Federally Funded Research and Development
Regulatory and Enforcement Updates for 2013

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I. Introduction

In light of the ongoing economic challenges, sequestration, and budget cuts, it comes as no surprise that 2013 was an eventful year for federally funded research and development ("R&D"). Though the exact level of federal R&D spending in 2013 is not yet known, the general trend is lower R&D spending than years prior, and continued declines are expected in 2014. Additionally, decreased funding was met with increased oversight and scrutiny, and 2013 was a year with numerous reported audits, settlements, and other enforcement actions by agencies seeking to ensure that contractors and grantees were responsible stewards of federal funds. On the regulatory front, there are several notable updates that signal an expansion in research programs and new guidelines for compliance and transparency.

This paper highlights representative enforcement actions and significant regulatory developments in the R&D space in 2013. Part II begins with a brief discussion of funding levels and a forecast for FY2014. Part III addresses enforcement actions related to fraud and research misconduct. Lastly, Part IV provides an overview of regulatory developments of which contractors and grantees engaged in R&D should be aware.

II. Funding Landscape

The proposed FY2013 federal budget for research and development was over $140 billion. Due to sequestration, rescissions, supplemental funding and a variety of other factors, final appropriation levels are, however, not yet known. Adjusted for inflation, the proposed FY2013 R&D budget represents a 0.2% decrease from the estimated FY2012 R&D funding level of $138.869 billion. John F. Sargent Jr., *Federal Research and Development Funding: FY2014,* Congressional Research Service, at 1-2 (Dec. 5, 2013). The Congressional Research Service published the following figures representing federal research and development funding over the past three years:

Federal Research and Development Funding by Agency, FY2011 – FY2013
(Budget Authority, dollar amounts in millions)

Department/Agency	FY2011 Actual	FY2012 Estimate	FY2013 Request	$ Change, 2012 to 2013	% Change, 2012 to 2013
Defense	77,500	72,739	71,204	-1,535	-2.1%
Health and Human Services	31,186	31,153	31,400	247	0.8%
Energy	10,673	11,019	11,903	884	8.0%
NASA	9,099	9,399	9,602	203	2.2%
National Science Foundation	5,486	5,680	5,904	224	3.9%
Commerce	1,275	1,258	2,573	1,315	104.5%
Agriculture	2,135	2,331	2,297	-34	-1.5%
Veterans Affairs	1,160	1,164	1,166	2	0.2%
Transportation	953	944	1,076	132	14.0%

As indicated above, two agencies saw a decrease in their allocated funding from the prior year – DOD's R&D budget was reduced by $1.535 billion (2.1%) and USDA by $34M (1.5%). The other five agencies saw increases: DOC, $1.315 billion (104.5%); DOE, $884 million (8.0%); HHS, $247 million (0.8%); NSF, $224 million (3.9%); and NASA, $203 million (2.2%). *Id.* The Department of Commerce received a significant increase in part because of mandatory proposals for NIST's Wireless Innovation Network and National Network for Manufacturing Innovation programs. *Id.* at n.9.

Because of the tighter federal R&D budgets, higher education research institutions and other nongovernmental entities are generally supporting a significant and increasing amount of the costs of R&D activity. In November 2013, the NSF National Center for Science and Engineering Statistics released a report stating that from FY2011 to FY2012, institution-funded R&D reached $13.7 billion -- an increase of over $1 billion from the previous fiscal year. Ronda Britt, *Higher Education R&D Expenditures Remain Flat in FY2012*, InfoBrief, National Science Foundation, at 1-2 (2013)**.** This figure includes funding from institutionally financed research ($7.7 billion), cost sharing on sponsored projects ($1.3 billion) and unrecovered indirect costs on sponsored projects ($4.6 billion). The report also noted that in FY2012, R&D expenditures by nonprofit organizations increased by over $180 million to reach $4 billion, and private business-funded R&D increased by $101 million to reach $3.3 billion. *Id.* The report noted that the increases in institutional and other non-governmental R&D funding coincided with a decline in FY2012 federal funding. *Id.* at 2-3. This trend will likely continue into 2014.

The budget projections for FY2014 signal that R&D remains a priority for the Obama Administration but that funding will remain slightly depressed. The President's R&D budget request for FY2014 is $142.773 billion, which when adjusted for inflation is more than a 2.6% decrease from the actual R&D spending in FY2012. John F. Sargent Jr., *Federal Research and Development Funding: FY2014*, Congressional Research Services, at 1 (Nov. 5, 2013)**.** The FY2014 budget request allocates 95.3% of the total federal R&D funding to seven agencies in the following amounts:

President's R&D Budget Request for FY2014
(Dollar amounts in billions)

Department/Agency	FY2014 R&D Budget Request	Percentage of Total R&D Request
Defense	68,291	47.8%
Health and Human Services	32,046	22.4%
Energy	12,739	8.9%
NASA	11,605	8.1%
National Science Foundation	6,148	4.3%
Commerce	2,682	1.9%
Agriculture	2,523	1.8%

Id. at 3-4. Thus, while funding remains steady, agencies are likely to take a more aggressive approach to compliance and monitoring of their R&D funds.

III. Agency Enforcement Actions of Research Misconduct and Fraud

As in prior years, 2013 saw a continued stream of enforcement activity in the areas of fraud and research misconduct.

A. False Claims Act and Related Agency Actions

The False Claims Act (FCA) continues to be an important enforcement tool in the R&D area. This section provides summaries of some of 2013's notable R&D-related FCA enforcement matters, as well as commentary by the U.S. Chamber of Commerce on possible amendments to the FCA. We will also briefly discuss one agency's administrative approach to resolving fraud allegations related to R&D activity.

i. Northwestern University settles False Claims Act claim for nearly $3M.

Northwestern University agreed to pay $2.93M to settle a FCA lawsuit brought by a former employee, Melissa Theis. Northwestern receives federal grant funding from NIH for research conducted by university medical facilities, faculty, and associated institutions. From 2007 to 2008, Theis worked as a purchasing coordinator in the hematology and oncology departments at Northwestern's Feinberg School of Medicine. In a civil FCA suit filed under seal in 2009, Theis alleged that Northwestern allowed one of its researchers, Dr. Charles L. Bennett, to submit false claims related to NIH grants and that the university refused to seriously address the issue when she raised concerns. Specifically, she alleged that from 2003 through 2010, Dr. Bennett improperly used federal funds to cover professional and consulting services, subcontracts, travel, hotels, food, and other expenses that benefitted Dr. Bennett and his friends and family.

