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◆ **Finalizing a document issued last year, on Nov. 9 the Food and Drug Administration issued "Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs,"** which FDA said "offers recommendations on how product sponsors can improve clinical trial diversity by accounting for logistical and other participant-related factors that could limit participation." Additionally, the final guidance "provides recommendations on broadening clinical trial eligibility criteria for clinical trials of investigational drugs intended to treat rare diseases and recommendations on improving enrollment and retention of participants with rare diseases. The guidance notes that sponsors should consider early engagement with patient advocacy groups and patients to elicit suggestions for designing trials that participants would be willing to enroll in and support," the agency said.

Changes that study sponsors could make include "reducing visit frequency, when appropriate, in addition to considering whether flexibility in visit windows is possible and whether electronic communications, such as phone, email, social media platforms, or other digital health technology tools can replace site visits and provide investigators with real-time data," according to FDA. The guidance also addresses ways of boosting trial inclusion of "pregnant women, racial and ethnic minorities, children, and older adults, and provides references to more specific guidances." (*11/12/20*)

◆ **Institutions that find it difficult to comply with the requirement for a single institutional review board (sIRB) for multisite studies during COVID-19 may have cheered recent guidance by the HHS Office for Human Research Protections (OHRP)**. But NIH has thrown a bit of cold water on the exception. On Oct. 9, OHRP announced "an exception to the requirement to use a single IRB is appropriate" for research that "is ongoing or initially reviewed by the IRB during the Coronavirus Disease 2019 (COVID-19) public health emergency" and "where reliance on a single IRB would not be practical; and for which the HHS division supporting or conducting the research approves of the use of this exception." OHRP said the exception would be in force "for the duration of the HHS-conducted or -supported research."

On Nov. 2, the NIH Office of Extramural Research announced a notice on implementation of OHRP's guidance, stating that awardees must request an exception and that the agency "anticipates the use of this exception will be rare." NIH said requests must "include a justification as to why the study meets the exception criteria defined by OHRP." (*11/12/20*)

◆ **A Miami resident is facing up to 20 years in prison after pleading guilty to fabricating results for a GlaxoSmithKline-funded study of asthma medication for pediatric patients**. The Department of Justice (DOJ) announced Nov. 2 that Lisett Raventos, a study coordinator with Unlimited Medical Research, "admitted that from approximately 2013 to 2016, she participated in a scheme to defraud" sponsors of the study. Although DOJ did not identify the study or the sponsor in its announcement, other court documents reviewed by *RRC* indicate the trial at issue is called VERITAS, a Phase IV study the pharmaceutical firm conducted from 2011 to 2016.

"Raventos admitted that she falsified medical records to make it appear as though pediatric subjects made

scheduled visits to UM Research, took study drugs as required, and received checks as payment," DOJ said. According to the court documents, Raventos, working with a physician, receptionist and another study coordinator, "fabricated written case histories" using information from patients in the physician's practice. One of the three is also accused of making hundreds of phone calls to the study's "e-diary system" and providing "false and fictitious answers in response to question[s] about the subjects' daily drug usage and experience." In reality, the practice "discarded" the drugs and kept the money from the study, the documents allege. Raventos pleaded guilty to one count of conspiracy to commit wire fraud before U.S. District Judge Beth Bloom, DOJ said, adding that Raventos "is the first defendant to plead guilty in connection with the scheme." The other three "are presumed innocent until proven guilty beyond a reasonable doubt." (*11/5/20*)

◆ **Apparently responding to news reports and a letter from four U.S. senators, Patricia Brown, director of the NIH Office of Laboratory Animal Welfare (OLAW), said in a statement** that she had determined that "transporting chimpanzees assessed by the facility veterinarian and the NIH Veterinary Panel to be significantly compromised by disease or exhibiting difficulty maintaining quality of life would be a violation" of the Animal Welfare Act and the Public Health Service policy. The Oct. 27 announcement on the OLAW website is headlined "Chimpanzees must remain in their current location and not be transported under certain conditions" and notes that the Alamogordo Primate Facility in New Mexico "is a government-owned, contractor-operated federal research facility, conducting non-invasive sample collection and observational behavioral studies." The statement does not mention any context for the announcement.

However, a week earlier, Sens. Tammy Duckworth, D-Ill., Tom Udall, D-N.M., Martha McSally, R-Ariz., and Martin Heinrich, D-N.M., sent a letter to NIH Director Francis Collins asking that he "ensure compliance" with the CHIMP Act's provisions on retirement and relocation. The Oct. 20 letter also "expressed particular concern for the 37 remaining chimpanzees" at the Alamogordo facility on the Holloman Air Force Base and requested responses to several questions, including a justification for why the primates had not been moved. Since NIH phased out invasive chimpanzee research five years ago, it has retired dozens to Chimp Haven, a sanctuary in Louisiana, where the senators and animal rights groups say the Alamogordo chimpanzees would enjoy appropriate care and a better life. However, *The New York Times* reported Oct. 6 that NIH was unwilling to revisit a September 2019 decision that the chimpanzees were too frail to relocate; local news media, including television stations, have also picked up the story. (*10/29/20*)

◆ **The HHS Office of Research Integrity (ORI) is seeking ideas to help "understand the key challenges to using training and educational efforts to foster a climate that encourages research integrity and the responsible conduct of research,"** according to a notice in the Oct. 19 *Federal Register.* ORI posed 21 questions in three categories: using training and education to foster research integrity; responsible conduct of research/research integrity program administration and facilitation of training; and research integrity/responsible conduct of research training sessions. Some of the questions have several parts.

For example, ORI asked, "What approaches engage learners and create an interactive session (*e.g.,* lectures, seminars, small group discussions, audience polling, problem solving, role play)? Are different approaches used when training faculty, staff, students, or postdoctoral researchers?" The agency said it "will actively consider all input as our office plans education and outreach activities." The deadline for comments is Dec. 18. (*10/29/20*)