

## Supporting Statement A

### Forms for Use with Applications to the Maternal and Child Health Bureau Research and Training Grants, New

OMB Control No. 0906-XXXX

#### A. Justification

##### 1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) is requesting OMB approval to collect information in conjunction with applications for Maternal and Child Health Bureau (MCHB) research and training grants that describe the qualifications of proposed researchers and the description of expected research participants.

In MCHB's research and training grant programs, the applicants will use the Biographical Sketch form to summarize the qualifications of each key personnel on their proposed research team. The grant reviewers will use this information to assess the capabilities of the research team to carry out the planned research project. Applicants will also use the Inclusion Enrollment form to summarize their expected population of research study participants at the time of submission of their proposal. This information will also be used by HRSA to support decision-making as part of the annual Noncompeting Continuation Award process. Monitoring inclusion enrollment is an important component of ensuring demographic diversity (race, ethnicity, and gender) among research study participants in MCHB's research grant portfolio. This allows MCHB to determine to what extent individuals of different backgrounds are participating in MCHB research and training programs.

MCHB evolved from the Children's Bureau established in 1912. The enactment of Title V of the Social Security Act of 1935, specifically Section 509, which states that "the Secretary shall designate an identifiable administrative unit with expertise in maternal and child health within the Department of Health and Human Services, which ... shall be responsible for ... promoting

coordination at the Federal level of the activities authorized under this Title [V],” sanctioned the Maternal and Child Health program as well as provided the foundation and overall structure for MCHB.<sup>1</sup> Situated within HRSA, MCHB continues to administer Title V and leads the nation in efforts to improve and promote the health of mothers and children. With the establishment of Title V, many programs aimed at extending health and welfare services to mothers and children were enacted. These programs have evolved since 1935 with the passage of several legislative amendments.

In 1981, the Omnibus Budget Reconciliation Act of 1981 (OBRA '81), Public Law (PL) 97-35, amended Title V of “the Social Security Act to establish a [block grant] program for maternal and child health services...by consolidating specified [categorical] programs of Federal assistance to States.” This amendment resulted in the creation of the Maternal and Child Health Block Grant. The categorical programs consolidated under the block grant program included: Maternal and Child Health and Children with Special Needs Services, Lead-Based Paint Poisoning Prevention Program, Genetic Disease Programs, Sudden Infant Death Syndrome Programs, Hemophilia Treatment Centers, and Adolescent Pregnancy Grants. Additionally, OBRA '81 authorized a set-aside of discretionary federal funds for Special Projects of Regional And National Significance (SPRANS) as part of the MCH Block Grant, “by setting forth provisions concerning: (1) the allotment of such funds; (2) payments to States; (3) use of grant money” in addition to other provisions. The set-aside of federal funds permits withholding of some of the MCH Block Grant appropriations each fiscal year to support certain categorical programs.

The Omnibus Budget Reconciliation Act of 1989 (OBRA '89), Public Law (PL) 101-239 specifically defined two set-asides for discretionary programs, SPRANS and Community Integrated Service Systems (CISS), by amending Section 502 of Title V to state:

[The] Secretary shall retain an amount equal to 15 percent for the purpose of carrying out activities described in section 501(a) (2) [and] of the amounts appropriated under section 510(a) for the fiscal year in excess of \$600,000,000, and the Secretary shall retain an amount equal to 12 ¾ percent thereof for the projects described in subparagraphs (A) through (F) of section 501(a) (3)” respectively.

## **2. Purpose and Use of Information Collection**

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<sup>1</sup> Section 509, Title V: Maternal and Child Block Health Services Block Grant, Social Security Act (US Code §§701-710, subchapter V, chapter 7, Title 42)

The proposed HRSA forms are based on the National Institute of Health's (NIH's) Biographical Sketch and Maternal and Child Health Bureau (MCHB) Inclusion Enrollment forms. MCHB has modified these forms in slightly different ways in order to meet the needs of its own research and training grant programs and with the required elements of the SF424 Research & Related application package.

In MCHB's research and training grant programs, the modified Biographical Sketch form will be used by applicants to summarize the qualifications of each key personnel on their proposed team; grant reviewers will also use this information to assess the capabilities of the team to carry out the project as planned.

Applicants will also use the Inclusion Enrollment form to summarize their expected population of research study participants at the time of submission of their proposal. This information will be used by HRSA to support decision-making as part of the annual Noncompeting Continuation Award process. Monitoring inclusion enrollment is an important component of ensuring demographic diversity (race, ethnicity, and gender) among research study participants in MCHB's research grant portfolio. This allows MCHB to determine to what extent individuals of different backgrounds are participating in MCHB research and training programs.

### **3. Use of Improved Information Technology and Burden Reduction**

This activity is fully electronic. Grantees will complete the forms as part of their online application via the grants.gov portal. The information will also be used for enrollment reporting during the annual noncompeting continuation award, which is administered electronically via the Electronic Handbooks system, and 100% of the responses will involve the use of automated technological collection via online system.

### **4. Efforts to Identify Duplication and Use of Similar Information**

Efforts have been made to align with other data collection efforts at HRSA and other Federal agencies, as required by Section 509(a)(5) of Title V of the Social Security Act. The data requested in these forms are unique to the research and training programs and are not available elsewhere.

## **5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this study. The information collected is only requested of HRSA grant applicants and awarded grantees. Typical applicants required to fill out this form include research organizations and academic institutions.

## **6. Consequences of Collecting the Information Less Frequently**

If this information is collected less frequently, there will be a gap in data available to monitor and ensure demographic diversity (race, ethnicity, gender) among study participants in HRSA's grant portfolio.

The data will be collected at the time of proposal submission from all grant applicants. The data will also be collected during the annual noncompeting continuation award to existing grantees. On average, the data collection will occur annually for applicable grantees.

## **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

The request fully complies with the regulation.

## **8. Comments in Response to the Federal Register Notice/Outside Consultation**

### **Section 8A:**

A 60-day Federal Register Notice was published in the Federal Register on September 13, 2018, Vol. 83, No. 178. Pages 46504-46505. There were no public comments.

### **Section 8B:**

The HRSA MCHB grantees were contacted in June, 2019 for consultation to review the draft Biographical Sketch and Maternal and Child Health Bureau (MCHB) Inclusion Enrollment forms. Six grantees and grantee program staff agreed to provide feedback on the form. The purpose of the form and process and frequency of data collection were explained to each respondent. Two main questions were asked of each respondent: (1) How long do you believe the form would take to complete? and (2) Do you have any suggestions for improvements on the form?

Names, title, telephone numbers, and e-mail addresses of those consulted are below:

1. Dr. Constance Wiemann, PhD, FSAHM, Associate Professor of Pediatrics, Baylor College of Medicine, Research Director, Adolescent and Sports Medicine, Texas Children's Hospital, One Baylor Plaza, BCM 320, Houston, TX 77030. Phone: 832-822-3360, Email: [CWeimann@bcm.edu](mailto:CWeimann@bcm.edu)
2. Blanca Estela Sanchez-Fournier, Program Manager, Texas Children's Hospital, One Baylor Plaza, BCM 320, Houston, TX 77030. Email: [blancas@bcm.edu](mailto:blancas@bcm.edu) , Phone: 832-824-1000.
3. Laura E Caulfield, PhD, Professor, Center for Human Nutrition, The Johns Hopkins Bloomberg SPH, 615 North Wolfe Street, W2041, Baltimore, MD 21205 USA, Phone: 410-955-2786, [Lcaulfi1@jhu.edu](mailto:Lcaulfi1@jhu.edu)
4. Ellen Bassuk, MD; President, The Bassuk Center on Homeless and Vulnerable Children and Youth, 200 Reservoir Street, Needham, MA 02494. Phone: (781) 247-1770, Email: [ebassuk@bassukcenter.org](mailto:ebassuk@bassukcenter.org)
5. Ruth Paris, PhD, LICSW, Associate Professor and Chair, Clinical Practice Department, Boston University School of Social Work, 264 Bay State Road, Boston, MA 02215, Phone: 617-353-7717, Email: [rparis@bu.edu](mailto:rparis@bu.edu)
6. Ruth Rose-Jacobs, ScD, MS. Associate Professor of Pediatrics, Trustees of Boston University, BUMC, 771 Albany Street, Boston, MA 02118. Phone: 617-414-5480, email: [rrosejac@bu.edu](mailto:rrosejac@bu.edu)