According to the Department of Justice, Northwestern fully cooperated during the investigation, and was released from all claims under the settlement agreement. The university did not admit liability. However, the terms of the agreement reserved the government's right to deny payment under the grants at issue, limit future grant awards, or pursue suspension or debarment. The government also maintained the right to pursue certain criminal claims against the university. Charges remain pending against Dr. Bennett. Ms. Theis will recover $498,100 of the settlement proceeds. *See* Department of Justice Press Release, *Northwestern University to Pay Nearly $3 Million to the United States to Settle Cancer Research Grant Fraud Claims* (July 30, 2013); *see also* Settlement Agreement, *United States ex rel. Melissa Theis v. Northwestern University*, Civ. No. 09-1943 (N.D. Ill. 2013); *see also* False Claims Act Complaint, *United States ex rel. Melissa Theis v. Northwestern*, No. 05-1631 (N.D. Ill. March 30, 2009).

ii. Emory University pays the United States and the state of Georgia $1.5M to settle False Claims Act investigation.

Emory University agreed to pay $1.5M to settle an FCA action brought by a former clinical research finance manager, Elizabeth Elliott. In a civil suit filed under seal in 2009, Elliott alleged that Emory's Winship Cancer Institute submitted false claims to the United States and the State of Georgia by billing Medicare and Georgia Medicaid for clinical trial services that should have been billed to clinical trial sponsors. Specifically, Elliott described an internal investigation conducted by the university into fourteen studies where Emory improperly billed patients' insurance providers— including Medicare and Medicaid— as well as the clinical trial sponsors. These fourteen studies represented those where participants had complained about overbilling, and Elliott expressed concern that there were many more instances of overbilling.

Of the $1.5M settlement, Emory agreed to pay just over $70,000 to the state of Georgia Department of Community Health, and $322,500, plus attorney's fees, and an additional $11,250 for wrongful termination claims to Elliot. *See* Department of Justice Press Release, *Emory University to Pay $1.5 Million to Settle False Claims Act Investigation* (Aug. 28, 2013); *see also* Settlement Agreement, *United States and State of Georgia ex rel. Elizabeth Elliott v. Emory University*, Civ. No.

09-3569, (N.D. Ga. Aug. 22, 2013); *see also* Complaint, *United States and State of Georgia ex rel. Elizabeth Elliott v. Emory University*, Civ. No. 09-3569, (N.D. Ga. Dec. 18, 2009).

iii. FCA whistleblower alleges fraudulent misrepresentation in NIH grant application.

Relator Gary Seibert alleged that Natera (formerly Gene Security Network), a biotechnology company based in northern California, made fraudulent statements when the company applied for and ultimately received three NIH grants under the Small Business Innovation Research (SBIR) program. The contract awards totaled almost $3.5M, and were awarded to perform molecular diagnostic tests for studies of in vitro fertilization. Seibert alleged that Natera did not comply with financial monitoring provisions governing NIH grantees.

In January 2013, the U.S. Government declined to intervene. However, Siebert proceeded with the action and in June, the court denied Natera's motion to dismiss. The U.S. District Court for the Northern District of California found Seibert had adequately pled the falsity, materiality, and scienter requirements necessary to establish a *prima facia* FCA complaint.

Specifically, the court rejected Natera's contention that Seibert failed to meet the falsity requirement. The relator's complaint traced program requirements and attached the grant applications at issue, which each included signed certifications of compliance with financial management system and administrative requirements. Seibert alleged, and the court agreed, that these certifications were false because Natera represented in a Financial Questionnaire that it had in place a time tracking system as required by NIH when it actually did not. The court found this satisfied the falsity requirement.

The court also rejected Natera's motion to dismiss on grounds that the certifications were not material to the government's decision to award the grant because the certifications were made post-award. The court pointed to language in the NIH Notice of Award letters, noting the requirement for further certification and compliance even after the decision for award. Therefore, Seibert adequately alleged that Natera's post-award certifications were material to NIH's decisions for payment.

Finally, the court found the scienter requirement was met by allegations that Natera knowingly certified compliance with NIH requirements when it had not. The case is set to proceed in the District Court of the Northern District of California. *See Siebert v Gene Security Network, Inc*., Civ. No. 11-01987 (N.D. Cal. 2013).

iv. U.S. Chamber of Commerce recommends False Claims Act reforms.

In an October 2013 report, the U.S. Chamber of Commerce criticized government enforcement of the False Claims Act as ineffective in detecting fraud. The report accused the Department of Justice of abusive use of treble-damages and threatening companies into entering into unduly large settlements. The Chamber noted that *qui tam* whistleblowers are given disproportionately large incentives in high-damage cases, and that companies should have greater incentive to create proactive compliance systems. The paper proposes several reforms aimed at increasing incentives to report fraud and improve enforcement mechanisms.

In its proposal, the Chamber suggested that FCA reform focus on incentivizing widespread adoption of certified and effective compliance programs. According to the report, the FCA currently emphasizes adversarial investigations and enforcement efforts that support litigation after the fraud has occurred. The Chamber proposed amendments intended to encourage companies to voluntarily adopt a certified compliance program that will prevent fraud before it happens or, at minimum, detect

fraud early so that it may be promptly reported to the government. Those companies that adopted certified compliance would be subject to more lenient FCA terms, as detailed below.

(1) *Calibration of multiplier to culpability*: Currently, a person who violates the FCA is liable for three times the amount of damages sustained by the government, though the statute provides for a reduction to double damages if certain requirements are met (i.e., when a company discloses wrongdoing without knowledge of an ongoing investigation, and fully cooperates with the government). The Chamber proposed instead a calibrated culpability framework where liability for treble damages is limited to entities that act with an intent to defraud. Entities whose employees engaged in misconduct despite the entity's good-faith attempt to ensure compliance would be subject to double damages, while entities that disclose wrongdoing promptly to the government would face a maximum multiplier of 1.5.

(2) *Jurisdictional bar on qui tam actions after a defendant's disclosure to the government*: Proposed reforms would foreclose *qui tam* actions in circumstances when companies with certified compliance programs have made disclosures to the government. If enacted, this would expand the current public disclosure bar (barring actions based upon information already publically disclosed) and the first-to-file bar (limiting rewards to only the first whistleblower to come forward).

(3) *Incentives for potential relators to report internally to their employers*: The Chamber's proposed reforms provide for dismissal of *qui tam* suits against companies with certified compliance programs when filed by an employee relator who failed to first report alleged conduct internally at least 180 days prior to filing suit. The FCA does not currently provide incentive to report concerns of potential fraud within the company. The Chamber contends, however, that internal reporting is more effective in reducing fraud and noted that other statutory and regulatory regimes—including the Sentencing Guidelines and the Dodd-Frank Act's whistleblower provisions—favor it over fostering a "race to the courthouse" regime.

