Report on
RESEARCH COMPLIANCE

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News and Analysis for Colleges, Universities, AMCs and Other Non-Federal Entities

Contents

HCCA

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After Paying HHS $1.45M, UNLV Enhances Award Oversight; OIG Touts Self-Disclosure

Nearly four years after noticing spending "irregularities" by a principal investigator (PI), the University of Nevada Las Vegas (UNLV) entered into a settlement agreement[1] with the HHS Office of Inspector General (OIG), refunding $1.07 million and paying a penalty of almost $400,000.[2] The four awards at issue—three from NIH and one from the Health Resources and Services Administration (HRSA)—totaled $5.7 million.

For UNLV, the experience led to the adoption of new policies and procedures, while OIG officials told *RRC* the case demonstrates the value of the agency's self-disclosure program.

According to the settlement, subaward payments under the three NIH awards "were unallowable either because they were made to organizations without sufficient documentation of whether the activities were for the performance of the awards, or because they were made to entities with which the PI had an undisclosed conflict of interest."

OIG added that the "awards were improperly charged for the salary and fringe benefits of the PI without adequate documentation, and for the travel and associated costs of at least two trips to Nigeria that were unallowable because there was no evidence that the trip was in furtherance of the NIH-funded research."

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Bills Boosting NSF Funding Spark Concern As Congress Takes Aim at Foreign Threats

Members of Congress from both parties are rallying around bills that would boost funding for the National Science Foundation (NSF), but they also contain provisions designed to shore up federally funded research from foreign interference that some say go too far. Advocates hope these provisions can be revised before coming to a full vote.

At the core of the legislative effort is S. 1260, the Endless Frontier Act,[1] which would create a new Directorate for Technology and Innovation at NSF, with a five-year appropriation of $100 billion. First introduced in the last session of Congress, a new, 160-page version was announced April 21 by Senate Majority Leader Chuck Schumer, D-New York. However, a fairly unusual process has proceeded because Schumer in February "directed the chairs and members of our relevant committees to start drafting a legislative package to outcompete China and create new American jobs," with the Endless Frontiers Act as the "centerpiece."[2]

Of immediate interest is a version more than twice as long as the base bill, which passed the Senate Commerce, Science, and Transportation Committee on May 12.[3] It would broaden the requirement for institutions applying for NSF funding to include in their applications a plan for providing responsible conduct of research (RCR) training to "faculty and other senior personnel." NSF has had an RCR training requirement since 2007, but it has only applied to students and post-doctoral researchers working on a project.

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Additionally, "training and mentorship" would have to "raise awareness of potential security threats and of Federal export control, disclosure, and reporting requirements."

The bill also calls for NSF to establish a $5 million Research Security and Policy Office, to be headed by a chief of research security. In March 2020, NSF appointed Rebecca Spyke Keiser to a new position of chief of research security strategy.

Nonbanned Talent Programs Face Scrutiny

Although mostly related to NSF, the bill has wider implications across federal agencies. For example, the bill requires the Office of Science and Technology Policy (OSTP), within 180 days of it becoming law, to "publish and widely distribute a uniform set of guidelines for Federal science agencies regarding foreign government talent recruitment programs."

These guidelines would then flow down to agencies for them to use in issuing their own policies on foreign talent programs. OSTP's new guidelines under the bill would "prohibit awards from being made for any proposal in which the principal investigator…or co-principal investigator is participating in a foreign government talent recruitment program" run by China, North Korea, the Russian Federation or Iran, and, "to the extent practicable, require institutions receiving funding to prohibit awards from being used by any individuals participating in a foreign government talent recruitment program" operated by these four nations.

However, the policies might affect talent recruitment programs not based in China, North Korea, Russia or Iran. If a principal or co-principal investigator applying for funding "discloses membership" in a talent program other than from one of the four, the institution must "ensure, to the maximum extent practicable, that the contract conforms with the Federal science agency's guidance on conflicts of interest, including those contained in relevant contract proposal and award policies and procedures."

Further, institutional officials would be required to send contracts for talent programs from other countries to the awarding agency for review, and the agency may "prohibit funding to the awardee if the obligations in the contract interfere with the capacity for activities receiving support to be carried out, or create duplication with Federally supported activities."

Tobin Smith, vice president for policy at the Association of American Universities, told *RRC* AAU would like to see foreign talent programs other than those from the four named countries be defined "as narrowly as possible," noting that not all "have ill intent."

Clearinghouse a 'Positive Step'

One provision AAU supports requires OSTP to contract with a "qualified independent organization" to create a "research security and integrity information sharing analysis organization," or RSI-ISAO, to "serve as a clearinghouse for information to help enable the members and other entities in the research community to understand the context of their research and identify improper or illegal efforts by foreign entities to obtain research results, know how, materials, and intellectual property."

The RSI-ISAO also would:

- "Develop a set of standard risk assessment frameworks and best practices, relevant to the research community, to assess research security risks in different contexts;
- "Share information concerning security threats and lessons learned from protection and response efforts through forums and other forms of communication;
- "Provide timely reports on research security risks to provide situational awareness tailored to the research and education community;
- "Provide training and support, including through webinars, for relevant faculty and staff employed by institutions of higher education on topics relevant to research security risks and response;

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- "Enable standardized information gathering and data compilation, storage, and analysis for compiled incident reports;
- "Support analysis of patterns of risk and identification of bad actors and enhance the ability of members to prevent and respond to research security risks; and
- "Take other appropriate steps to enhance research security."

AAU, Smith said, considers the creation of the ISAO "a very positive step forward to help universities as they seek to assess the risks involved in foreign partnerships."

