example, human subjects) and the reader should be cognizant of significant volatility in these regulations.

The college or university has systems that comply with federal and, where necessary, state and local government regulations and with requirements of non-federal sponsors in the areas of protection of human subjects¹ and of animals, the environment, and in the operation of its facilities.

PRACTICE A.

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

Indicator 1.

An office or individual is identified to provide coordination between and among the appropriate parties.

Indicator 2.

The institution has a triage system in the case of issues for which multiple committees share responsibilities for various aspects of compliance.

PRINCIPLE VII-1 HUMAN SUBJECTS

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

PRACTICE A.

The college or university has filed a written assurance with the Department of Health and Human Services and received approval in accordance with federal regulations.

Indicator 1.

The institution has written and disseminated policies and procedures consistent with the approved assurance that describe the specific review procedures when human subjects are used in research.

¹ Referred to as "human research participants" in recent federal guidelines

Indicator 2.

The institution has educational programs to ensure that personnel engaged in human subject research are adequately trained.

Indicator 3.

Where required, acknowledgement of formal training is provided and institutional records are maintained which record such training.

PRACTICE B.

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

Indicator 1.

There is adequate recognition of responsibility for protection of the rights and welfare of human subjects.

Indicator 2.

The institution has protocol review procedures and mechanisms for certain kinds of research that meet the definitions for exempt protocols and expedited reviews as defined by the government.

Indicator 3.

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

Indicator 4.

Each IRB includes at least one member from outside the institution.

Indicator 5.

The institution has a system to meet requirements for continuing review and monitoring of approved protocols.

Indicator 6.

The review committee has representation on a continuing or "ad hoc" basis when vulnerable populations are being considered as research subjects (e.g., prisoners, handicapped, elderly, children).

Indicator 7.

When proposed research involves foreign sites, the IRB's records demonstrate that it has obtained adequate information about the local research context to address concerns of risk-benefit and vulnerable categories of subjects.

Indicator 8.

If IRB review of proposals to external sponsors is not completed prior to submission, a system exists for subsequent review and notification of the results of that review, with procedures to insure approval of protocol before initiation of the activity. Adherence to the just-in-time process of NIH is documented.

Indicator 9.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Indicator 10.

No greater than 12 months separates continuing review and approval of protocols as required and the results documented.

Indicator 11.

The IRB maintains detailed records of the results of its meetings and makes these records available as required.

Indicator 12.

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

PRACTICE C.

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

PRACTICE D.

Changes in policies and procedures are made in a timely fashion and, where appropriate, communicated to the college or university community.

Indicator 1.

Changes in federal regulations that impact the operation of the IRB and human subject research are identified and incorporated into institutional policy and procedures.

PRACTICE E.

Policies exist to notify appropriate personnel when emergency treatment of patients is required and to provide for such treatment when necessary.

PRACTICE F.

The college or university conducts clinical research studies including trials in compliance with applicable institutional and sponsor data safety monitoring requirements.

Indicator 1.

Written policies describe the institution's safety monitoring boards and other oversight provisions for conduct of clinical studies from Phase I through Phase IV clinical trials.

Indicator 2.

The institution has mechanisms to establish, evaluate and monitor relevant programs for possible future implementation.

PRACTICE G.

There are policies and procedures in compliance with federal, state and local laws, to protect the privacy of both patient health information and human biological specimens used in research.

Indicator 1.

The IRB-approved protocol indicates the level of protection for the privacy of this information.

Indicator 2.

Clinical authority exists for examination of patient records and/or, if appropriate, human biological specimens.

PRINCIPLE VII-2 ANIMAL CARE

The college or university has a system to assure the existence of policies and procedures which comply with federal, and where necessary, with state and local government regulations and with the requirements of non-federal sponsors to humanely, efficiently, effectively, and legally use live vertebrate animals in research covered by such regulations.

PRACTICE A.

The college or university has filed a written assurance with the Department of Health and Human Services and received approval thereof, and has also secured Department of Agriculture registration.

Indicator 1.

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

Indicator 2.

The institution has written and disseminated policies and procedures consistent with the approved assurance and which describe the specific procurement and review procedures when animals are used in research.

PRACTICE B.