(4) *No mandatory or permissive exclusion or debarment*. As a final incentive, the Chamber proposes revision of the government regulations so that companies with certified compliance programs are not subject to mandatory or permissive exclusion or debarment.

In addition to modified rules that apply to companies with certified compliance programs, the Chamber posed a number of other suggestions, including a reduction in the relator's share of government recovery, a redefinition of "false or fraudulent claim" to exclude implied false certification liability, and reform of DOJ's policies related to Civil Investigative Demands (CIDs) in an effort to decrease the number of CIDs issued.

v. NSF considers action under the Program Fraud Civil Remedies Act.

OIG investigations that uncover potential fraud are commonly referred to DOJ for civil action under the False Claims Act. The DOJ may then decide to pursue the matter or not. The Program Fraud Civil Remedies Act (PFCRA) provides agencies with an option to pursue perceived fraudulent conduct without the need for DOJ involvement. Under the PFCRA, agencies can recover money from the grantee for any fraudulent claim that does not exceed $150,000. PFCRA actions also provide agencies with a means to seek funds not recovered by a criminal action, as PFCRA claims can be brought subsequent to a criminal conviction.

In 2013, the NSF OIG found that a California small business that received a SBIR award of almost $100,000 of American Recovery and Reinvestment Act (ARRA) funds had failed to properly

segregate and track costs (as required under ARRA) and did not properly document expenditures for over half of the funds received. The company also falsely certified compliance with ARRA requirements. After DOJ declined to accept the OIG's referral for FCA action, the OIG then recommended NSF pursue a PFCRA action against the small business

NSF's decision in the California SBIR matter is currently pending, but could result in recovered funds and penalties totaling $76,052. NSF OIG has commented it now considers "the use of PFCRA as a possible remedy in all substantiated fraud investigations." *See Semiannual Report to Congress*, National Science Foundation, Office of Inspector General, September 2013; Program Fraud Civil Remedies Act, Public Law 99–509 (codified at 31 U.S.C. § 3801–3812); National Science Foundation Program Fraud Civil Remedies Act, 74 Fed. Reg. 26,793 (June 4, 2009).

B. Agency Audits of Federally Funded Research and Development

OIG audits are also an effective and commonly used way to detect and recoup misspent R&D costs. In a mid-year 2013 report, the HHS OIG touted $521M in audit receivables in the first half of FY2013 alone. *See* HHS OIG *Semiannual Report to Congress* at i (March 2013). OIGs have stressed that agencies need to continue to improve their monitoring procedures and compliance controls in order to ensure that their R&D funds are being handled appropriately. For example, in its March 2013 semiannual report, the NSF OIG stated that NSF should "impose stronger cost surveillance measures for high-risk, high-dollar cooperative agreements used in large facility projects." NSF OIG, *Semiannual Report to Congress* at 3 (March 2013). The OIG's recommendation was spurred in part by an audit of the University of Wisconsin, Madison, which NSF claimed revealed significant areas of noncompliance in three major cooperative agreements (discussed below).

In 2013, NSF indicated increased reliance on a new method of analyzing data to identify high-risk awardees and flag indicators of potentially misspent funds. The NSF OIG Office of Audit issued, in November 2012, a report describing this method, known as "data analytics", at length. It explained that data analytics utilizes a dual-phase methodology. In the first phase, NSF identifies high-risk institutions by surveying and monitoring all applicable internal and external awardee data. Internal data includes proposals, quarterly expense reports, and cash draw-downs, and external data encompasses A-133 audits, data from the institutions' financial systems such as subaward data and general ledger figures, as well as reports and data from accountability and transparency organizations such as the Recovery Board, USA Spending and Guidestar (external). If the data reveals anomalies such as unusual expenditure rates, NSF proceeds to phase two in which it delves deeper into potentially questionable expenditures. In the second phase, NSF gathers awardee transaction data surrounding particular anomalies and looks for further "fraud indicators" that may indicate misuse of the NSF funds. Where more red flags are present and NSF monitoring controls may be lacking, NSF will likely choose to initiate an audit. *See* NSF OIG, *Annual Office of Audit Work Plan, FY 2013* (Nov. 16, 2012).

NSF states that the data analytics methodology will prove more economical for the Office of Audit, as it has limited staff and resources to perform audits or monitor audits performed by outside auditors. However, many institutions argue that the methodology is flawed in that it can produce false conclusions and result in a burdensome audit process. For example, the Report on Research Compliance published an article discussing a data analytics audit of the University of California Santa Barbara ("UCSB") in which UCSB disputed NSF's findings of $6.3M in questionable costs based on the data analytics methods employed. UCSB stated that they were burdened by having to

submit responses to hundreds of data requests in an unreasonably short period of time and that NSF relied on erroneous data submitted by personnel whose names NSF would not disclose. Yet, while institutions may criticize the methodology, increasing references by NSF to data analytics suggest that it is becoming the favored approach to monitoring compliance; a trend that other agencies may soon follow. *See* Report on Research Compliance, *"Data Analytics Takes Center Stage in OIG Work Plan, Amid Contentious Audit Report,* Vol. 10, No. 1 at 2 (Jan. 2013).

i. DCAA determines University of Wisconsin, Madison Was Not in Compliance with the Cost Accounting Standards.

The NSF OIG Semiannual report to Congress (March 2013) announced that the Defense Contract Audit Agency ("DCAA") had conducted, on behalf of NSF, a review of direct costs claimed by the University of Wisconsin–Madison ("UW-M"). DCAA questioned $2,134,379 of costs based on alleged noncompliance with the Cost Accounting Standards ("CAS"). The audit focused on $218.8 million of incurred direct costs claimed by UW-M under three cooperative agreements with NSF to build the IceCube Neutrino Observatory in Antarctica from 2002-2011. DCAA made the following findings:

- UW-M improperly reclassified subawards as service agreements without consent from NSF or adequate written documentation to justify the changes, which led to excess recovery of indirect costs. Under the terms and conditions of the cooperative agreements, the university was entitled to recover indirect costs only on the first $25,000 of a subaward; there was no similar limitation on service agreements. DCAA recommended disallowing the excessive indirect costs and encouraged UW-M to establish procedures that would require UW-M to document its subaward versus service agreement determinations, and seek prior written approval from the contracting officer prior to making any classification changes.

- UW-M comingled indirect facilities and administrative (F&A) costs charged to the IceCube Cooperative Agreements with its direct costs, and reported the two types of costs in one line item as "Other Expenditures" in its financial reports. This practice was contrary to its institutional practice of reporting all F&A costs as a separate line item. Accordingly, DCAA found UW-M's practice to be a violation of CAS 501, which requires that "an educational institution's cost accounting practices used in accumulating and reporting actual costs for a contract shall be consistent with the institution's practices used in estimating costs in pricing the relating proposal." DCAA recommended that UW-M submit a cost impact proposal and revised financial statements indicating actual costs for the three cooperative agreements.

