auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of June 15, 2022 (87 FR 36135), FDA published a notice announcing the availability of a draft guidance entitled ''Q9(R1) Quality Risk Management.'' The notice gave interested persons an opportunity to submit comments by July 15, 2022.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies on January 18, 2023.

This guidance finalizes the draft guidance of the same title issued on June 15, 2022. The final guidance includes: (1) updated references, (2) a dedicated section to the subjectivity of QRM, (3) clarification on the application of risk management in the use of digitalization and emerging technologies, (4) an emphasis on root cause analysis, (5) a clearer definition of ''risk-based decision-making,'' and (6) an improved distinction between hazards, harms, and associated risks. The final guidance further addresses detection controls' link to reducing the probability of the occurrence of harm, situations which call for higher levels of QRM formality, and the importance of QRM regarding distribution practices.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Q9(R1) Quality Risk Management.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice requirements have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: May 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09517 Filed 5–3–23; 8:45 am]

BILLING CODE 4164–01–P

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; Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System, OMB No. 0915–0298—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA is submitting a request for public comment on redesigned Maternal and Child Health Bureau (MCHB) Performance Measures for Discretionary Grant Information System (DGIS) forms. The purpose of the redesigned DGIS forms is to facilitate higher quality data collection and develop streamlined, clear DGIS metrics to support communications about the range of HRSA's maternal and child health (MCH) programs. Proposed revisions include eliminating 52 forms, adding 25 new forms, and revising 23 existing forms. In addition, three forms have not undergone substantive revisions since the previously approved Office of Management and Budget (OMB) package and are included in the time burden estimate. HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the Information Collection Request (ICR).

DATES: Comments on this ICR must be received no later than July 3, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call 301–594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: MCHB Performance Measures for DGIS, OMB No. 0915–0298 Revision.

Abstract: Approval from OMB is sought to implement revisions to the MCHB Performance Measures for DGIS. The goals of the redesigned performance measures are to: (1) improve clarity and validity of DGIS forms; (2) increase alignment with MCHB's Strategic Plan and other performance measurement efforts; (3) produce timely, actionable data for program management; (4) support communications about the range of HRSA's MCH programs; (5) reduce the number and complexity of data collection forms; and (6) improve data quality.

The revised forms are grouped into two general categories: central measures and program specific measures. Central measures include basic, topical, activity, and outcome forms. There are also four sets of program-specific forms. Grant programs are assigned forms based on their activities and individual grantees respond to only a limited number of forms that are relevant to their specific program. Many of these forms are specific to certain types of programs and are not required of all grantees.

Forms are proposed to be added, removed, or revised beyond what was specified in the **Federal Register** notice (87 FR 35220) published on June 9, 2022. Many of the changes are a result of the redesigned categorization of measures. For example, the proposed set of activity forms capture common types of activities conducted across MCHB investments and replace the set of Population Domain forms (Adolescent Health, Capacity Building, Child Health, Children with Special Health Care Needs (CSHCN), Life Course/Cross Cutting, Maternal/Women Health, and Perinatal/Infant Health). The proposed set of basic forms consolidate and simplify the set of financial forms (Form 1, 3, 5, 7, and 8). Other changes reflect efforts to reduce burden or the need to relocate measures from the Population Domain forms to program-specific forms (*i.e.,* Healthy Start). Specifically, HRSA is making the following changes to the current information collection for DGIS:

