

statistical analysis using modified intent-to-treat populations, inclusion of patient-reported outcomes as a factor to be considered as part of the benefit-risk evaluation, provision of additional reference citations, and addition of references to FDA’s Q-Submission Program, which can be used to request feedback on aspects of a proposed clinical study design.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on “Medical Devices with Indications Associated with Weight Loss—Pre-market Considerations”. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA considered the applicability of Executive Order 14192, per Office of Management and Budget (OMB) guidance in M–25–20, and finds this action to be neither an E.O. 14192 regulatory nor an E.O. 14192 deregulatory action.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov> and at <https://www.fda.gov/regulatory-information/search-fda-guidance>

documents. Persons unable to download an electronic copy of “Medical Devices with Indications Associated with Weight Loss—Pre-market Considerations” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00019046 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR Part or Guidance	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56	Protection of Human Subjects and Institutional Review Boards	0910–0130
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995,

HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than April 13, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests

submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System, OMB No. 0906–0017—Revision

Abstract: This request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Performance Measurement Information System. The MIECHV Program is administered by the Maternal and Child Health Bureau within HRSA in partnership with the Administration for Children and Families, and provides support to all 56 states and jurisdictions, as well as tribes and tribal organizations. Through a needs assessment, states, jurisdictions, tribes, and tribal organizations identify target populations and select the home visiting service delivery model(s) that

best meet their needs. State and jurisdiction MIECHV funding recipients report annual demographic and performance data to HRSA through Form 1—Demographic Performance Measures and Form 2—Benchmark Performance Measures. MIECHV funding recipients also report program information on a quarterly basis through Form 4—Quarterly Data Collection (currently approved under OMB No. 0906–0016). This ICR will now include Forms 1, 2, and 4, so all the components of data collection for the MIECHV Program are in one request. OMB No. 0906–0016 will be discontinued after OMB approval of this ICR.

HRSA is revising the data collection forms for the MIECHV Program to reduce administrative burden where possible and to increase alignment with current clinical and evidence-based guidelines and with performance measures of other maternal and child health programs.

HRSA proposes the following changes:

- Form 1 cross-cutting changes:
 - Remove new and continuing participant categories from Tables 4, 5, 18, 19, and 20.
 - Remove pregnant participant and caregiver categories for Table 9, 10, 11, and 18.
 - Add Section D: Place Based Services to collect, on an annual basis, information previously reported quarterly on Form 4.
 - Renumber tables as appropriate per other changes and minor edits to data labels.
 - Form 1, Tables 1 and 2: Combine Tables 1 and 2 into one table that captures new and continuing participants and households together.
 - Form 1, Table 4: Decrease the number of response categories for age of adult participants from 10 to 6.
 - Form 1, Tables 6 and 7: Update response categories to align with OMB's Statistical Policy Directive 15: Standards for Maintaining, Collecting and Presenting Federal Data on Race and Ethnicity.
 - Form 1, Table 8: Remove this table from the data collection form.
 - Form 1, Table 11: Streamline reporting for adult participants by housing status by decreasing "Not Homeless" data sub-categories from 5 to 1 and "Homeless" sub-categories from 3 to 2.
 - Form 2, Performance Measure 3: Add a sub-measure to collect data on anxiety screening.

- Form 2, Performance Measure 5: Expand the postpartum visit window to within 12 weeks (84 days) of delivery.
- Form 2, Performance Measure 6: Update the measure definition to explicitly mention e-tobacco.
- Form 2, Performance Measure 7: Update the safe sleep measure to specify a 2-week lookback period for the reporting window.
- Form 2, Performance Measure 17: Add a sub-measure to collect data on completed anxiety referrals.
- Form 4, Table A2: Remove the table from Form 4; the table will be moved to Form 1.
- Form 4, Table A3: Remove this table from data collection.
- Forms 1, 2, and 4: Update Definition of Key Terms to reflect the changes.

A 60-day notice was published in the **Federal Register** on December 22, 2025, vol. 90, No. 243; pp. 59844–45. HRSA received one comment from the Association of State and Tribal Home Visiting Initiatives expressing appreciation that HRSA gave their members the opportunity to provide input throughout the process of making changes and noted the need for ongoing support for the performance measure changes.

Since publication of the 60-day notice, HRSA made minor edits to wording throughout Form 2 to improve consistency of terminology use across measure titles and to use more plain language to describe the measures. These changes do not alter definitions or specifications of the measures and have no impact on burden hours.

Need and Proposed Use of the Information: HRSA uses performance information to demonstrate program accountability and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, state, and local level. HRSA is seeking to revise and extend collection of (1) demographic, service utilization, and select clinical indicators for participants enrolled in home visiting services, and location of services (annually via Form 1); (2) a set of standardized performance and outcome indicators that correspond with the statutorily identified benchmark areas (annually via Form 2); and (3) home visiting program capacity and staffing data (quarterly via Form 4).

This information will be used to demonstrate awardees' compliance with legislative and programmatic requirements. It will also be used to monitor and provide continued oversight of awardee performance and to target technical assistance resources for awardees. Revisions to the forms meet a statutory requirement to reduce administrative burden for MIECHV funding recipients (Section 511(h)(6)(A) of the Social Security Act). HRSA reviewed the information collected and streamlined, where possible, to collect optimum amount of data necessary to fulfill awardee performance measurement and demonstration of improvement requirements. Additionally, other revisions have been made to align performance measures with other maternal and child health programs, with current Statistical Policy Directive 15 (Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity), and current clinical and evidence-based guidelines. The revisions reflect feedback from current MIECHV funding recipients, home visiting model developers, and federal partners.

