

## Report on Research Compliance Volume 21, Number 5. April 25, 2024 In This Month's E-News: May 2024

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By Theresa Defino

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(FDA) and the HHS Office for Human Research Protections have received a little more than two dozen comments on draft guidance the agencies published in the March 1 *Federal Register* that addresses requirements in the revised Common Rule to include a “key information” section in informed consent documents.** The draft guidance includes “a sample approach to the key information section that is based, in part, on research regarding patient understanding of information found in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

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