- UW-M failed to segregate and track contingency costs, leading to a noncompliance with CAS 501 for failing to follow institutional practices (quoted above) and OMB Circular A-110, sec. C.21.b.4 for failing to track costs in a manner such that they can be compared to the budget. DCAA also determined that because the contingency costs were not segregated, it was difficult to tell whether they were charged to NSF as direct or indirect costs. Noting that UW-M did not discuss treatment of contingency costs in its CAS Disclosure Statement, DCAA recommended that UW-M establish a practice to segregate contingency costs in its accounting records, clearly identify direct and indirect costs on its pricing proposal summary, and revise its CAS Disclosure Statement to reflect its treatment of contingency costs. DCAA noted that UW-M's contingency costs were not unallowable under this award because they were proposed to cover specific technical

risks and uncertainties set forth in the statement of work, in contrast to general contingency costs that are unallowable under OBC Circular A-21 J.11 because they are contributed to a reserve for future uncertain events.

- UW-M charged some relocation expenses as direct costs in contravention of its institutional practice of charging such expenses as indirect costs. Because UW-M did not provide an explanation for the practice on its CAS Disclosure Statement, DCAA found UW-M to be noncompliant with CAS 502, which states that "all costs incurred for the same purpose, in like circumstances, are either direct costs only or indirect costs only with respect to final cost objectives." DCAA recommended that a portion of those costs be disallowed.

See NSF OIG Audit Report No. OIG-13-1-003 (March 29, 2013). UW-M disagreed with each instance of noncompliance alleged by DCAA and provided NSF with a detailed response substantiating its position.

ii. HHS Finds the University of Colorado, Denver lacked effort reporting controls and mischarged general expenses.

In June 2013, the HHS OIG released an audit report covering its review of University of Colorado, Denver's ("CU Denver") charging practices. The OIG reviewed a sample of the $151.2 million in costs that CU Denver incurred in FY2010 on 971 grants, contracts and other awards from NIH, CDC and HRSA. Specifically, the OIG audited a sample of $10.5 million in salary charges and $32 million in non-salary charges (100 transactions each), and estimated that $1,419,524 was unallowable. The OIG determined that these costs were unallowable because they included salary charges that should have been treated as F&A, undocumented charges, salary charges for unapproved student researchers, charges on two awards after the awards were relinquished to another institution and indirect costs charged as direct costs. The most significant portion of the disallowance was attributable to weaknesses in CU Denver's time keeping practices.

In addition, the OIG stated that fourteen of the 100 salary transactions lacked sufficient documentation to determine whether hourly payroll costs were allocated based on actual costs or budgeted costs. With respect to unallowable nonsalary costs, the most significant findings related to allegedly improper charging of general-use office supplies and services by charging such expenses directly to HHS-funded awards as opposed to recovering them through the university's indirect cost rate. HHS recommended that CU Denver refund the disallowed costs to the Federal Government and that CU Denver exercise more stringent oversight of its federal awards to ensure future compliance. *See* DHS OIG, *The University of Colorado Denver Did Not Always Claim Selected Costs Charged Directly to DHHS Awards in Accordance with Federal Regulations*, A-07-11-06013 (June 2013).

iii. HHS OIG Claims Cornell University improperly charged F&A as direct costs.

On September 16, 2013, the HHS OIG released a report detailing the results of an audit of Cornell's sponsored agreements with NSF. The agency reviewed a sample of all direct costs charged to NSF sponsored agreements from April 1, 2008 through June 30, 2011, and concluded that an estimated $794,221 plus associated fringe benefits and F&A costs were unallowable. The auditors determined that $11,945 of the unallowable costs was charged to American Recovery and Reinvestment Act (ARRA) awards. The majority of the unallowable costs related to supply and material expense transactions ($660,699), which NSF found were unallowable because they were

charged as direct costs rather than recovered through the university's indirect cost rate. For example, Cornell allegedly charged items such as laptops, monitors and toner cartridges, and expenses for meetings and conferences directly to NSF. Other unallowable costs ($75,312) were attributed to instances when Cornell charged recharge center expenses directly instead of indirectly. Recharge centers are university facilities that provide specialized goods and/or services, such as computer centers, animal facilities and supply centers, to internal and (sometimes) external users for a fee. The other unallowable costs were associated with general administrative expenses charged as direct costs ($34,085), costs of foreign travel that exceeded the applicable per diem rate and that occurred outside the authorized travel dates, or was otherwise unallowable ($17,544), and clerical and administrative salaries that should have been treated as indirect costs ($6,581). *See* NSF OIG, *Cornell University, Audit Report No. OIG-13-1-004* (Sept. 26, 2013).

Cornell disputed 60 of the 86 transactions questioned by NSF. Included in its rebuttal, Cornell argued that NSF mischaracterized its computer and computer-related expenses as general office supplies, and that such costs could be directly assigned to a specific award and thus were properly charged as direct costs. Cornell also disputed a majority of NSF's questioned costs related to travel and general expenses, asserting that it sufficiently documented these expenses in accordance with NSF regulations, and that Cornell's internal controls ensure that only valid costs are covered. *Id.* at Appendix E: Cornell University Comments.

iv. Stanford University cited by NSF for noncompliance with EarthScope SAFOD cooperative agreements.

An audit conducted by NSF and published in September 2013 questioned $339,277 in costs claimed by Stanford University for the EarthScope San Andreas Fault Observatory at Depth (SAFOD) project for the period September 1, 2003 to March 31, 2009. Stanford held one of four cooperative agreements for the EarthScope project, which monitors a creeping and seismically active fault zone. Of the $753,541 reviewed, the NSF OIG found that $290,000 was improperly used to replace a subcontractor's uninsured lost drilling equipment; $43,024 was spent over the subaward agreement ceiling price; and $6,253 was spent on unallowable costs such as sales taxes, promotional items, and alcohol. With regard to the uninsured lost equipment, NSF contended that Stanford should have enforced the terms of its subcontract agreement, which required the subcontractor to have insurance coverage; failure to do so was a violation of Section J.25 of OMB Circular A-21, which states that losses that could have been covered by permissible insurance are unallowable. Regarding the excess payments to the subcontractor, NSF concluded that Stanford had failed to account for pre-award expenditures by the subawardee when calculating the remaining balance owed, which resulted in payments in excess of the terms of the subaward agreement. Various other smaller expenditures were deemed to be unallowable because they conflicted with Stanford's internal policies and OMB Circular A-21.

