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◆ "Effective immediately," investigators conducting human gene transfer protocols will no longer be required to register such trials, seek approval from NIH's Recombinant DNA Advisory Committee, or submit previously mandatory reports, NIH and the Food and Drug Administration (FDA) announced Aug. 16. NIH has proposed a new oversight framework, which is open for comment until Oct. 16. "We hope this interim step will ease some of the burden for research that already falls under FDA oversight as NIH considers the proposed changes outlined in the Federal Register," Carrie Wolinetz, NIH deputy director for science policy, explained in a blog post. "These trials remain subject to FDA and other clinical trial regulations, and only after FDA, [institutional biosafety committee] and other relevant approvals are in place can these protocols proceed." In addition to the blog post and Federal Register notice, the announcement was accompanied by a statement from NIH Director Francis Collins, and an opinion article by Collins and FDA Commissioner Scott Gottlieb published in The New England Journal of Medicine. (8/23/18)

◆ The HHS Office for Human Research Protections is "currently reviewing both studies and their impact on the community," an OHRP official recently wrote to the watchdog organization Public Citizen. OHRP was responding to Public Citizen's 14-page letter outlining concerns about now-suspended research involving ketamine use by the police on "agitated" individuals in emergency situations. After an investigation by the Star Tribune, an ongoing ketamine study was shuttered by Hennepin County Medical Center in Minneapolis; an earlier one it also sponsored concluded in 2016. The medical center's institutional review board deemed the studies minimal risk and waived informed consent—an "incorrect" determination, according to Public Citizen, which alleged the trials violated other OHRP and FDA regulations. (8/23/18)