Rulemaking Changes Status of Public Officials in the Common Rule

On January 19, a group of 16 agencies including the Department of Health and Human Services published a final rule updating the Federal Policy for the Protection of Human Subjects. Also known as the “Common Rule,” the regulations make changes to requirements for certain aspects of informed consent, institutional review boards (IRBs), and more. The final rule eliminates the current exemption excluding from IRB review research on public officials and candidates for public office that used methods like educational tests, surveys, interviews, or observation of public behavior without participation by the investigator. The majority of the rule’s provisions go into effect on January 19, 2018. A new requirement for U.S. institutions conducting cooperative research to use a single IRB, with some exceptions, will take effect in January 2020.

APSA opposed the removal of the exemption for public officials, warning that it would place unnecessary barriers to public inquiry of government institutions and representatives. Supplementary information included in the final rule makes note of opposition to this change and states that the new rule addresses these concerns in alternative ways through an exemption provision in § .104(d)(2) of the rule. The provision exempts surveys, interviews, and observation of public behavior from the Common Rule requirements under certain circumstances, including where “[a]ny disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability” or lead to specified types of damage. Additionally, the supplementary information notes that “If the research is designed to provide sensitive generalizable knowledge about officials, then the identifiable private information obtained should be kept confidential as required by this final rule.” However, if research aims “to hold specific elected or appointed officials up for public scrutiny, and not keep the information confidential” the activity does not fall under the definition of research as it pertains to the scope of the regulations.

Beyond the impact on research on public officials, the rule also creates new requirements for information shared with prospective research subjects during the informed consent process. A full summary of major changes accompanies text of the rule. The rule is wide-ranging and also includes notable decisions for scholars of other disciplines including history, journalism, anthropology, public health, and biological sciences.

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