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FEDERAL RESEARCH COMPLIANCE 101: WHAT COUNSEL NEEDS TO KNOW

Part I: Administrative Compliance

**William Ferreira
Hogan Lovells US LLP
Washington, DC**

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 obligations. But federal sponsors strictly enforce these

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.

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 property in

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.

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.

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,

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>

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 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.

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

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.