

## Report on Research Compliance Volume 19, Number 4. March 24, 2022 RRC E-Alerts: March 17, 2022

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### **OHRP Issues First Oversight-Related Document Since September 2020**

A six-year review of the institutional review board (IRB) at National Jewish Health (NJH) of Denver has been resolved, with the organization outsourcing the services, according to a Feb. 28 compliance determination letter posted by the HHS Office for Human Research Protections (OHRP). In the letter, the first such enforcement and oversight document OHRP has issued since Sept. 28, 2020, OHRP officials described finding via a not-for-cause evaluation in September 2016 that NJH “did not have adequately trained HRPP [human research protection program] staff or sufficient IRB written procedures per regulatory requirement[s] and as described in OHRP’s guidance,” OHRP said. A follow-up visit two years later found that NJH “had made significant changes to address deficits in their HRPP” but that “additional concerns related to their compliance with HHS regulations persisted. OHRP acknowledges that NJH was still in the process of hiring qualified staff to better manage their HRPP, in the beginning stages of implementing an electronic protocol management system, had updated their IRB written procedures, and implemented new IRB forms and checklists.”

OHRP had also “observed little evidence of the HRPP’s preparation for the January 2019 implementation of the revised Common Rule. Further, interviews with the IRB members, staff and researchers revealed minimal knowledge of the revised Common Rule or plans to implement changes that would assure that the institution would be able to comply with the new requirements in the revised Common Rule,” according to the letter. “Additionally, through OHRP’s review of IRB records and observations made during an NJH IRB meeting, it appeared that significant IRB member training would be needed for the IRB to properly comply with HHS regulations. OHRP provided NJH with specific studies which appeared to illustrate compliance issues with the IRB’s review.” According to the new letter, as of May 2020, NJH transferred its IRB functions to an external organization. “NJH still recognizes its continuing institutional responsibility to maintain appropriate oversight over the human subjects research in which NJH is engaged. OHRP has determined that concerns identified during the two site evaluations have been adequately addressed,” the letter said. OHRP’s letter gives no indication whether the agency ever took any action against NJH for the apparent “compliance issues” before the transfer was made, nor did the agency post any of the correspondence to which it referenced. NJH’s website indicates IRB functions are handled by Biomedical Research Alliance of New York, founded and led by “a consortium of academic medical centers including NYU School of Medicine, Montefiore Medical Center, and Icahn School of Medicine at Mount Sinai.”

[Link to OHRP letter to NJH](#)

[Link to NJH IRB information](#)

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