

Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of the SAMHSA PDMP Electronic Health Record (EHR) Integration and Interoperability Expansion Program—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2009, drug overdose deaths became the leading cause of injury death in the United States (U.S.), exceeding motor vehicle traffic crash deaths for the first time, a trend that continued in 2010. Prescription drugs, particularly opioid pain relievers, have been identified as the main driver of this increase. The number of overdose deaths per year involving opioid pain relievers increased more than four-fold from 1999 to 2010 (from 4,030 to 16,651), outnumbering overdose deaths involving all illicit drugs combined. Morbidity associated with opioid pain reliever abuse increased in parallel. The rate of emergency department visits associated with the misuse or abuse use of opioid pain relievers increased 153% from 2004 to 2011, while rates for illicit drugs remained largely stable.

This project involves an evaluation of the Substance Abuse and Mental Health

Services (SAMHSA) Prescription Drug Monitoring Program (PDMP) Electronic Health Record (EHR) Integration and Interoperability Expansion Program (PEHRIIE) which has funded projects in nine states via cooperative agreements.

Under these cooperative agreements, the Centers for Disease Control and Prevention (CDC) is responsible for conducting a comprehensive process and outcomes evaluation of the PEHRIIE program. The primary goals of the qualitative evaluation component of this work are:

1. To understand the processes, challenges, and successes in implementing and sustaining integration of PDMP data with Health Information Technology (HIT) systems and interoperability of PDMP systems across states; and

2. To understand the experiences of clinical end users with the systems being upgraded under the PEHRIIE program and to capture their recommendations, if any, for how the goals of the PEHRIIE could have been better accomplished.

In order to achieve these evaluation goals, CDC requests OMB approval for 24 months in order for the CDC evaluation team to conduct qualitative interviews with those individuals involved in the planning and implementation of the PEHRIIE projects (i.e., key project staff and stakeholders)

as well as with the clinical end users (i.e., prescribers and pharmacists) of the PDMPs in the states where these projects are taking place. Through this evaluation, CDC will better understand the impact of PDMP integration and interoperability in the funded states.

The total annual estimated burden hours for the planned qualitative information collection are 119 hours. Total burden time includes the time to conduct interviews with key project staff/stakeholders and clinical end users, and the time spent by recruiters at the PEHRIIE implementation sites to identify potential clinical end user interviewees.

Staff/stakeholder interviews will be conducted with key project staff members/stakeholders across the nine PEHRIIE-funded states. Interviews will also be conducted with key project staff/stakeholders representing companies working with multiples states involved in the PEHRIIE program.

End user interviews will be conducted at implementation sites distributed across all nine PEHRIIE states. The CDC will work with one recruiter per implementation site to complete these tasks.

There are no costs to respondents other than their time. The total estimated annual burden hours are 119 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
Key Project Staff/Stakeholders	Key Project Staff/Stakeholders Interview Guide	53	1	45/60
Clinical End Users	End Users Interview Guide	59	1	1
Clinical End User Recruiters	N/A	20	1	1

Kimberly S. Lane,

Deputy Director, Office of Science Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. App.), 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 Mental Health Special Emphasis Panel Review of Eating Disorders Dimensional Research (R01).

Date: December 3, 2013.

Time: 11:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Rebecca C Steiner, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, steinerr@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 6, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information on Alternative Skin Sensitization Test Methods and Testing Strategies and for Comment on ICCVAM's Proposed Activities

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is developing a U.S. plan for the evaluation of alternative skin sensitization test methods and testing strategies. The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests information that ICCVAM might use to develop this plan and comments on proposed ICCVAM activities.

DATES: Information should be submitted by December 9, 2013.

ADDRESSES: Responses submitted by email to niceatm@niehs.nih.gov are preferred. NICEATM, National Institute of Environmental Health Sciences, P.O. Box 12233, Mail Stop: K2-16, Research Triangle Park, NC 27709. Web site: <http://ntp.niehs.nih.gov/go/niceatm>.

FOR FURTHER INFORMATION CONTACT: Dr. Warren S. Casey, Acting Director, NICEATM; email: warren.casey@niehs.nih.gov; telephone: (919) 316-4729.