The college or university 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.

Adequate scientific justification is required prior to approval, including consideration of alternative or in vitro methods.

Indicator 2.

IACUC membership includes at least one person from outside the institution.

Indicator 3.

If review by the IACUC of proposals to external sponsors is not completed prior to submission, a system exists for subsequent review and notification of the results of that review, with procedures to insure approval of the protocol before initiation of the activity.

Indicator 4.

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.

Indicator 5.

The IACUC requires scientific justification provided by investigators for the number of animals requested.

Indicator 6.

Adequate scientific justification is required prior to approval of protocols involving unrelieved pain or distress.

Indicator 7.

The institution has a policy to ensure when necessary the certification of research staff using any physical methods of euthanasia.

PRACTICE C.

The college or university has programs and procedures for training and medical examination of scientists, animal technicians, and other personnel involved in animal care or use.

Indicator 1.

The training program includes information on the humane practice of animal care and use and training to minimize animal distress.

Indicator 2.

Lines of authority and responsibility for administration of the animal care and use program exist.

Indicator 3.

Medical examinations are required of all individuals who have direct contact with animals at the levels required by federal regulation.

PRACTICE D.

Adequate systems are in place to track, report and maintain compliance with the Animal Welfare Act and the PHS Good Laboratory Practices Guide as well as any applicable occupational health and safety regulations.

PRACTICE E.

The college or university has a disaster recovery plan and emergency procedures for dealing with catastrophic events that could affect animal facilities.

Indicator 1.

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.

Indicator 2.

The institution has mechanisms to establish, evaluate and monitor relevant programs for possible future implementation.

**PRINCIPLE VII-3
ENVIRONMENTAL SAFETY**

The college or university has a system to assure the existence of policies and procedures which comply with federal and, where necessary, with state and local government regulations pertaining to environmental safety.

PRACTICE A.

With respect to biohazards and hazardous waste, the college or university has in place a process which complies with requirements for the identification, classification and control of biological hazards (biohazards)² and other hazardous waste associated with research (including recombinant DNA).

Indicator 1.

Guidelines have been developed to specify minimum training standards of personnel competence and procedures for physical containment and proper handling of the various classes of biohazards and hazardous wastes.

Indicator 1a.

A program exists which provides the necessary training to meet the minimum standards established by the institution.

Indicator 1b.

Adequate reference materials are available to the college or university's community.

Indicator 1c.

The institution has developed appropriate training programs in biohazard and laboratory safety, hygiene and sanitation.

² 18 U.S.C. 175 contains provisions criminalizing possession of biological agents, toxins or delivery systems for use as a weapon. Implementing regulations (42 CFR, Part 72) mandate registration of laboratories that transfer or receive select biological agents. In addition, the USA PATRIOT Act (P.L. 107-56) prohibits possession of select biological agents by "restricted persons." Further legislation and/or regulations in this area were pending as of the date of this revision.

Indicator 2.

The college or university has a Biological Safety Committee to establish policies, procedures and standards, provide education and consultant services, review biological research proposals for compliance with standards, and recommend training and education methods for (biohazard) laboratory personnel exposed to biohazards.

Indicator 2a.

Responsibilities for the control of biohazards and chemical carcinogen use and safety of employees, facilities, and the public have been established.

Indicator 2b.

A policy and procedure for disposal of potentially infectious or radioactive materials exist.

Indicator 2c.

The institution has a biosafety officer charged with oversight and management of institutional compliance with the health and safety of laboratory staff and facilities.

Indicator 3.

A procedure is in place for review of grant and contract proposals prior to submission to an external agency or prior to project initiation when such proposals involve recombinant DNA research that is not exempt and/or include use of or exposure to potential biohazards.

Indicator 4.

The institution has policies and procedures for the management of its hazardous waste or radioactive material.

Indicator 4a.

Procedures of individual investigators are monitored and their protocols approved in advance of initiation of research programs using radioactive materials.

Indicator 4b.

Monitoring and record keeping requirements of state and federal agencies are followed.

Indicator 4c.

The institution packages, collects, stores, and disposes of hazardous waste, including chemical, biohazardous, radioactive, and infectious waste in a safe manner and in accordance with federal, state, and local regulations.