Removing the following 52 existing forms: Capacity Building (CB) 1 (State Capacity for Advancing the Health of MCH Populations), CB 3 (Impact Measurement), CB 4 (Sustainability), CB 5 (Scientific Publications), CB 6 (Products), CB 8 (Quality Improvement), Women's/Maternal Health (WMH) 1 (Prenatal Care), WMH 2 (Perinatal/Postpartum Care), WMH 3 (Well Woman Visit/Preventive Health Care), WMH 4 (Depression Screening), Perinatal Infant Health (PIH) 1 (Safe Sleep), PIH 2 (Breast Feeding), PIH 3 (Newborn Screening), Child Health (CH) 1 (Well Child Visit), CH 2 (Quality of Well Child Visit), CH 3 (Developmental Screening), CH 4 (Injury Prevention), CSHCN 1 (Family Engagement), CSHCN 2 (Access to and Use of Medical Home), CSHCN 3 (Transition to Adult Health Care), Adolescent Health (AH) 1 (Adolescent Well Visit), AH 2 (Injury Prevention), AH 3 (Screening for Major Depressive Disorder), Life Course/Cross Cutting (LC) 1 (Adequate Health Insurance Coverage), LC 2 (Tobacco and eCigarette Cessation), LC 3 (Oral Health), Division of Workforce Development (Training) 01 (MCH Training Program and Healthy Tomorrows Family Member/Youth/Community Member Participation), Training 05 (Policy), Training 06 (Diversity of Long-Term Trainees), Training 10 (Leadership), Training 11 (Work with MCH Populations), Training 12 (Interdisciplinary Practice), Emergency Medical Services for Children (EMSC) 01 (Using NEMSIS Data to Identify Pediatric Patient Care Needs), EMSC 02 (Pediatric Emergency Care Coordination), EMSC 03 (Use of Pediatric-Specific Equipment), EMSC 05 (Pediatric Traumatic Emergencies), EMSC 06 (Written Inter-facility Transfer Guidelines that Contain All the Components as per the Implementation Manual), EMSC 07 (Written Inter-facility Transfer Agreements That Covers Pediatric Patients), Healthy Start (HS) 01 (Reproductive Life Plan), HS 02 (Usual Source of Care), HS 03 (Interconception Planning), HS 05 (Father/Partner Involvement during Pregnancy), HS 06 (Father and/or Partner Involvement with Child 0–24 Months), HS 07 (Daily Reading), HS 08 (CAN Implementation), HS 09 (CAN Participation), Form 3 (Budget Details by Types of Individuals Served), Form 5 (Number of Individuals Served (Unduplicated)), Form 7 (Discretionary Grant Project Summary Data and Demographics), Form 9 (Program-Specific Project Performance/Outcome Measures), Technical Assistance/Collaboration Form, and Continuing Education Form.

Adding the following 25 new forms: Direct and Enabling Services, Training and Workforce Development, Partnerships and Collaboration, Engagement of Persons with Lived Experience, Technical Assistance, Outreach and Education, Research, Guidelines and Policy, Data and Information Systems, Quality Improvement and Evaluation, Knowledge Change, Behavior Change, EMSC 10 (Prehospital Emergency Medical Services Pediatric Readiness Recognition Program), HS 10 (Prenatal Care), HS 11 (Perinatal/Postpartum Care), HS 12 (Well Woman Visit/Preventive Health Care), HS 13 (Depression Screening), HS 14 (Safe Sleep), HS 15 (Breastfeeding), HS 16 (Well Child Visit), HS 17 (Adequate Health Insurance Coverage), HS 18 (Prenatal Tobacco and eCigarette Use), HS 19 (Low Birthweight), HS 20 (Preterm Birth), and HS 21 (Infant Mortality).

Revising the following 23 existing forms: Health Equity, Healthy Start Site Form, Family to Family Form 1, Financial Form (MCHB Project Budget Details), Project Abstract (MCH Discretionary Grant Project Abstract), Project Abstract-Research Projects Only, Form 10 (Program-Specific and Project Developed Measures), Products, Publications, and Submissions Data Collection Form, Faculty and Staff Information, Short-Term Trainees, Medium-Term Trainees, Long-Term Trainees, Former Long-Term Trainees, LEAP Trainee Information, Training 02 (MCH Training Program and Healthy Tomorrows Cultural Competence), Training 03 (Healthy Tomorrows Title V Collaboration), Training 04 (Title V Collaboration), Training 07 (MCH Pipeline Program-Work with MCH Populations), Training 08 (MCH Pipeline Program-Work with underserved or vulnerable populations), Training 09 (MCH Pipeline-Graduate Program Enrollment), Training 15 (Consultation and Training for Mental and Behavioral Health), HS 04 (Intimate Partner Violence Screening), and EMSC 04 (Pediatric Medical Emergencies).

The following 3 forms are included with no substantive changes from the prior approved OMB package: Training 14 (Medium-Term Trainees Skill and Knowledge), EMSC 08 (Established Permanence of EMSC), and EMSC 09 (Established Permanence of EMSC by Integrating EMSC Priorities into Statutes/Regulations).

Additional non-substantive revisions include updates to terminology, goals, benchmark data sources, and significance sections included in the measures' detail sheets. A performance measure detail sheet defines and describes each performance measure. Forms and detail sheets showing the proposed revisions are available upon request.