SUPPLEMENTARY INFORMATION:

Background: Allergic contact dermatitis (ACD), a skin reaction characterized by localized redness, swelling, blistering, or itching after direct contact with a skin allergen, is an important public health challenge. ACD frequently develops in workers and consumers exposed to skin-sensitizing chemicals and products. Pesticides and other marketed chemicals, including cosmetic ingredients, are routinely tested for skin sensitization hazard so that products can be appropriately labeled for safe use and handling. Fostering the evaluation and promotion of alternative test methods for regulatory use in skin sensitization hazard assessment has been one of ICCVAM's long-standing priorities (see <http://ntp.niehs.nih.gov/go/40445>).

Skin sensitization is a complex process. For substances that initiate the

process through covalent binding to skin proteins, the key biological events have been fairly well characterized. These events form the basis for an "adverse outcome pathway" (AOP) for skin sensitization (OECD, 2012). An AOP is a conceptual model that links exposure to a substance to a toxic effect by identifying the sequence of biochemical events required to produce the toxic effect. The AOP for skin sensitization provides a framework for the development of alternative toxicity tests that can assess chemical effects on each biological event in the pathway and thereby provide evidence on whether a substance causes skin sensitization.

ICCVAM is committed toward continued work in this area and believes it has promise for the near-term development of testing strategies that do not require the use of animals. Specific ICCVAM or NICEATM activities include the following:

- ICCVAM consideration of a nomination from the National Institute of Occupational Safety and Health to assess the electrophilic allergen screening assay, a test method that identifies electrophilic substances that may produce skin sensitization by measuring their tendency to bind to skin proteins, the first key event in the AOP.

- NICEATM collaboration with academic scientists to develop and evaluate chemical structure—activity relationship (SAR) models to predict skin sensitization.

- NICEATM collaboration with industry scientists to develop an open-source Bayesian network as an operational framework for an integrated testing strategy that uses multiple physicochemical, *in silico*, *in chemico*, and *in vitro* inputs to predict skin sensitization properties of test substances.

- NICEATM evaluation of various high-throughput screening assays for skin sensitization in coordination with NIEHS Tox21 activities.

ICCVAM is also aware of significant international efforts to replace the use of animals in skin sensitization testing for hazard and potency assessment by government organizations including the Organisation for Economic Co-operation and Development (OECD) and the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), and by the industry organization Cosmetics Europe (formerly COLIPA). Some specific ICCVAM and NICEATM activities include:

- Providing expertise and advice to EURL ECVAM to support their evaluation of several *in chemico* or *in*

vitro methods (the direct peptide reactivity assay, human cell line activation test, KeratinoSensSM, and myeloid U937 skin sensitization test), which cover key events in the AOP for skin sensitization (Adler et al., 2011).

- Participation in the International Cooperation on Alternative Test Methods (ICATM, <http://ntp.niehs.nih.gov/go/40113>), through which ICCVAM and NICEATM help eliminate redundancy in validation studies sponsored by ICATM partners and promote harmonization in the resultant test method recommendations.

- Communication with trade associations and non-government organizations (e.g., Cosmetics Europe) to receive information regularly on efforts toward evaluation of alternative test methods for skin sensitization that cover key events in the AOP and data integration for hazard identification and potency assessment.

ICCVAM's Proposed Plans: ICCVAM's involvement with national and international efforts (see Background above) is consistent with its goal to advance the state of the science for alternative test methods and testing strategies for skin sensitization. ICCVAM is developing a plan of action to augment and support this goal and, as such, is considering the following activities:

- Holding implementation workshops and webinars, and developing guidance documents to promote the use of validated test methods and testing strategies for skin sensitization.

- Participating in OECD skin sensitization activities to ensure that new and relevant test guidelines and guidances meet U.S. regulatory requirements as well as foster cross-fertilization between domestic and international research efforts in skin sensitization.

- Participating in validation management groups sponsored by ICATM partner organizations to ensure that the relevant validation studies for skin sensitization test methods and strategies meet U.S. regulatory needs as well as those of the sponsoring country.

- Providing expertise, data, and other resources when feasible to support NICEATM's efforts in the development of an integrated testing strategy for skin sensitizers.

- Evaluating alternative test method and testing strategy submissions for skin sensitization for reliability and relevance for the intended purpose.

- Consulting with organizations that are currently developing alternative test methods and testing strategies for skin sensitization to provide guidance that will increase U.S. regulatory acceptance.