PRACTICE B.

With respect to the environment, the college or university has established an environmental health and safety office that is charged with general institutional responsibility in the area of environmental compliance.

Indicator 1.

The institution demonstrates knowledge of and compliance with federal and state environmental regulations.

Indicator 2.

The work environment is evaluated to assure that exposure of personnel to toxic and nuisance substances is within acceptable limits as defined by occupational health standards.

Indicator 3.

The institution has developed appropriate training programs in techniques for the safe use and disposal of hazardous and radioactive materials.

Indicator 4.

The institution performs periodic inspections of its facilities to document compliance with federal regulations.

PRINCIPLE VII-4 FACILITIES

The college or university has a system to assure the existence of regulations concerning security for campus buildings, other college or university facilities, equipment, information systems and, if appropriate, other materials.

PRACTICE A.

The college or university has policies and procedures for the security of the buildings, grounds, information systems, facilities, and animals of the institution to provide protection from loss or disruption of institutional and/or sponsor investments in its research programs.

Indicator 1.

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

Indicator 2.

The institution has procedures for authorized access to its buildings and laboratories.

Indicator 3.

Individuals of sufficient rank have been assigned the positions of facility and information systems security officers to oversee the security classification systems.

Indicator 4.

The institution is committed to providing a safe and healthy environment for its employees, faculty, students, and visitors.

PRACTICE B.

Regulations pertaining to compliance requirements for health and safety standards in the workplace, including compliance with OSHA regulations, where appropriate, are published and disseminated to employees.

Indicator 1.

Information, procedures, and requirements on industrial insurance and accident protection and reporting exist.

Indicator 2.

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

Indicator 3.

The institution has an occupational safety and health program for faculty, staff, and students involved in research activities, including ongoing training as required for employees in the areas of health and safety in the workplace, fire safety and extinguisher use, good laboratory practices, and security of physical and information systems.

PRACTICE C.

The college or university reviews building construction and renovation design drawings to assure that safety and health requirements are met and that the institution complies with federal requirements on the construction of research facilities.

PRACTICE D.

The college or university 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 internally and those that will be transferred.

Indicator 3.

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

Indicator 4.

Appropriate indemnification and hold harmless provisions are inserted into contract and grant documents.

Indicator 5.

Appropriate insurance and bonding provisions are incorporated into contract and grant documents.

Indicator 6.

Contractual insurance and bonding provisions are monitored for contractor compliance.

Indicator 7.

The institution has a system for the management and resolution of liability claims.

Indicator 8.

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

Indicator 9.

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

PRACTICE E.

The college or university has a disaster recovery plan and emergency procedures for dealing with catastrophic events that could affect facilities, equipment, and other institutional systems and materials.

Indicator 1.

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

PRINCIPLE VIII. PROPOSAL AND AWARD MANAGEMENT

PRINCIPLE VIII-1 PREAWARD AND PROPOSAL REQUIREMENTS

The college or university provides information on prospective sponsors and processes proposals in compliance with sponsor guidelines and requirements.

PRACTICE A.

The college or university provides information to principal investigators on sources of support for research activities and provides adequate review of proposals prior to their submission to a sponsor.

Indicator 1.

The institution has written procedures defining what approvals are required for proposals to external sponsors.

Indicator 2.

The principal investigator formally accepts responsibility for the information in the proposal and certifies compliance with sponsor requirements.

Indicator 3.

Institutional officials provide adequate review of proposals prior to submission and certify to the accuracy of institutionally-negotiated costs (i.e. fringe benefits, facilities and administrative costs, etc.)

Indicator 4.

Sponsored programs personnel ensure receipt of completed and authorized proposals from proposed sub-recipients prior to their inclusion in a proposal submission to a potential sponsor.

Indicator 5.

Where required, the institution has the ability to prepare and submit electronic proposals to potential sponsors.

PRINCIPLE VIII-2 AWARD MANAGEMENT

The college or university has a system to manage externally funded programs in accordance with the requirements of each sponsoring agency.

PRACTICE A.

The college or university has written procedures and standards for financial management systems.

PRACTICE B.

The college or university has a system for seeking required sponsor prior approvals, where required, and has developed procedures to implement the federal expanded authorities as provided in OMB Circular A-110.

