FEDERAL RESEARCH COMPLIANCE 101: WHAT COUNSEL NEEDS TO KNOW

Part I: Administrative Compliance

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The federal government funded over $150 billion in academic research and development at higher education institutions in the past five years. This support plays an indispensable role in scientific advancement in the United States and abroad. Although for each institution the greatest and most important challenge is achieving a project's medical and scientific aims, each must also wrestle with a formidable array of regulatory compliance obligations.

An increasingly complex web of statutes, regulations, and policies touch nearly every aspect of federally sponsored projects. These policies and regulations are enforced through administrative, civil, and criminal penalties that the government does not hesitate to enforce against colleges and universities. Recent years have seen hundreds of audits and investigations of universities and many millions of dollars of settlements and repayments to the government based on noncompliance with the terms and conditions of federal grants and contracts.[1] Survival in this regulatory framework requires resources and a commitment of top management to understand the regulatory regime and to administer an effective compliance program. Counsel in particular must appreciate the basic rules of the road that apply to research, and the primary areas of legal exposure.[2]

Federal research compliance obligations commonly are separated into three broad categories: (1) administrative compliance; (2) financial compliance; and (3) scientific and bioethics compliance. This paper focuses on the first category—administrative compliance obligations—with an emphasis on OMB Circular A-110 (codified at 2 CFR Part 215), which sets forth uniform standards for the administration and management of grants and cooperative agreements issued by federal agencies to institutions of higher education.[3] It may seem counterintuitive to deem "administrative compliance" among the core "research" compliance

[1] For additional information on federal investigations and enforcement actions related to federally sponsored research, see the author's 2010 NACUA paper titled "The False Claims Act and Fraud Allegations In Sponsored Research", available at the NACUA website and www.hoganlovells.com.

[2] This paper does not address issues that may arise under privately-funded and nonfederal research.

[3] It's important to note that the area of administrative compliance obligations currently is under review by the federal government. On February 1, 2013, the Office of Management and Budget (OMB) issued proposed guidance titled "Reform of Federal Policies Relating to Grants and Cooperative Agreements; Cost Principles and Administrative Requirements (Including Single Audit Act)" (78 Fed. Reg. 7282). "OMB proposes these reforms to the guidance for Federal policies relating to grants in order to ensure that Federal grants meet the high standards of a 21st-Century government." Comments are due on June 2, 2013. The proposed reforms would not overhaul the items addressed in the paper, but the final guidance likely will merit modification to several issues discussed here.

obligations. But federal sponsors strictly enforce these administrative requirements, terminating awards and bringing enforcement actions for noncompliance.[4]

This paper presents an illustrative summary of administrative compliance obligations; many of the topics addressed are complex and merit short papers of their own. Highlighted below are only the most fundamental administrative obligations of federal grant and cooperative agreement recipients under OMB Circular A-110. By its nature, this paper comes into contact with related financial and scientific compliance obligations, but companion papers will focus on the latter areas.

OMB Circular A-110 (2 CFR Part 215)

OMB Circular A-110 (2 CFR Part 215) ("Circular A-110") sets forth uniform standards for the administration and management of grants and cooperative agreements issued by federal agencies to institutions of higher education, hospitals, and other nonprofit organizations.[5] Most federal agencies that sponsor academic research implement Circular A-110 through agency regulations that are imposed on recipients through the funding instrument (i.e., the award document) and through various agency policies. For example, the Department of Health and Human Services has implemented Circular A-110 with slight modification in 45 CFR Part 74, and various HHS components (such as the National Institutes of Health, NIH) have issued supplemental policies applicable to grants and cooperative agreements (e.g., the NIH Grants Policy Statement).[6]

Circular A-110 is separated into four subparts. Subpart A contains general information, such as definitions of key terms, procedures for deviations from the standards set forth in the Circular, and the Circular's applicability to subawards. Subpart B addresses pre-award requirements, such as appropriate award instruments and special conditions that may be imposed on recipients. Subpart C is the most extensive section; it discusses post-award requirements, such as financial management systems, property and procurement standards, reports and records required, and termination and default provisions. Subpart D addresses steps the grantee must take after the conclusion of the award.

Below is a summary of salient points set forth in the terms and conditions of Circular A-110.

Subpart A: General Information

Definitions (A-110 § .2; 2 CFR § 215.2)

Several key definitions appear in this section, including but not limited to these:

- *Award* means financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements in the form of money, or

[4] Several federal audit reports cite institutions for noncompliance with administrative requirements. For example, see NSF audit reports (available at http://www.nsf.gov/oig/auditpubs.jsp#external) and HHS audit reports (available at https://oig.hhs.gov/reports-and-publications/oas/).

[5] A "grant" and a "cooperative agreement" are nearly identical in terms of basic compliance requirements; under cooperative agreements, the sponsor tends to participate substantially in the project and often works collaboratively with the awardee.

[6] This paper does not focus on agency-specific policies, but they are a critical source of compliance obligations.

property in lieu of money, by the federal government to an eligible recipient. The term does not include: technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; direct payments of any kind to individuals; and, contracts which are required to be entered into and administered under procurement laws and regulations.

- *Contract* means a procurement contract under an award or subaward, and a procurement subcontract under a recipient's or subrecipient's contract.
- *Cost sharing or matching* means that portion of project or program costs not borne by the federal government.
- *Equipment* means tangible nonexpendable personal property including exempt property charged directly to the award having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. However, consistent with recipient policy, lower limits may be established.
- *Obligations* means the amounts of orders placed, contracts and grants awarded, services received and similar transactions during a given period that require payment by the recipient during the same or a future period.
- *Prior approval* means written approval by an authorized official evidencing prior consent.
- *Program income* means gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award (see exclusions in 2 CFR § 215.24(e) and (h)). Program income includes, but is not limited to, income from fees for services performed, the use or rental of real or personal property acquired under federally-funded projects, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and interest on loans made with award funds. Interest earned on advances of federal funds is not program income. Except as otherwise provided in federal awarding agency regulations or the terms and conditions of the award, program income does not include the receipt of principal on loans, rebates, credits, discounts, etc., or interest earned on any of them.
- *Subaward* means an award of financial assistance in the form of money, or property in lieu of money, made under an award by a recipient to an eligible subrecipient or by a subrecipient to a lower tier subrecipient. The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract, but does not include procurement of goods and services nor does it include any form of assistance which is excluded from the definition of "award" in 2 CFR § 215.2(e).
- *Subrecipient* means the legal entity to which a subaward is made and which is accountable to the recipient for the use of the funds provided. The term may include foreign or international organizations (such as agencies of the United Nations) at the discretion of the federal awarding agency.

Applicability to Subawards (A-110 § .5; 2 CFR § 215.5)

Unless Circular A-110 specifically excludes subrecipients from coverage, its provisions apply to subrecipients that perform work under federal awards if such subrecipients are institutions of higher education, hospitals, or other non-profit organizations. (State and local

government subrecipients are subject to the provisions of a separate Circular A-102.) Prime awardees are required to monitor its subrecipient's compliance with Circular A-110.

Subpart B: Pre-Award Requirements

Special Award Conditions (A-110 § .14; 2 CFR § 215.14)

If a recipient (a) has a history of poor performance, (b) is not financially stable, (c) has a management system that does not meet the standards prescribed by Circular A-110, (d) has not conformed to the terms and conditions of a previous award, or (e) is not otherwise "responsible" (interpreted broadly), federal sponsors may impose additional requirements as needed on the recipient. These special award conditions, when inflicted on colleges and universities, complicate the research administration process and demand special compliance resources.

