the child's primary caregiver (who will be the mother if she is available), (2) direct assessments of child development, (3) a semi-structured interview with the caregiver, (4) surveys with the child's teacher, (5) a direct assessment of the caregiver, and (6) 15 minutes of videotaped interactions between the caregiver and child. In addition to collecting these data, the MIHOPE–LT project will also maintain up-to-date consent forms for the collection of administrative data. Future information collection requests and related **Federal Register** Notices will describe future data collection efforts for this project.

Data collected during the kindergarten follow-up study will be used to estimate the effects of MIECHV-funded programs on seven domains: (1) Maternal health; (2) child health; (3) child development and school performance; (4) child maltreatment; (5) parenting; (6) crime or domestic violence; and (7) family economic self-sufficiency.

Respondents: The respondents in this follow-up study will include 4,115 families who participated in MIHOPE and 4,115 teachers of the focal children from those families.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Survey of caregivers	4115	1372	1	1	1372
Direct assessments of children	4115	1372	1	1.5	2058
Semi-structured interview with caregivers	100	33	1	2	66
Survey of the focal children's teachers	4115	1372	1	0.5	686
Direct assessments of caregivers	4115	1372	1	0.25	343
Videotaped caregiver-child interactions	8230	2743	1	0.25	686

Estimated Total Annual Burden Hours: 5,211.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request *Title:* Tribal Maternal, Infant, and Early Childhood Home Visiting Program: Guidance for Submitting an Annual or Final Report to the Secretary

OMB No.: 0970–0409.

Description: Section 511(e)(8)(A) of Title V of the Social Security Act requires that grantees under the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program for states and jurisdictions submit an annual report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. Section 511(h)(2)(A) further states that the requirements for the MIECHV grants to tribes, tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

The Administration for Children and Families, Office of Child Care, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, has awarded grants for the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal Home Visiting). The Tribal Home Visiting discretionary grants support cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally-relevant, evidence-based home visiting programs in at-risk tribal communities; establish, measure, and report on progress toward meeting performance measures in six legislatively-mandated benchmark areas; and conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

Tribal Home Visiting grantees have been notified that in every year of their grant, after the first year, they must comply with the requirement for submitting an Annual Report to the Secretary that should feature activities carried out under the program during the past reporting period and a final report to the Secretary during the final year of their grant. In order to assist grantees with meeting the requirements of the Annual and Final Report to the Secretary, ACF created guidance for grantees to use when writing their reports. The existing guidance (OMB Control No. 0970–0409, Expiration Date 10/31/18) provides sections where grantees must address the following:

- Update on Home Visiting Program Goals and Objectives
- Update on the Implementation of Home Visiting Program in Targeted Community(ies)

- Progress toward Meeting Legislatively Mandated Benchmark Requirements
- Update on Rigorous Evaluation Activities
- Home Visiting Program Continuous Quality Improvement (CQI) Efforts
- Administration of Home Visiting Program
- Technical Assistance Needs

The proposed data collection form is as follows:

ACF is requesting approval to renew and update the existing Tribal Home Visiting Guidance for Submitting an Annual or Final Report to the Secretary (OMB Control No. 0970–0409) that will include instructions for grantees to submit either an annual or final report on the progress of their program to the Secretary, depending on the reporting period.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Managers (The information collection does not include direct interaction with individuals or families that receive the services).

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total annual burden hours
Annual/Final Report to the Secretary (depending on reporting period)	25	1	1	50	1250

Estimated Total Annual Burden Hours: 1,250.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office Planning, Research and Evaluation, 370 L'Enfant Promenade SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of theagency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0129]

Evaluating Inclusion and Exclusion Criteria in Clinical Trials; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled ''Evaluating Inclusion and Exclusion Criteria in Clinical Trials.'' Convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA, the purpose of the public meeting is to bring the stakeholder community together to discuss a variety of topics related to eligibility criteria in clinical trials and their potential impact on patient access to investigational drugs, and how to facilitate the enrollment of a diverse patient population.

DATES: The public meeting will be held on April 16, 2018, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the National Press Club, 529 14th St. NW, Washington, DC 20045. For additional travel and hotel information, please refer to the following website: *https://healthpolicy.duke.edu/events/evaluating-inclusion-and-exclusion-criteria-clinical-trials.* There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Meeting*).

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993, 301–796–2500, *Dianne.Paraoan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public meeting implements FDA's mandate under section 610 of the FDA Reauthorization Act of 2017 to convene a public meeting to discuss clinical trial inclusion and exclusion criteria that will ultimately inform an FDA guidance on this subject. Among other things, the public meeting will include discussion about various ways in which participation in clinical trials can be improved, including through alternative trial designs and expanded access trials (see Section II. Topics for Discussion at the Public Meeting).

Inclusion of relevant subpopulations in drug development programs helps ensure that approved products will be safe and effective for the population likely to be treated when the drug is marketed. However, certain eligibility criteria in clinical trials can exclude patient subgroups, resulting in the enrollment of study populations that may not be fully representative of that broader patient population. FDA has and will continue its efforts to encourage greater diversity in clinical trial populations. For example, FDA regulations require marketing applications to provide analyses of safety and effectiveness by demographic and other relevant subgroups (see 21 CFR 314.50(d)(5)(v)). In addition, in 2016, FDA published guidance on the collection of race and ethnicity data in clinical trials (available on FDA's guidance web page at *https://www.fda.gov/downloads/*