Indicator 1.

The institution has policies and procedures for obtaining written prior approvals from sponsors, where required, and maintaining records of approvals granted.

Indicator 2.

The institution has procedures to provide for project director certification that requested cost transfers are timely, beneficial, project related and consistent with approved project objectives.

PRACTICE C.

The college or university has developed procedures to establish awards in its accounting system in a timely manner, including receipt of electronic awards.

Indicator 1.

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

PRACTICE D.

The college or university has procedures regarding notification of upcoming termination dates for sponsored projects to appropriate internal offices.

PRACTICE E.

The college or university has policies and procedures for issuing subrecipient agreements and for monitoring the performance of subrecipients.

Indicator 1.

Policies and procedures are in place to determine whether subrecipients have established adequate systems prior to receiving subrecipient agreements.

Indicator 2.

Written agreements with subrecipients specifying terms and conditions, including required flowdown clauses, are prepared and executed by both parties thereto.

Indicator 3.

The institution has trained and competent individuals available to write, negotiate, and administer subrecipient agreements.

Indicator 4.

Compliance with both fiscal and technical reporting requirements are monitored.

Indicator 5.

The institution can assure itself that its intended subrecipients have met the applicable federal audit requirements, exhibit no material weaknesses or material noncompliance with federal regulations, and are not subject to federal suspension or debarment.

Indicator 6.

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

Indicator 7.

Ongoing monitoring of technical performance is documented by the principal investigator and of administrative and fiscal requirements by the sponsored programs or other responsible administrative office

Indicator 8.

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

PRINCIPLE VIII-3 REPORTS, RECORDS, AND MANAGEMENT OF TECHNICAL DATA

The college or university has a system to assure adequate reporting of performance of sponsored programs as well as for the management of records and other technical data.

PRACTICE A.

The college or university 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 research.

Indicator 2.

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

Indicator 3.

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

PRACTICE B.

The college or university has policies and procedures regarding retention and access to financial and administrative records generated under sponsored programs.

Indicator 1.

Retention requirements for financial and administrative records are in accordance with the requirements of Circular A-110, the Federal Acquisition Regulations, and sponsor regulations and are clearly communicated within the institution.

Indicator 2.

Responsibilities are assigned for retention and disposal of records.

Indicator 3.

There are written policies with respect to records retention schedules that adhere to the requirements of external 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 assure only authorized retrieval of records.

Indicator 7.

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

Indicator 8 .

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

PRACTICE C.

The college or university has policies regarding the retention of technical records (e.g. samples, data, specimens, lab books, etc.) pertaining to a sponsored project.

Indicator 1.

There is a written requirement for retention of technical records pertaining to individual sponsored projects.

Indicator 2.

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

Indicator 3.

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

Indicator 4.

Procedures exist for the disposal of technical records when appropriate, particularly when those records are of a toxic or hazardous nature when retained for long periods of time.

PRACTICE D.

The college or university clearly communicates requirements for the management of technical data to principal investigators and others involved in the research process.

Indicator 1.

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

Indicator 2.

Ownership of patient medical records remains with the institution

Indicator 3.

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

Indicator 4.

Access to medical and other personal records is strictly safeguarded pursuant to the parameters of the IRB-approved protocol, the consent forms, and the Health Insurance Portability and Accountability Act (HIPAA) requirements.

PRACTICE E.

The college or university has developed policies relating to implementing the federal Freedom of Information Requirements (FOIA) (see OMB Circular A-110, __.36).

Indicator 1.

These policies and the name of an institutional official to aid in the process of complying with the FOIA request has been communicated to researchers.

Indicator 2.

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

PRINCIPLE IX INTELLECTUAL PROPERTY

The college or university has an intellectual property management system adequate to comply with terms and conditions of its agreements with external sponsors and institutional policies, as well as with pertinent laws and regulations including those of the federal government.

PRACTICE A.

The college or university's intellectual property management system has the capability of properly managing patentable inventions, copyrightable works (including but not limited to scientific and technical writings, computer software, and technical data in any form), tangible research products over which control of distribution is maintained, and privileged data maintained as proprietary know-how, trade secrets, or confidential information, as permitted by institutional policy.