Certifications and Representations (A-110 § .17; 2 CFR § 215.17)

Agencies may require recipients to make certain annual certifications and representations of compliance with statutes, executive orders, or regulations. Today, many of these certifications are made through the online System for Award Management (SAM), where a recipient must register in order to be eligible for federal funds.[7] A list of typical certifications made in connection with receipt of federal research grant funds is available via SF-424B, titled "Assurances – Non-Construction Programs".[8]

Subpart C: Post Award Requirements

Financial Management Systems (A-110 § .21; 2 CFR § 215.21)

The recipient of federal research funds must maintain a financial management system that provides the following:

- Accurate, current and complete financial information for the project.
- Adequate identification of the source and use of funds for the project.
- Effective controls over all federal funds, property and other assets.
- A comparison of expenses with budgeted amounts.
- Written procedures to minimize the amount of time between receipt and disbursement of federal funds.
- Written procedures to determine the reasonableness, allocability, and allowability of costs in accordance with the provisions of the applicable federal cost principles and the terms and conditions of the award. (For colleges and universities, the applicable federal cost principles are established in OMB Circular A-21, which is intricate and not conducive to summarization in this paper, but which is nonetheless a major compliance responsibility of recipients and a source of potential audit exposure and other liability.)
- Accounting records supported by source documentation.

[7] See the SAM website at https://www.sam.gov/portal/public/SAM/

[8] See http://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf

Payments of Federal Funds to Recipients (A-110 § .22; 2 CFR § 215.22)

The recipient may be paid by the sponsor in advance of grant expenditures, provided that (1) it maintains written procedures to minimize the time between receipt and disbursement of funds; and (2) has a compliant financial management system. (When these conditions for advance payment are not satisfied, the recipient will be paid on a reimbursement basis.) Various agencies have policies that strictly limit the amount of time that may elapse between drawing federal funds and expending those funds. For example, NIH states "Although the grant may be financed by advance payments, the intent is that grantees draw funds on an as-needed basis—specifically, no more than 3 days before the funds are needed."[9]

Funds advanced by the agency must be deposited in insured accounts whenever possible, and normally in an interest bearing account. The recipient is not obligated to maintain separate depository accounts for funds advanced by the agency, provided the recipient can adequately account for the receipt, obligation, and expenditure of all funds.

Cost Sharing or Matching (A-110 § .23; 2 CFR § 215.23)

Some awards require that the recipient provide, without reimbursement by the government, a portion of the cost of the project (i.e., cost sharing or matching). Cost sharing can be in the form of cash, property, equipment, supplies, and services contributed by the recipient or a third party donor. Cost sharing also may include unrecovered indirect costs, subject to the prior approval of the federal sponsor.

In order for a contribution to be accepted as part of the recipient's cost sharing or matching obligation, the contribution must

- Be verifiable, i.e., auditable, from the recipient's records.
- Not be included as cost matching for any other federal program.
- Be necessary and reasonable for proper and efficient accomplishment of project or program objectives.
- Be allowable under applicable cost principles.
- Not be paid by the federal government under another program, except where authorized by federal statute to be used for cost sharing or matching.
- Be provided for in the approved budget when required by the federal awarding agency.
- Be subject to the provisions of Circular A-110.

Specific standards govern the cost sharing value of donated land, buildings, equipment, and supplies.

Program Income (A-110 § .24; 2 CFR § 215.24)

Recipients must account for any gross income ("program income" – see definition above) earned by it that is directly generated as a result of the federal project. Recipients must retain

[9] *NIH Grants Policy Statement* (Oct. 1, 2011), Sec. 6.

program income earned during the award period and must use the income in one of the following ways, as specified in agency regulations or the award terms and conditions: (a) Adding the income to funds committed to the project to further eligible project objectives; (b) Using the income to finance the non-federal share of the project; or (c) Deducting the income from the project's total allowable costs used to determine the net allowable costs on which the federal share of costs is based.

Unless otherwise specified in agency regulations or award terms and conditions, (a) generally the recipient is not obligated to the federal government relative to program income earned after the end of the award period; and (b) the recipient has no obligation to the federal government with respect to program income earned from license fees and royalties for copyrighted materials, patents, patent applications, trademarks, and inventions produced under an award.

Generally, recipients must disburse program income prior to drawing down additional federal funds.

Revision of Budget or Program (A-110 § .25; 2 CFR § 215.25)

The recipient is not permitted to modify the project or the award budget without certain prior approvals from the agency. For instance, certain budget modifications and program activities require sponsor prior approval, but the agency may, in its discretion, waive certain prior-approval requirements. However, recipients always must seek prior approval for (a) a change in the scope or the objective of the project (even if there is no associated budget revision that requires prior written approval); (b) the need for additional funding; (c) changing a "key person" specified in the application or award document (e.g., the principal investigator); (d) the absence for more than three months or a 25% or more reduction in time devoted to the project by the approved project director or principal investigator.

Audits and Reporting (A-110 § .26; 2 CFR § 215.26)

Colleges and universities that expend $500,000 or more in federal grant and contract funds in each fiscal year must have an audit conducted in accordance with the provisions of OMB Circular A-133. (Circular A-133 describes the audit requirements and specifies auditor and auditee responsibilities.) In addition, the government must be given access to, and the right to examine, all recipient records, books, papers, or documents related to the award. Recipients may need to return funds to the government based on adverse audit findings. Generally, a prime awardee also negotiates for the right to audit a subrecipient's performance. The recipient must maintain financial records, supporting documents, and all other records for approximately three years after the award.

Property Management (A-110 § .30-.35; 2 CFR § 215.30-35)

The recipient must adhere to rules that govern the management and disposition of property furnished by the federal government or funded by federal funds.

- Insurance: The recipient must maintain a level of insurance on equipment and real property purchased with federal funds that is at least equivalent to the insurance it has on its own property.

- Federally-Owned Property: Title to federally-owned property remains vested in the federal government. The recipient must submit annually an inventory of federally-owned property in its custody. After completion of the award, the recipient must return the property to the sponsor. The recipient must have a mechanism to differentiate between federally owned equipment and other equipment.
- Real Property: Title to real property acquired in whole or in part with federal funds vests in the recipient. When the property is no longer needed for the project, the recipient must seek the sponsor's written approval to use the real property for another federal project. When the property is no longer needed for any federal project, the recipient must seek disposition instructions from the agency.
- Equipment: Title to equipment purchased with federal funds generally vests with the recipient. The recipient must use the equipment in the project or program for which it was acquired for as long as needed. When no longer needed for the original project, the recipient either may use the equipment for other federally funded activities (with priority given to programs sponsored by the same agency) or obtain disposition instructions from the sponsor. The recipient must take a physical inventory of equipment at least once every two years. In addition, the recipient must maintain a record with information for each piece of equipment purchased with federal funds, and the recipient must safeguard and maintain the equipment.
- Supplies: Title to supplies and other expendable property vests in the recipient upon acquisition.
- Exempt Property: Under the Federal Grant and Cooperative Agreement Act, 31 USC § 6306, agencies may permit non-profit institutions of higher education and non-profit organizations whose primary purpose is the conduct of scientific research to obtain title to equipment and supplies acquired under grants for support of basic or applied scientific research without further obligation to the federal government, subject to certain exceptions. For example, in its implementation of this statute, NIH reserves the right to require transfer of title to equipment with an acquisition cost of $5,000 or more to the federal government or to an eligible third party named by the NIH within 120 days of the completion or termination of an award.

