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RRC E-Alerts: November,2018

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◆ During the final day of its two-day meeting this week, the Secretary's Advisory Committee on Human Research Protections (SACHRP) adopted a series of recommendations designed to strengthen the independence and financial support afforded the Office for Human Research Protections (OHRP). SACHRP was asked by HHS to weigh in on two reports by the agency's Office of Inspector General trigged by OHRP's actions related to a study of oxygen levels provided to premature infants (RRC 8/18, p. 3). After NIH officials complained, OHRP backed off an earlier requirement that the study's coordinating center revise consent documents to comply with human subjects protection regulations (RRC 6/14, p. 4). (10/18/18)

◆ Planning to update grantee requirements for information sharing, NIH on Oct. 10 announced key provisions it is considering including as it develops a replacement for its existing policy on dissemination of scientific data. The eight-page document describes possible components of a data management and sharing plan that would be required to accompany "applications and proposals that result in scientific data," such as specifying how much data will be collected and where it will be stored and archived. In a related blog post, Carrie Wolinetz, NIH associate director for science policy, said NIH's request for information (RFI) seeks comments particularly related to the definition of scientific data to be covered, elements of required data management and sharing plans, and the "optimal timing, including possible phased adoption, for NIH to consider in implementing various parts of a new data management and sharing policy, as well as how possible phasing could relate to needed improvements in data infrastructure, resources, and standards." Dec. 10 is the deadline for comments.

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