Need and Proposed Use of the Information: The performance data collected through the DGIS serves several purposes, including grantee monitoring, program planning, and performance reporting, and the ability to demonstrate alignment between MCHB discretionary programs and the Title V

MCH Services Block Grant program. This revision will facilitate higher quality data collection; streamlined, clear DGIS metrics; and support communications about the range of HRSA's MCH programs.

Likely Respondents: Grantees for MCHB Discretionary Grant Programs.

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.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Responses per respondent	Total responses	Burden hours per response	Total burden hours
Project abstract	817	1	817	1.33	1,087
Project Abstract (Research Projects Only)	58	1	58	0.66	38
Financial Form	817	1	817	0.87	711
Health Equity	817	1	817	0.47	384
Direct and Enabling Services	476	1	476	1.89	900
Training and Workforce Development	250	1	250	2.42	605
Partnerships and Collaboration	380	1	380	1.04	395
Engagement of Persons with Lived Experience	416	1	416	1.58	657
Technical Assistance	300	1	300	2.24	672
Outreach and Education	500	1	500	0.61	305
Research	65	1	65	3.11	202
Guidelines and Policy	78	1	78	0.70	55
Data and Information Systems	50	1	50	0.67	34
Quality Improvement and Evaluation	346	1	346	0.29	100
Knowledge Change	200	1	200	1.64	328
Behavior Change	200	1	200	1.56	312
Products and Publications	672	1	672	4.23	2,843
Training Form 2	168	1	168	0.69	116
Training Form 3	41	1	41	0.99	41
Training Form 4	130	1	130	1.52	198
Training Form 7	6	1	6	0.83	5
Training Form 8	6	1	6	0.75	5
Training Form 9	6	1	6	0.92	6
Training Form 14	6	1	6	3.64	22
Training Form 15	52	1	52	3.17	165
Faculty and Staff Information	124	1	124	1.92	238
Short-Term Trainees	8	1	8	0.67	5
Medium-Term Trainees	121	1	121	2.49	301
Long-Term Trainees	112	1	112	6.37	713
Former Long-Term Trainees	106	1	106	1.60	170
LEAP Trainee Information	6	1	6	0.65	4
HS 4	101	1	101	0.57	58
HS 10	101	1	101	0.31	31
HS 11	101	1	101	0.61	62
HS 12	101	1	101	0.33	33
HS 13	101	1	101	0.50	51
HS 14	101	1	101	0.43	43
HS 15	101	1	101	0.45	45
HS 16	101	1	101	0.39	39
HS 17	101	1	101	0.40	40
HS 18	101	1	101	0.33	33
HS 19	101	1	101	0.38	38
HS 20	101	1	101	0.37	37
HS 21	101	1	101	0.36	36
Healthy Start Site Form	101	1	101	0.32	32
EMSC 4	58	1	58	0.92	53
EMSC 8	58	1	58	0.09	5
EMSC 9	58	1	58	0.42	24
EMSC 10	58	1	58	0.46	27
Family to Family Form 1	59	1	59	2.76	163
Form 10	200	2	400	12.87	5,148
Total	*817		817		17,615

*The number of grantees is an estimate as it fluctuates each year.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–09466 Filed 5–3–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

Date: May 26, 2023.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Sandip Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20852, (240) 292–0189, *sandip.bhattacharyya@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 28, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09441 Filed 5–3–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute on Minority Health and Health Disparities Special Emphasis Panel.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (R13).

Date: June 15, 2023.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIMHD, DEM II, Suite 800, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Xinli Nan, M.D., Ph.D., Scientific Review Officer, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (301) 594–7784, *Xinli.Nan@nih.gov.*

Dated: April 28. 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09449 Filed 5–3–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel: Centers for Oceans and Human Health 4: Impacts of Climate Change on Oceans and Great Lakes.

Date: May 23–25, 2023.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27713 (Virtual Meeting).

Contact Person: Linda K. Bass, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, 984–287–3236, *bass@niehs.nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel: Research Mechanism for Emerging Contaminant/Exposure Studies in the Environmental Health Sciences.

Date: June 5, 2023.

Time: 10:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27713 (Virtual Meeting).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, 984–287–3340, *worth@niehs.nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences, Special Emphasis Panel: VICTER Award R01 Grant Applications.

Date: June 13–14, 2023.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.