Stanford disagreed with the questioned costs for uninsured drilling equipment, alleged overpayments to a subcontractor in excess of the ceiling price, and $907 of $6,253 in allegedly unallowable costs on grounds that the $907 was spent on allowable publications. Stanford concurred with NSF's finding that $6,253 in sales taxes, alcohol and other expenses was unallowable and offered to return the funds to NSF. *See* NSF OIG, *Audit of EarthScope San Andreas Fault Observatory at Depth (SAFOD) Expenditures*, OIG-13-1-005 (Sept. 30, 2013).

v. Thomas Jefferson University's HHS expenditures found generally to be allowable.

In FY 2009 and FY 2010, Thomas Jefferson University ("TJU") claimed $63 million in costs incurred on 528 grants, contracts and other agreements under various HHS components. During this period, it also received $6.2 million in ARRA awards. In an audit of $3.3 million in salary transactions and $2.4 million in nonsalary transactions from this period, the HHS OIG found that the large majority of TJU's transactions were allowable; specifically, only 1 of 100 salary transactions and 19 of 104 nonsalary transactions were fully or partially unallowable, for a total of $96,418 in unallowable charges. Those unallowable costs included one instance of effort charged to an award without supporting data, and numerous F&A costs for office supplies and general use equipment that were charged as direct costs, undocumented costs, and unallowable individual institutional membership charges to an award. The OIG recommended that TJU refund $93,102 to the Federal Government and that TJU exercise more stringent oversight of its federal awards to ensure future compliance. It also noted that TJU's Office of Research should implement a practice to review nonsalary transactions under $5,000 to ensure they comply with Federal regulations. *See* DHHS OIG*, Thomas Jefferson University Generally Claimed Selected Costs Charged Directly to DHHS Awards in Accordance with Federal Regulations*, A-03-11-03300 at 1 (June 2013).

vi. Audit of 31 NSF awards to Jackson State University questions over $900K.

The NSF OIG commissioned an independent CPA firm to conduct an audit of Jackson State University's ("JSU") expenditures on federal awards for the period ending on September 30, 2012. In an audit report released in February 2013, NSF announced that the audit identified $943,474.74 in questioned costs. Some of these questioned costs included improper application of indirect costs to participant support expenses and to subawards over the $25,000 threshold (universities may only recover F&A on the first $25,000 of a subaward). . The auditors also found that JSU charged indirect costs above the sponsor-approved fixed dollar ceiling. Additionally, the auditors questioned $15,390 of equipment costs for four laptops purchased two days prior to the award's expiration, which the auditors determined were not allocable. Further, NSF questioned fringe benefits charged to NSF awards without corresponding salary transactions. Finally, the auditors questioned $553,316.57 of charges that they believed were either unsupported or not adequately supported. Many of these questioned costs pertained to labor charges that were not supported by effort reports or for which the effort reports were purportedly defective. Additional non-labor costs were questioned for lack of invoices or information on the invoices to support the charge.

NSF requested that JSU provide supporting documentation to justify approximately $800,000 of the questioned costs. As of the time of publication of this report, a final resolution has not been published by NSF or JSU. *See* NSF OIG, *Jackson State University, Audit Report No.* OIG-13-1-002 (Feb. 5, 2013).

C. Research Misconduct

To give context to the developments regarding research misconduct, we start with a brief background on the regulatory framework. In 2000, the White House Office of Science and Technology Policy (OSTP) issued a final policy addressing misconduct in federally funded research activities. Policy makers recognized that reliable research data and records are fundamental to advances in all areas of science. Thus, the policy is intended, at least in part, to build public trust in the processes underlying federally funded R&D activity, and, through that confidence, the scientific advances derived from federally sponsored projects.

The OSTP policy defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." Office of Science and Technology Final Policy on Research Misconduct, 65 Fed. Reg. 76,260 (Dec. 6, 2000) ("OSTP Policy"). It also provides key definitions:

- Fabrication is making up data or results and recording or reporting them.
- Falsification is 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.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Id. Findings of research misconduct require that the misconduct was performed intentionally, knowingly, or recklessly. The policy is not intended to cover honest errors or mere differences of scientific judgment or opinion. Research misconduct must constitute "a significant departure from accepted practices of the relevant research community," and allegations must be proven by a preponderance of the evidence. *Id.*

All federal agencies or departments supporting intramural or extramural research were instructed to implement consistent rules or regulations within one year of notice of the final policy. Most agencies or departments have rules or regulations in place, including the Public Health Service and the National Science Foundation, which are among the most significant federal sponsors. The Department of Energy has published a Notice of Proposed Rulemaking. In addition, five department policies have been drafted and are undergoing internal review: Agriculture, Commerce, Education, Interior, and Justice. (To access a complete list of agency rules, *see Federal Policies*, The Office of Research Integrity, at http://ori.hhs.gov/federal-policies.)

When research misconduct is found in cases involving federal funding, the funding agency can impose a range of sanctions. Although agencies do not have authority to impose direct monetary penalties against a researcher, many of the sanctions have significant monetary implications. For example, a sponsor may disallow costs, request the return of funds, or terminate the award. In extreme cases, an agency could refer a case to the Office of the Inspector General or Department of Justice for fraud investigation, or permanently debar an individual from receiving federal research funds and from participating in federal projects. More commonly, however, agencies may issue temporary debarment for a period of years, or halt current research altogether. Often agencies will require retraction of any article including false, fabricated, or plagiarized material. In addition, administrative settlements often require certification by an institution employing the research professional that any federally funded research projects in which the professional is involved, or even their research proposals, are based on actual experiments or otherwise legitimately derived. Though institutions are not typically party to these agreements, instances of research misconduct are publicly known in the research community and easily discoverable during pre-employment due diligence. If a university or company conducting federally funded research knowingly fails to comply with the terms of the agreement, it could face a range of allegations, possibly including a false claims allegation. In the academic context, even non-monetary sanctions can result in severe reputational damage to both the researcher and the institution and, therefore, serve as a strong deterrent. Acts of scientific misconduct frequently reach the media, which can

severely tarnish a research professional's reputation (as well as the reputation of his or her institution) and harm potential for future work opportunities.