Intangible Property/Intellectual Property (A-110 § .36; 2 CFR § 215.36)

The recipient may copyright written materials developed under the award. The government receives a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for U.S. government purposes. With respect to data, the government may use data first produced under the award and authorize others to use such data for U.S. government purposes; if the government uses the data to develop an "agency action" that has the force and effect of law (e.g., a federal regulation), non-proprietary research data may be released to the public under FOIA.

The Bayh-Dole Act, implemented via 37 CFR Part 401, governs patents and inventions under federal research awards. An invention is subject to these regulations if it is "conceived or first actually reduced to practice in the performance of work under a funding agreement." Generally, the recipient may retain title to inventions conceived or reduced to practice under an

award if it timely reports the invention to the government; the government receives a nonexclusive, nontransferable, irrevocable, paid-up, worldwide license to practice or have practiced for or on behalf of the United States the invention throughout the world. This is commonly known as "government-purpose" rights. An agency maintains "march-in" rights, which allows the government to step into the shoes of the patent-holder and grant additional "compulsory" licenses to the invention upon investigation and certain findings. Grounds for march-in include, among others, (a) a finding that such action is "necessary to alleviate health or safety needs which are not reasonably satisfied" by the patent-holder, its assignees, or licensees; and (b) a finding that the owner or assignee has not taken effective steps to achieve practical application of the invention. (The government has not exercised these rights with any frequency, if at all, but the existence of the right must be understood.) The recipient must submit periodic reports on the utilization of an invention or on efforts to obtain such utilization; must share royalties collected on an invention with the PI inventor; and must use royalties or income earned to support scientific research or education. Unless a waiver is obtained, products that embody the invention or that are produced through use of the invention must be manufactured substantially in the United States.

Procurement of Supplies, Equipment, Real Property, and/or Services with Federal Funds (A-110 §§ .40-48; 2 CFR §§ 215.40-48)

Specific rules govern the procurement of supplies, equipment, real property, and services with federal grant funds. The recipient must establish a written Code of Conduct that governs employees who award or administer contracts or subcontracts supported with federal funds. The Code of Conduct must set out disciplinary actions applicable to violations. No employee of the recipient may participate in the selection, award, or administration of a federally-funded contract, subcontract, or purchase if a real or apparent conflict of interest will arise. Furthermore, employees of the recipient may not solicit or accept gifts, gratuities, or anything of monetary value from vendors or subcontractors paid with federal funds. However, exceptions may be made for gifts of nominal value.

To the maximum extent practical, all procurement transactions must be conducted in a manner that provides open and free competition. Thus, sole source awards should not be the normal practice. Procurement awards must be based on benefit to the recipient, responsiveness to the solicitation, price, and quality.

The recipient must establish written procedures to govern federally-funded procurement activities. At a minimum, the procedures must provide for (i) avoidance of the purchase of unnecessary items; (ii) a determination, when applicable, of whether a purchase or lease would be more advantageous for the federal government; and (iii) solicitations with clear requirements and evaluation factors. The recipient must follow the following procedures in procurements with federal funds:

- To the fullest extent practicable, make an effort to use a small business, minority-owned business, and women's business.
- Use the appropriate type of procurement instrument (e.g., fixed price contracts, cost reimbursement contracts, purchase orders, and incentive contracts).

- Do business only with responsible contractors with the ability to perform the work successfully and not enter into contracts with debarred or suspended entities.
- Maintain adequate procurement records and make those records available for inspection and review by the sponsor.
- Perform and document a cost or price analysis for every procurement action.
    - Cost analysis – evaluation of the reasonableness, allocability, and allowability of each element of the cost.
    - Price analysis – comparison of offer price to market price and other quotes.
- For procurements over the simplified acquisition threshold (currently $150,000), procurement records must indicate (a) basis for contractor selection; (b) justification for lack of competition when competitive bids or offers are not obtained; and (c) basis for award cost or price.

The recipient also must implement a system to monitor contractor conformance with the terms, conditions, and specifications of the contract and ensure adequate and timely follow up of all purchases. For contracts that exceed the simplified acquisition threshold, the recipient must include the following contract provisions in its subcontracts:

- Remedies for breach.
- Termination provisions (generally good practice for agreements below the threshold).
- Audit rights clauses that permit the recipient and the federal government to gain access to the contractor's books, documents, and records.
- The clauses set forth at Appendix A of Circular A-110 (as applicable).
- Note: Additional requirements are imposed for construction contracts.

Reports and Records (A-110 §§ .50-53; 2 CFR §§ 215.50-53)

The recipient must monitor each project, program, subaward, function, or activity supported by the award. The recipient also must monitor its subrecipient's performance and compliance with award terms. Developments that have a significant impact on the award-supported activities, as well as problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award, must be reported to the sponsor. The report must include a statement of the action taken or contemplated, and any assistance needed to resolve the situations.

The recipient must maintain financial records, supporting documents, and all other records for three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, except when (i) litigation requires retention until matters have been resolved; (ii) the records are transferred to the agency, in which case retention requirements end; (iii) the records are for real property and equipment acquired with federal funds, in which case they must be retained for 3 years after final disposition of such property; (iv) the records are indirect cost rate proposals or cost allocation plans, in which case (a) if submitted for negotiation of the rate, 3 years from the date of such submission; and (b) if not submitted for negotiations, 3 years from

the end of the fiscal year (or other accounting period) covered by the proposal or plan. Copies of the original records may be substituted for the original records if authorized by the sponsor.

Termination and Enforcement (A-110 §§ .60-62; 2 CFR §§ 215.60-62)

These sections provide uniform termination and enforcement procedures. The federal agency may terminate an award if the recipient fails to comply with its terms and conditions, or if the recipient consents to termination. The recipient may terminate awards via written notification to the sponsor of the reasons for termination, the effective date, and in the case of partial termination, the portion to be terminated. If the agency determines that a reduced or modified award will not accomplish the purpose of the original award, the agency may terminate the award in its entirety.

Federal agencies may take any or all of the following enforcement actions if the recipient materially fails to comply with an award's terms and conditions:

- Impose special award conditions.
- Temporarily withhold cash payments pending correction of the deficiency.
- Disallow all or part of the cost of the activity or action that is not in compliance.
- Suspend or terminate the award, in whole or in part.
- Withhold future awards.
- Take any other legally available remedies.

Normally, costs that result from obligations incurred during a suspension or after termination of an award are not allowable, unless expressly authorized by the agency.

Subpart D: After-Award Requirements

Award Closeout (A-110 §§ .70-73; 2 CFR §§ 215.70-73)

These sections contain procedures that the grantee must follow when closing out a federally sponsored award.

Within 90 days after the date the award is completed, the recipient must provide to the sponsor all financial, performance, and other reports required by the terms and conditions of the award. Unless an extension is granted, within 90 days after the funding period or the date of completion, the recipient must liquidate all obligations incurred under the award. The recipient must promptly refund all unobligated cash provided by the sponsor that is not authorized to be retained for use in other projects. The sponsor retains the right to recover amounts determined to be unallowable in any subsequent audit.

