

## Report on Research Compliance Volume 15, Number 6. June 30, 2018 RRC E-Alerts: June 2018

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◆ Members of institutional review boards (IRBs) and officials who oversee human research protections programs have two new guidance documents to aid them, courtesy of the Food and Drug Administration (FDA) and the HHS Office for Human Research Protections (OHRP). On May 17, FDA and OHRP jointly published guidance on written procedures for IRBs, finalizing a draft issued two years ago. "OHRP and FDA revised the guidance to clarify which written procedures are specifically required, and which are recommended. In addition, editorial changes were made to improve clarity," the agencies announced. The guidance also contains a "checklist for written procedures for the IRB and recommendations about operational details to include to support each of these requirements." (5/17/18)

◆ In an audit of the University of California, Davis (UC-Davis), OIG questioned \$2,330,503 and "recommended that the University strengthen its administrative and management controls for the areas in which findings were identified. As a result of its resolution efforts, NSF has determined that \$2,243,650 will be allowed and that \$86,853 will be disallowed," NSF said in the resolution report. The majority of the questioned costs that NSF allowed were for senior salaries OIG said exceeded NSF limits. (5/10/18)

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