Similar to other areas of research fraud, investigations of research misconduct have increased in recent years. For example, according to the Office of Research Integrity (ORI), a division within HHS that is tasked to oversee and direct most Public Health Service (PHS) research integrity activities, administrative action was taken in only two cases of misconduct investigated by the office in 2009. In 2012, that number jumped to thirteen, and as of late 2013, ORI had reported misconduct findings in nine cases. *See generally Case Summaries*, The Office of Research Integrity, at http://ori.hhs.gov/case_summary. Additionally, the number of articles retracted from scientific journals jumped from just 46 in 2002 to 415 in 2012 alone. Kana Inagaka, *Novartis Hit by Scandal Over Japanese Drug Studies*, The Wall Street Journal Online, Aug. 11, 2013.

i. Agencies Crack Down on Falsification, Fabrication and Plagiarism by University Professors, Fellows and Students

In 2013 there were several notable instances of falsification, fabrication and plagiarism. For instance, ORI found a professor at a Canadian university engaged in misconduct relating to research supported by the National Institute of Allergy and Infectious Diseases (NIAID) and NIH. ORI found the professor falsified data, specifically claiming successful treatment of two animals receiving renal allografts when the transplant surgery had failed and survival was based on other circumstances. *See Case Summary: Wang, Hao*, The Office of Research Integrity, Nov. 20, 2013, *available at* http://ori.hhs.gov/content/case-summary-wang-hao. In a similar case, ORI found that a former graduate student engaged in research misconduct when he falsified and fabricated quantitative data to support summary material for his research hypothesis. *See Case Summary: Aggarwal, Nitin*, The Office of Research Integrity, Oct. 17, 2013, *available at* http://ori.hhs.gov/content/case- summary-aggarwal-nitin. In another case, a university professor admitted to plagiarizing significant portions of research she submitted to NIH and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Plagiarized sources include other NIAMS and NIH grant applications, as well as scientific articles and one U.S. patent application available on the internet. *See Case Summary: Karnik, Pratima*, The Office of Research Integrity, Aug. 8, 2013, *available at* http://ori.hhs.gov/content/case-summary-karnik-pratima.

In each of these cases, the researcher entered into a voluntary settlement agreement, agreeing for a period of time to conduct research according to an ORI-approved supervision plan, and to exclude him or herself from serving in any advisory or consulting capacity to the U.S. Public Health Service, and to institutional certifications and representations. In addition, each settlement agreement requires the employer institution to submit certifications for any federally funded research grant application, report or abstract on which the researcher works.

With respect to data fabrication, the NSF OIG found that two professors and a graduate student acted recklessly to an extent constituting falsification in publishing an article that omitted experimental details and overstated experimental results. The university's investigation found that a research team member had falsified material, but had done so carelessly, and, therefore, did not commit research misconduct. Despite team members' claims that they reviewed raw data, the NSF OIG investigation of laboratory records showed the raw data available actually contradicted the claims made in the article. As a result, the OIG concluded the co-authors recklessly falsified their work in a manner constituting research misconduct, and recommended retraction of the article, a bar of three years for each coauthor as an NSF reviewer, advisor or consultant, and three years of

certifications and assurances for each. *See Semiannual Report to Congress*, National Science Foundation, Office of Inspector General, September 2013.

Regarding plagiarism, the NSF OIG found a pattern of plagiarism in proposals submitted for federal funding by a Principal Investigator at an undisclosed Texas university. While under investigation by the university, the individual admitted to submitting one proposal that included unquoted text copied verbatim from another source, but stated he was under the belief that including a citation, alone, was sufficient to avoid allegations of plagiarism. The university did not find research misconduct, but NSF OIG determined otherwise, noting that citation standards in the individual's research field did not differ from those in other disciplines that require the use of quotations or offsetting. In addition, in the course of conducting its investigation, NSF OIG discovered two additional NSF proposals submitted by the individual that contained significant plagiarism. NSF OIG recommended two years of certifications and assurances from the faculty member, as well as a bar from participation as a reviewer, advisor or consultant to NSF for one year. *See Semiannual Report to Congress*, National Science Foundation, Office of Inspector General, March 2013.

ii. Company executive indicted for fraudulently applying for overlapping Small Business Innovation Research (SBIR) grants.

Ali Kashani and Yang Zhao, executives at San Jose-based research company Atlas Scientific, were indicted in the U.S. District Court for the Northern District of California for wire fraud, conspiracy to commit wire fraud and money laundering. According to the press release issued by the U.S. Attorney's office, Mr. Kashani, the owner and founder of Atlas Scientific, and Ms. Zhao, the company's principal investigator applied for and received multiple Small Business Innovation Research (SBIR) grants with the National Science Foundation (NSF) and the National Aeronautics and Space Administration (NASA). The SBIR program requires a grantee to disclose when he or she submits similar or "essentially equivalent" proposals to another federal agency. The government claims that Mr. Kashani and Ms. Zhao knowingly made "materially false statements" in denying that Atlas Scientific had submitted overlapping SBIR project proposals to multiple agencies. In so doing, the indictment claims, the two created a false impression in violation of the law and defrauded NASA and the NSF out of the $1.2 million in grant money. The prosecution also alleges that Ms. Zhao falsely misrepresented her employment status with the University of California Berkley in grant applications submitted to the government. The matter is still pending in district court. If found guilty, each defendant faces up to 20 years in federal prison for the conspiracy charges and 10 years for the fraud charges, in addition to fines. *See* Department of Justice Press Release, *Defendant Indicted for Defrauding NASA and NSF* (March 29, 2013); *see also* Indictment*, United States v. Kashani and Zhao*, No. 13-00201 (Mar. 27, 2013).

iii. HHS sends strong post-settlement message to research community in case of Dr. Philippe Bois.

In March 2013, the U.S. Department of Health and Human Services (HHS) entered into a settlement agreement with Dr. Philippe Bois, former postdoctoral fellow at St. Jude's Children's Research Hospital. This settlement followed two years of litigation over HHS findings that Dr. Bois engaged in misconduct by falsifying data in support of research funded by the National Institute of General Medical Sciences (NIGMS).

The case dates back to 2011, when ORI concluded that Dr. Bois knowingly and intentionally falsified data he had reported under federally funded research. Dr. Bois denied the misconduct, claiming the mistake was honest error and therefore did not constitute research misconduct, and

immediately took action to try to clear his name. He requested review by the HHS Board of Appeals, but the Administrative Law Judge denied Dr. Bois' request for a hearing, and entered a Debarment Order against him. Dr. Bois then sued in U.S. District Court. In March 2012, the district court judge issued an order vacating HHS' Debarment Order, affirming the HHS Board of Appeals' decision in part, but finding that the dismissal of Dr. Bois's hearing request was arbitrary and capricious as to findings of falsified data in some areas of his research. The court remanded to give Dr. Bois the opportunity for a hearing before the board of appeals. The judge commented that the ruling should "not be read as any sort of exoneration," but that Dr. Bois "must have the opportunity to present his highly factual defense, which may or may not withstand cross-examination and any rebuttal evidence ORI elects to present."

In March 2013, before a hearing could be held before the Board, Dr. Bois and HHS entered into an agreement to dismiss the pending civil action. In the Settlement Agreement, Dr. Bois agreed not to further appeal ORI's findings, but denied that he committed research misconduct. The full terms of settlement and ORI's research misconduct findings were published in the Federal Register.