Likely Respondents: MIECHV Program funding recipients that are states, jurisdictions, and, where applicable, nonprofit organizations providing home visiting services within states.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

HRSA updated the estimated burden hours based on data collected in summer 2024 under OMB No. 0906–0094, titled "Implement MIECHV Program 2022 Legislative Changes: Assessment of Administrative Burden." The same group of 56 respondents will complete each form.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Form 1: Demographic, Service Utilization, Select Clinical Indicators, and Program Locations	56	1	56	448	25,088
Form 2: Performance Indicators and Systems Outcome Measures	56	1	56	723	40,488
Form 4: Quarterly Performance Report	56	4	224	35	7,840
Total	56	280	73,416

Maria G. Button,*Director, Executive Secretariat.*

[FR Doc. 2026-04900 Filed 3-12-26; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary****Findings of Research Misconduct****AGENCY:** Office of the Secretary, HHS.**ACTION:** Notice.

SUMMARY: Findings of research misconduct have been made against Chen-Yeh “George” Ke, Ph.D. (Respondent), former postdoctoral fellow, Department of Cell, Development and Regenerative Biology, Icahn School of Medicine at Mount Sinai. Dr. Ke engaged in research misconduct under 42 CFR part 93 in research included in one (1) draft manuscript and two (2) National Institutes of Health (NIH) Research Performance Progress Reports, specifically R01 DE022363-07 and R01 DE022363-08 submitted to the National Institute of Dental and Craniofacial Research (NIDCR), NIH. The questioned research was supported by U.S. Public Health Service (PHS) funds, specifically NIDCR, NIH, grant R01 DE022363-06A1. Administrative actions, including supervision for a period of three (3) years, were implemented and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Sheila R. Garrity, JD, MPH, MBA, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453-8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Chen-Yeh “George” Ke, Ph.D., Icahn School of Medicine at Mount Sinai (ISMMS): Based on evidence and findings of an investigation conducted by ISMMS, ORI’s oversight review of

ISMMS’ investigation, and additional analysis conducted by ORI in its oversight review, ORI found that Chen-Yeh “George” Ke, Ph.D. (Respondent), former postdoctoral fellow, Department of Cell, Development and Regenerative Biology, ISMMS, engaged in research misconduct under 42 CFR part 93 in research included in one (1) draft manuscript and two (2) NIH Research Performance Progress Reports (RPPRs), specifically R01 DE022363-07 and R01 DE022363-08 submitted to NIDCR, NIH. The questioned research was supported by PHS funds, specifically NIDCR, NIH, grant R01 DE022363-06A1.

ORI found by a preponderance of the evidence that Respondent intentionally and knowingly falsified and/or fabricated western blot images, intentionally and knowingly falsified and/or fabricated microscopy images of mouse embryonic palatal mesenchymal (MEPM) cells stained with alkaline phosphatase (AP) for cell differentiation studies to falsely represent different experiments, and intentionally and knowingly falsified and/or fabricated calcium cellular imaging of MEPM cells in one PHS-supported unpublished manuscript. Respondent’s falsification and/or fabrication of experiment results also were reported in two RPPRs. The affected manuscript and RPPRs are:

- Transient activation of ERK promotes cell differentiation through non-canonical Wnt Signaling. Not submitted for publication (hereafter referred to as “Manuscript 2022”).
- R01 DE022363-07 (hereafter referred to as “RPPR 2019”).
- R01 DE022363-08 (hereafter referred to as “RPPR 2020”).

Specifically, ORI found by a preponderance of the evidence that Respondent engaged in research misconduct by intentionally and knowingly falsifying and/or fabricating:

- western blot data by reusing blot band images after manipulating, splicing together, and falsely relabeling them to represent different experiments in Figure 1B in Manuscript 2022 and reporting false statements in RPPR 2019

and RPPR 2020 based on these falsified data. The specific manipulations in Manuscript 2022 are as follows:

- The FGF +BIM-1 0 minute (min) timepoint for p-ERK shows evidence that it was cut and pasted.
- The noise pattern in FGF +BIM-1 0 min is identical to the FGF 0 min timepoint in the same panel.
- The 0, 60, and 120 minute FGF lanes have been duplicated to the PDGF treatment in the +PMA 0, 60, and 120 minute treatment lanes after horizontal flipping.
- The 60 min FGF lane has been duplicated in the top row as 15 min FGF +BIM-1 lane.
- The four lanes denoting the 0, 15, 60, and 120 min following FGF +PD0325901 treatment are all one image that has been duplicated and shifted vertically.

- microscopic image data for cell differentiation studies by duplicating, manipulating, and relabeling a single image of AP-stained MEPM cells to falsely represent AP staining under different experimental conditions four times in Figures 3 and 5 in Manuscript 2022 and reporting false statements in RPPR 2019 and RPPR 2020 based on these falsified data. The image panel in row one, column one of Figure 3C in Manuscript 2022 reports to be the results of MEPM cells under “Vector/Control” treatment; specifically, the panel is:

- duplicated and flipped on its vertical axis in the Vector/Control panel of Figure 3D
- duplicated to represent the PX459 Vector/Control panel of Figure 5A
- duplicated to represent the Control/YAP-KO panel of Figure 5E

- microscopic image data for cell differentiation studies by duplicating, manipulating, and relabeling a single image of AP-stained MEPM cells to falsely represent AP staining under different experimental conditions four times in Figures 3 and 5 in Manuscript 2022 and reporting false statements in RPPR 2019 and RPPR 2020 based on