

Publications: Protective human monoclonal antibodies target conserved sites of vulnerability on the underside of influenza virus neuraminidase. Lederhofer, Julia et al. *Immunity*, Volume 57, Issue 3, 574–586.e7.

Intellectual Property: PCT/US2023/071194 filed 28 July 2023 (NIH Ref. No. E-177-2022).

Licensing Contact: To license this technology, please contact Haiqing Li at 240-627-3708, or lihai@mail.nih.gov, and reference E-177-2022.

Dated: September 18, 2024.

Christopher M. Kornak,

Acting Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity review.

Date: October 29, 2024.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney, National Institute of Health, 6707 Democracy Boulevard, Rm. 7353, Bethesda, MD 20892-2542, (301) 594-8898, barnardm@extra.niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition

Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: September 18, 2024.

Miguelina Perez,

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

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

Proposed Project: New: The Center for Substance Abuse Prevention Online Reporting Tool and Grant Programmatic Progress Report to replace Division of State Programs—Management Reporting Tool (DSP-MRT) (OMB No. 0930-0354).

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Substance Abuse Prevention (CSAP) is requesting approval from the Office of Management and Budget (OMB) to monitor CSAP discretionary grant programs through administration of a suite of data collection instruments for grant compliance and programmatic performance monitoring.

This package describes the data collection activities and proposed instruments. Grant compliance monitoring will be conducted via a single data collection instrument to be completed by all CSAP discretionary grant recipients. Programmatic performance monitoring will be conducted via a suite of data collection instruments with each instrument tailored to a specific CSAP discretionary program. This request for data collection will replace OMB No. 0930-0354: Division of State Programs—Management Reporting Tool.

CSAP intends to monitor six grant programs through this data collection effort:

- *Strategic Prevention Framework—Partnerships for Success (SPF-PFS):* The purpose of the SPF-PFS program is to help reduce the onset and progression of

substance misuse and its related problems by supporting the development and delivery of state and community substance misuse prevention and mental health promotion services. This program is intended to promote substance use prevention throughout a state jurisdiction for individuals and families by building and expanding the capacity of local community prevention providers to implement evidence-based programs. In addition, the program is intended to expand and strengthen the capacity of local community prevention providers to implement evidence-based prevention programs. With this program, SAMHSA aims to strengthen state and community level prevention capacity to identify and address local substance use prevention concerns, such as underage drinking, marijuana, tobacco, electronic cigarettes, opioids, methamphetamine, and heroin.

- *Sober Truth on Preventing Underage Drinking (STOP Act):* The purpose of this program is to prevent and reduce alcohol use among youth and young adults ages 12–20 in communities throughout the United States through evidence-based screening, programs and curricula, brief intervention strategies, consistent policy enforcement, and environmental changes that limit underage access to alcohol as authorized by 42 U.S.C. 290bb-25b. The program aims to: (1) address norms regarding alcohol use by youth, (2) reduce opportunities for underage drinking, (3) create changes in underage drinking enforcement efforts, (4) address penalties for underage use, and/or (5) reduce negative consequences associated with underage drinking.

- *Strategic Prevention Framework for Prescription Drugs (SPF Rx):* The purpose of the SPF Rx grant program is to provide resources to help prevent and address prescription drug misuse within a State or locality. The program is designed to raise awareness about the dangers of sharing medications as well as the risks of fake or counterfeit pills purchased over social media or other unknown sources, and work with pharmaceutical and medical communities on the risks of overprescribing. Whether addressed at the state level or by an informed community-based organization, the SPF Rx program will raise community awareness and bring prescription substance misuse prevention activities and education to schools, communities, parents, prescribers, and their patients. In addition, grant recipients will be required to track reductions in opioid related overdoses and incorporate relevant prescription and overdose data

into strategic planning and future programming.

• *First Responders-Comprehensive Addiction and Recovery Act (FR CARA):*

The purpose of this program is to allow first responders and members of other key community sectors to administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

• *Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO):*

The purpose of this program is to support first responders and members of other key community sectors to administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for emergency reversal of known or suspected opioid overdose. Recipients will train and provide resources to first responders and members of other key community sectors at the state, tribal, and local levels on carrying and administering a drug or device approved or cleared under the FD&C Act for emergency treatment of known or suspected opioid overdose.