This version is sponsored by Sen. Maria Cantwell, D-Washington, who chairs the commerce committee. After passage, Schumer thanked committee members for "working in a bipartisan fashion," and emphasized he expected the Senate to consider the bill before the end of May.

Shift From OSTP to OMB Opposed

A competing bill to the Endless Frontiers Act that may be appended to a final version is S. 1351, the Safeguarding American Innovation Act, which passed the Senate Homeland Security and Government Affairs (HSGA) Committee on May 12.[4]

S. 1351 was reintroduced from the previous session of Congress, and organizations such as AAU have the same concerns, Smith told *RRC.*

The bill would establish a Federal Research Security Council within the Office of Management and Budget (OMB) to "develop federally funded research and development grant making policy and management guidance to protect the national and economic security interests of the United States."

This would essentially move the functions of the National Science and Technology Council (NSTC), which coordinates science policy throughout the government, along with the council's Joint Committee on the Research Environment (JCORE) functions, from OSTP to OMB. While this could appear to be more of an administrative change, it would broaden OMB's purview and authority into science, research and security policy areas.

JCORE was created in 2019 as the result of the fiscal year 2020 National Defense Authorization Act. "We note that OMB is represented on, and actively participates in the existing JCORE Research Security Subcommittee," officials from AAU, the Association of American Medical Colleges, the Association of Public and Land-grant Universities, and the American Council on Education wrote in a July letter to HSGA committee leaders.[5]

"We believe OSTP and the NSTC remain the appropriate bodies for these complicated issues," and the proposed change could give "OMB excessive authority to set and 'implement' policy on an unlimited range of security issues, depriving universities and other organizations the normal remedies for informing and, when necessary, challenging federal policies," they said.

Proposed Visa Changes a Worry

The organizations also expressed concerns about changes to visa programs contained in section 5, which the groups said last year give "the U.S. Department of State unfettered authority to define the rules and could potentially bar foreign student and scholar visa applicants simply because of their nationality and/or chosen course of study." They asked that the bill "more clearly delineate the specific parameters by which the State Department can choose to deny visas to foreign visitors and should not undo longstanding federal policies on fundamental research."

Additionally, proposed changes to reporting requirements for foreign gifts and contracts under Section 117 of the Higher Education Act are likely to "add excessive burdens and limited benefits"; in particular, the reporting threshold would be reduced from $250,000 to $50,000.

In an announcement praising committee passage, Sens. Tom Carper, D-Delaware, and Rob Portman, R-Ohio, said the bill would punish "individuals who intentionally fail to disclose foreign support on federal grant applications, with penalties ranging from fines and imprisonment for not more than five years or both and a five-year prohibition on receiving a federal grant."[6]

According to the sponsors, other provisions include "mandating a standardized U.S. government grant process" by authorizing OMB "to work with federal grant-making agencies to standardize the grant application process; share information about grantees; and create a U.S. government-wide database of federal grantees."

Strategic Competition Act Also a Concern

Another bill gaining attention is S. 1169, the Strategic Competition Act, which also contains new requirements related to gifts from foreign sources.[7] The bill passed the Senate Foreign Relations Committee on April 21 with a provision intact that AAU and the other organizations had sought to change.

Section 138 of the bill would "expand the scope of the current Committee on Foreign Investment in the United States (CFIUS) reviews to include certain gifts and contracts between universities in the United States and foreign entities and individuals," as AAU described on its website.[8]

This section "would only make it harder for our institutions to carry out important and groundbreaking research," the groups wrote in an April 20 letter to House committee leaders.[9] "The proposed expansion of CFIUS's role would damage U.S. research and our economic competitiveness," and Section 138 "is a sweeping provision that would require expensive and time-consuming reviews of a wide range of university gifts and contracts against unknown and ill-defined criteria by an agency not designed or equipped to carry out this task."

AAU's Smith said organizations are "engaging" with Senate staff to see if changes can be made. "We are still greatly concerned and do not feel CFIUS is the right vehicle to address the concerns they are trying to address. It was intended for a different purpose," he said.

The House has its own set of bills on NSF funding and research security, but advocacy groups believe the Endless Frontiers Act currently has more momentum. ✧

Endnotes

1. Endless Frontier Act, S. 1260, 117 Cong. (2021), https://bit.ly/3oowg0z.
2. Senate Democrats, "TRANSCRIPT: Schumer Directs Senate Committees To Craft Legislation To Strengthen U.S. Semiconductor Industry, To Protect American Jobs And Outcompete China," news release, February 23, 2021, https://bit.ly/3w5cJoz.
3. Endless Frontier Act, S. 1260, 117 Cong. (2021), as reported by U.S. Senate Committee on Commerce, Science and Transportation, May 12, 2021, https://bit.ly/3fjFRld.
4. Safeguarding American Innovation Act, S. 1351, 117 Cong. (2021), https://bit.ly/3ofmXQD.
5. Mary Sue Coleman, Peter McPherson, David J. Skorton, and Ted Mitchell, letter to Ron Johnson and Gary Peters, July 20, 2020, https://bit.ly/3hnJXLO.
6. Homeland Security and Government Affairs, "Portman, Carper, Rubio Applaud Committee Passage of Bipartisan Safeguarding American Innovation Act to Stop Theft of U.S. Research & Intellectual Property by Global Competitors," news release, May 12, 2021, https://bit.ly/2RnkG9M.
7. Strategic Competition Act, S. 1169, 117 Cong. (2021), https://bit.ly/3brNCnW.
8. Association of American Universities, *AAU Weekly Wrap-up*, April 23, 2021, https://bit.ly/33RaIQI.
9. Barbara R. Snyder, Peter McPherson, Ted Mitchell, and David J. Skorton, letter to Bob Menendez and James E. Risch, April 20, 2021, https://bit.ly/33Halbh.

