

consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations must also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed

information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: November 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: MCH Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906-XXXX, New

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

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, or any other aspect of the ICR related to the Maternal and Child Health (MCH) Jurisdictional Survey that is to be

administered in the U.S. territories and jurisdictions (excluding the District of Columbia) for purposes of collecting information related to the well-being of all mothers, children, and their families.

DATES: Comments on this ICR must be received no later than January 15, 2019.

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 paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

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

Information Collection Request Title: MCH Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906-XXXX New.

Abstract: The purpose of the Title V MCH Block Grant is to improve the health of the nation's mothers, infants, children, including children with special health care needs, and their families by creating federal/state partnerships that provide each state/jurisdiction with needed flexibility to respond to its individual MCH population needs. Unique to the MCH Block Grant is a commitment to performance accountability, while assuring state flexibility. Utilizing a three-tiered national performance measure framework, which includes National Outcome Measures (NOMs), National Performance Measures (NPMs), and Evidence-Based and Evidence-Informed Strategy Measures, State Title V programs report annually on their performance relative to the selected national performance and outcome measures. Such reporting enables the state and federal program offices to assess the progress achieved in key MCH priority areas and to document Title V program accomplishments.

By legislation (Section 505(a) of Title V of the Social Security Act), the MCH Block Grant Application/Annual Report must be developed by, or in consultation with, the State MCH Health agency. In establishing state reporting requirements, HRSA's Maternal and Child Health Bureau (MCHB) considers the availability of national data from other federal agencies. Data for the national performance and outcome measures are pre-populated for states in

the Title V Information System. National data sources identified for the NPMs and NOMs in the MCH Block Grant program seldom include data from the Title V jurisdictions, with the exception of the District of Columbia. The eight remaining jurisdictions (American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico, and U.S. Virgin Islands) have limited access to significant data and MCH indicators, with limited capacity for collecting these data.

Sponsored by HRSA’s MCHB, the MCH Jurisdictional Survey is designed to produce data on the physical and emotional health of mothers and children under 18 years of age in the following eight jurisdictions—American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico, and Virgin Islands. More specifically, the MCH Jurisdictional Survey collects information on factors related to the well-being of children, including health status, visits to health care providers, health care costs, and health insurance coverage. In addition, the MCH Jurisdictional Survey collects information on factors related to the well-being of mothers, including health risk behaviors, health conditions, and preventive health practices. This data

collection will enable the jurisdictions to meet federal performance reporting requirements and to demonstrate the impact of Title V funding relative to MCH outcomes for the U.S. jurisdictions in reporting on their unique MCH priority needs.

The MCH Jurisdictional Survey was designed based on information-gathering activities with Title V leadership and program staff in the jurisdictions, experts at the Centers for Disease Control and Prevention, and other organizations with relevant data collection experience. Survey items are based on the National Survey of Children’s Health, the Behavioral Risk Factor Surveillance System (BRFSS), the Youth Behavior Surveillance System, and selected other federal studies. The Survey is designed as a core questionnaire to be administered across all jurisdictions with a supplemental set of survey questions customized to the needs of each jurisdiction.

Need and Proposed Use of the Information: Data from the MCH Jurisdictional Survey will be used to measure progress on national performance and outcome measures under the Title V MCH Block Grant Program. This survey instrument is critical to collecting information on factors related to the well-being of all mothers, children, and their families in

the jurisdictional Title V programs, which address their unique MCH needs.

Likely Respondents: The respondent universe is women age 18 or older who live in one of the eight targeted U.S. jurisdictions (Puerto Rico, U.S. Virgin Islands, Guam, Northern Mariana Islands, American Samoa, Palau, Marshall Islands, and Federated States of Micronesia) and who are mothers or guardians of at least one child aged 0–17 years living in the same household.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. Included is 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 Information Collection Request are summarized in the table below.

Total Estimated Annualized Burden Hours:

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Burden hours per form | Total burden hours |
|--|---------------------|-----------------------|------------------------------------|--|-----------------------|--------------------|
| Adult Parents—Puerto Rico | Screener | 1,250 | 1 | 0.03 | 37.50 | 217.50 |
| | Core | 200 | 1 | 0.83 | 166.00 | |
| | Jurisdiction Module | 200 | 1 | 0.07 | 14.00 | |
| Adult Parents—U.S. Virgin Islands | Screener | 1,428 | 1 | 0.03 | 42.84 | 222.84 |
| | Core | 200 | 1 | 0.83 | 166.00 | |
| | Jurisdiction Module | 200 | 1 | 0.07 | 14.00 | |
| Adult Parents—Guam | Screener | 908 | 1 | 0.03 | 27.24 | 207.24 |
| | Core | 200 | 1 | 0.83 | 166.00 | |
| | Jurisdiction Module | 200 | 1 | 0.07 | 14.00 | |
| Adult Parents—American Samoa | Screener | 461 | 1 | 0.03 | 13.83 | 189.83 |
| | Core | 200 | 1 | 0.83 | 166.00 | |
| | Jurisdiction Module | 200 | 1 | 0.05 | 10.00 | |
| Adult Parents—Federated States of Micronesia | Screener | 856 | 1 | 0.03 | 25.68 | 201.68 |
| | Core | 200 | 1 | 0.83 | 166.00 | |
| | Jurisdiction Module | 200 | 1 | 0.05 | 10.00 | |
| Adult Parents—Marshall Islands | Screener | 856 | 1 | 0.03 | 25.68 | 207.68 |
| | Core | 200 | 1 | 0.83 | 166.00 | |
| | Jurisdiction Module | 200 | 1 | 0.08 | 16.00 | |
| Adult Parents—Northern Mariana Islands | Screener | 666 | 1 | 0.03 | 19.98 | 201.98 |
| | Core | 200 | 1 | 0.83 | 166.00 | |
| | Jurisdiction Module | 200 | 1 | 0.08 | 16.00 | |
| Adult Parents—Palau | Screener | 499 | 1 | 0.03 | 14.97 | 184.97 |
| | Core | 200 | 1 | 0.83 | 166.00 | |
| | Jurisdiction Module | 200 | 1 | 0.02 | 4.00 | |
| Total | | 6,924 | | | | 1,633.72 |