Conclusion

Administrative compliance obligations touch nearly every aspect of the research function at institutions of higher education. Several factors—including lack of knowledge and organizational obstacles to compliance—can make it appear that institutional leadership knowingly and willfully violated these regulations. Such allegations can seriously damage the

institution's research mission. An effective compliance program must have the support of senior institutional officials, competent personnel, and knowledgeable counsel. An extended appraisal of compliance strategies is beyond the scope of this paper. However, following is a broad list of sponsored research compliance program elements that NIH developed in an effort to promote voluntary compliance programs among recipients of NIH awards:

- Compliance Leadership: Designate a compliance officer and compliance oversight committees.
- Policies and Procedures: Implement written policies and procedures that foster an institutional commitment to stewardship and compliance.
- Roles and Responsibilities: Define roles and responsibilities across the institution and assign oversight responsibility.
- Training: Conduct effective training and education.
- Communication: Develop effective lines of communication.
- Monitoring: Conduct internal monitoring, quality review, audits, and assurance.
- Enforcement: Enforce standards through well-publicized disciplinary guidelines.
- Corrective Response: Respond promptly to detected problems, undertake corrective action, and report to the appropriate agencies when necessary.

FEDERAL RESEARCH COMPLIANCE 101: WHAT COUNSEL NEEDS TO KNOW

Part II: Financial Compliance

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Many federal policies and guidelines must be followed to ensure proper grants management. Working cooperatively with the Federal grant-making agencies and the grantee community, the Office of Management and Budget (OMB) leads the development of government wide policy to assure that grants are managed properly and federal dollars are spent in accordance with applicable laws and regulations. OMB does not award grants but rather measures the quality of Federal agency programs, policies, and procedures, assesses competing funding demands among agencies, and sets funding priorities.

Federal research compliance obligations applicable to colleges and universities commonly are separated into three broad categories: (1) administrative compliance; (2) financial compliance; and (3) scientific and bioethics compliance. This paper focuses on the second category--financial compliance--with a concentration on certain sections of OMB Circular A-21 (codified at 2 CFR Part 220), which sets forth the principles for determining the costs applicable to federally sponsored research and development, training, and other sponsored work performed by colleges and universities under grants, contracts, and other agreements with the Federal Government.

Circular A-21 describes factors affecting allowability of costs, treatment of direct costs, the allowability of specific items of cost, when a cost can be directly charged to the project and when a cost should be covered by the university's Facilities & Administrative (indirect or overhead) rate for cost recovery, and also addresses the determination and application of Facilities and Administrative Rates. There is much to understand in reading Circular A-21. This paper presents an overview summary of some of the most important cost principles underlying financial compliance obligations.[1] Highlighted here are the cost principles key to compliance with post award financial management obligations and which often has been the focus of external review and enforcement. To be sure, some of these cost principles have had lengthy white papers dedicated to elucidating single topics of cost.[2]

[1] This paper does not address the identification and assignment of Facilities and Administrative (F&A) Costs, the determination and application of F&A cost rates or the Simplified method for small institutions.
[2] See Council on Governmental Relations white paper, *POLICIES AND PRACTICES COMPENSATION, EFFORT COMMITMENTS, AND CERTIFICATION* (March 1, 2007).

OMB Circular A-21 (2 CFR Part 220)

Circular A-21 is organized into ten sections A through K, three exhibits and one appendix. This paper will touch on four key sections: C. Basic Considerations; D. Direct Costs; E. F&A Costs; J. General Provisions for Selected Items of Cost.[3]

Section C. Basic Considerations

Factors affecting allowability of costs (A-21 §C.2-4)

To be allowable, costs must be reasonable, allocable and given consistent treatment. Reasonable and allocable are defined as:

- Reasonable costs. A cost may be considered reasonable if the nature of the goods or services acquired or applied, and the amounts involved therefore, reflect the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made. Major considerations involved in the determination of the reasonableness of a cost are: (a) whether or not the cost is of a type generally recognized as necessary for the operation of the institution or the performance of the sponsored agreement; (b) the restraints or requirements imposed by such factors as arm's-length bargaining, Federal and State laws and regulations, and sponsored agreement terms and conditions; (c) whether or not the individuals concerned acted with due prudence in the circumstances, considering their responsibilities to the institution, its employees, its students, the Federal Government, and the public at large; and, (d) the extent to which the actions taken with respect to the incurrence of the cost are consistent with established institutional policies and practices applicable to the work of the institution generally, including sponsored agreements.
- Allocable costs. A cost is allocable to a particular cost objective (i.e., a specific function, project, sponsored agreement, department, or the like) if the goods or services involved are chargeable or assignable to such cost objective in accordance with relative benefits received or other equitable relationship. Subject to the foregoing, a cost is allocable to a sponsored agreement if (1) it is incurred solely to advance the work under the sponsored agreement; (2) it benefits both the sponsored agreement and other work of the institution, in proportions that can be approximated through use of reasonable methods, or (3) it is necessary to the overall operation of the institution and, in light of the principles provided in Circular A-21, is deemed to be assignable in part to sponsored projects. Where the purchase of equipment or other capital items is specifically authorized under a sponsored agreement, the amounts authorized for such purchases are assignable to the sponsored agreement regardless of the use that may subsequently be made of the equipment or other capital items involved.
- Any costs allocable to a particular sponsored agreement under the standards provided in this Circular may not be shifted to other sponsored agreements in order to meet deficiencies caused by overruns or other fund considerations, to avoid restrictions

[3] The full index of sections include: A-Purpose & Scope; B-Definition of Terms; C-Basic Considerations; D-Direct Costs; E-F&A Costs; F-Identification and Assignment of F&A Costs; G-Determination and Application of F&A Cost Rate(s); H-Simplified Method for Small Institutions; J-General Provisions for Selected Items of Cost; K-Certification of Charges.

imposed by law or by terms of the sponsored agreement, or for other reasons of convenience.

Consistency in allocating costs incurred for the same purpose (A-21 § C.11)

- All costs incurred for the same purpose, in like circumstances, are either direct costs only or F&A costs only. No cost shall have allocated to it as an indirect cost any cost, if other costs incurred for the same purpose, in like circumstances, have been included as a direct cost of that or any other final cost objective. Further, no final cost objective shall have allocated to it as a direct cost any cost, if other costs incurred for the same purpose, in like circumstances, have been included in any F&A cost pool to be allocated to that or any other final cost objective.

Section D. Direct Costs (A-21 § D.1)

Direct costs are those that can be identified specifically with a particular sponsored project, and instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy. Costs incurred for the same purpose in like circumstances must be treated consistently as either direct or F&A costs. Where an institution treats a particular type of cost as a direct cost of sponsored agreements, all costs incurred for the same purpose in like circumstances shall be treated as direct costs of all activities of the institution.

Section E. F&A Costs (A-21 § E.1)

F&A, also sometimes referred to as indirect or overhead, costs are those that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity.