SACHRP: Thorny Sponsor Interactions With Subjects Require Approval, Oversight

Under the leadership of new chair Douglas Diekema, M.D., the Secretary's Advisory Committee on Human Research Protections (SACHRP) has forwarded its first recommendations of 2021 to new HHS Secretary Xavier Becerra. These address the need for institutional review boards (IRBs) and institutions to play a greater role in overseeing—and perhaps halting—certain activities by study sponsors that involve research subjects.[1]

Additionally, members weighed in on IRBs' authority to restrict data that result from research that in some way violates the HHS Common Rule or Food and Drug Administration (FDA) requirements (these recommendations will be addressed in a subsequent issue of *RRC*).[2]

The sponsor recommendations were drafted by SACHRP's Harmonization Subcommittee, led by Mark Barnes, partner with Ropes & Gray LLP, and David Forster, chief compliance officer for WIRB-Copernicus Group. SACHRP approved the recommendations at its March 23-24 meeting,[3] and they were recently posted to the website of the Office for Human Research Protections (OHRP).

The past several years have seen "an increasing relationship in both intensity and frequency between sponsors of research on the one hand and the research subjects and research subject families and disease advocacy groups on the other," Barnes explained at the meeting, "and this has led to a number of questions about…what is the appropriate role of a sponsor, either an industry sponsor or academic medical sponsor, in the course of interventional clinical research with living, breathing subjects."

The purposes of the recommendations are to "assess what the current problems are now that our researchers, IRBs and subjects and others have run into…and identify some of the issues that have arisen, but also to look at articulating some principles that we hope ultimately could find their way into guidance documents either at the FDA, at OHRP [or] at other agencies that fund and sponsor clinical research," he added.

According to descriptions of such instances included in the recommendations, which Barnes said are based on "sanitized, real-life examples," subjects enrolled in ongoing gene therapy studies who have shown improvement have been asked to publicly discuss their experiences in interviews "for philanthropic, fund-raising" purposes "and to entice others to be screened for the study."

Close Ties Raise Concerns

"Another example which we see a lot of these days is industry sponsors securing the services of third-party vendors who in turn provide recruitment services," said Barnes. Such organizations may either have their own databases of unknown origin or may "comb" pharmacy or other medical records for potential enrollees.

These individuals "would be either approached by their treating physicians, the investigator, and in some plans, the third-party vendor might approach these individuals themselves under the waiver of authorization or under a business associate agreement," said Barnes, who called such situations "not rare."

The problems are more pronounced when studies are for rare pediatric diseases and involve investigators and physicians who may have formed friendships and otherwise have "such strong relationship[s] with patient advocacy groups that they give notice to the advocacy groups and the families in an advocacy group about the opening of a study," Barnes said.

"The line between advising or giving information to a disease advocacy group versus becoming an advocate for people affiliated with the advocacy group to get first priority for Phase 1 or Phase 2 trials can itself be problematic," he added.

The complexities and possible conflicts are not just confined to industry or commercial sponsors, nor to their third-party vendors that help with recruitment and other activities, but also to academic medical centers and other institutional sponsors who may be supporting investigator-initiated or "homegrown" studies, Barnes noted.

One subcommittee member, who Barnes said he did not want to identify, told him the document "sets forth the most problematic areas of my professional life for the last few years in terms of trying to advise investigators what to do and our contracting office how

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SACHRP-Recommended Limits on Sponsor-Subject Interactions

At its first meeting of the year, the HHS Secretary's Advisory Committee on Human Research Protections forwarded two sets of recommendations to the agency (see related story, p. 4).[1] One addresses the increasingly nettlesome interactions between study sponsors and research subjects and the rise of third-party vendors, outlining a role for institutional review boards (IRBs) in establishing a framework for such interactions and for vendor activities.[2]

Noting that there are other "applicable standards and regulations," including from the Food and Drug Administration, the following are among the principles committee members said "should be respected in sponsor, investigator and site interactions with subjects:"

- "Sponsor or third-party vendor involvement in recruitment activities should not place sponsor or vendor staff in the role of final determination of trial eligibility. These personnel may share and discuss study eligibility information and answer questions from prospective subjects regarding eligibility criteria. With appropriate consents and authorization, these personnel may also collect relevant clinical information relating to prospective subjects, in order to share that information with site investigators, but should avoid acting in the role of the clinician-investigator who ultimately must make eligibility determinations based on their assessments of patients, their medical conditions and their verified medical records.
- "Sponsor or vendor interactions with subjects during the course of studies (for example, continued assistance with lodging and transportation) should respect professional and ethical boundaries, and should avoid personal involvement that could bias study results or give subjects and their families misimpressions of the sponsor's obligations. Sponsors should seek to avoid that in the course of their trial support activities, sponsor personnel (or a vendor's personnel) develop relationships with subjects and their families that exceed the sponsor support activities pre-approved by the IRB and pre-cleared with the investigator.
- "All sponsor and sponsor's vendors' interactions with subjects or prospective subjects must be planned and executed to respect applicable privacy obligations of sponsors and vendors, as well as the privacy obligations of patients' and subjects' health care providers and of research sites and investigators. As a baseline sponsor obligation in these interactions, prospective subjects should be informed of how their personal information will be used and disclosed by the sponsor and/or the sponsor's vendor performing recruitment services.