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.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-25070 Filed 11-15-18; 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: Notice is hereby given that on October 22, 2018, the U.S. Department of Health and Human Services (HHS) Debarring Official, on behalf of the Secretary of HHS, issued a final notice of debarment based on an Administrative Law Judge's finding of research misconduct against Rakesh Srivastava, Ph.D., former Eminent Scholar and Professor, University of Kansas Medical Center (KUMC). Dr. Srivastava engaged in research misconduct in research proposed or reported in grant application 1 R01 CA175776-01, submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), on June 5, 2012. The administrative actions, including two (2) years of debarment, were implemented beginning on October 22, 2018, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Wanda K. Jones, Dr. P.H., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8200.

SUPPLEMENTARY INFORMATION:

Rakesh Srivastava, Ph.D., University of Kansas Medical Center: Based on the evidence and findings of an investigation conducted by KUMC and additional information obtained by the Office of Research Integrity (ORI) during its oversight review, ORI found by a preponderance of the evidence that Dr. Rakesh Srivastava (Respondent), former Eminent Scholar and Professor, KUMC, intentionally and knowingly submitted extensive plagiarized text in grant

application 1 R01 CA175776-01, "Regulation of Mitochondrial Metabolism by SIRT4," submitted to NCI, NIH, to obtain U.S. Public Health Service (PHS) funds. Specifically, ORI found that the Respondent intentionally and knowingly plagiarized scientifically significant text from the Specific Aims and Research Strategy sections of a grant application under review at NIH into his own grant application, 1 R01 CA175776-01, submitted to NIH eight months later. Significant text was included in Respondent's grant application, with plagiarized text accounting for 40% of the Specific Aims and 50% of the Research Strategy sections.

ORI issued a charge letter making a finding of research misconduct and proposing HHS administrative actions. Dr. Srivastava subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board to dispute the finding. ORI moved for summary judgment. On September 5, 2018, the ALJ granted summary judgment in favor of ORI and issued his recommended decision, finding that Respondent intentionally committed research misconduct by submitting to NIH a grant application that included plagiarized words, which included significant text from another principal investigator's grant application that was contained in the Specific Aims and Research Strategy sections of the Respondent's grant application without attribution to the other principal investigator. The ALJ held that appropriate administrative actions included a two-year debarment from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government referred to as "covered transactions." 2 CFR parts 180 and 376. The ALJ held that it was an appropriate administrative action to also impose a two-year prohibition from serving in any capacity to PHS including, but not limited to, service on any PHS advisory committee, board, or peer review committee, or as a consultant. Under the regulation, the ALJ's recommended decision went to the Assistant Secretary for Health, who did not modify it and forwarded it to the HHS Debarring Official, who is the deciding official for the debarment. The ALJ decision constituted the findings of fact to the HHS Debarring Official in accordance with 2 CFR 180.845(c). On October 22, 2018, the HHS Debarring Official issued a final notice of debarment to begin on

October 22, 2018, and end on October 21, 2020.

Thus, the research misconduct finding set forth above became effective, and the following administrative actions have been implemented for a period of two (2) years, beginning on October 22, 2018:

(1) Dr. Srivastava is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 CFR part 376) of Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (2 CFR part 180); and

(2) Dr. Srivastava is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Wanda K. Jones,

Interim Director, Office of Research Integrity.

[FR Doc. 2018-25065 Filed 11-15-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Appointment to the Tick-Borne Disease Working Group

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice will serve to announce that the U.S. Department of Health and Human Services (HHS) is seeking nominations of non-federal individuals who represent diverse scientific disciplines and views and are interested in being considered for appointment to the Tick-Borne Disease Working Group (Working Group). Resumes or curricula vitae from qualified individuals who wish to be considered for appointment as a member of the Working Group are currently being accepted.

DATES: Nominations must be received no later than 5:00 p.m. EST, on December 14, 2018.

ADDRESSES: All nominations should be sent to the Tick-Borne Disease Working Group email address at tickbornedisease@hhs.gov. Alternately, nominations can be sent by mail to: