Attention to research misconduct continues to grow. Recent headlines decry the alleged falsification by a South Korean scientist of DNA testing data regarding embryonic stem cells. In the past year, prestigious institutions, including the Mayo Clinic, Cornell University’s Weill Medical College, and Rush University Medical Center, paid tens of millions of dollars to settle allegations of research fraud. At the same time, the journal *Nature* published a survey finding that one-third of early or mid-career researchers admit to committing some form of research misconduct.\(^1\) Also during the last year, the U.S. Department of Health and Human Services (DHHS) published new rules governing the use of government research dollars; DHHS’s Office of Inspector General (OIG) published draft compliance program guidance for recipients of federal research grants; the U.S. Attorney for the District of Massachusetts brought criminal charges against a study coordinator for making false statements regarding safety efforts; and Congress announced its intention to investigate the misuse of federal research grants.

Assuming that ethically challenged research activity is as prevalent as the *Nature* article suggests, and given the government’s increasing focus to how its research funds are spent, institutions that receive federal grants or that require federal approval to conduct medical research are well advised to evaluate their research programs to verify that they are complying with federal rules. In this process, policies should be carefully reviewed to determine whether seemingly routine practices could lead to charges of research misconduct under the new rules; audit procedures should be analyzed to ensure they are rigorous enough to identify individual misconduct; and employees should be trained in appropriate compliance measures. To that end, this article examines the plethora of recent allegations of research fraud and offers a detailed analysis of the new federal regulations.

I. SEVERAL PROMINENT INSTITUTIONS HAVE SETTLED ALLEGATIONS OF RESEARCH MISCONDUCT

On April 14, 2005, the University of Alabama at Birmingham and two related entities paid $3.39 million to settle allegations that they had violated the False Claims Act with respect to claims submitted in connection with the University’s health research activities. The government and the relators (plaintiffs) in two parallel qui tam lawsuits (one brought by a former research compliance officer for the school and the other by a physician who had previously served on the medical school faculty) alleged that the University had unlawfully billed Medicare for clinical health services provided to patients enrolled in clinical research trials that were also billed to the sponsor of the research trials. The complaints further alleged that in completing applications for federal health science research grants or in drawing down funds on such grounds, the school had overstated the percentage of work effort that the researchers were able to devote to the grants.\(^2\)

In late May 2005, the U.S. Department of Justice (DOJ) announced that the Mayo Foundation (Foundation), the parent organization of the Mayo Clinic, paid the United States $6.5 million to “resolve allegations that it charged the government under federal grants for research costs unrelated to the research projects sponsored by those
The charges and settlement were based on the hundreds of grants the Mayo Clinic receives each year from the National Institutes of Health (NIH) and other federal agencies. DOJ and a whistleblower had accused the Foundation of applying funds from grants in which the project was under-budget to projects that had run over-budget and, as a result, obtaining more money from the government than the amount to which the Foundation was entitled. DOJ stated that “[t]he government’s investigation showed not only improperly transferred expenses, but also that Mayo had an accounting system unable to monitor and manage charges made to federal grant awards in the manner required by federal law.”

Nearly one month later, Cornell University agreed to pay over $4.3 million to the government to resolve allegations of research fraud. A professor in the University’s school of medicine accused her superiors of using funds from a $23 million NIH grant to pay the salaries of nurses who also treated non-research patients in New York-Presbyterian Hospital’s pediatric wing. The professor also accused the hospital and the school of listing in its grant application “phantom nurses” who supposedly were employed by the hospital, misstating the number of hospital days that research subjects would require, and improperly concentrating control of NIH grants in a few members of the faculty.

Cornell’s settlement is particularly noteworthy because one of the central accusations—shifting study funds to cover other hospital operations when the study’s expenses are under-budget—is thought to occur routinely. Indeed, the Mayo Clinic faced similar charges, and Brian Martinson, one of the authors of the Nature article discussed above, noted that scientists frequently re-allocate funds from over-funded to under-funded projects. This practice reportedly is viewed by many as proper because it ensures efficient use of limited resources, without causing harm to any individual or project. Thus, for example, nurses hired for a research project who have extra time may be sent to other areas of the hospital requiring extra assistance. Martinson speculates that few institutions, if any, actually return excess grant funds to the government as required.