Indicator 1.

Personnel trained in intellectual property management, supplemented as necessary by service arrangements with qualified external organizations, are employed in the management system. (Management system means all offices that are involved with activities that may negotiate intellectual property terms in funding agreements, receive disclosures, and seek to protect and/or commercialize intellectual property created at the institution.)

PRACTICE B.

The college or university has written policies and procedures governing the operation of its intellectual property management system.

Indicator 1.

The institution has procedures to obtain disclosure and, where appropriate, assignment of intellectual property developed by its employees (i.e., staff, faculty, students, visitors, consultants, etc.) to the extent required for compliance with agreements of external sponsors.

Indicator 2.

The institution has procedures for the timely reporting of intellectual property within the institution and, if required by project agreements, to external sponsors.

Indicator 3.

The institution has procedures, which may include license formats, in place to comply with the requirements of the federal patent, copyright, and data rights regulations and institutional policies regarding licensing.

Indicator 4.

The institution has a policy on and procedures for implementing royalty sharing with inventors/authors, as required by institutional policies, interinstitutional agreements and federal regulations.

Indicator 5.

The institution has a policy and procedures that designate the use of institutional royalty revenue (after expenses) derived from federally-funded research, for scientific research or education purposes, consistent with Bayh-Dole Act requirements.

Indicator 6.

The institution has training and awareness programs to inform and train institutional employees on their rights and responsibilities with respect to all aspects of the institution's intellectual property policy and any terms or conditions imposed by external sponsors in the agreement (including individual agreements before the creation of intellectual property under those agreements).

Indicator 7.

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

Indicator 8.

The institution, in its management of intellectual property and data, takes appropriate measures 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 federal government sponsors, as well as with the provisions of other relevant regulations and executive orders, and has adequate controls to identify data which is subject to such laws and regulations

Indicator 9.

The institution has procedures to ensure compliance with the Bayh-Dole Act, including but not limited to, reporting of federally-funded inventions, timely election of title to inventions, granting of a non-exclusive, royalty free license for government purposes, and other appropriate mechanisms to fully comply with government rights.

Indicator 10.

The institution has procedures, consistent with academic practices, to share, track and manage tangible research materials or other research tools in order to comply with terms and conditions relative to the sharing or transfer of such materials and tools.

Indicator 11.

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

Indicator 12.

If the institution utilizes tax exempt bond financing, written guidelines or other institutional processes exist for review before acceptance of intellectual property provisions involving such facilities to assure that they are in accordance with financing covenants.

PRACTICE C.

The college or university has policies and procedures for obtaining sufficient rights in intellectual property to satisfy the requirement of agreements with external sponsors and for transferring these inventions to the marketplace.

Indicator 1.

Procedures have been established to obtain written agreements with all technical and professional faculty and staff regarding reporting and assignment of intellectual property as required by federal regulations.

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 intellectual property terms and conditions required by external sponsors to be flowed down.

Indicator 4.

Institutional policies assure retention of agreements in order to appropriately evaluate downstream intellectual property rights of sponsors.

PRACTICE D.

The college or university has policies and education programs in place that state the intellectual property rights of students and fellows.

Indicator 1.

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

PRINCIPLE X. RESEARCH INTEGRITY

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

PRACTICE A.

The college or university has written statements that demonstrate an understanding of ethical scholarship and provide procedures for raising and resolving questions of what professional or ethical standards in conducting research 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 research outcomes, such as protecting faculty, students and staff from requirements for prior approval by parties external to the college or university.

Indicator 3.

The institution encourages research investigators to abide by or develop standards, appropriate to the discipline, for data management and reporting to the scientific community and to assure 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 faculty and senior researchers to mentor students and research staff in the understanding of ethical standards of research conduct.

Indicator 5.

Programs are in place that meet Public Health Service (PHS) education requirements for education in research integrity, including mandatory formal and informal instruction on scientific integrity and ethical principles in research for PHS-supported trainees.

Indicator 6.

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

PRACTICE B.

The college or university has written policy that addresses treatment of allegations of research misconduct and that meets sponsor requirements.

Indicator 1.

