

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 Human Genome Research Institute Special Emphasis Panel; Gabriella Miller Kids First Review.

Date: September 8–9, 2016.

Time: 7:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, Room Chevy Chase 1, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Ste. 4076, MSC 9306, Bethesda, MD 20892–9306, 301–402–0838, barbara.thomas@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: August 5, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

[Docket No. SAMHSA–2016–0002]

Request for Comment on Report Entitled: Advancing the Care of Pregnant and Parenting Women With Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment, in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain public comment on a report entitled: Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and their Infants: A Foundation for Clinical Guidance. The report is available at: <http://www.regulations.gov/docket?D=SAMHSA-2016-0002>.

This report describes the formal process agreed on and followed under

the guidance of the federal steering committee (FSC). It explains the RAND Corporation (RAND)/University of California Los Angeles (UCLA) Appropriateness Method (RAM), justifies its adoption, and reports the outcomes of its application that will form the basis for the development of clinical guidance. This report will serve as the foundation for the development of clinical guidance to be used by providers caring for women with opioid use disorder and their infants.

DATES: *Comment Close Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. no later than 30 days after date of publication in the **Federal Register**.

ADDRESSES: You may submit comments identified by Docket No. [SAMHSA–2016–0002] by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Electronically:* You may submit electronic comments to samhsa.ppdarom@samhsa.hhs.gov.

- *By regular mail:* You may mail written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852 Attn: Docket No. [SAMHSA–2016–0002]. Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *By express or overnight mail:* You may send written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Attention: DPT **Federal Register** Representative, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852 Attn: Docket No. [SAMHSA–2016–0002].

- *By hand or courier:* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period: For delivery in Rockville, MD: Substance Abuse and Mental Health Services Administration, Attention: DPT **Federal Register** Representative, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852. To deliver your comments to the Rockville address, call telephone number (240) 276–2700 in advance to schedule your delivery with one of our staff members.

Instructions: To avoid duplication, please submit only one copy of your comments by only one method. All submissions received must include the

agency name and Docket Number. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For access to the report or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Melinda Campopiano, MD, Medical Officer, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Email: samhsa.ppdarom@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments:

All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received by the deadline will be available for public inspection at the Substance Abuse and Mental Health Services Administration, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (240) 276–2700.

Background: SAMHSA led a federal steering committee in overseeing the application of the RAND/UCLA Appropriateness Method (RAM) to the available evidence concerning the optimal management of opioid use disorder for women who are pregnant or parenting and the management of their infants. After completion of the literature review, generation of the indications, and the expert panel RAM rating process—all described in this report—this report was generated for the purpose of producing a clinical guide that will be written to facilitate optimal management of pregnant and parenting women with opioid use disorder and their infants across disciplines and treatment settings. The guide will have a dual purpose: first, to serve as a tool that will increase provider willingness and confidence to manage pregnant and parenting women with opioid use disorder and their infants; and second to help assure the care provided this population optimizes the outcomes for both mother and infant.

The purpose of this effort is to produce a patient-centered guide to be used in a range of clinical settings. SAMHSA plans to organize the results described in this report around clinical scenarios and interventions consistent

with the range of ways that women with opioid use disorder may access substance use treatment or maternity care. The guide will provide options for clinical interventions that recognize the complexities of patients' lives. The guide will also include discussion of any conflicting evidence and clinician, treatment or patient characteristics that directly influence the appropriateness or effectiveness of a given clinical intervention. The paucity of the evidence to support specific interventions will be addressed in the guide. As such, the guide will present options based on current clinical practice, paired with the risks and benefits of each option as currently understood.

Public comment is sought in two general areas: The outcomes of the RAM process and the strategy to translate these findings into a clinical guide. Relevant public comment will inform the development and final appearance of the guide. Members of the expert panel, FSC, and a variety of professional societies will be asked to provide input into the guide outline and drafting of the guide which will then be subject to a formal federal clearance process including scientific review.

Supporting and Related Material in the Docket: The report contains the materials to help inform public comment. The appendices include listings of participants, more detailed information about the literature search, citations of primary references and data tables that were used by SAMHSA to develop the findings in the report. The information provided includes:

- (1) The REPORT
- (2) Supporting appendices: Appendix A: RAM Process Participants; Appendix B: Literature Review Methods; Appendix C: RAM Reference List and Appendices D–E7: Rated Indications

Charles LoDico,
Chemist, SAMHSA/CSAP.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at 240–276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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) ways to enhance 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.

Proposed Project: SAMHSA Disaster Technical Assistance Center Disaster Behavioral Health Needs Assessment and Customer Satisfaction Surveys (OMB No. 0930–0325)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting approval for a revision to the data collection associated with the SAMHSA Disaster Technical Assistance Center (DTAC) Disaster Behavioral Health Needs Assessment and Customer Satisfaction Surveys (OMB No. 0930–0325), which expire on May 31, 2017. Specifically, SAMHSA DTAC plans to consolidate the Needs Assessment Survey and Customer Satisfaction Surveys into a single instrument. The new revised instrument, entitled SAMHSA DTAC Customer Feedback Survey (CFS), under this effort will also include a change in administration to make it appropriate for a single, streamlined survey.

The proposed data collection effort will provide feedback on the overall effectiveness of SAMHSA DTAC's services, ongoing needs at the national level, and areas that require enhanced technical assistance (TA) services.

SAMHSA DTAC will be responsible for administering the data collection instrument and analyzing the data. SAMHSA DTAC will use data from the instrument to inform current and future TA activities and to ensure these

activities continue to align with state and local needs.

A three-year clearance is being requested. The SAMHSA DTAC CFS is designed to allow the agency to collect feedback on the overall effectiveness of the services provided by SAMHSA DTAC, as well as ongoing data regarding disaster behavioral health (mental health and substance use-related) needs at the national level and areas that require enhanced training and technical assistance (TA) services. This is the information that was previously collected as part of the SAMHSA DTAC Needs Assessment Survey (NAS) and Customer Satisfaction Survey (CSS). Data from this effort will continue to be used to improve services to jurisdictions, which will lead to (1) better integration of disaster behavioral health (DBH) needs with all-hazards disaster preparedness and response, and (2) improved outcomes at the state, territory, tribal, and local levels with less burden on participants. The new Customer Feedback Survey integrates and consolidates questions from the previously utilized NAS and CSS, which will reduce burden associated with the number of instruments and survey questions. SAMHSA DTAC will continue to be responsible for survey administration and analysis of the data collected, which SAMHSA will use to inform current and future training and TA activities. Table 1 shows the estimated burden associated with CFS data collection activities and the associated costs. It is anticipated that the survey will be administered once each year.

Participation in the Customer Feedback Survey will be solicited from all 50 states, the U.S. territories, and the District of Columbia. The survey will be administered to individuals who have requested TA within the six months prior to administration and those who are subscribed to DTAC's e-communications, *SAMHSA DTAC Bulletin*, or *The Dialogue*, at the time of administration. Internet-based technology will be used to collect data via web-based survey for data entry and management.