4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2727]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled "Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On November 27, 2023, the Agency submitted a proposed collection of information entitled "Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0130. The approval expires on December 31, 2026. A copy of the supporting statement for this information collection is available on the internet at https://www.reginfo.gov/public/do/PRAMain.

Dated: January 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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