The institution has an Assurance of Compliance with PHS regulations accepted by the DHHS Office of Research Integrity.

Indicator 2.

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

Indicator 3.

The institution has designated Research Integrity Officer(s) and staff prepared to respond to an allegation with practical approaches for securing and protecting (sequestering) source data, laboratory notebooks, and other relevant materials.

Indicator 4.

The institution's policy contains commitment for protection of the rights of the whistleblower and party against whom the allegation is made. The rights and reputations of all parties involved in any inquiry or investigation are fully protected by the institution and strict confidentiality of the proceedings is observed to the maximum extent possible.

Indicator 5.

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

Indicator 6.

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

Indicator 7.

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

PRACTICE C.

The college or university has a written policy to assist faculty, students and research investigators in determining whether and to what extent outside public and private activities may conflict with their primary research and academic activities or other institutional responsibilities.

Indicator 1.

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

Indicator 2.

The policy of the institution clearly assigns to the employee or research investigator the responsibility for disclosing to the institution whether or not a personal financial interest might pose a conflict of interest (COI).

Indicator 3.

The institution's policy complies with sponsor requirements if applicable for identifying, disclosing, and managing financial conflicts of interest, and any other requirements imposed by state government on conflict of interest.

Indicator 4.

The institution's policy has a process that assures at least annual confirmation that the investigator is in compliance with the COI policies of the external sponsor.

Indicator 5.

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

Indicator 6.

In addition to a faculty mentor, students—both graduate and undergraduate—are provided access to resources and individuals who can advise students with respect to specific conflict of interest concerns.

PRACTICE D.

The college or university has procedures for managing or resolving individual financial conflicts of interest.

Indicator 1.

The institution has clear lines of responsibility and authority for the review of disclosed potential conflicts, the determination of specific management plans that eliminate, reduce or manage the disclosed conflict, and the timely and informed communication of required management practices to investigators with disclosed conflicts.

Indicator 2.

The institution has regular follow-up and internal checks to assure that management plans are being complied with.

Indicator 3.

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

Indicator 4.

Adequate enforcement mechanisms and/or sanctions exist.

PRACTICE E.

The institution has policies and procedures that identify potential financial conflicts of interest of the institution, its senior management, a sub-unit, or related organization (such as a university foundation), and has mechanisms in place for managing them.

Indicator 1.

The institution has in place an institutional financial conflict of interest process—for both financial holding-related conflicts and those involving senior officers—that follows a three-fold approach³: always *disclose* the conflict; *manage* the conflict in most cases; and *prohibit* the activity when necessary to protect the public interest or the interest of the university.

Note: Both university groups and the federal government are in the process of considering guidelines or regulations to institutions that would deal with institutional conflicts of interest, and the reader should be aware of any developments in this area subsequent to the date of this revision.

³ as recommended by the Association of American Universities (AAU; Report dated October, 2001). Other professional associations also are assessing the issues in this area.

PRINCIPLE XI

ELECTRONIC RESEARCH ADMINISTRATION

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

PRACTICE A.

Electronic research administration (eRA) is fully integrated into the college or university's overall strategy for e-business and is recognized as a significant element in development of approaches to e-commerce.

Indicator 1.

There is evidence of cooperation between offices at an institution in developing enterprise-wide solutions that respond to multiple needs and utilize the electronic commerce opportunities now available.

Indicator 2.

Institutional personnel periodically review the information provided through electronic government initiatives and incorporate that information into institutional planning.

Indicator 3.

There is evidence that an institution has adequately trained personnel to support e-commerce initiatives, including electronic research administration, both in central administration and in the academic units.

Indicator 4.

A strategy is being developed for replacement of hardware and software used in eRA on a regular schedule.

PRACTICE B.

The college or university stays current with respect to the electronic research initiatives of research sponsors.

Indicator 1.

The institution is developing strategies to be able to submit proposals, receive awards, and provide financial reports to agencies in an electronic format when electronic commerce is mandated by the agency.

Indicator 2.

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

Indicator 3.

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

Indicator 4.

The institution has adequately trained personnel to provide support to faculty members and other researchers in preparing and submitting electronic proposals and other data to sponsors.

Indicator 5.