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- "When, in investigator-initiated studies, the sponsor is effectively the AMC [academic medical center] or university employer of the investigator, the AMC or university should approach these issues with a respect for institutional and investigators' responsibilities and duties regarding respect for and protection of human research participants and the integrity of the research process; these responsibilities and duties may be distinct from other institutional interests. For example, it would appear to be over-reaching for an AMC or university to pressure its investigator to persuade unwilling or hesitant subjects to undergo publicity interviews, or even to expect investigators in ongoing trials to become deeply involved in crafting positive trial-specific publicity messaging meant to enhance institutional profile.
- "Sponsors planning contact and/or interactions with enrolled subjects during the course of a study must be transparent about such plans with investigators and with any cognizant IRB or ethics committees. In addition, sponsors should not contact or interact with subjects without the pre-approval of relevant activities by the site investigator and IRB/ethics committee," although there may be some exceptions.
- "Sponsors interacting with subjects during trials (as well as research institutions and investigators interacting with subjects for reasons other than regular medical care or fulfillment of trial protocol requirements) should do so in ways that are least intrusive to subjects and should be respectful of any reluctance of subjects or their families to engage in such interactions. In approaching subjects (which should be done through the site investigator initially), sponsors and investigators must be mindful of the possible perception of subjects and families that they may have little meaningful choice but to cooperate in these 'extra' requests, and should calibrate approaches accordingly.
- "Sponsor and investigator/site requests to subjects and families to engage in media and public relations activities should be confined to the period after the subject has completed his or [her] trial participation. Optimally, such requests and activities would occur after the site has completed study visits for *all* enrolled subjects," and interviews/testimonials "should accurately portray clinical studies as use of unproven, though promising, experimental agents or procedures."

Endnotes

1. Theresa Defino, "SACHRP: Thorny Sponsor Interactions With Subjects Require Approval, Oversight," *Report on Research Compliance* 18, no. 6 (June 2021).
2. "Attachment B - New Challenges in Interactions among Sponsors, Clinical Trial Sites, and Study Subjects," HHS Office for Human Research Protections, last reviewed May 4, 2021, https://bit.ly/3txzQ9v.

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to deal with sponsors who want to undertake these kinds of activities," he said.

Barnes noted that, to date, "there really is a lack of guidance in this area."

IRBs and others needing assistance have only a 25-year-old document from FDA that addresses that an investigation plan for a specific recruitment would have to be reviewed by an IRB and another related to the taping of an investigator demonstrating a test device during surgery with a subject in a trial.

Coercion, HIPAA Addressed

In sum, the new recommendations call for "transparency with the IRBs, investigators and subjects," as well as "a commitment to non-coercion," "careful analysis of the potentially coercive elements and the potential…unconscious influence on data collection that occurs when…subjects are approached in a middle of a trial, still participating in a trial," Barnes said.

"There needs to be IRB review and approval of these kinds of approaches and of interventions with subjects and their families," he added. The document lays out a series of principles to guide such activities (see related story, p. 5)[4] and also addresses HIPAA considerations for the use of third-party vendors.

A business associate agreement "between a health care provider and third-party vendor has very defined protections for subjects and sets forth in great detail the duties and obligations for the third-party vendor [about] potentially contacting patients," said Barnes. "A waiver authorization is only a waiver and is only as good as the way in which the recruitment process, the record review process is designed and the contractual obligations between the third-party vendor and the sponsor paying for the third-party vendor services."

New SACHRP member Kevin Weinfurt, vice chair for research in the Department of Health Sciences at Duke University School of Medicine, called the sponsor recommendations "terrific," and praised their "level of detail" and comprehensiveness.

Saying he "really appreciated this document," Weinfurt said the recommendations are "timely because more and more companies…especially in the rare disease space…are being encouraged to be in closer contact with the patients."

Work Continues on 'Justice' Document

Members also discussed, but did not vote on, draft recommendations on the importance of justice as an ethical concept in research, a document being spearheaded by Stephen Rosenfeld, M.D., former SACHRP chair. At the start of the 90-minute discussion, Diekema said his goal was for the document to win approval, as the meeting marked the third time SACHRP had considered the recommendations.

Among those raising objections was Consuelo Wilkins, M.D., vice president for health equity at Vanderbilt University Medical Center, and professor of medicine at Vanderbilt University School of Medicine, who said that "any document that is talking about justice as it relates to racial injustice that doesn't talk about racism is invalid."

Said Diekema: "I think our plan at the next SACHRP meeting should be to present this document, discuss it and then vote on it. And we'll just see where committee members stand based on a vote. I don't think we are going to make everybody perfectly happy with this document, so I think at some point we'll just have to see if it is good enough."

He told members to contact Rosenfeld directly with "specific comments…so that we're not doing micro-edits the next time around." Rosenfeld noted that the document was now on its 10th revision.

It was not clear from member comments whether there will be enough consensus to approve the recommendations when another draft is presented.

Diekema became chair in early January following his appointment to SACHRP in July. A professor in the Department of Pediatrics and an adjunct professor in the departments of Bioethics & Humanities and Emergency Medicine at the University of Washington School of Medicine, the March meeting was Diekema's first as chair. The meeting also marked the last for Leslie Wolf, director of Georgia State University's Center for Law, Health & Society, whose term began in December 2016.

SACHRP's next meeting is scheduled for July 21-22. ✧

Endnotes

1. "Attachment B - New Challenges in Interactions among Sponsors, Clinical Trial Sites, and Study Subjects," HHS Office for Human Research Protections, last reviewed May 4, 2021, https://bit.ly/3txzQ9v.
2. "Attachment A – IRB Authority Use of Data Collected and Developed," HHS Office for Human Research Protections, last reviewed May 4, 2021, https://bit.ly/3y7xHou.
3. "March 23-24, 2021 - SACHRP Meeting," virtual meeting, accessed May 17, 2021, https://bit.ly/33CMjhR.
4. Theresa Defino, "SACHRP-Recommended Limits on Sponsor-Subject Interactions," *Report on Research Compliance* 18, no. 6 (June 2021).