All respondents reported it would take less than 2 hours to complete each form. Suggestions included clarifying form field language and instruction items. No concerns were reported.

#### **9. Explanation of any Payment/Gift to Respondents**

Respondents will not receive any payments or gifts.

## **10. Assurance of Confidentiality Provided to Respondents**

This information collection request does not involve the reporting of information about identifiable individuals; therefore, the Privacy Act is not applicable to this activity. The modified Biographical Sketch and Maternal and Child Health Bureau Inclusion Enrollment forms will collect individual information such as participant name, education/training, institution location, race and ethnicity, positions and honors, contributions to science, research support, and scholastic awards. The office does not assure the public that this information will be confidential other than the privacy offered by the Privacy Act.

## **11. Justification for Sensitive Questions**

MCHB's modified PHS Inclusion Enrollment form will be used by applicants to summarize their expected population of research study participants. The form collects race/ethnicity information, which is considered sensitive in nature. The form collects this information to ensure that federal grant and cooperative agreement awards are reaching a broad diversity of populations. Monitoring inclusion enrollment is one important component of ensuring demographic diversity (race/ethnicity) among research study participants in MCHB's research and training grant portfolio. This allows MCHB to determine to what extent individuals of different backgrounds are participating in MCHB's research and training programs.

## **12. Estimates of Annualized Hour and Cost Burden**

This section summarizes the total burden hours for this information collection in addition to the cost associated with those hours.

Burden was estimated by current grantees reviewing the instructions and data elements of the form and estimating the amount of time it would take to complete.

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Biographical Sketch for MCHB research and training grant applicants	200	5	1000	2	2000
PHS Inclusion Enrollment form for MCHB research and training grant applications	200	1	200	.05	100
Total	400	-----	1200	-----	2100

**12B.**

**Estimated Annualized Burden Costs**

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Research and Training Grant Applicants	2100	\$48.48	\$50,904
Total	2100		\$50,904

<https://www.bls.gov/oes/current/oes194061.htm>

**13. Estimates of other Total Annual Cost Burden to Respondents or Record keepers/Capital Costs**

Other than their time, there is no cost to respondents.

**14. Annualized Cost to Federal Government**

<b>Type of Cost</b>	<b>Description of Services</b>	<b>Annual Cost</b>
Oversight of Form Administration (Government Program Analyst - 10%)	Federal staff time to administer TA activities	\$3,136.20
Administration of the Modified Biographical Sketch form (Government Program Analyst – 5%)	Federal staff time to administer, analyze, and report on Modified Biographical Sketch form data	\$3,763.44

HRSA anticipates the average annual cost for the federal government will include personnel costs for data collection oversight. This will include a federal program analyst at Grade 13 Step 4 (\$52.27 hourly rate) for 60 hours (approximately 5 hours per month). Additionally, the federal government will support the administration of the Modified Biographical Sketch form, which will include staff time to analyze and report on the form data. This will also include a federal program analyst at Grade 13 step 4 (\$52.27) for 72 hours (approximately 6 hours per month).

The total cost to the federal government for these activities is \$6899.64 per year.

**15. Explanation for Program Changes or Adjustments**

This is a new information collection; changes in burden are not applicable to this section.



**16. Plans for Tabulation, Publication, and Project Time Schedule**

The information that is collected will be used for internal grant monitoring purposes in identifying inclusion and enrollment of research and training participants. There are no complex analytical techniques planned to be used for the analysis of collected data.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The OMB number and Expiration date will be displayed on every page of every form/instrument.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.