Individuals, too, have been charged with research fraud. In March 2005, federal prosecutors reached a plea agreement with a former tenured professor of medicine at the University of Vermont College of Medicine who had been accused of using false and fabricated research data to obtain $2.9 million in research funding from NIH and the U.S. Department of Agriculture. The researcher pled guilty to one count of making a material false statement in connection with preparing, signing, and submitting a $542,000 grant application to NIH. In addition, the researcher agreed to pay $180,000 to settle a civil complaint relating to numerous false grant applications filed while at the University of Vermont. He also agreed to be barred for life from seeking or receiving any federal funding, to submit letters of retraction and correction to various scientific journals that had published his false data, to be permanently excluded from participation in all federal healthcare programs, and to pay $16,000 in attorneys’ fees to the former research assistant who reported him.

In May 2005, the Food and Drug Administration (FDA) and the U.S. Attorney for the District of Massachusetts charged Anne Butkovitz, a clinical study coordinator, with making false statements regarding follow-up safety calls to human subjects enrolled in a recent study. According to the Information (the charging document), the researcher was responsible for contacting the parents of children taking an experimental vaccine to inquire about “serious adverse experiences” (SAEs). The government alleged that the coordinator never made these contacts but instead falsified records to indicate that contact had been made and that no SAEs had been reported. The U.S. Attorney reported that if Ms. Butkovitz is convicted, she could be imprisoned for five years, serve three years of supervised release, and pay a $250,000 fine.

Interestingly, institutions have begun to self-report research misconduct in the hope of minimizing eventual repercussions. For example, the Massachusetts Institute of Technology announced in October that, following an internal investigation, it had dismissed a professor who fabricated and falsified data. The University also intended to seek the retraction of the professor’s discredited publication and to forward a copy of the University’s findings to the federal government’s Office of Research Integrity for further review. Similarly, Rush University Medical Center voluntarily disclosed “billing errors” relating to federal reimbursement for Medicare patients involved in the University’s clinical studies. The disclosure was made to the U.S. Attorney’s Office for the Northern District of Illinois in 2003. After the government investigated, but before formal charges were brought, the University agreed to pay approximately $1 million to settle the matter. The OIG decided not to ask for a Corporate Integrity Agreement but the University did commit to certifying its compliance program for the next three years.

II. NEW DHHS RULES GOVERNING RESEARCH MISCONDUCT

The many incidents of research fraud discussed above reflect increased government interest in research integrity.
On May 17, 2005, DHHS published its “Public Health Service Policies on Research Misconduct” (hereafter “Research Misconduct Rules” or “Rules”) that became effective June 16, 2005. The new regulations establish a comprehensive mechanism for investigating and punishing research misconduct, with much of the responsibility for identifying, investigating, and reporting allegations of such misconduct placed squarely on the institutions that receive federal grant funds. The confluence of recent enforcement action and the publication of the expansive research misconduct regulations suggest that research fraud will be a fertile area for government prosecutors in the time to come.

Briefly summarized, the Research Misconduct Rules, which remove 42 C.F.R. §§ 50.101-50.105 and add a new Part 93, require entities that receive research funds from the Public Health Service (PHS) to:

1. Develop and implement policies and procedures to investigate allegations of research misconduct; and
2. Report to the Office of Research Integrity (ORI) the results of its investigation.

Based on the information it receives from the institution, DHHS can undertake administrative action against the subject researcher or the institution or both. The regulations make clear that adverse administrative action is in addition to and not in lieu of other enforcement action that may be available. The regulations authorize ORI to cooperate with other enforcement agencies, including the DHHS OIG and the DOJ.

In the preamble to the regulations, DHHS acknowledges it has received criticism that the Research Misconduct Rules continue a trend toward legalization of scientific disputes by immediately casting parties into adversarial roles (70 Fed. Reg. 28370). The more realistic view may be that when public money is in play, the government can do what it believes it needs to do to protect the public fisc. In the case of biomedical and behavioral research and research involving federal funds, the Research Misconduct Rules establish that entities receiving PHS funds have an affirmative duty to ensure the integrity of government-funded research and have primary responsibility for promptly responding to and reporting allegations of research misconduct.

A. Scope and Definitions

Under the new Part 93, any institution that applies for or receives PHS support for biomedical research, research training, or activities related to that research or research training must comply with the Research Misconduct Rules. Colleges and universities, research and development centers, national user facilities, industrial laboratories or other research institutes, small research institutions, and independent researchers that have obtained PHS funding or submitted applications or proposals for such funding are all “institutions” subject to the Research Misconduct Rules. Because of the reach of the PHS itself and the amount of biomedical and behavioral research it supports, a very substantial part of all government-funded medical research will be subject to the Rules.

New 42 C.F.R. § 93.103 defines broadly the term “research misconduct.” For purposes of the regulations, research misconduct means fabrication, falsification, or plagiarism. If research or in reporting research results. Fabrication 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. Research misconduct does not include honest error or differences of opinion.

A finding of research misconduct requires that there be a “significant departure” from accepted practices of the relevant research community. Importantly, it also requires that the misconduct be committed intentionally, knowingly, or recklessly. 42 C.F.R. § 93.104.

The destruction, absence of, or failure to provide research records adequately documenting the questioned research will be deemed evidence of research misconduct, if it can be shown that the subject researcher (a) intentionally, knowingly, or recklessly had research records and destroyed them; (b) had the opportunity to maintain the records but did not do so; or (c) maintained the records and failed to produce them in a timely manner. In each such instance, the conduct must reflect significant departure from accepted practices of the relevant research community. 42 C.F.R. § 93.106(b)(1).

The Rules establish certain evidentiary standards. For example, an allegation of misconduct must be proven by a preponderance of the evidence. 42 C.F.R. § 93.104. Depending upon whether the matter is at the institution investigation stage or the administrative action stage, the burden of proving research misconduct is on the institution or DHHS, respectively. 42 C.F.R. § 93.106(b)(1) and (2).

The Research Misconduct Rules will apply to research misconduct occurring within six years of the date DHHS
or the institution receives an allegation of misconduct. The six-year limitation does not apply where the alleged misconduct could possibly have a substantial adverse effect on the health or safety of the public. 42 C.F.R. § 93.105(b)(2). Allegations received by DHHS or an institution before June 16, 2005 are not subject to the Rules. 42 C.F.R. § 93.105(b)(3).

Importantly, the Research Misconduct Rules are in addition to and do not supplant other existing law and regulation governing the handling of fiscal improprieties, the ethical treatment of human research subjects, criminal matters, or other actions that can be taken under DHHS debarment and suspension regulations. The Rules also do not prohibit or otherwise limit how institutions handle allegations of misconduct that do not fall within the regulatory definition of research misconduct or that do not involve PHS support. 42 C.F.R. § 93.102(c), (d).

B. Responsibilities of Institutions

The regulations require institutions that receive PHS support for biomedical or behavior research or research training to assume the following obligations, many of which reflect elements of OIG Compliance Program Guidance for providers and manufacturers in other areas:

- Have written policies and procedures for inquiring into and investigating research misconduct that meet the requirements of Part 93.
- Respond to each allegation of research misconduct for which the institution is responsible in a thorough, competent, and fair way. This includes taking precautions to ensure that those responsible for carrying out the research misconduct proceedings do not have an improper bias or conflict of interest.
- Foster a research environment that promotes the responsible conduct of research, discourages research misconduct, and deals with allegations or evidence of misconduct in a prompt and timely way.
- Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses, and hearing committee members and protect them from retaliation.
- Maintain confidentiality as required by 42 C.F.R. § 93.108 for all respondents, complainants, and research subjects identifiable from the research records. Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited to those who need to know, consistent with fair hearing proceedings.
- Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings.
- Cooperate with DHHS during any research misconduct proceedings or compliance review.
- Assist in administering any DHHS administrative actions imposed on institutional members.
- Have an active assurance of compliance.

1. Compliance and Assurances

An institution with PHS-supported research must provide PHS with an assurance of compliance with new Part 93. PHS funding for biomedical and behavioral research, research training, or activities related to that research or research training will only be awarded to institutions that have approved assurances and required renewals on file with ORI.

The written assurance submitted on behalf of the institution by the responsible institutional official must assure: (1) that the institution has written policies and procedures for inquiring into and investigating research misconduct; and (2) that the institution complies with these policies and procedures as well as with the requirements of Part 93. 42 C.F.R. § 93.301. Institutions will also be required to file annual reports with ORI regarding their compliance with its assurances.

2. Institutional Policies and Procedures

In order to obtain an approved assurance, institutions must have written policies and procedures that address the inquiry into, and investigation and institutional resolution of, research misconduct. The policies and procedures must conform to the standards articulated in Part 93.

At a minimum, the policies and procedures must: provide for necessary confidentiality; secure a fair hearing for the affected individuals; provide for protection and custody of the evidentiary record; assure timely prosecution and completion; take reasonable measures to protect from actual or potential retaliation good faith complainants, witnesses, and those participating in the review process; provide for interim institutional action if necessary to protect public health, federal funds, and the integrity of the research process; and assure necessary notice, communication, and cooperation with ORI. 42 C.F.R. § 93.304.