ACD Okays AI/ML Research Program, Expects 'UNITE' Update This Month

During a quick meeting[1]—its second special session so far this year—the NIH Advisory Committee to the Director (ACD) gave unanimous approval to a "bold" $50 million program to fund a consortium to conduct research involving electronic health records (EHRs) using artificial intelligence (AI) and machine learning (ML). The goal is to seek ways to reduce health disparities. ACD members also got a preview of the agenda for the regularly scheduled meeting to be held this month.

Typically the ACD, the highest-ranking external panel advising NIH Director Francis Collins, meets twice yearly—in June and December. A May 6 meeting was called especially for the purpose of approving the consortium. Because Congress specified that funds for what NIH is jointly calling AI/ML must be used during this fiscal year (FY), which ends Sept. 30, Collins said NIH couldn't wait until the ACD's June 10-11 meeting.

Larry Tabak, NIH principal deputy director, gave an overview[2] of findings by the "AI/ML Electronic Medical Records for Research Purposes" ad hoc working group to the ACD. Tabak said the current membership was a follow-up to a 2019 working group on AI.

It was not clear when the new working group was empaneled or met, but its charges were to "identify unique research opportunities for NIH to apply resources in a practical way" to EHRs, "identify EHR research challenges that AI/ML could have the greatest impact" on, and "determine barriers to the widespread use/deployment of AI/ML capabilities" that NIH support could "help overcome," Tabak said.

The new panel made clear that, "regardless of what suite of approaches that we adopt, we've got to define who the partners would be that would help us scale these capabilities," he explained, particularly "nontraditional partners," including those who "serve

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the underserved" and in "marginalized parts of our society."

EHR Data a 'Proving Ground'

Dina Paltoo, assistant director for scientific strategy and innovation for the National Heart, Lung, and Blood Institute, described the program.[3]

In FY 2021 appropriations, Congress addressed AI and big data, commending NIH for "leveraging the potential of ML to accelerate the pace of biomedical innovation," and included $105 million "to support the agency's efforts." Fifty million dollars was appropriated "to expand the number of ML-focused grants" and $55 million for NIH's Office of Data Science Strategy, Paltoo said. Collins added that $50 million was a "starting point," with the possibility of additional funds being available in the future.

Working with a "concept team" and the working group's findings, NIH decided to create, and the ACD at the May meeting gave approval to, a new Digital Health Equity, Training and Research Consortium. Paltoo said the multiyear program would "establish mutually beneficial and coordinated partnerships to increase the participation and representation of researchers and communities currently underrepresented in the development of AI/ML models and enhance the capabilities of this emerging technology, beginning with EHR data."

As Paltoo explained, "EHR data can be a great proving ground to begin to build capacity and learning, but we also need to have a path over time to add in all these other data types," such as social determinants of health, genetic, imaging and other types of information.

The next step is for NIH to allow for "stakeholder engagement," Paltoo said. "We want to hear from the institutions as to their interest and their needs in both infrastructure, training and partnerships and potential research areas," she said. "We will use that information to refine the initiative. We would publish the research opportunity announcements later in the summer and then try to provide the awards by the end of September."

Added Collins: "This is pretty bold—the idea of taking on something as challenging as AI/ML of electronic health records, but to do it in a fashion that puts health disparities at the very beginning instead of some further step down the line, which, unfortunately, is often what is done."

UNITE Initiative 'Engagement' Underway

After the vote, ACD member Spero Martin Mason, the Colorado Trust Chair in American Indian Health in the School of Public Health at the University of Colorado, Denver, requested that Collins provide an update on NIH's new UNITE initiative to combat structural racism at the meeting later this month.

Announced in February at the ACD's first special meeting of the year,[4] UNITE was created to "identify and address structural racism within the NIH-supported and the greater scientific community."

The initiative was accompanied by a pledge of $60 million over five years from NIH's Common Fund for 20 awards. UNITE gets its name from five committees whose objective is "tackling the problem of racism and discrimination in science, while developing methods to promote diversity and inclusion across the biomedical enterprise."

In addition, on March 1, NIH issued a request for information (RFI), with a deadline of April 9, seeking "input on practical and effective ways to improve the racial and ethnic diversity and inclusivity of research environments and diversity of the biomedical research workforce across the United States, to the extent permitted by law."

In response to Mason, Tabak said NIH has "had a very extensive engagement through the RFI," promising that officials will have responses "analyzed by then and [will] be able to report out some of the trends and themes." He added that NIH also may have "internal information that we might be able to share as well, as we work with our own community here at NIH."

AAMC Calls for Working Group

To date, NIH has not posted responses to the RFI, but some organizations have shared theirs. Ross McKinney Jr., chief scientific officer for the Association of American Medical Colleges, said AAMC "strongly shares the NIH's commitment to end structural racism and racial inequities in biomedical research through the newly launched UNITE initiative and is dedicated to working with the agency on this critical issue."[5]

AAMC's nine-page letter makes the following points, among others:

- NIH "must also recognize that a focus on diversity without the integration of solutions that likewise enhance inclusion, community, or equity, will thwart even the most well-strategized and funded initiatives. NIH should implement a mechanism to foster 'communities' of trainees from underrepresented backgrounds."
- The agency should "involve trainees (undergraduates, graduate students, postdoctoral researchers) into

panels or groups that discuss critical conversations around a diverse and inclusive research workforce. For individual institutions, asking underrepresented researchers what needs to be improved at their own institutions may [be] another effective way to find problems and make local improvements."