Section J. General Provisions for Selected Items of Cost (A-21 § J.1-54)

This section of Circular A-21 provides pointed guidance on principles to be applied in establishing allowability of 54 specific costs. These principles should apply irrespective of whether a particular item of cost is properly treated as direct cost or F&A cost. Below is a summary discussion of some but not all of these cost items. For some costs, the guidance is extremely clear and rarely subject to debate while others are subject to interpretation because the principle is unable to be precise given the array of recipients of federal awards and the many ways in which accounting and management systems are designed and carried out, or simply because the particular item of cost is dependent on particular facts and circumstances at the time it was incurred and the terms and conditions of the specific award to which it is charged. In a case of discrepancy between provisions of a sponsored agreement and section J, the agreement should govern. Below are examples of cost items that are fairly straightforward:

- *Advertising* - Allowable for recruiting of personnel for the project, procurement of goods and services, and disposal of scrap materials. Unallowable for advertising and public relations to promote the institution, cost of promotional items and memorabilia, cost of meetings related to other activities of the institution (J.1)

- *Advisory councils* - Costs incurred by advisory councils or committees are allowable as a direct cost where authorized by the Federal awarding agency or as an indirect cost where allocable to sponsored agreements (J.2)
- *Alcoholic beverages* - Costs of alcoholic beverages are unallowable (J.3)
- *Alumni/ae activities* - Costs incurred for, or in support of, alumni/ae activities and similar services are unallowable (J.4)
- *Employee morale, health, and welfare costs and costs* - The costs of employee information publications, health or first-aid clinics and/or infirmaries, recreational activities, employee counseling services, and any other expenses incurred in accordance with the institution's established practice or custom for the improvement of working conditions, employer-employee relations, employee morale, and employee performance are allowable. Such costs must be equitably apportioned to all activities of the institution. Income generated from any of these activities will be credited to the cost thereof unless such income has been irrevocably set over to employee welfare organizations (J.16).
- *Entertainment costs* - Costs of entertainment, including amusement, diversion, and social activities and any costs directly associated with such costs (such as tickets to shows or sports events, meals, lodging, rentals, transportation, and gratuities) are unallowable (J.17).
- *Fund raising and investment costs* - Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred solely to raise capital or obtain contributions, are unallowable. Costs of investment counsel and staff and similar expenses incurred solely to enhance income from investments are unallowable. Costs related to the physical custody and control of monies and securities are allowable (J.20)
- *Goods or services for personal use* - Costs of goods or services for personal use of the institution's employees are unallowable regardless of whether the cost is reported as taxable income to the employees (J.22)
- *Housing and personal living expenses* - Costs of housing (e.g., depreciation, maintenance, utilities, furnishings, rent, etc.), housing allowances and personal living expenses for/of the institution's officers are unallowable regardless of whether the cost is reported as taxable income to the employees (J.23)
- *Labor relations costs* - Costs incurred in maintaining satisfactory relations between the institution and its employees, including costs of labor management committees, employees' publications, and other related activities, are allowable (J.27)
- *Memberships, subscriptions and professional activity cost* - Costs of the institution's membership in business, technical, and professional organizations are allowable. Costs of the institution's subscriptions to business, professional, and technical periodicals are allowable. Costs of membership in any civic or community organization are unallowable. Costs of membership in any country club or social or dining club or organization are unallowable (J.33)

- *Pre-agreement costs* - Costs incurred prior to the effective date of the sponsored agreement, whether or not they would have been allowable thereunder if incurred after such date, are unallowable unless approved by the sponsoring agency (J.36)
- *Proposal costs* - Proposal costs are the costs of preparing bids or proposals on potential federally and non-federally funded sponsored agreements or projects, including the development of data necessary to support the institution's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as F&A costs and allocated currently to all activities of the institution, and no proposal costs of past accounting periods will be allocable to the current period. However, the institution's established practices may be to treat proposal costs by some other recognized method. Regardless of the method used, the results obtained may be accepted only if found to be reasonable and equitable (J.38)
- *Student activity costs* - Costs incurred for intramural activities, student publications, student clubs, and other student activities, are unallowable, unless specifically provided for in the sponsored agreements (J.48)
- *Training costs* - The cost of training provided for employee development is allowable (J.51)

Compensation and Personal Services (A-21 § J.10)

Perhaps the least straightforward and most often misunderstood item of cost, from a compliance and management perspective, is J.10 compensation and personnel services. By far salaries and associated fringe benefit costs are the largest category of charges to federal awards, representing approximately two-thirds of all direct charges. It is important here, to briefly discuss the concept and term "effort reporting".[4] Interestingly neither this section nor the entire Circular A-21 uses the term "effort reporting"; however, it has come to be understood generally as a concept and method for meeting the principles described in J.10 and more specifically is associated with the examples of acceptable methods for payroll distribution described in J.10.c. Effort reporting is the mechanism used to confirm that salaries and wages charged to each sponsored agreement are reasonable in relation to the actual work performed. Certification of an effort report must reasonably reflect the activity for which the employee is compensated by the institution. Following are summaries of salient points covered in J.10 subsections for Payroll Distribution, Examples of Acceptable Methods of Payroll Distribution, and Salary Rates for Faculty.

Payroll Distribution (A-21 § J.10.b.)

- In the use of any methods for apportioning salaries, it is recognized that, in an academic setting, teaching, research, service, and administration are often inextricably intermingled. A precise assessment of factors that contribute to costs is not always feasible, nor is it expected. Reliance, therefore, is placed on estimates in which a degree of tolerance is appropriate.

[4] For an in-depth discussion see 2008 NACUA paper by Bob Kenney titled "Effort Reporting: Best Practices and Recent Enforcement Actions" available at the Higher Education Compliance Alliance website (www.higheredcompliance.org)

- There is no single best method for documenting the distribution of charges for personal services.
- The payroll distribution system must be incorporated into the official records of the institution; reasonably reflect the activity for which the employee is compensated by the institution and encompass both sponsored and all other activities on an integrated basis, but may include the use of subsidiary records.
- The method must recognize the principle of after the fact confirmation or determination so that cost distributed represent actual costs. Direct cost activities and F&A cost activities may be confirmed by responsible persons with suitable means of verification that the work was performed. Confirmation by the employee is not a requirement for either direct or F&A cost activities if other responsible persons make appropriate confirmations.
- Practices vary among institutions and within institutions as to the activity constituting a full workload. Therefore, the payroll distribution system may reflect categories of activities expressed as a percentage distribution of total activities.
- Charges may be made initially to sponsored agreements on the basis of estimate made before services are performed. When such estimates are used, significant changes in the corresponding work activity must be identified and entered into the payroll distribution system.
- Short term (such as one or two months) fluctuation between workload categories need not be considered as long as the distribution of salaries and wages is reasonable over the longer term, such as an academic period.
- The system will provide for independent internal evaluations to ensure the system's effectiveness and compliance with standards.[5]
- For systems which meet these standards, the institution will not be required to provide additional support or documentation for the effort actually performed.

Examples of Acceptable Methods for Payroll Distribution (A-21 § J.10.c.)

Though there are 3 methods described as examples, the majority of institutions use either the Plan Confirmation or After-the-fact Activity Reports.

- Plan Confirmation – under this method, distribution of salaries and wages applicable to sponsored agreements is based on budgeted, planned, or assigned work activity, updated to reflect any significant changes in work distribution. At least annually a statement must be signed by the employee, principal investigator, or responsible official(s) using a suitable means of verification that the work was performed, stating that salaries and wages charged are reasonable in relation to the work performed.
- After the fact Activity Records – under this system the distribution of salaries and wages will be supported by activity reports that reflect the distribution of activity expended by employees covered by the system. The reports will reflect an after the fact reporting of

[5] Many institutions overlook this requirement. A-21 does not prescribe how independent it must be or how often it must be done.

the percentage distribution of activity by employees and be signed by the employee, principal investigator, or responsible official(s) using suitable means of verification. For professorial and professional staff, the reports will be prepared each academic term, but no less frequently than every six months. For other employees, unless alternate arrangements are agreed to, the reports will be prepared no frequently than monthly and will coincide with one or more pay periods. Where an institution uses timecards or other forms of after the fact payroll documents as original documentation for payroll charges, such documents shall qualify as records for purposes of after the fact as long as they reflect distribution of activity for each sponsored agreement, and are signed by the employee, principal investigator or responsible official(s) confirming the work was performed.

- Multiple Confirmation Records – under this system, the distribution of salary and wages of professorial and professional staff will be supported by records which certify separately for direct and F&A cost activities.

