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By Theresa Defino

◆ **City University of New York (CUNY) has accused neuroscientist Hoau-Yan Wang, a CUNY faculty member and longtime collaborator with embattled biotech firm Cassava Sciences, of misconduct involving 20 papers, the journal *Science* reported.** Many of Wang's papers provided key support for the experimental Alzheimer's drug simufilam's trtansition from the lab into clinical studies. The investigative committee found numerous signs that images were improperly manipulated. For example, the investigation found that a 2012 paper in *The Journal of Neuroscience* suggested that simufilam can blunt the pathological effects of beta-amyloid contained signs that the images had been improperly manipulated. The report also concluded "that Lindsay Burns, Cassava's senior vice president for neuroscience and co-author on several papers, bears primary or partial responsibility for some of the possible misconduct or scientific errors."

However, the committee could not prove its allegations because Wang did not produce the original raw data. Instead, the panel said its finding of wrongdoing was based on "long-standing and egregious misconduct in data management and record keeping by Dr. Wang." The 50-page report obtained by *Science* said Wang failed to turn over to the panel "even a single datum or notebook in response to any allegation" and cites "Wang's inability or unwillingness to provide primary research materials to this investigation" as a "deep source of frustration." The report said Wang offered a variety of defenses, including that much of his original data had been "thrown away in response to a request from [City College of New York] to clean the lab during the COVID-19 pandemic." The panel could find no evidence of such a request. The investigation began in the fall of 2021 in response to allegations from other investigators that the HHS Office of Research Integrity forwarded. Given the CUNY report, some scientists have called for the two ongoing simufilam trials to be suspended. (*10/19/23*)

◆ **The NIH Office of Laboratory Animal Welfare (OLAW) has released a webinar recording on how the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3R) Experimental Design Assistant (EDA) can assist researchers' plans for their studies involving animals.** The webinar is part of OLAW's push for the research community to take advantage of OLAW's available resources for research plans to strengthen the rigor, reproducibility and translatability of NIH-supported animal research. The free online tool from U.K.-based NC3R helps users build a diagram representing an experimental plan, provides customized feedback and can make suggestions on statistical methods, randomization, blinding, sample sizes and other critical design aspects.

Esther Pearl, NC3R programme manager for experimental design, said the tool can help researchers design in vivo experiments. "We are aware that many researchers don't have access to statistical support, so we have tried to replicate that support as much as possible in the EDA." Pearl noted that the tool is free, secure and focuses on rigorous study design, which she said will help lead to reliable results and help reduce bias. (*10/19/23*)

◆ **Illinois State University managed NIH awards appropriately and complied with financial conflict of interest (FCOI) requirements, including disclosures and training, according to an audit by the HHS Office of Inspector General (OIG) posted online.** "We reviewed 698 expenditures totaling $1,234,300 that the University charged to 5 awards, and we determined that the costs complied with Federal and award requirements," auditors said. In

addition, the university "properly maintained training records and monitored disclosures of significant outside activity to meet FCOI requirements associated with the seven employees in our sample who had received NIH awards as Principal Investigator or Co-Principal Investigator."

During the audit period—Oct. 1, 2016, through Sept. 31, 2019—there were 17 NIH awards and a total of $2,387,677 costs claimed against them. Auditors "reviewed the University's policies and procedures to determine whether the University had controls in place during our audit period to ensure allowability of costs in accordance with Federal award requirements during the audit period." Specifically, they examined "time and effort reports for salaries and wages, fringe benefit calculations, in-state travel related costs, direct costs (including equipment, scientific and medical supplies), calculated indirect cost rates, and subrecipient subawards to other universities." To address FCOI compliance, auditors "reviewed policies and procedures the University had in place during our audit period for ensuring that employees received adequate FCOI training and that outside interest disclosures were sufficiently monitored to meet FCOI requirements." Because they made no findings of noncompliance or unallowability of costs, auditors issued no recommendations. (*10/12/23*)

◆ **A former University of Alabama in Huntsville (UAH) assistant professor of chemistry has signed a three-year supervisory agreement with ORI after the agency determined she committed research misconduct by falsifying or fabricating data in four unfunded grant applications.** According to a recent notice in the *Federal Register*, Surangi Jayawardena reused "data from the same source and falsely relabel[ed] the data as representing different experimental conditions with antibiotic particles or bacteria" and engaged in 12 instances of image manipulation accompanying four applications submitted to the National Institute of Allergy and Infectious Diseases. One application was submitted in 2018, and three others on various dates in 2019. All four were "administratively withdrawn" on different dates in 2019 and 2021.

According to the *Federal Register* notice, for three years beginning Aug. 18, Jayawardena's work will be supervised by a committee of investigators familiar with her work should she receive Public Health Service funding. She also cannot serve as an advisor or peer reviewer for HHS during the supervisory period. UAH officials told *RRC* Jayawardena was employed there from Aug. 14, 2017, to Dec. 17, 2021. "We cannot share any more details," they added. Jayawardena did not respond to emails from *RRC*. (*10/12/23*)

◆ **"We are paying attention to overcitation as part of our proper stewardship of taxpayer funds and to assure that the results of NIH funding are properly reported," Michael Lauer, NIH director of extramural research, said in a recent blog post.** Lauer noted that "researchers are required to acknowledge NIH grants that support the work described in their papers, but only if they contributed to the project," adding that although "we do not collect data on how often overcitation happens, we come across it in different ways. We have seen situations where an NIH grant was linked to a paper, yet private sector sponsors or non-federal grants fully supported the research. Some of these come to our attention because NIH systems like My Bibliography connect publications and grants. It takes effort to untangle these errors when working out the details with the researchers involved."

