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◆ **NIH has opened its "initial data set and tools" in its All of Us research program to investigators under a new beta model that does not allow downloading of information**. And on June 16, the program announced that it will conduct COVID-19 antibody tests on samples from "10,000 or more participants who joined the program most recently, starting with samples from March 2020 and working backward until positive tests are no longer found." The goal is to "show the prevalence of novel coronavirus exposure among All of Us participants, and help researchers assess varying rates across regions and communities." The All of Us program is part of a precision medicine initiative launched by President Obama that began recruitment just two years ago, with the goal of enrolling a million individuals. Some 350,000 have become involved to date; of the total, data from 225,000 is now accessible to researchers, according to CEO Josh Denny. (*6/18/20*)

◆ **In an unusual move, the National Science Foundation agreed with an Office of Inspector General (OIG) audit finding that Arizona State University (ASU) had transferred a "significant" portion of an award to a new institution as a subaward allegedly without NSF approval but is only seeking partial repayment**. NSF did not request repayment of $890,982 in costs OIG had questioned; instead, it reached a negotiated settlement with ASU to repay just $75,000, according to a June 11 resolution report. ASU had opposed the finding in its response to the draft audit, saying that a program officer was aware of its actions. All told, the April 2019 audit, which spanned from Jan. 1, 2014, to Dec. 31, 2016, questioned $1,178,488 in direct and indirect costs, including the subaward payments. (*6/18/20*)

◆ **In new audits, OIG concluded two NIH institutes need to make improvements in how they screen funding applicants before awards are made**. In reviews of the National Eye Institute (NEI), issued May 22, and the National Cancer Institute (NCI), published June 1, auditors said both institutes had either failed to conduct a "financial capability" review or to adequately document such a review, which is required of organizations that have not received an award in the prior three years. This was the case for two of six NEI awards OIG reviewed and five of 14 at NCI. In addition, OIG faulted both NEI and NCI for inadequate reviews of certain applicants that have had previous funding. (*6/11/20*)

◆ **NSF disagreed with a recommendation by OIG to debar a principal investigator for one year** who "plagiarized text into an NSF proposal from two awarded NSF proposals that he received in confidence from a colleague." Instead, NSF is requiring the man to "certify compliance with university-imposed requirements and provide certifications and assurances" and to refrain from advising NSF for four years. Additionally, in the case of a post-doctoral researcher found to have falsified data in at least four publications and in "multiple" progress reports to NSF, the agency took no action at all because it said too much time had elapsed. OIG had said the researcher should be required to provide certifications, be barred from advising for two years and "provide proof that he completed the university-mandated training." Details about these cases are found in OIG's new semiannual report to Congress and reflect the only misconduct cases NSF resolved during the six-month period ending March 31. (*6/4/20*)

◆ **In an unusual move, the Food and Drug Administration (FDA) on June 2 issued final guidance "to provide recommendations regarding the key factors and procedures"** that institutional review boards (IRBs) "should

consider when reviewing expanded access submissions for individual patient access to investigational drugs for treating COVID-19." FDA noted that it has "received a substantially increased volume" of such requests. Although it previously issued guidance "on expanded access requests, including expanded access for individual patients," FDA is aware that IRBs "seek clarity regarding the key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions, including for reviews conducted by a single member of the IRB." (*6/4/20*)

◆ **Research conducted at the University of Kentucky (UK) on sheep involving a product called Novalung—which was approved by the FDA in February—violated numerous regulations, FDA recently warned a UK animal researcher**. According to a March 26 warning letter to Professor of Surgery Joseph Zwischenberger that FDA posted on May 5, an inspection conducted from Nov. 4 to Nov. 21, 2019, found numerous violations dating back to 2016, including failure of both the study director and the quality assurance unit (QAU) to "fulfill [their] responsibilities." FDA said the director "did not ensure that raw data, specimens, and records were transferred to the archives for the nonclinical study; and did not ensure that the protocol was adequately followed"; and that incorrect and incomplete data about sheep involved in the study were reported. For example, one sheep had 15 "episodes of fever which were not documented in the final report," it said. (*5/28/20*)

◆ **Two years after his 2016 paper was retracted for likely falsifications, the HHS Office of Research Integrity (ORI) said Logan Fulford, a former graduate student at the University of Cincinnati and research assistant at Cincinnati Children's Hospital Medical Center, engaged in research misconduct** "by intentionally, knowingly, and/or recklessly falsifying" Western blot images and immunochemistry data. In its May 19 notice, ORI said Fulford "did not admit or deny" he committed misconduct but agreed to have his research supervised for two years, beginning May 8, should he receive any Public Health Service funding. The article, "The transcription factor FOXF1 promotes prostate cancer by stimulating the mitogen-activated protein kinase ERK5," was published in the journal *Science Signaling.* ORI said falsifications/fabrications also occurred in an unpublished paper. (*5/28/20*)

◆ **The federal government needs to do a better job assisting universities with understanding and complying with export control requirements, which also should be revised to reflect current risks, according to a new report by the Government Accountability Office**. Released May 12, the report was requested by Sen. Chuck Grassley, R-Iowa, as part of his "concerns about foreign threats to U.S. research." Grassley said the report "underscores the need for continued close scrutiny of the issue and a coordinated government effort to protect sensitive research and technology." (*5/28/20*)