Salary rates for faculty members (A-21 § J.10.d)

- Salary rates must be based on regular compensation. In no event will charges to sponsored agreements exceed the proportionate share of the base salary for that period. Since intra-university consulting is assumed to be undertaken as a university obligation requiring no compensation in addition to full time base salary, the principle also applies to faculty members who function as consultants or otherwise contribute to a sponsored agreement conducted by another faculty member of the same institution. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the consultant is in addition to his regular departmental load, any charges for such work representing extra compensation above the base salary are allowable provided that such consulting arrangements are specifically provided for in the agreement or approved in writing by the sponsoring agency.
- For periods outside the academic year - Work performed during summer months will be paid a rate not in excess of the base salary divided by the period to which the base salary relates.

FEDERAL RESEARCH COMPLIANCE 101: WHAT COUNSEL NEEDS TO KNOW

Part III: Scientific and Bioethics Compliance

June 19 – 22, 2013

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This paper is the third in a series of pieces regarding the basics of federal compliance requirements that govern federally-funded research. As William Ferreira and Mary Lee Brown note in Parts I and II of the series, the multitude of compliance requirements that govern federally-funded research generally fall into three key areas: (1) administrative compliance; (2) financial compliance; and (3) scientific and bioethics compliance.[1] This paper addresses scientific and bioethics compliance, focusing in particular on federal regulatory requirements regarding human subjects research, animal care and use, financial conflicts of interest, and research misconduct.[2]

I. Human Subjects Research

The Federal Policy for the Protection of Human Subjects (the "Common Rule") is the core federal regulatory framework for human subjects research funded by the federal government. This paper focuses on U.S. Department of Health and Human Services ("HHS") regulations that implement the Common Rule for HHS-funded research. See 45 C.F.R. Part 46 (hereinafter referred to as the "Common Rule").[3] For a list of other agencies that have adopted the Common Rule and cites to their implementing regulations, see http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html.

The Office for Human Research Protections ("OHRP") is the office responsible for overseeing compliance with the Common Rule on behalf of HHS. OHRP's website (www.hhs.gov/ohrp) offers useful resources, including OHRP guidance documents, forms, FAQs, and determination letters issued by OHRP to individual institutions about specific compliance issues.

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[1] See William Ferreira, "Federal Research Compliance 101: What Counsel Needs to Know, *Part I: Administrative Compliance*" and Mary Lee Brown, "Federal Research Compliance 101: What Counsel Needs to Know, *Part II: Financial Compliance*" (NACUA Annual Conference, June 19-22, 2013).

[2] This paper highlights certain basic elements of these substantive compliance areas; it does not provide an in-depth presentation of them. Though important, specific issues such as environmental health and safety/biosafety considerations in research are beyond the scope of this paper.

[3] In July 2011, HHS published an Advance Notice of Proposed Rulemaking ("ANPRM"), entitled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators." 76 Fed. Reg. 44512 (July 26, 2011). As of the date of this paper, HHS has not published proposed rules in follow up to the ANPRM.

A. Research Covered by the Common Rule

The Common Rule applies to "all research involving human subjects" that is conducted or supported by HHS. See 45 C.F.R. § 46.101(a). The regulations define "research" and "human subject" as follows:

1. "Research" is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d).

2. A "human subject" is "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information." 45 C.F.R. § 46.102(f).

    a. "Intervention" is defined to include "both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes." Id.

    b. "Interaction" is defined to include "communication or interpersonal contact between investigator and subject." Id.

    c. "Private information" is defined to include "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)." The regulations provide that private information "must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects." Id. OHRP guidance addresses the circumstances under which research involving coded private information is or is not covered by the Common Rule. See OHRP, "Guidance on Research Involving Coded Private Information or Biological Specimens" (October 16, 2008), http://www.hhs.gov/ohrp/policy/cdebiol.html.

B. Research Exempt from the Common Rule

Certain categories of research involving human subjects are exempt from the Common Rule. Those categories are identified explicitly in the regulations and can be found at 45 C.F.R. § 46.101(b). They include, for example: (i) research activities that are "conducted in established or commonly accepted educational settings, involving normal educational practices" (e.g., "research on regular and special education instructional strategies"); and (ii) research activities "involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded

by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects." Id. (Emphasis added).

C. Federalwide Assurance

Each institution "engaged" in research that is covered by the Common Rule and funded or conducted by HHS must have an approved Federalwide Assurance ("FWA"). See 45 C.F.R. 46.103.[4]

The regulations do not define the term "engaged" and determining whether an institution is "engaged" in covered research is not always straightforward. OHRP has provided guidance in this area. See OHRP, "Guidance on Engagement of Institutions in Human Subjects Research (December 23, 1999), http://www.hhs.gov/ohrp/policy/engage08.html. Per that guidance, an institution is generally "considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research." OHRP's guidance defines "employees or agents" to mean "individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities" and notes that the term may include "staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation."

FWAs are submitted to and approved by OHRP. Instructions regarding the content of and process for submitting and updating FWAs are available on OHRP's website.

D. Institutional Review Board

Research subject to the Common Rule must be reviewed and approved by an Institutional Review Board ("IRB") that is registered with OHRP. See OHRP's website at http://www.hhs.gov/ohrp/assurances/irb/index.html for information regarding IRB registration requirements. Among other things, the regulations (a) establish certain requirements with respect to the composition of IRBs, see 45 C.F.R. § 46.107, (b) mandate that IRBs adopt and follow written procedures in certain areas (such as procedures for communicating findings and actions to investigators, and making required reports to OHRP), see 45 C.F.R. § 46.108 and OHRP, "Guidance on Written IRB Procedures" (July 1, 2011), http://www.hhs.gov/ohrp/policy/irbgd107.html, and (c) set forth criteria that IRBs must apply in determining whether to approve research protocols, see 45 C.F.R. § 46.111.

An institution's FWA must provide information regarding its IRB(s) or, if the institution does not have its own IRB(s), information regarding the outside IRB that will review covered research on behalf of the institution. See FWA Instructions, Item #6. If an institution relies on an outside IRB for review of research covered by the Common Rule, the arrangement is reflected

[4] An institution may elect to apply the terms of its Assurance to both its federally-funded and non-federally-funded human subjects research. See OHRP, Assurance Process - FAQs, at http://answers.hhs.gov/ohrp/categories/1563.

in a written agreement commonly referred to as an "IRB Authorization Agreement." See http://www.hhs.gov/ohrp/assurances/forms/index.html.

E. Reporting requirements

An IRB is authorized 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." 45 C.F.R. § 46.113. If an IRB suspends or terminates approval, the IRB's decision must be "reported promptly" not only to the investigator and "appropriate institutional officials" but also to the appropriate federal agency (OHRP, in the case of HHS funded-research). Id. Whether or not a protocol has been suspended or terminated, the institution must report to the appropriate federal agency (e.g., OHRP) any "unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with [the Common Rule] or the requirements or determinations of the IRB." 45 C.F.R. § 46.103(b)(5). See OHRP, "Guidance on Reporting Incidents to OHRP" (June 20, 2011), http://www.hhs.gov/ohrp/compliance/reports/index.html; OHRP, "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events" (January 15, 2007).

F. Recordkeeping requirements

The Common Rule requires institutions to generate and retain "adequate documentation of IRB activities." 45 C.F.R. § 46.115. Such documentation must include, for example, research protocols reviewed by the IRB, consent documents approved by the IRB, minutes of IRB meetings (in "sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution"); IRB correspondence with investigators; a list of IRB members; and written IRB procedures. Id. The regulations establish a record retention period. In general, required records must be retained for at least 3 years, and "records relating to research which is conducted" must "be retained for at least 3 years after completion of the research." Id.

