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OHRP Finds Numerous Areas of Noncompliance at BRANY IRB

A Phase II study of a "new endometrial sampling device" approved by the institutional review board (IRB) of Biomedical Research Alliance of New York (BRANY) violated federal criteria that "requires an IRB to ensure, when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects," the HHS Office for Human Research Protections (OHRP) told BRANY, according to a 4,000-word determination letter OHRP recently posted on its website. The July 13 letter identified numerous other issues associated with specific studies and with BRANY operations that were uncovered during OHRP's site visit in April 2021—all of which OHRP said were later resolved to its satisfaction. OHRP said a "description of the criteria the [endometrial] study would use to evaluate the safety of the experimental sampling device was not found in the study documents. No data and safety monitoring plans were evident; however, the protocol stated that an analysis of the data will be conducted once 50% of study subjects have been enrolled." Further, the IRB did not have sufficient information to know "whether the device was safe and effective and, thus, the IRB did not have sufficient information to evaluate the risk-benefit ratio of the study as required." OHRP also found multiple problems with the consent forms used in this study. OHRP recounted changes BRANY made in its overall review processes but did not address this particular study except to say it "closed in October 2021." The number of subjects who had been enrolled was not disclosed.

In addition, a study of "patients" with dermatitis was inappropriately approved under expedited review when it did not qualify because it "involve[d] a skin punch biopsy which appears to be invasive," OHRP said. The agency also reported that "during the record reviews, OHRP noted that the files in the IRB records seemed inconsistently named and the location of the files varied among study records, which made it a challenge to reconstruct a complete history of some IRB actions related to a protocol review." Moreover, OHRP made several findings related to the functioning of IRB meetings, noting, for example, that it was not clear whether members "had access to documents that included revisions to the protocol or consent form that were proposed by the primary or secondary IRB reviewers. Other IRB members seemed to rely on the primary and secondary reviewers' oral description of their proposed changes to the protocol and consent form. The IRB did not appear to summarize the conditions for approval prior to taking a vote on whether to approve the research." For another study of an online system for addressing teen depression in primary care, OHRP said, "the protocol describes two phases of the research, and it was unclear to the OHRP site visit team how the waiver of consent or waiver of documentation of consent were applied and to which phase." The corrective actions OHRP said BRANY took in response to these concerns included retraining and the implementation of new policies and procedures. This marks only the third determination letter OHRP has posted this year. In 2021 it posted zero, and in 2020, just four. In the past, OHRP posted dozens per year.

Link to BRANY letter