

§ 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 26, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–26252 Filed 12–4–19; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request Autism Spectrum Disorder (ASD) Research Portfolio Analysis, NIMH**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: The Office of Autism Research Coordination, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9663, Room 6184, Bethesda, Maryland 20892 or can email your request, including your address to: *iaccpublicinquiries@mail.nih.gov* or *nimhrapubliccomments@mail.nih.gov* or can call Melba O. Rojas, NIMH, NIH at 301–402–0279. Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** on October 3, 2019, page 52888 (84 FR 52888) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been

extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

*Proposed Collection:* Autism Spectrum Disorder (ASD) Research Portfolio Analysis, NIMH, 0925–0682, expiration date 12/31/2019, EXTENSION, National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The purpose of the ASD research portfolio analysis is to collect research funding data from U.S. and international ASD research funders, to assist the Interagency Autism Coordinating Committee (IACC) in fulfilling the requirements of the Autism Collaboration, Accountability, Research, Education and Support (CARES) Act of 2019, and to inform the committee and interested stakeholders of the funding landscape and current directions for ASD research. Specifically, these analyses will continue to examine the extent to which current funding and research topics align with the *IACC Strategic Plan for ASD Research*. The findings will help guide future funding priorities by outlining current gaps and opportunities in ASD research as well as serving to highlight annual activities and research progress.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 714.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Number of respondents	Number of projects per respondent	Average time per response (in hours)	Total burden hours
U.S. Federal .....	25	88	15/60	550
U.S. Private .....	9	63	15/60	142
Individuals/households—International Government .....	1	61	15/60	15
Individuals/households—International Private .....	2	13	15/60	7
<b>Total .....</b>		<b>1434</b>		<b>714</b>

Dated: November 27, 2019.

**Melba O. Rojas,**

*Project Clearance Liaison, National Institute of Mental Health, National Institutes of Health.*

[FR Doc. 2019–26260 Filed 12–4–19; 8:45 am]

**BILLING CODE 4140–01–P**