Dr. Bois commented publicly on ORI's decision to settle, seeing it as a "clear signal" that the court would have found the allegations of misconduct inadequate and that the proposed three-year debarment was unreasonable. Taking issue with how the settlement was characterized in the press, ORI issued a public update in May. Specifically, ORI commented that there was no agreed to statement that Dr. Bois' misconduct was "inadvertent," nor was there a ruling by a judge finding as much. ORI stated it was important to make these corrections, as it was "concerned the scientific community was misinformed about the outcome and significance of this case." *See Update on Philippe Bois Research Misconduct Case*, The Office of Research Integrity, May 21, 2013, *available at* http://ori.hhs.gov/blog/update-philippe-bois-research-misconduct-case .

IV. Regulatory updates in Federally Funded Research and Development

A. SBA releases new size and eligibility restrictions for SBIR and STTR programs.

On January 28, 2013, new Small Business Administration (SBA) regulations went into effect that changed the size and eligibility restrictions that apply to small businesses participating in the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. *See* 77 Fed. Reg. 76,215-27 (Dec. 27, 2012) (codified at 13 C.F.R. pt. 121). The SBA's final rule implemented provisions of the National Defense Authorization Act for Fiscal Year 2012 which allows for a certain percentage of SBIR program funds to be awarded to small business concerns that are majority-owned by multiple venture capital operating companies (VCOCs), hedge funds, or private equity firms. The final rule also amended the SBA affiliation requirements by adding a new section of affiliation rules that apply specifically to SBIR/STTR program participants.

Specifically, the new regulations now allow for a SBIR awardee to be at least 50% owned by multiple VCOCs, hedge funds, and private equity firms (or any combination thereof), so long as no single VCOC, hedge fund, or private equity firm owns more than 50% of the concern. To ensure domestic ownership and control, each VCOC, hedge fund and private equity firm must "have a place of business located in the United States and be created or organized in the United States, or under the law of the United States or of any State." The provision only applies to the SBIR program, thus STTR awardees may not be majority-owned by multiple VCOCs, hedge funds, or private equity firms.

Because the regulations have been relaxed to allow for ownership by multiple investment companies, they have also been amended to allow SBIR and STTR awardees to be majority-owned by more than one small business concern. Prior to the amendment, an awardee must have been a small business concern, which was at least 51% owned and controlled by U.S. citizens, permanent resident aliens, or another small business concern, which in turn was at least 51% owned and controlled by U.S. citizens or permanent resident aliens. Over the years, SBA had interpreted "citizens" to refer to individual human beings, rather than to corporations, effectively preventing multiple levels of corporate ownership. The final rule removes the restriction that only one business concern may be the majority owner of the awardee and allows for multiple business concerns to own and control more than 50% of all eligible SBIR/STTR awardees, as long as those businesses are more than 50% directly owned and controlled by individuals that are U.S. citizens or permanent resident aliens in order to ensure domestic participation in the programs.

With regard to new affiliation rules, most of the affiliation principles that apply to SBIR and STTR participants are identical to those set forth in 13 C.F.R. § 121.103, which generally apply to SBA programs. However, the new rule deviates in a few respects. For example, the new regulations contain a modified version of the rule regarding affiliation based on ownership, which finds affiliation with minority owners controlling 40% or more of the company. The new rule states that a concern will be affiliated with an "individual, concern, or entity that owns or has the power to control more than 50 percent of the concern's voting equity," or with an "individual, concern, or entity that owns or has the power to control 40% or more of the voting equity based upon the totality of the circumstances." This is a departure from the general SBA minority ownership rule which states, "if two or more persons (including any individual, concern or other entity) each owns, controls, or has the power to control less than 50 percent of a concern's voting stock, and such minority holdings are equal or approximately equal in size, and the aggregate of these minority holdings is large as compared with any other stock holding, SBA presumes that each such person controls or has the power to control the concern." In an effort to simplify and clarify the minority ownership rule, the SBA looked to determinations by its Office of Hearings and Appeals ("OHA") and found that it was far more likely to find affiliation with minority shareholders holding 40% or more equity in the business than those who held less, and hence incorporated the 40% threshold into the new regulations.

The final rule also clarifies whether small business concerns that are majority-owned by multiple VCOCs, hedge funds, and private equity firms will be affiliated with portfolio companies of these investment firms. Generally, the answer will be that the concern is not affiliated with the portfolio company simply on the basis that the two entities share investors, even if the VCOC, hedge fund, or private equity firm is affiliated with the concern. However, where a VCOC, hedge fund, or private equity firm is affiliated with the small business concern and it also owns a majority of the portfolio company or holds a majority of seats on the portfolio company's board of directors, then the portfolio company will also be deemed to be affiliated with the concern.

The allowance of venture and investment fund-backed small businesses into SBIR programs will expand the pool of small businesses competing for SBIR awards, and these competitors are likely to have ample resources and well-formulated designs based on their majority ownership. There are eleven federal agencies that participate in the SBIR program, and each may only award a portion of their SBIR funds to venture-backed companies if they so choose. In June 2010, NIH elected to make 25% of its SBIR funding open to small business majority-owned by venture capital firms. Most agencies have yet to follow.

B. OMB releases OMB Super Circular.

On December 19, 2013, the Office of Management and Budget ("OMB") released final guidance on the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, which consolidates and supersedes requirements from all existing OMB circulars. This consolidation has been dubbed the "OMB Super Circular." In an effort to eliminate duplicative language and clarify situations in which policy applies differently to various types of grantees, this newly proposed circular combines eight existing circulars into a single document that applies to all federal grantees. The OMB's stated goal behind the Super Circular is to "reduce administrative burden for non-Federal entities receiving Federal awards while reducing the risk of waste, fraud and abuse." *See* OMB Final Guidance, *available at* https://www.federalregister.gov/articles/2013/12/26/2013-30465/uniform-administrative-requirements-cost-principles-and-audit-requirements-for-federal-awards. The Super Circular regulations are located in Title 2, Chapters I and II of the Code of Federal Regulations.

NIH denies march-in petition to control the price of drugs under Bayh-Dole Act.

The Bayh-Dole Act, (Pub. L. 96-517, Patent and Trademark Act Amendments of 1980) is a statute adopted in 1980 addressing the intellectual property rights that arise from federally funded research. Prior to Bayh-Dole, inventions supported by federal funds were considered the property of the federal government. The Bayh-Dole Act changed the order of property rights, and allowed universities, small businesses or non-profit institutions to pursue ownership of an invention.