- Mentoring should be required for all funding mechanisms, as the current lack of consistency in this requirement introduces "variability [and] blind spots in the continuum of mentoring." Noting that "the R grant, a key driver of biomedical discovery, does not require a specific mentoring component," McKinney said research shows underrepresented scientists "have unique mentoring needs and may benefit from a culturally sensitive mentor who can help guide them with challenges unique to their background." Such a requirement "for all grants that support research trainees, regardless of funding mechanism, can boldly reinforce the importance of mentorship at all stages, as well as draw attention to the unique mentoring needs of underrepresented individuals."
- McKinney suggested that NIH "consider creating a grant mechanism to help institutions establish and continue the work of mitigating unconscious bias at academic institutions, and additionally request that applicants for training grants address how potential bias in the recruitment process will be addressed," and recommended as a model the University of California at Davis's Center for the Advancement of Multicultural Perspectives on Science initiative.
- NIH's study section selection process must be changed on an "urgent" basis, "such that it represents a significantly broader pool of researchers, beyond those who have received significant funding/R01 grants from the agency." AAMC recommended the creation of a working group "primarily comprised of underrepresented researchers from the extramural community, and/or release a request for information to examine the peer review process and scoring system and identify opportunities for reform."
- Such a working group should consider "the requirement for a scientific review officer at every section specifically trained in diversity, equity, and inclusion issues; more training and education on bias for all study section members; the need to sufficiently justify any weaknesses identified in a submission, particularly when dealing with research regarding inequities or health disparities; redefining impact so that particular areas of study are not penalized; targeted recruitment of reviewers who have the necessary expertise to evaluate the research under review; and changing scoring criteria so that investigator or intuitional reputation ('environment') do not override scientific merit." ✧

Endnotes

1. NIH, "Advisory Committee to the Director - May 2021," VideoCast, May 6, 2021, https://bit.ly/3uTHJYA.
2. Larry Tabak, "Report of the ACD Working Group Ad Hoc Virtual Meeting on AI/ML Electronic Medical Records for Research Purposes," NIH Advisory Committee to the Director, May 6, 2021, https://bit.ly/3hkZ34A.
3. Dina Paltoo, "Digital Health Equity, Training and Research Consortium: Broadening the Benefit of Artificial Intelligence/Machine Learning (AI/ML) Technologies to Reduce Health Inequities and Enhance Diversity of the AI/ML Workforce," NIH Advisory Committee to the Director, May 6, 2021, https://bit.ly/3tFqrNl.
4. Theresa Defino, "To Combat Racism, NIH Advised to Require Annual Data, Issue Institutional 'Report Card,'" *Report on Research Compliance* 18, no. 4 (April 2021), https://bit.ly/3feZjiP.
5. Ross McKinney, "Re: Request for Information (RFI): Inviting Comments and Suggestions to Advance and Strengthen Racial Equity, Diversity, and Inclusion in the Biomedical Research Workforce and Advance Health Disparities and Health Equity Research (NOT-OD-21-066)," letter, Association of American Medical Colleges, April 9, 2021, https://bit.ly/2RddH3l.

UNLV Pays HHS $1.45M

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Additionally, between Sept. 1, 2015, and Feb. 6, 2018, UNLV "improperly charged a portion of the salary of a nurse practitioner" in its HIV clinic even though there was not "sufficient documentation to support such salary costs charged to the award."

Although the facts indicate it could have been, the case was not settled under the False Claims Act (FCA), but instead under the Civil Monetary Penalties Law (CMPL), 42 U.S.C. § 1320a-7a(o), which is applicable to "violations of grants, contracts and other agreements" for which HHS has provided funding.

"Under this OIG authority, OIG may sanction anyone that engages in fraud or certain other improper conduct related to HHS grants, contracts, and other agreements," OIG spokesman Don White told *RRC.* "The authorities in this section of the CMPL, which have been delegated to OIG, include civil monetary penalties, assessments, or exclusion from federal health care programs."

Both the FCA and the CMPL allow penalties that are triple the amount of misspent funds. In this case, as noted, the penalty was considerably smaller.

Misspending Spanned Years

The award numbers listed in the settlement agreement are linked to Echezona Ezeanolue, M.D., who did not respond to multiple requests for comment

RRC made via phone calls and emails to numerous organizations with which he is or has been associated.

Executive Vice President/Provost Chris Heavey told the *Las Vegas Review-Journal* that UNLV was "not alleging malfeasance or wrongdoing on the part of the investigator."[3]

The following timeline of events leading up to the settlement is based on information UNLV provided, details in the settlement, and on *RRC*'s reporting.

- July 2015: Ezeanolue joined UNLV as associate professor of pediatrics and public health. He also served as the director of the maternal-child HIV program at UNLV's School of Medicine.
- Sept. 24, 2015, to Aug. 31, 2018: Improper payments occurred.
- Fall 2017: A "standard oversight process" identified "irregularities with grant expenditures." UNLV did not specify which award was initially at issue. UNLV suspended funding for the three NIH grants, "pending an internal review," and transferred the HRSA grant to another PI.
- Early 2018: UNLV told *RRC* it "identified financial conflicts of interest related to some grant expenditures for the PI."
- March 30, 2018: Ezeanolue's employment with UNLV ended. Tony Allen, spokesman for UNLV, would not discuss the terms of his departure, stating that personnel matters cannot be disclosed.
- April 2018: "Upon conclusion of a thorough internal review," UNLV "notified NIH of its findings and requested cancellation of three grants," which NIH agreed to.
- Spring 2018 (exact date not provided): UNLV "posted its conflict of interest disclosure on a public, accessible website, per NIH protocol."
- June 11, 2018: UNLV self-reported to OIG there were "compliance issues" with the four grants.
- Jan. 22, 2021: The Nevada System of Higher Education, on behalf of UNLV, reached a settlement agreement with the OIG for repayment of $1.07 million "for non-compliant expenditures related to referenced NIH and HRSA grants" and a $380,000 fine, Allen told *RRC.* "The settlement was paid through investment fund revenue and not from state, donor or tuition dollars." The exact amount was $1,450,947.81.
- Feb. 3, 2021: OIG posts the settlement on its website under self-disclosures.

