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◆ **"As a steward of the nation's biomedical research enterprise, NIH is dedicated to ensuring that when data and biospecimens are shared, that it is done ethically and securely, and with respect for the privacy, autonomy, and well-being of research participants and the communities to which they belong," the agency said in a recent notice**. "As part of this commitment, NIH is working with stakeholders to identify best practices for developing and implementing effective consent practices to inform prospective research participants about potential risks and benefits of data and biospecimen sharing for future research."

NIH provided sample language it said could be used even for studies in which "data and biospecimens are completely delinked from identifiers and cannot be linked back to the participant." Sections address the need to give participants "the option to agree to, or opt out of, having their data and biospecimens stored and shared for future research." NIH noted that mandating "storage and sharing may be considered coercive if the participant does not want to agree to sharing of data and biospecimens but feels compelled to agree anyway in order to join a possibly beneficial clinical trial." NIH stressed that "any use of the sample informed consent language is completely voluntary and shall not be required." Feedback on the sample language and points to consider "will be essential in ensuring this resource is maximally useful to the community," the NIH Office of Science and Technology Policy said in a July 7 email announcing the notice. Comments are due by Sept. 29 and will be accepted via a web portal. Developing informed consent procedures has generally been undertaken by the HHS Secretary's Advisory Committee on Human Research Protections; it is not clear whether SACHRP has been involved with NIH on this project. The Common Rule does not require consent for use of unidentified biospecimens or data as studies involving them are not considered human subjects research. (7/15/21)

◆ **The University of South Carolina agreed to repay $140,360 in costs questioned by the National Science Foundation Office of Inspector General (OIG) following a recent audit**. Auditors tested 229 transactions totaling more than $1.7 million of $40.9 million in costs incurred from March 1, 2016, to Feb. 28, 2019. "Specifically, the auditors identified $93,738 in purchases and adjustments near or after award expiration, $25,277 in inadequate documentation, $20,883 in unallocable and unreasonable costs, and $462 in foreign currency conversion errors," according to the June 29 report. OIG flagged 21 purchases or transactions that were charged to eight awards, including more than $27,000 for tube assemblies purchased 11 and 46 days after awards expired and approximately $22,000 for five Apple laptops and computers. They were purchased when there were just 27 to 54 days left on the awards.

Among the purchases and expenditures lacking documentation and thus unallowable was $5,183 for bad debt. "Supporting documentation could not be located. Furthermore, bad debt expenditures are unallowable," the auditors wrote. Among the unallocable transactions were $856 for publication costs. These expenses "were incurred to cover the publication costs of the results generated from the project," OIG said the university told auditors. "However, the invoice provided was for an advertisement for a job posting described as a Postdoctoral Position in Plant Biology." In its responses and agreement to make repayment, university officials described a number of improvements that have occurred since fiscal year 2018. "Within the last several years, the Grants and Funds Management Office has experienced more than 80% turnover in staff. As a result, the University seized the opportunity to evaluate and upgrade the positions to gain a more experienced and knowledgeable staff of

accountants, including hiring a new Director and Assistant Director in FY18," they said. (*7/15/21*)

◆ **A sample of more than 40% of awards the National Heart, Lung, and Blood Institute (NHLBI) made through a process called "other transactions," or OTs, from 2016 to 2019 did not comply with federal requirements, according to a new audit by the HHS OIG**. OIG explained that agencies "generally uses OTs for high-risk, high-reward research and development projects. Although OTs are subject to fewer restrictions than contracts, grants, or cooperative agreements, they must be awarded and administered in a way that ensures proper stewardship of Federal funds." In addition, "OT authority provides NHLBI the flexibility to negotiate terms and conditions appropriate to fund research projects and to procure goods and services. NHLBI's Director must approve all OT initiatives."

According to OIG, "NIH's use of OTs increased from $34 million in fiscal year (FY) 2016 to more than $348 million in FY 2019." NHLBI "has had OT authority longer than any other HHS component," and from Oct. 1, 2016, through Sept. 30, 2019, NHLBI made 29 OTs for a total of $84.3 million awards. "For the 12 OTs in our sample, NHLBI did not adequately document: (1) its justifications for using OTs rather than traditional award instruments; (2) that awarded amounts were fair and reasonable and incurred costs were allowable; or (3) that it complied with Federal requirements for obligating annual appropriations," OIG said. Problems occurred because NHLBI's "internal controls for awarding and administering OTs were ineffective" and it could not "ensure the proper stewardship of Federal funds used to award OTs, including the $71.9 million we reviewed." NIH accepted OIG's recommendations that NHLBI "strengthen its internal controls for OTs by updating its policies and procedures to properly document its justifications for using OTs instead of traditional award instruments and to determine fairness and reasonableness of award amounts, allowability of costs, and compliance with Federal funding requirements." Improvements would be made by Nov. 15, NIH told OIG. (*7/15/21*)

◆ **Following publication in December of a draft version, the National Science Foundation (NSF) on June 22 published a final Proposal & Award Policies & Procedures Guide (PAPPG), which is applicable for proposals "submitted or due on or after" Oct. 4**. As described on the NSF Policy Office website, new sections address "requests for reasonable and accessibility accommodations regarding the proposal process or requests for accessibility accommodations to access NSF's electronic systems, websites and other digital content," and the necessity of assuring that meetings for which support is requested have a "written policy or code-of-conduct addressing harassment."

Biographical sketches will be allowed to increase in length from two to three pages under the new PAPPG, which also includes a table that "identifies where pre- and post-award current and pending support disclosure information must be provided." NSF said "proposers and awardees may begin using this table immediately to assist with completing the relevant proposal and project report sections." In a June 29 email, Jean Feldman, NSF policy head, also announced that the agency had issued new FAQs on current and pending support to harmonize with the table. In reporting to its members about the new PAPPG, the Council on Governmental Relations (COGR) said NSF had responded to some changes it requested in the draft, but not all. COGR is seeking clarification on "how NSF defines visiting scholar, the treatment of consulting permitted by an individual's appointment versus consulting that falls outside of an individual's appointment, and questions related to start-up companies." (*7/1/21*)