One caveat to this preference in ownership rights granted to nongovernmental entities is that the funding agency retains "march-in rights" which permit it to grant licenses to "other reasonable applicants" to use the subject invention. The purpose of these march-in rights is to ensure that taxpayers benefit from government sponsored research. Specifically, an agency can require a contractor to grant additional licenses to third parties if it finds that:

(1) the contractor has failed in a reasonable amount of time to take effective steps to achieve practical application of the subject invention;

(2) a license is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor;

(3) a license is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor; or

(4) a license is necessary to ensure that the invention is substantially manufactured in the United States.

35 U.S.C. § 205.

On October 12, 2012, NIH received a petition from Knowledge Ecology International, the American Medical Students Association, the U.S. Public Interest Research Group, and the Universities Allied for Essential Medicines (the "requestors") to exercise march-in rights with respect to six patents that are owned and used by AbbVie in the manufacture of the drug Norvir. The six patents cover inventions that are directed at the treatment of patients with HIV/AIDS, and were developed with FDA funds. The 2012 petition replicated in substance a previous petition filed by Abbott in 2004 which requested that the agency grant compulsory licenses on grounds that the

significant price increase of Norvir "raised issues of practical application, pricing and health and safety needs." NIH Office of the Director, *Determination in the Case of Norvir Manufactured by AbbVie* (Nov.1, 2013). NIH denied the petition in 2004, determining that "it did not have the information that leads it to believe that the exercise of march-in rights might be warranted…within the meaning of 35 U.S.C. § 203."

On November 1, 2013, consistent with its 2004 ruling, NIH rejected the requestor's march-in petition stating that AbbVie's pricing and policies did not trigger any of the four above-referenced march-in criteria. In its decision, NIH cited the stated policy and objective of the Bayh-Dole Act:

> [T]o use the patent system to promote the utilization of inventions arising from federally supported research or development; …to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government, and protect the public against nonuse or unreasonable use of inventions… (35 U.S.C. § 200).

After considering the facts that Norvir is readily available on the market, it has been approved as safe and effective, and no statutes or regulations require public use for Norvir, NIH found the requestor's petition to fall outside the purpose of the statute. It stated, "[T]he general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH's march-in authorities."

C. NIH Releases New Grants Policy Statement.

In October 2013 NIH released its newest revision of the NIH Grants Policy Statement ("NIHGPS"), which governs all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2013. The revision supersedes, in its entirety, the 2012 NIHGPS, though the 2012 revision still governs NIH grants and cooperative agreements with budget periods that began between October 1, 2013 and September 30, 2013. The 2013 revision does not introduce any new material, but does modify existing policy, clarify terms, and implement various statutory, regulatory and policy changes. A brief summary of relevant changes in the 2013 NIHGPS follows.

- The NIHGSP includes a new Dual Use of Research Concern ("DURC") Policy in Section 4.1.24.4. DURC is research in the life sciences arena that, if misapplied, could pose a threat to public health, safety, plants, animals, environments or national security. The DURC Policy applies to research that involves one or more of fifteen listed pathogens and toxins that are being used in projects with specified experimental aims that may result in research products, technology or information that could be misused to pose particular risks. The Policy requires that Federal agencies continually monitor funded research for dual use research potential. When DURC is identified, Federal agencies are to work with the institutions and investigators conducting the research to develop an appropriate risk mitigation plan. The new policy requires institutions, Project Directors, and Principal Investigators to develop risk mitigation plans. *See also* NIH Notice NOT-0D-13-107.

- Section 6.4 of the NIHGSP implements the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (PL 112-248), signed into law on January 10, 2013, which establishes the Do Not Pay Initiative to reduce improper payments or awards. Improper payments occur when funds go to the wrong recipient, the recipient receives the incorrect amount of funds (including overpayments and underpayments),

documentation is not available to support a payment, or the recipient uses funds in an improper manner. HHS has implemented provisions of IPERIA through integrating use of the Do Not Pay system into the current payment processes managed by the DPM, HHS.

- In order to collect demographic data about the size and nature of the biomedical research workspace, Electronic Research Administration ("eRA") Commons IDs are required for all individuals in graduate or undergraduate student roles who participate in NIH-funded projects for at least one month or more. Research Performance Progress Reports will not be accepted by NIH without this information. Sec. 2.2.1.3. *See also* NIH Notice NOT-OD-13-097.

- Section 4.1.22 of the NIHGPS implements program-specific Terms of Award for all grants funded under the U.S. President's Emergency Plan for AIDs Relief (PEPFAR) program (such as opposition to prostitution and sex trafficking).

- Section 11.3.13.4 of the NIHGPS encourages institutions to assist graduate students and postdoctoral researchers to achieve their career goals within the biomedical research workforce through the use of Individual Development Plans (IDPs). Institutions are encouraged to report on this in all progress reports submitted on/after October 1, 2014, using the Research Performance Progress Report (RPPR). *See also* NIH Notice NOT-OE-13-093. This provision applies to all researchers supported on Institutional Training Grants.

- Section 2.5.1 and 18.5 of the NIHGPS have been amended to reflect the new SBA SBIR/STTR eligibility requirements (discussed supra, section IV.A).

D. Obama Administration Publishes Updates on Transparency Initiatives

In September 2011, the Obama Administration launched the National Action Plan as part of an overall effort to promote openness in Government by increasing transparency, public participation and collaboration. Presidential Document: Memorandum on Transparency and Open Government, 74 Fed. Reg. 4,685 (Jan. 26, 2009); *see also* The Open Government Partnership: National Action Plan for the United States of America (Sept. 20, 2011). The National Action Plan included twenty-six commitments to "help increase public integrity, promote public participation, manage public resources more effectively, and improve public services." One of these commitments was to increase access to the results of scientific research, as the drafters recognized that information available to the government might also be leveraged to assist consumers and aid scientific research. Specifically, the Plan called for developing "Federal guidelines to promote the preservation, accessibility, and interoperability of scientific digital data produced through unclassified research supported wholly or in part by funding from the Federal science agencies." The Open Government Partnership: National Action Plan for the United States of America (Sept. 20, 2011).

In February 2013, the Administration affirmed its commitment to providing citizens with access to the results of research "paid for by their tax dollars." The Office of Science and Technology Policy issued a policy memorandum directing agencies responsible for federally backed research and development expenditures totaling $100 million or more annually to develop rules for the public release of data and research results within a year of publication in a scientific or technical journal. Public access can include storage in agency computers or digital repositories, so long as they are "publicly accessible to search, retrieve, and analyze." The affected agencies, which include the Department of Defense, Department of Agriculture, Department of Commerce, and Department

of Health and Human Services, were instructed to develop draft rules for White House review within six months of the policy memorandum. *See* The Open Government Partnership: Government Self-Assessment Report for the United States of America (March 29, 2013); *see also* The Open Government Partnership: National Action Plan for the United States of America (Sept. 20, 2011).