G. Food & Drug Administration Requirements

To the extent that a human subjects study involves the clinical investigation of a drug, device, or other product subject to regulation by the Food & Drug Administration ("FDA"), FDA's human subjects protection requirements will also need to be considered. See 21 C.F.R. Parts 50, 56, 312, and 812. The FDA's regulations apply regardless of the source of funding (federal or non-federal). Although the FDA regulations contain many of the elements present in the Common Rule, counsel should be mindful that there are some differences between the two regulatory regimes. An analysis of such differences is beyond the scope of this paper. The FDA has prepared its own comparison of the Common Rule and FDA regulations, available at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/educationalmaterials/ucm112910.htm.

II. Animal Care and Use

A. PHS Policy

The Public Health Service Policy on Humane Care and Use of Laboratory Animals ("PHS Policy") governs the care and use of live vertebrate animals in research, research training, experimentation or biological testing that is conducted or supported by the Public Health Service ("PHS"). PHS Policy, sections I, II, and III.A. The PHS Policy establishes the Guide for the Care and Use of Laboratory Animals (National Academies Press) ("the Guide") as the required foundation for an institution's animal care and use program. PHS Policy, sec. IV.A.1.

1. Assurance

An institution may not undertake PHS-funded or PHS-conducted covered activities involving animals unless the institution has an approved written Assurance on file with the Office of Laboratory Animal Welfare ("OLAW"). PHS Policy, section IV.A. Instructions regarding the content of and process for submitting and updating/renewing Assurances are available on OLAW's website: http://grants.nih.gov/grants/olaw/obtain_assurance.htm.

2. IACUC

An institution that seeks to participate in PHS-funded or -conducted covered activities involving animals must establish an Institutional Animal Care and Use Committee ("IACUC") that is "qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures." PHS Policy, section IV.A.3. The IACUC must be appointed by the institution's "Chief Executive Officer," have at least five members, and meet certain other requirements regarding its composition. Id.

One of the IACUC's principal responsibilities is to review proposed research involving animals to determine whether the components of the research that are related to animal care and use are consistent with the PHS Policy, the Animal Welfare Act (as applicable – see Part II.B below), the Guide ("unless acceptable justification for a departure is presented"), and the institution's Assurance. PHS Policy, section IV.C. The IACUC must also evaluate whether the proposed research involving animals meets certain specific criteria set forth in the PHS Policy. Id. Such criteria include, for example:(a) "Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design"; (b) "The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied"; and (c) "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures." Id. Investigators are required to obtain IACUC approval prior to making any "significant changes" to approved activities. Id.

In addition to reviewing specific protocols, the IACUC is charged with performing more general oversight functions related to the institution's animal care and use functions. See PHS

Policy, section IV.B. It must perform semi-annual inspections (at least once every six months) of the institution's animal care and use program and animal facilities (including satellite facilities), "using the Guide as a basis for evaluation," and provide reports regarding such inspections to the Institutional Official for the animal care and use program. Id. (The Institutional Official is the individual authorized to sign the Assurance on behalf of the institution. PHS Policy, section III.G.) The IACUC must also "review concerns involving the care and use of animals at the institution," and provide "recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training." PHS Policy, section IV.B.

3. Reporting requirements

The IACUC may, by a majority vote at a meeting in which a quorum is present, "suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or [the PHS Policy]." PHS Policy, section IV.C.6. After reviewing the basis for the suspension, the Institutional Official must "take appropriate corrective action" and promptly report the matter to OLAW. PHS Policy, section IV.C.7, F.3. The Institutional Official is also required to promptly report to OLAW "any serious or continuing noncompliance" with the PHS Policy and any "serious deviation" from the Guide. PHS Policy, section IV.F.3. Certain annual updates (e.g., changes in IACUC members) are also required. PHS Policy, section IV.F.1-2.

4. Recordkeeping requirements

The PHS Policy requires institutions to keep certain records, including, for example, the Assurance, minutes of IACUC meetings ("records of attendance, activities of the committee, and committee deliberations"), protocols and IACUC decisions, and IACUC reports and recommendations on semiannual inspections. PHS Policy, section IV.E. Such records must be maintained for a minimum of three years, and records relating "directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC" must be kept "for the duration of the activity and for an additional three years after completion of the activity." Id.

B. Animal Welfare Act / Department of Agriculture Regulations

The use of warmblooded animals in research, teaching, testing, experimentation or exhibition (regardless of whether the activity is funded by the federal government or some other source) is subject to regulation by the U.S. Department of Agriculture's ("USDA's") Animal and Plant Health Inspection Service ("APHIS"), see 9 C.F.R. Chapter 1, Subchapter A, under the Animal Welfare Act, 7 U.S.C. § 2142. (Certain exceptions apply – for example, birds and certain rats and mice used in research are not covered by the regulations. 9 C.F.R. § 1.1). APHIS' website contains relevant guidance, including APHIS' Animal Care Policy Manual (http://www.aphis.usda.gov/animal_welfare/policy.php).

The PHS Policy and USDA/APHIS regulations overlap in certain respects (for example, both contain requirements pertaining to the establishment of an IACUC), but there are differences between the two regulatory frameworks. This paper does not undertake to address

such differences. The Institutional Animal Care and Use Committee Guidebook (2d ed. 2002), published by the Applied Research Ethics National Association & OLAW, compares various requirements in the PHS Policy and USDA/APHIS regulations. The Guidebook is available on OLAW's website (http://grants.nih.gov/grants/olaw/olaw.htm).

III. Conflicts of Interest in Research

Certain federal sponsors impose on institutions requirements pertaining to conflicts of interest in research projects. This paper focuses on regulations adopted by HHS for PHS-funded research. See 42 C.F.R. Part 50, Subpart F (applicable to grants and cooperative agreements); 45 C.F.R. Part 94 (applicable to contracts).[5] Resources and guidance regarding the HHS regulations are available on NIH's Financial Conflicts of Interest website, at http://grants.nih.gov/grants/policy/coi/.[6]

A. Policy Requirement

The HHS regulations require that the institution "[m]aintain an up-to-date, written enforced policy on conflicts of interest that complies with [the regulations]" and is posted on a "publicly accessible Web site."[7] 42 C.F.R. § 50.604(a).

B. Investigator Disclosure and Training

Per the regulations, institutions must mandate that investigators make certain disclosures at the time they apply for PHS funding and during the period of any award. 42 C.F.R. § 50.604(e). Specifically, "each Investigator who is planning to participate in the PHS-funded research" must "disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research." 42 C.F.R. § 50.604(e)(1). Each investigator "participating in the PHS-funded research" must also provide "an updated disclosure of significant financial interests at least annually . . . during the period of the award," and "within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest." 42 C.F.R. § 50.604(e)(2)-(3).

1. Investigator

An "investigator" is defined as "the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or

[5] For convenience, this paper generally cites only to the HHS financial conflict of interest regulations for grants and cooperative agreements. As noted above, parallel provisions can be found in 45 C.F.R. Part 94.

[6] The National Science Foundation ("NSF") is another common federal sponsor of university research that requires recipients to adhere to conflict of interest in research requirements. See NSF, Proposal and Award Policies and Procedures Guide (January 2013), Award and Administration Guide, chapter IV.A, at http://www.nsf.gov/publications/pub_summ.jsp?ods_key=papp.

[7] In the rare case that an institution does not have a "current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request." 42 C.F.R. § 50.604(a).

reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants." 42 C.F.R. § 50.603.

