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◆ **Some funding applications submitted to NIH beginning Jan. 25 will face new requirements and undergo a revised peer review process**. To prepare investigators and institutions, NIH launched a dedicated website with details about specific changes and recently issued what Mike Lauer, NIH director of extramural research, called an "uber notice." Lauer discussed the changes in a recent blog post. They include a simplified review framework applicable to most research project grant applications, revisions to the NIH fellowship application and review process and the use of common forms for biographical sketches and current and pending support. (*4/18/24*)

◆ **The Food and Drug Administration (FDA) and the HHS Office for Human Research Protections have received a little more than two dozen comments on draft guidance the agencies published in the March 1 *Federal Register*** that addresses requirements in the revised Common Rule to include a "key information" section in informed consent documents. The draft guidance includes "a sample approach to the key information section that is based, in part, on research regarding patient understanding of information found in labeling for prescription drugs." (*4/18/24*)

◆ **In its first misconduct finding since November, the HHS Office of Research Integrity (ORI) announced on April 4 that Gian-Stefano Brigidi—most recently an assistant professor at the University of Utah (UU)—agreed to have his work supervised for five years if he is supported by Public Health Service funding**. Brigidi was a postdoctoral fellow at the University of California at San Diego (UCSD) prior to joining UU. ORI said the finding was based on an assessment by UU and an inquiry by UCSD. The paper was published in *Cell* in 2019. According to ORI, Brigidi "engaged in research misconduct by knowingly or intentionally falsifying and/or fabricating data and results by manipulating primary data values" and dozens of figures included in a paper, nine applications for funding and several presentations. The false data was used from 2015 to 2022. (*4//11/24*)

◆ **Standards for the use of National Science Foundation (NSF) logos "have been implemented into the updated award terms and conditions and will become a requirement as the updates take effect," the agency announced in an April 5 blog post**. "In the interim, NSF encourages award recipients to begin implementing these practices (such as including the agency's full-color logo) along with their otherwise required funding acknowledgments in print and digital products related to NSF-invested research and activities. This includes property signage and markings such as on facilities/buildings; instrumentation and equipment that is valued $150,000 or above; websites; educational materials; press materials; exhibit, conference and event materials; and other outreach materials." (*4/11/24*)

◆ **Federal health officials are aware that, "as part of medical students' courses of study and training, patients have been subjected to sensitive and intimate examinations – including pelvic, breast, prostate, or rectal examinations – while under anesthesia without proper informed consent being obtained prior to the examination,"** HHS said in an April 1 letter to medical schools and teaching hospitals. HHS said it is "critically important" to "set clear guidelines to ensure providers and trainees performing these examinations first obtain and document informed consent from patients before performing sensitive examinations in all circumstances." HHS also noted that "informed consent includes the right to refuse consent for sensitive examinations conducted for teaching purposes and the right to refuse to consent to any previously unagreed examinations to treatment

while under anesthesia." HHS's Centers for Medicare & Medicaid Services also issued a revised "interpretive guidance" document to its state surveyors to ensure they are documenting hospitals have such processes and are complying with them. (4/4/24)

◆ **In separate letters both dated March 21 posted online, the FDA is seeking responses from Corinne M. Rogers, director of the New York State Psychiatric Institute institutional review board (IRB), and from Bret R. Rutherford, M.D., who FDA addressed as with the institute but who has resigned, according to press reports**. Noncompliance concerns found during 2022 and 2023 FDA inspections are related to the IRB's failure to report the suicide of a subject enrolled in a trial for which Rutherford was the principal investigator and his conduct of the trial, including the failure of subjects to complete the appropriate wash-out period before beginning the study medication. (4/4/24)

◆ **According to the Council on Governmental Relations (COGR), agencies that are part of the U.S. Department of Defense "are beginning to more regularly conduct risk reviews on fundamental research" funding applications**. The agencies "are requiring specific risk mitigation steps prior to issuing an award, and COGR member institutions have reported that agencies are requesting a variety of risk mitigation measures that may require substantial time to complete," the association said in a March 15 post on its website. (3/27/24)

◆ **An audit by the National Science Foundation (NSF) Office of Inspector General (OIG) of the Center for Space, High-performance, and Resilient Computing (SHREC) at Virginia Tech found compliance with federal requirements, and no transactions were questioned. SCHREC is among more than 80 NSF-funded, industry-university cooperative research centers (IUCRCs)**. "Launched in 2018, SHREC assists industrial partners, government agencies, and research organizations in mission-critical computing research in the following areas: space computing for earth science, space science, and defense; high-performance computing for a broad range of applications; and resilient computing for dependability in harsh or critical environments," auditors said. "At the time of our audit, the award was in the fifth year of its Phase I award. In addition to SHREC, at the time of our audit, Virginia Tech was part of at least six other IUCRCs." (3/27/24)