UNLV: Outside Payments Not Disclosed

UNLV has a dedicated webpage for "Conflicts of Interest/Compensated Outside Interests" (see https://www.unlv.edu/research/coi). In addition to posting policies and procedures, disclosure forms, FAQs and other related information, the page has a link to "Financial Conflicts of Interest (FCOI) with research funded by the Public Health Service" (see https://bit.ly/3tO4KKQ).

The webpage explains that the FCOI "reporting process allows institutions to report the existence of any identified financial conflicts of interest to the Public Health Service as required by Federal regulation, specifically Title 42 Code of Federal Regulation Part 50 Subpart F for grants and cooperative agreements."

Allen said the FCOIs leading to the settlement were unique. Indeed, the only document that can be downloaded from the link shows six entries—all for Ezeanolue. No dates of disclosure of the FCOIs are included but are listed as "unknown." Total payments listed are $357,379, coming principally from "Sunrise Foundation" ($144,527) and an entity called "Easy Access" ($200,372).

Healthy Sunrise Foundation, based in Las Vegas, is an organization "with a core mission to improve birth outcomes through enhanced maternal-child health programs."[4] Its website lists Ezeanolue as vice president.

Risk Assessments, COI Forms Updated

White said his agency did not require UNLV to take corrective actions as part of the settlement. Lack of mandatory corrective actions or a compliance plan—which can be costly and time-consuming to implement—is one benefit to self-disclosure.

"OIG operates with a strong presumption against requiring compliance obligations in the context of a settlement arising from a self-disclosure," White said.

Despite not being required to do so, UNLV "tightened its policies and procedures related to grant expenditures as a result of this experience," Allen said. "A few examples include restructuring the Office of Sponsored Programs to strengthen its checks and balances, implementing electronic business processes through UNLV's financial system, and developing a robust risk assessment for subawardees."

He added that UNLV "takes these matters seriously and investigates them thoroughly, and the strategies we followed are those that all institutions in similar situations should consider."

UNLV "regularly reviews its business processes, and it's fair to say this experience has led to updates in several areas, including research," Allen said.

He noted that "all academic faculty and professional staff are required to complete annual Conflict of Interest and/or Compensated Outside Services disclosure forms whether or not they engaged in any outside activities," and that the forms "have been

updated in recent years to include a greater focus on international relationships and activities."

OIG: Case 'Highlights Risk Areas'

RRC also asked White what could be learned from this situation, including what led to the settlement and the value of self-disclosure.

"This self-disclosure and the resulting settlement highlight the benefits of self-disclosing to report and resolve improper conduct impacting a grant award. It also highlights risk areas for grant recipients, including monitoring of subrecipients, proper disclosure of conflicts of interest, and the need to maintain adequate documentation," White said. "OIG encourages self-disclosure by any recipient who may have criminal, civil, or administrative liability related to any HHS grant, contract, or other agreement. Prompt disclosure, full cooperation, and robust internal investigation of potential violations are key indicators of an award recipient's integrity."

White added that there are "many benefits to self-disclosure."

OIG "resolves self-disclosed conduct with a lower settlement amount than if the government had initiated the investigation," he said. "For entities or individuals seeking to resolve conduct impacting multiple HHS awards or multiple awarding divisions, submitting a single self-disclosure to OIG may be more administratively streamlined."

As noted earlier, this case involved four awards from two different HHS agencies. ✧

Endnotes

1. HHS, "Final UNLV-OIG Settlement Agreement," settlement agreement, accessed May 17, 2021, https://bit.ly/3uUJqVG.
2. HHS OIG, "University of Nevada, Las Vegas Agreed to Pay $1.4 Million for Allegedly Violating the Civil Monetary Penalties Law by Submitting Improper Claims to NIH and HRSA Grants," Enforcement Actions, February 3, 2021, https://bit.ly/33GTrcP.
3. Julie Wootton-Greener, "UNLV settles with US, pays $1.45M over alleged misuse of grant funds," *Las Vegas Review-Journal* March 11, 2021, https://bit.ly/3tNS86P.
4. "Our Mission," HealthySunrise Foundation, accessed May 17, 2021, https://healthysunrise.org/.

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◆ **Clemson University is pushing back against recommendations by auditors for the National Science Foundation Office of Inspector General (OIG) that it repay $276,440, agreeing only to refund NSF $133,736 of $61 million in costs claimed on awards from March 1, 2017, to February 2020**. According to the April 30 report, auditors questioned "$83,248 of inappropriately applied indirect costs; $57,318 of inappropriately allocated expenses; $58,000 of unreasonable and unallocable computer cluster node access expenses; $45,620 of inadequately supported expenses; $23,689 of unallowable expenses; and $8,565 of indirect costs over-applied to supplemental funding." They also "identified four compliance related findings for which there were no questioned costs: non-compliance with Federal requirements for pass-through entities; non-compliance with NSF terms and conditions; non-compliance with Clemson policies; and incorrect application of proposed indirect cost rates."