There are adequate hardware/software resources to support the institution's electronic research initiatives both in centralized offices and in academic units.

PRACTICE C.

The college or university demonstrates a commitment to providing the resources necessary to operate the research enterprise in an electronic environment.

Indicator 1.

The institution periodically updates its strategic initiatives to provide support to eRA.

Indicator 2.

The institution has developed a management structure that provides appropriate communication between the various offices with eRA responsibilities or requirements.

Indicator 3.

The institution is developing on-line training and educational programs for both mandatory and voluntary research regulatory requirements, such as in use of human or animal research subjects and conflicts-of-interest.

PRACTICE D.

The college or university 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 research proposals to agency required systems (such as NSF's FastLane) when mandated by the federal agency and advises faculty and other researchers of those requirements

Indicator 2.

The institution has identified the personnel charged with institutional management of NSF's FastLane system, ONR's AdminWeb and AdminAward systems, and similar systems for other federal agencies as they are implemented.

Indicator 3.

The institution provides education to principal investigators as well as research accounting, licensing, property, and sponsored programs officials to enable them to utilize the electronic systems offered by the various federal agencies.

Indicator 4.

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

Indicator 5.

Personnel charged with central institutional reporting on sponsored programs utilize, where available, electronic processes for submission of data.

PRACTICE E.

The college or university has electronic systems for proposal development, routing, approval, and submission to potential sponsors.

Indicator 1.

Procedures are in place to allow for electronic creation of proposals in a prescribed format, such as the approved proposal transaction system TS194.

Indicator 2.

Institutional proposal routing systems, with all the required PI certifications, are available for use by researchers. The system automatically routes proposals according to certain criteria to those who are in the proposal approval chain, as required.

Indicator 3.

Research proposals are made available electronically for review and approval by institutional officials, including specialized reviews as required for animal and human subjects compliance, conflict of interest, etc.

PRACTICE F.

The college or university 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 effect rapid financial billing and reporting and to receive funds and payments on federal awards.

Indicator 2.

The institution complies with electronic fund transfer requirements of all federal agencies.

Indicator 3.

The institution has provided the necessary Central Contractor Registry (CCR) registration to allow it to receive payments electronically from the Department of Defense.

Indicator 4.

Electronic systems for providing services such as procurement and payroll recognize special requirements related to research awards and comply with sponsor-imposed terms and conditions.

Indicator 5.

The requirement to maintain data and records electronically, both at centralized and decentralized levels, is well understood and individuals adhere to institutional requirements in this regard.

Indicator 6.

The institution utilizes the electronic databases of NSF (FastLane), ONR (AdminWeb and AwardWeb), NIH (Edison) and other electronic tools and educates faculty and other researchers in their availability and use.

PRINCIPLE XII. GENERAL RESEARCH MANAGEMENT

PRINCIPLE XII-1 POLICY REQUIREMENTS

The college or university has a clearly defined process for the review of research management policies and for decision-making on implementation of such policies.

PRACTICE A.

Responsibility for reviewing externally imposed policy requirements related to general research management is clearly defined.

Indicator 1.

Appropriate personnel are identified to respond to requests for comment on research policies published in the Federal Register.

Indicator 2.

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

PRACTICE B.

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

PRACTICE C.

Periodic reviews are performed to assure that institutional policies and procedures are in written form and reflect current management of the organization.

PRINCIPLE XII-2 ADMINISTRATIVE REQUIREMENTS

The college or university has trained personnel who are knowledgeable of sponsor regulations, requirements and procedures.

PRACTICE A.

Roles and responsibilities are clearly delineated for academic, 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.

Adequate training is available for administrative personnel in academic units as well as central areas on the administrative and financial requirements (including the appropriate OMB circulars) of contracts and grants.

PRACTICE B.

The college or university 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.

Procedure manuals maintained at the unit level are reviewed and updated at least annually.

PRACTICE C.

Coordination between institutional offices responsible for varied aspects of sponsored programs is evident.

Indicator 1.

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

Indicator 2.

Appropriate notification is provided to all offices affected by a policy or procedural issue or change.

Indicator 3.

A triage system with designated responsibilities is in place to coordinate between offices and policies in extraordinary situations.

PRACTICE D.

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

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