To deal with the eventuality that an individual may be wrongly accused of research misconduct, the policies must incorporate reasonable measures to protect and restore
the individual’s reputation—not a simple or easy task, to be sure. 42 C.F.R. § 93.304(k). The policies must also provide for “full and continuing cooperation with ORI” during its oversight review and any subsequent administrative hearings.

If an institution is too small to handle research misconduct proceedings, it may file a “Small Organization Statement” with ORI in place of the formal institutional policies and procedures required by the regulations. By submitting a Small Organization Statement, the institution agrees to report all allegations of misconduct to ORI. ORI or another DHHS office would then work with the institution to implement a process for handling allegations of misconduct.

a. Duty to Inquire

The point of the required policies and procedures is to require institutions to articulate a mechanism for inquiry and investigation that will result in a meaningful assessment of whether research misconduct has occurred. Because the institution is required to notify ORI of an investigation and provide the results of the investigation to the agency, the policies also serve to create a road map upon which DHHS or other government agencies may base later enforcement action.

The initial step in the research misconduct process is the inquiry. An institution must initiate an inquiry upon receipt of an allegation that is “sufficiently credible and specific so that potential evidence of research misconduct may be identified.” 42 C.F.R. § 93.307 (a). The institution must notify the subject of the inquiry that it is embarking on the inquiry. It must also promptly take all reasonable and practical steps to obtain custody of all research records, inventory the records and the evidence, and “sequester them in a secure manner.”

The purpose of the inquiry is to conduct an initial review of the evidence to determine whether an investigation should be conducted. An investigation will be warranted if:

• There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct;
• The research involves PHS-supported biomedical or behavioral research, research training, or activities related to that research or research training; and
• Preliminary information-gathering indicates that the allegation may have substance.

Upon completion of the inquiry, the institution must prepare a written report that includes the name and position of the subject (referred to in the regulations as the “respondent”), a description of the allegation of research misconduct, the nature of PHS support (including grant numbers if applicable), and the basis for recommending that the alleged actions warrant investigation. The subject of the report must be given an opportunity to review and comment on the inquiry report.

The institution must complete the inquiry within sixty calendar days of its initiation. The report and the attached comments of the respondent must be provided to ORI within thirty days of finding that an investigation is warranted.

If the institution determines that an investigation is not warranted, it must keep sufficiently detailed records of the inquiry to permit a later assessment by ORI of the reasons that the institution decided not to conduct the investigation. These records must be maintained for seven years.

b. Duty to Investigate

An investigation must be initiated within thirty days after an inquiry determines that it is warranted. The institution must notify the respondent in writing of the allegations before the investigation begins.

The regulations charge the institution with ensuring a “fair” investigation—a broadly stated requirement. Under the regulations, this includes the participation of persons with appropriate expertise who do not have financial or personal conflicts with those involved. The complainant, the respondent, and any other person identified as having relevant information must be interviewed, and the results of every interview must be recorded and transcribed. The institution is required to pursue all leads.

Following completion of its investigation, the institution must prepare a written report, giving the respondent a copy of the draft report and an opportunity to respond to it. The final report must be provided to ORI and include:

• A description of the allegations;
• A description of the PHS support, including grant numbers, applications, and contracts;
• A copy of the institutional policies and procedures under which the investigation was conducted;
• Identification and summary of the research records and evidence reviewed;
• For each separate allegation of research misconduct, a finding as to whether misconduct did or did not occur, and if so, (a) whether the research misconduct
involved falsification, fabrication, or plagiarism and whether it was knowing, intentional, or in reckless disregard; (b) a summary of the facts and analysis that support the conclusion and consideration of the merits of any reasonable explanation by the respondent; (c) identification of specific PHS support; (d) identification of any publications that need correction or retraction; (e) identification of the persons responsible for the misconduct; and (f) a list of any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies; and

- Inclusion and consideration of any comments made by the respondent.

The institution must maintain and provide to ORI upon request all relevant research records and the records of the proceeding. The institution must also provide ORI with information regarding the institution’s final action in the matter, indicating whether the institution accepts the findings of the investigation and describing any pending or completed administrative actions imposed by the institution. All aspects of the investigation, including preparation of and transmittal of the final report to ORI, and completion of internal institutional appeals procedures must be accomplished within 120 days. 42 C.F.R. §§ 93.311; 93.314.