However, Clemson officials said $49,814 of the questioned indirect costs, which were for a building addition, were valid, as was $20,471, spent primarily for a camera and publication expenses. In addition, Clemson disputed the entire $58,000 for computer expenses for six awards that auditors flagged that relate to "expedited and priority access to its Palmetto Computer Cluster nodes." Clemson agreed that it used the wrong indirect cost rates on 25 NSF awards. Auditors said Clemson and its subawardees used negotiated indirect cost rate agreement (NICRA) amounts that were in effect when award proposals were submitted, instead of correctly applying ones as of the date awards were made. Clemson stated that it allowed principal investigators and subawardees "to apply the indirect cost rates included in their NSF-approved proposals because it did not want to 'punish' PIs and subawardees by increasing the indirect cost rate applied to their awards and subawards because the NICRA rates increased between the proposal submission date and the grant award date." The university agreed to update its indirect cost rate policies to comply with the negotiated rates. (*5/13/21*)

◆ **The Environmental Protection Agency should "discontinue implementation of the 2019 directive that seeks to reduce ongoing animal research and ultimately eliminate mammalian studies by 2035,"** Louis Justement, president of the Federation of American Societies for Experimental Biology (FASEB), wrote in a May 4 letter to EPA Administrator Michael Regan. "FASEB applauds the new administration's efforts to restore the role of science and scientists in policy development and thanks the agency for pointedly stating this pledge. As the EPA finalizes its transition and reviews former policies to identify barriers that impede scientific

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integrity," now is the time to abandon the 2019 directive, according to Justement, as it "will stifle toxicological research progress and is inconsistent with the EPA's commitment to ensure that the best available science informs agency policies." (*5/13/21*)

◆ **Following a confirmation hearing on April 30, the Senate Commerce, Science, and Transportation Committee expects to vote sometime later this month on the nomination of Eric Lander, director of the Broad Institute, to be the new director of the Office of Science and Technology Policy (OSTP)**. The committee will hold the record open until May 13 to accept additional comments and questions for Lander, after which time a vote will be scheduled. The nomination will then move to the full Senate for approval. This marks the first time an OSTP leader faces confirmation, as President Biden elevated the job to the cabinet level. In his opening statement, Lander stressed the need for more science, technology, engineering and math education, saying most Americans "lack access to great STEM schools." (*5/6/21*)

◆ **After issuing a warning letter nearly a year ago for failure to post required summary trial results on ClinicalTrials.gov, the Food and Drug Administration (FDA) has given Cambridge, Massachusetts-based Acceleron Pharma Inc. a month to submit data** from a Phase 2 trial of medications for the treatment of advanced renal cancer or it will face sanctions, including fines. This is the first time FDA has taken action against a firm for noncompliance with reporting requirements. According to FDA's April 27 letter to Acceleron, FDA alerted the firm in July of "potential noncompliance" and requested it "submit all required results information promptly." (*5/6/21*)

◆ **As promised earlier, the HHS Office of Research Integrity (ORI) announced the implementation of a secure means of uploading documents. In a May 3 blog post, ORI officials said the ORI File Transfer System (ORI-FTS),** a "FedRAMP authorized, cloud-based system for secure file transfer," is now operational. The system is in response to expressed need from institutions for "an electronic file transfer system that would facilitate the secure submission of reports, files, and other documents to ORI." The agency also "recognized the need for such a resource and has worked to identify and implement a solution. With the launch of ORI-FTS, RIOs [research integrity officers] and Institutional Officials are now able to send material securely and directly to ORI's file transfer system, facilitating the process of sending and receiving such files," the agency said. (*5/6/21*)

◆ **HHS has reversed a 2019 requirement that "all research applications for NIH grants and contracts proposing the use of human fetal tissue from elective abortions will be reviewed by an Ethics Advisory Board," NIH recently announced**. As a result, the Human Fetal Tissue Research Ethics Advisory Board will not meet, NIH said April 16. However, other requirements for funding of extramural fetal tissue research "remain unchanged." The reversal reflects the Biden administration's policies toward the use of tissue from elective abortions, which the Trump White House had opposed. NIH established the board in 2019, and it only met once, recommending that just one of 14 applications be funded. The notice did not mention the previous ban on fetal tissue studies by intramural researchers, but it was also lifted, according to a *Science* article. (*4/26/21*)

◆ **A former Ohio hospital researcher whose wife has already been sentenced to 30 months in prison after her guilty plea was himself given a 33-month term** for "conspiring to steal exosome-related trade secrets concerning the research, identification and treatment of a range of pediatric medical conditions," the Department of Justice (DOJ) announced. Yu Zhou and his wife, Li Chen, worked at Nationwide Children's Hospital's Research Institute for 10 years. "They pleaded guilty to conspiring to steal at least five trade secrets related to exosome research" from their labs at the hospital, DOJ said. "The couple will forfeit approximately $1.45 million, 500,000 shares of common stock of Avalon GloboCare Corp. and 400 shares of common stock of GenExosome Technologies Inc. They were also ordered to pay $2.6 million in restitution." (*4/26/21*)

◆ **Mingqing Xiao, a math professor at Southern Illinois University-Carbondale, "fraudulently obtained $151,099 in federal grant money from NSF by concealing support he was receiving from the Chinese government and a Chinese university," DOJ announced**. The NSF grant was for a "project set to run from 2019 to 2022," which Xiao was awarded "without informing NSF about another, overlapping grant he had already received from the Natural Science Foundation of Guangdong Province, China. Xiao also allegedly failed to inform NSF that he was on the payroll of Shenzhen University, a public university in Guangdong Province, and that he had already committed to teaching and conducting research at Shenzhen University from 2018 to 2023." (*4/26/21*)