2. Significant Financial Interest

A "significant financial interest" is defined as a "financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities[8]:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests."

42 C.F.R. § 50.603 (emphasis added).

Certain types of financial interests (such as "income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education") are explicitly excluded from the definition of a significant financial interest. Id.

The regulations also provide that investigators must "disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities," unless the travel is reimbursed or sponsored by "a Federal, state, or local government agency, an Institution of higher education as defined at 20

[8] "Institutional responsibilities" are defined as "an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards." 42 C.F.R. § 50.603.

U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education." Id. The disclosure must specify the "purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration," along with any additional details required by the institution's policy. Id.

3. Training

The institution must provide training to investigators regarding the institution's conflict of interest policy and the investigators' disclosure obligations. 42 C.F.R. § 604(b). Each investigator must complete the training "prior to engaging in research related to any PHS–funded grant and at least every four years." Id. In addition, an investigator must complete the training immediately if: (a) the institution changes its policy or procedures "in any manner that affects the requirements of Investigators"; (b) the investigator "is new to an institution"; or (c) the institution determines that the investigator "is not in compliance with the Institution's financial conflict of interest policy or management plan." Id.

C. Review Disclosures, Managing, and Reporting Conflicts of Interest

In reviewing investigator disclosures, institutions must make two determinations:

(1) Is the investigator's significant financial interest "related to PHS-funded research"? The answer is "yes" if the institution "reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research." 42 C.F.R. § 604(f).

(2) For any significant financial interest that is "related to PHS-funded research," does the significant financial interest represent a "financial conflict of interest"? The answer is "yes" if the institution "reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS–funded research." Id.

Financial conflicts of interest must be managed and must be reported to the appropriate PHS awarding component within prescribed time periods. 42 C.F.R. §§ 50.603 (g),(h), 50.605. The required elements of financial conflict of interest management plans and reports to PHS are addressed in the regulations. 42 C.F.R. § 50.605.

Should the institution determine that a financial conflict of interest was "not identified or managed in a timely manner," the institution must, "within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research." 42 C.F.R. § 50.605(a)(3). The regulations include documentation and reporting obligations associated with such reviews. Id.

D. Subrecipients

To the extent that the prime awardee conducts PHS-funded research with the assistance of a subrecipient, the prime awardee must "take reasonable steps to ensure that any subrecipient Investigator complies" with the regulations. 42 C.F.R. § 50.604(c). This can be accomplished in one of two ways: (1) subrecipient investigators comply with the subrecipient's policy (if the subrecipient has a policy that meets the requirements of the regulations); or (2) the investigators comply with the prime awardee's policy. Id. The prime awardee's written agreement with the subrecipient must indicate which institution's policy will govern subrecipient investigators and include certain other provisions specified in the regulations. Id.

E. Recordkeeping Requirements

As a general rule, the institution must keep "records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS" (for grants and cooperative agreements) and "for at least three years from the date of final payment" (for contracts). Longer retention periods may apply in certain circumstances. See 45 C.F.R. §§ 74.53(b), 92.42(b); 48 C.F.R. Part 4, Subpart 4.7.

IV. Research Misconduct

The Federal Research Misconduct Policy is the principal source of federal authority in the research misconduct area and has been implemented by individual federal agencies through regulation. This paper focuses on HHS' regulations, codified at 42 C.F.R. Part 93. (HHS's regulations are hereinafter referred to as the "Federal Research Misconduct Policy.") It is important to note that the regulations apply not only to funded research-related activities but also to proposals for such funding (regardless of whether an award is ever made). 42 C.F.R. § 102(a). The Office of Research Integrity ("ORI") is the office responsible for administering the Federal Research Misconduct Policy on behalf of HHS.

A. Definition of research misconduct

Research misconduct is defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" and "does not include honest error or differences of opinion." 42 C.F.R. § 103. The three categories of research misconduct are further defined as follows:

1. Fabrication = "making up data or results and recording or reporting them."

2. Falsification = "manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record."

3. Plagiarism = "the appropriation of another person's ideas, processes, results, or words without giving appropriate credit."

To find research misconduct, a "preponderance of the evidence" must show that there was a "significant departure from accepted practices of the relevant research community" and that it was "committed, knowingly, or recklessly." 42 C.F.R. § 93.104.

B. Stages of research misconduct reviews

1. Assessment of allegation

An allegation of research misconduct must be reviewed to determine whether it "[f]alls within the definition of research misconduct" and is "sufficiently credible and specific so that potential evidence of research misconduct may be identified." 42 C.F.R. § 93.307(a). If the allegation meets these criteria, the institution proceeds to the next step, which is an inquiry. Id.

2. Inquiry

An inquiry is "preliminary information-gathering and preliminary fact-finding," the purpose of which is to determine whether a more formal investigation should be conducted. 42 C.F.R. § 93.307. "At the time of or before beginning an inquiry," the institution is required to "make a good faith effort" to provide written notice to the respondent. Id. As any additional respondents are identified, they too must receive written notice of the inquiry. Id. The institution is also required to "promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments." Id.

The institution must proceed to an investigation if the following criteria are met: (1) there is a "reasonable basis for concluding that the allegation falls within the definition of research misconduct" (and "involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training"); and (2) "[p]reliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance." 42 C.F.R. § 93.307(d). A written inquiry report must be prepared (and must include certain information outlined in the regulations) and the respondent must be permitted to review and comment on the report. 42 C.F.R. §§ 93.307(e), 309(a). The respondent's comments, if any, must be attached to the inquiry report. Id. The respondent must also be informed of the results of the inquiry (i.e., whether the institution is proceeding to an investigation). 42 C.F.R. § 93.308.

As a general rule, the inquiry must be completed "within 60 calendar days of its initiation unless circumstances clearly warrant a longer period" and the institution documents the basis for the additional time required. 42 C.F.R. § 93.307(g). If the institution decides that it needs to proceed to an investigation, ORI must be notified of that determination within 30 days, and such notification must include a copy of the institution's inquiry report. 42 C.F.R. § 93.309(a). If the

institution decides that an investigation is not warranted, the institution is required to maintain (for a minimum of seven years after the inquiry ends) "sufficiently detailed documentation" to "permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation." 42 C.F.R. § 93.309(c).

3. Investigation

An investigation must be initiated within 30 days of the institution's decision to proceed to that phase. 42 C.F.R. § 93.310(a). The respondent must receive written notice of the allegations that will be reviewed in the investigation "within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins," and must subsequently be provided "written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation." 42 C.F.R. § 93.310(c). To the extent there were any sequestration steps not taken in earlier stages, the institution is required to "take all reasonable and practical steps to obtain custody of all the research records and evidence," and, "[w]henever possible," must do so "[b]efore or at the time the institution notifies the respondent" and "[w]henever additional items become known or relevant to the investigation." 42 C.F.R. § 93.310(d).

As a general rule, the investigation must be concluded within 120 days of its initiation. 42 C.F.R. § 93.311. If additional time is required, ORI approval must be sought. Id. A final written investigation report is required and the regulations address specific requirements pertaining to the content of the report. 42 C.F.R. § 93.313. The institution must notify ORI of its determination regarding whether research misconduct occurred (and by whom), provide a copy of the investigation report to ORI, and inform ORI what administration actions are or will be taken, if any. Id. ORI is authorized to perform "oversight reviews" of institutions that have conducted research misconduct proceedings and may, on the basis of such reviews, "take appropriate action." Id.