An institution’s failure to comply with its responsibilities for dealing with research misconduct under Part 93 may result in enforcement action against the institution. Penalties for institutional non-compliance may range from issuing a letter of reprimand to debarring or suspending the entity. Findings of institutional noncompliance and DHHS action in response to such noncompliance may be made public. 42 C.F.R. § 93.413.

It is important to note that, unlike peer review proceedings in the usual medical context, those involved in the misconduct proceedings as fact finders, experts, witnesses, and participants do not have immunity from personal liability for their actions. In the preamble to the regulations, DHHS observes that there is no statutory basis for such immunity, and it encourages interested parties to submit evidence as to whether there is a need for federal legislation to provide such protection. 70 Fed. Reg. 28380.

C. ORI Investigation and Final DHHS Action

ORI has broad authority to review allegations of research misconduct, before, during, or after an institution’s response to the matter. 42 C.F.R. § 93.400. It may conduct its own assessment of research misconduct allegations (42 C.F.R. § 93.402) or review institutional proceedings (42 C.F.R. § 93.403).

After completing its review, ORI may close a case without finding research misconduct, or obtain DHHS approval for the imposition of administrative action or settlement. 42 C.F.R. § 93.404. If ORI determines that a criminal or civil fraud violation may have occurred, it must refer the matter promptly to the DOJ, the OIG, or other appropriate enforcement agency. When such referral occurs, ORI may provide expertise and assistance to the investigative agency. ORI may also notify PHS funding components so that these agencies can make “appropriate interim responses” to conserve public funds. 42 C.F.R. § 93.401(b).

ORI can recommend to DHHS a wide variety of administrative actions and/or sanctions, including:

- Clarification, correction, or retraction of the research record;
- Letters of reprimand;
- Imposition of special certification or assurance requirements to ensure compliance with applicable regulations or PHS grant or contract terms;
- Suspension or termination of a PHS grant, contract, or cooperative agreement, or restrictions on specific activities or expenditures under an active PHS grant, contract, or cooperative agreement;
- Special review of all requests for PHS funding;
- Imposition of supervision requirements;
- Certification of attribution or authenticity in all requests for support from PHS;
- No participation in any advisory capacity to PHS;
- Adverse personnel action if the respondent is a federal employee;
- Suspension or debarment; and
- Recovery of PHS funds.

In determining the administrative action to be imposed, DHHS may consider aggravating or mitigating factors. These include whether the conduct was knowing, intentional, and reckless, whether the misconduct constituted an isolated event or reflected a pattern of conduct, whether the misconduct had a significant impact, whether the respondent accepted responsibility, and other relevant factors. 42 C.F.R. § 93.408.

ORI must give a respondent written notice of its finding of research misconduct and intent to impose administrative action in the form of a charge letter. In the case of a recommendation for debarment or suspension, the DHHS debarring official will issue a notice of proposed debarment or suspension as part of the charge letter.
D. Opportunity to Contest Adverse ORI Findings

Individuals and entities may contest ORI findings of research misconduct and DHHS administrative action by requesting an administrative hearing before an administrative law judge (ALJ) affiliated with the DHHS Departmental Appeals Board. The administrative hearing procedures are quite detailed, however, and failure to observe technical and substantive filing requirements may result in dismissal of the matter.

For example, the regulations require that there be a genuine dispute over facts material to the findings of research misconduct or proposed administrative action before a hearing will be permitted. A hearing request must specifically deny each finding of research misconduct in the charge letter, each basis for the finding, and each DHHS administrative action in the charge letter, or it will be considered an admission by the respondent. 42 C.F.R. § 93.503(b). If the hearing request does not specifically dispute the DHHS administrative action, it will be considered accepted by the respondent. The ALJ may only grant a hearing request if the ALJ determines that there is a genuine dispute over facts material to the findings of research misconduct or proposed administrative action. A general denial or assertion of error will not be sufficient to establish a genuine dispute 42 C.F.R. § 93.503(b).

The regulations permit the ALJ to retain one or more persons with scientific or technical expertise to assist the ALJ in evaluating scientific or technical issues related to the misconduct. The expert’s advice to the ALJ will be provided in the form of a written report that will be served on the parties who may respond to the report. Both the report and the response will be made part of the record.

The ALJ hearing is intended to provide an independent de novo review of the ORI findings of research misconduct and the proposed DHHS administrative action. The burden of proof is on ORI, which must establish by a preponderance of the evidence that research misconduct occurred. ORI also bears the burden of proving that the proposed DHHS administrative action is reasonable under the circumstances of the case.

