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OHRP Posts First Determination Letter Since October—a Follow-Up

The HHS Office for Human Research Protections (OHRP) approved of corrective actions the University of Arkansas at Little Rock (UALR) implemented following a finding that it had not updated its research protection and institutional review board (IRB) policies to comply with the 2018 revised Common Rule, according to a July 6 letter OHRP posted online. This is the first determination letter OHRP has posted since Oct. 7—and that one was also to UALR. At that time, the agency concluded “UALR did not have satisfactory IRB written procedures that the IRB can follow to ensure adequate review and compliance with the 2018 Requirements as required by 45 CFR 46.108(a)(3)(i) (e.g., conducting initial and continuing review of research and for reporting findings and actions to the investigator and the institution),” the new letter recounted. “For example, the existing IRB written procedures provided by UALR that were dated May 2018 did not include the 2018 Requirements’ additional informed consent provisions.”

UALR explained to OHRP in a Nov. 8 letter that as of May 2022, it had revised its policies to “include all the required written procedures that are relevant to the research portfolio currently reviewed by UALR’s IRB, which appears to include largely research that qualifies for exempt or expedited review under the 2018 Requirement.” OHRP’s newest letter to UALR said no further involvement by the agency was necessary. The May 2022 letter was one of eight OHRP posted last year. OHRP has had fewer investigators in recent years and, as of December, had a 62% vacancy rate, with 20 staff members and 12 positions on hold. It has been led by Acting Director Julie Kaneshiro since longtime head Jerry Menikoff retired in December.

[Link to UALR determination letter](#)

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