Report on Research Compliance Volume 15, Number 8. August 31, 2018

Agencies' Guidance Offers Checklist For Written Procedures Governing IRBs

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Two years after issuing a draft version, the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) have jointly released final guidance on written procedures for institutional review boards (IRBs) that officials hope will "prompt a thorough evaluation" of current policies "that help to ensure the protection of human research subjects."

"OHRP and FDA frequently receive questions about the scope and content of written procedures," and the agencies understand that "some IRBs develop written procedures for the IRB that simply restate the regulations at 45 CFR 46.103(b)(4) and (5) , and at 21 CFR 56.108(a) and (b) ," the guidance states.

But this "does not provide sufficient detail about the IRB's operations to ensure that the IRB's operations meet the applicable regulatory requirements," they said. The basis for written procedures is a "comprehensive and critical assessment of the IRB's responsibilities, functions, and operations, and the institution's organizational structure."