III. OIG INVOLVEMENT

Reacting to the many incidents of research fraud that made news in 2005, House Energy and Commerce Committee Chairman Joe Barton (R-TX) requested that the DHHS Inspector General examine the use of NIH research dollars and audit some of the largest grants to determine if there had been misconduct or waste.20 According to Chairman Barton, “[t]he alleged misuse of NIH grant funds raises serious public policy concerns of waste, effectiveness, and integrity of taxpayer supported research programs.”21

Perhaps responding to Chairman Barton’s request, the OIG in late November published draft compliance program guidance for recipients of PHS grants.22 The Draft Guidance, which was modeled on other OIG compliance guidance publications, discussed “Risk Areas” for institutions receiving federal research dollars and the elements of a robust compliance program. The OIG stated that while not mandatory, institutions that follow the Draft Guidance are likely to identify problems earlier, thereby reducing the possibility of government audits or investigations.23 The OIG’s publication marked the first time that Compliance Guidance had been issued to address non-Medicare or Medicaid issues.

The three Risk Areas identified were (1) “Time and Effort Reporting,” (2) “Properly Allocating Charges to Award Projects,” and (3) “Reporting Financial Support From Other Sources.”24 In the first area, the OIG acknowledged that researchers often have several responsibilities and perform many tasks for their institutions each day, including teaching, performing administrative tasks, and conducting clinical work. According to the OIG, the multiple tasks require that time be accounted for carefully. For example, “it would be clearly improper for researchers in award applications to separately report to three awarding agencies that they intend to spend 50 percent of their time on each of the three awards.”25 In the second area, the OIG noted the importance of properly accounting for funds from multiple sources. According to the OIG, researchers must not allocate funds from one project to another or “bank” funds for later work.26 Finally, when describing the third Risk Area, the OIG wrote that researchers and institutions must accurately report all sources of funding to assure that grant-awarding divisions of the government can effectively allocate limited resources.27 According to the OIG, hiding sources of financing, whether intentionally or accidentally, can lead to criminal or civil fraud investigations.28 In a related observation, the OIG noted that this Risk Area could be implicated by “charging . . . both award funds and Medicare [or] other health care insurers for performing the same services.”
The OIG used the Draft Guidance to review the seven elements that “have been widely recognized as fundamental to an effective compliance program.” These elements include: “(a) Implementing written policies and procedures, (b) Designating a compliance officer and compliance committee, (c) Conducting effective training and education, (d) Developing effective lines of communication, (e) Conducting internal monitoring and auditing, (f) Enforcing standards through well-publicized disciplinary guidelines, [and] (g) Responding promptly to detected problems and undertaking corrective action.” Additionally, the OIG identified an eighth element that, while not discussed in earlier compliance guidance publications, is “especially important to research institutions.” That element is “defining roles and responsibilities and assigning oversight responsibility.” While the OIG acknowledges “there is no single ‘best’ compliance program,” these elements are intended to serve as a “voluntary . . . checklist of items” it believes are fundamental to a successful program.

IV. CONCLUSION

In light of the Commerce Committee’s, DHHS’, and the OIG’s growing interest in research fraud, a national focus on the proper use of research grants will continue.

END NOTES

4 Id.
8 Id.
9 Id.
10 Id.
12 Information, United States v. Bathurst, Case No. 05-CR-10128-DBW (D. Mass.)
13 Id.
15 See Press Release, Massachusetts Institute of Technology, MIT Professor Dismissed for Research Misconduct (Oct. 27, 2005).
16 See Press Release, Rush University Medical Center, Rush Settlement with Government May Help Clarify Billing Requirements for Medicare Patients in Research Studies (Dec. 9, 2005).

Additionally, because the new regulatory scheme puts primary responsibility for responding to allegations of research misconduct directly on the institutions themselves, there should be little doubt that the number of inquiries and investigations will increase. Indeed, as complainants realize that—dedication to research integrity notwithstanding—they may benefit financially from federal whistleblower statutes, including the False Claims Act, that coexist with the Research Misconduct Rules, the level of investigative activity may skyrocket.

Institutions receiving PHS research funds should begin as soon as possible evaluating whether existing policies and procedures conform to the new requirements. If need be, new policies should be drafted, and training on their terms should be conducted. In a legal environment where compliance officers can report their employers and benefit handsomely from it, greed and ethics can conflict. Adherence to the Rules and the Draft Guidance will protect not only PHS funds but also the researchers and institutions that receive them.

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