Lauer provided two examples of inappropriate citations. One was a study involving human participants that cited a grant that "did not allow for human participant research." Although there was a concern that "the researchers may have violated laws that protect human subjects," NIH discovered "the researcher on the original paper simply cited that unrelated grant because they thought it would benefit them in some way." In the second example, an author cited an award as a source of support but was "not linked to the award" and "cited the grant deliberately without the knowledge of the principal investigator." Lauer did not disclose whether there are consequences for such misattribution but wrote that, "If warranted, we reach out to the recipient to learn more about whether the grants were cited correctly or not." (*10/12/23*)

◆ The HHS Office for Human Research Protections (OHRP) has posted the agenda for the Oct. 18-19 meeting for

the Secretary's Advisory Committee on Human Research Protections (SACHRP). The meeting will be held in person and webcast, according to a notice in the *Federal Register*. OHRP recently announced two new SACHRP members, bringing its total to nine; that is enough for a quorum, although the charter calls for 11. The agenda posted on OHRP's website indicates SACHRP will hear from a panel of experts on the "ethical and regulatory considerations for the inclusion of LGBTQI+ populations" in research supported by HHS and receive remarks from Rachel Levine, M.D., HHS assistant secretary for health, on Oct. 18.

Later that day, SACHRP will continue crafting its recommendations on quality measures for institutional review boards in response to a Government Accountability Office report on the issue. Also scheduled for the first day is a discussion of "uninformative research," a new topic for SACHRP. Oct. 19 is scheduled to be a half-day; the agenda calls for discussion of the "best interests standard" related to retaining participants in research that has been paused or discontinued—apparently also a new topic. Information on the location of the meeting and how to view the webcast has not yet been posted. (*10/5/23*)

◆ **"Whether you are a principal investigator considering a subaward arrangement with either a domestic or foreign institution, or a research administrator eager to deepen your understanding of the prerequisites and regulations governing compliant subaward agreements," NIH has a webinar for you.** The agency recently announced it will hold a one-hour webinar on subawards on Oct. 17 and will post a recording of the event within seven business days afterward.

Speakers from the Office of Policy for Extramural Research Administration will guide attendees "through the various sections of a subaward agreement, offering detailed guidance and highlighting key policies." The webinar will also include a live question-and-answer period. (*10/5/23*)

◆ **With fiscal year 2024 set to begin Oct. 1 and no appropriations legislation yet approved by Congress, the White House Office of Management and Budget has updated its FAQs for federal agencies addressing a lapse in government funding.** Last issued in 2019, the 17-page document has eight sections and 30 questions covering multiple topics. Of interest to institutions, one question asks, "If websites are down, will agencies be able to extend deadlines for applications that would otherwise have been due during the lapse in appropriations?" The answer provided is, "To the extent permitted by law, agencies may extend deadlines for activities, as necessary to compensate for the period of the lapse in appropriations and the unavailability of the website." The FAQs were updated Sept. 22.

Meanwhile, the Council on Governmental Relations (COGR) on Sept. 26 posted recommendations to help institutions manage federally sponsored projects. The document, "Preparing for a Government Shutdown: A List of Institutional Considerations," combines "past shutdown experiences with information and guidance that has been received to date. ***This list is a starting point and not exhaustive of all considerations*** and will be updated accordingly as more information is gathered and released," COGR said. (*9/28/23*)

◆ **Effective the beginning of next year, prime awardees with foreign subrecipients must sign a written agreement requiring them to "provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes** as described in the progress report, to the primary recipient with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission," NIH announced Sept. 15. The timing of "no less than once per year" is a change from a new policy NIH announced this summer in response to concerns that NIH needs to strengthen its oversight of foreign subrecipients raised by the HHS Office of Inspector General and Government Accountability Office. The earlier version of the guidance also required subrecipients to provide copies of the notebooks and other documentation, rather than access to them. Additionally, the revised policy specifies that the required access "may be entirely electronic."

The agency said it "expects recipients to update existing subaward agreements to address this requirement within 60 days of the effective date of this notice. NIH recognizes that recipients may need additional time depending on the number of agreements an institution has in place for each project. Therefore, extensions may be requested, if needed." NIH solicited comments on the policy when it was first announced in June and revised the guidance to reflect feedback. "We want to underscore our strong and longstanding support of robust international research collaborations. We appreciate concerns regarding how best to mitigate excessive administrative burdens and other unintended adverse consequences," according to the notice. In a blog post, Michael Lauer, NIH director of extramural research, noted NIH developed a subaward webpage and FAQs on the foreign subawardee agreement policy. (*9/28/23*)