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In This Month's E-News: August 2020

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◆ **Higher education groups and others are hailing a decision by the administration to rescind planned rules that would have required students in the United States on certain visas to attend class in person or return home**. The reversal came during a hearing before a judge in Boston presiding over a challenge to the rules filed by more than a dozen states and spearheaded by Massachusetts Attorney General Maura Healey. Harvard University and the Massachusetts Institute of Technology had also filed suit after Immigration and Customs Enforcement announced on July 6 it planned to publish a temporary final rule stating that "nonimmigrant F-1 and M-1 students attending schools operating entirely online may *not* take a full online course load and remain in the United States." Healey called the proposed rule "senseless and illegal the minute it came out" and said that the "hundreds of thousands of international students across this country…enrich our institutions and strengthen our communities." She vowed to "remain vigilant in protecting our international students from these harmful disruptions." (*7/16/20*)

◆ **A device manufacturing firm in Pennsylvania has agreed to pay the government $70,000 to resolve False Claims Act allegations in connection with a National Science Foundation (NSF) award**. The U.S. Attorney's Office for the Middle District of Pennsylvania alleged that Nascent Devices Inc. "improperly charged unallowable and unallocable costs toward the award, applied a significantly higher overhead rate to account for underspending, and provided false certifications on its final report cover page in 2015." In the July 13 announcement, NSF Inspector General Allison Lerner said NSF expects award recipients to "abide by the award terms and conditions, including the federal cost principles. Expenses charged to grants must be allowable, allocable and reasonable. Similarly, awardees cannot significantly underspend awards and keep the surplus funds without consequence." (*7/16/20*)

◆ **The HHS Office for Human Research Protections (OHRP) developed a decision chart related to compliance with the 2018 revised Common Rule and another showing pre-2018 requirements**. OHRP announced the documents in an email, stating, "The Wait is Over! New Decision Charts are Here!" The "graphic charts are designed to help you decide if an activity is research involving human subjects that must be reviewed by an institutional review board (IRB) and whether informed consent, or documentation of informed consent, can be waived," the email said. The 2018 revisions have been in effect since Jan. 21, 2019, except for the requirement for a single IRB for multisite research, which took effect this year. (*7/16/20*)

◆ **Without providing much detail, the NIH Office of Laboratory Animal Welfare (OLAW) issued a notice on July 13 stating that, as of Oct. 1, it would be implementing the 2020 edition of the *Guidelines for the Euthanasia of Animals***, published by the American Veterinary Medical Association (AVMA). OLAW noted that Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals "requires that euthanasia methods be consistent with the recommendations" in the AVMA guidelines "unless adequate scientific justification is provided." Similar requirements are applicable to contracts. "OLAW encourages Assured institutions to begin using the 2020 *Guidelines* when reviewing research projects as soon as possible and expects full implementation after October 1, 2020," the notice said. "Previously approved projects undergoing continuing review according to PHS Policy… which requires a complete review at least once every three years, must be reviewed using the 2020 Guidelines after October 1, 2020." OLAW added that "After October 1, 2020, grant applications and contract proposals must

be consistent" with the 2020 edition. (7/16/20)

◆ **The Secretary's Advisory Committee on Human Research Protections (SACHRP) will take on two new topics at its meeting later this month, as well as possibly finalize previously discussed recommendations on several topics**, including research involving donor organs from deceased individuals. Although planned as an in-person meeting, SACHRP will meet virtually July 22-23 because of COVID-19; the meeting will be webcast. According to a notice in the July 6 *Federal Register*, SACHRP will first discuss recommendations for NIH regarding its draft data management and sharing policy, and then review recommendations on deceased organ intervention research. "The remainder of the meeting will be devoted to a new topic, the interpretation of Public Health Surveillance…as well as consideration of a second new topic, Risks to Non-subjects in Human Subjects Research," the notice states. When available, the full agenda and links to watch the webcast will be available at http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html. (7/9/20)

◆ **NIH has issued a request for information (RFI) to assist a working group of the Advisory Committee to the Director (ACD) as it develops a final report on ways the agency can "improve the scientific rigor, reproducibility, translatability, and transparency of the research it supports,"** in the words of Michael Lauer, deputy director for extramural research. Lauer described the RFI and the ACD's efforts in a recent blog post, noting that, at last month's ACD meeting, working group members (of which he is one) "discussed the benefits and burdens of preregistering certain animal studies, potential financial implications for grants, and training needs to ensure animal studies are rigorous and transparent." (7/9/20)