• *Improving Access to Overdose Treatment (ODTA):*

The purpose of this program is to expand access to naloxone and other Food and Drug Administration (FDA) approved overdose reversal medications for

emergency treatment of known or suspected opioid overdose. The recipients will collaborate with other prescribers at the community level to implement trainings on policies, procedures, and models of care for prescribing, co-prescribing, and expanding access to naloxone and other FDA-approved overdose reversal medications to the specified population of focus (*i.e.*, rural or urban). With this program SAMHSA aims to expand access to naloxone and other FDA approved overdose reversal medications for emergency treatment of known or suspected opioid overdose.

Grant compliance monitoring: All SAMHSA awards require grantees to submit performance and progress reports through the electronic Research Administration (eRA) Commons, an end-to-end Grants Management system. The frequency and program-specific instructions for preparation and submission of these reports are identified in the terms and conditions found in the Notice of Award. CSAP discretionary grant compliance monitoring will be conducted through the submission of the Programmatic Progress Report (PPR). The PPR contains fields for grantees to enter information on activities and accomplishments that occurred during the reporting period

based on identified goals and objectives. It also contains fields for grantees to share evaluation updates and outcomes as well as planned activities for the upcoming reporting period as well as any challenges that grantees have experienced.

The Center for Substance Abuse Prevention Online Reporting Tool (CORT) is comprised of two components. The first provides fields for grantees to enter annual goals for key programmatic measures. The second provides fields for reporting quarterly progress toward achieving these goals. CSAP intends to have grantees report progress on a quarterly basis to allow for consistent, periodic analyses which will allow for the administration of technical assistance supports when grantees are falling behind in achieving these goals. Quarterly reporting will also allow the Center to review the overall progress of grant programs. Program specific instruments have been developed to ensure optimal alignment with individual grant requirements. These instruments were developed based on instruments approved in OMB 0930–0391: Harm Reduction Grant Program Annual Targets and Quarterly Progress Reports.

Annualized Data Collection Burden

TABLE 1—BURDEN TABLE: ANNUALIZED BURDEN—ANNUAL TARGETS

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage ¹	Total respondent cost
STOP Act	202	1	202	1	202	\$48.35	9,766.70
SPF–PFS	315	1	315	1	315	48.35	15,230.25
FR CARA	87	1	87	1	87	48.35	4,206.45
PDO	18	1	18	1	18	48.35	870.30
ODTA	8	1	8	1	8	48.35	386.80
SPF–Rx	27	1	27	1	27	48.35	1,305.45
Total	657	657	657	31,765.96

TABLE 2—BURDEN TABLE: CENTER FOR SUBSTANCE ABUSE PREVENTION ON-LINE REPORT TOOL (CORT)—QUARTERLY PERFORMANCE ANNUALIZED BURDEN

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage ¹	Total respondent cost
STOP Act	202	4	808	5.75	4,646	\$48.35	224,634.10
SPF–PFS	315	4	1,260	6	7,560	48.35	365,526.00
FR CARA	87	4	348	6	2,088	48.35	100,954.80
PDO	18	4	72	6	432	48.35	20,887.20
ODTA	8	4	32	6	192	48.35	9,283.20
SPF–Rx	27	4	108	6	648	48.35	31,330.80
Total	657	2,628	15,566	752,616.10

¹ Grantee Project Director or Evaluator hourly wage is based on the mean hourly wage for state government managers, as reported in the 2022 Occupational Employment (OES) by the Bureau of Labor Statistics (BLS) found at https://www.bls.gov/oes/current/naics4_999200.htm#11-0000. Accessed on December 13, 2023.

TABLE 3—ANNUALIZED BURDEN TABLE: CSAP’S GRANT PROGRAMMATIC PROGRESS REPORT

CSAP grant program	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Average hourly wage ¹	Total respondent cost
STOP Act	202	1	202	4	808	\$48.35	39,066.80
SPF–PFS	315	1	315	4	1,260	48.35	60,921.00
FR CARA	87	1	87	4	348	48.35	16,825.80
PDO	18	1	18	4	72	48.35	3,481.20
ODTA	8	1	8	4	32	48.35	1,547.20
SPF Rx	27	1	27	4	108	48.35	5,221.80
Total	657				2,628		127,063.80

TABLE 4—BURDEN TOTALS BY YEAR: ALL DATA COLLECTION INSTRUMENTS

Year	Number of grantees	Annual burden hours	Total burden hours	Average hourly wage ¹	Total cost
Year 1	657	~28–29	18,851	\$48.35	911,445.85
Year 2	700	29	20,088	48.35	971,254.80
Year 3	700	29	20,088	48.35	971,254.80
Year 4	700	29	20,088	48.35	971,254.80
Year 5	700	29	20,088	48.35	971,254.80
Total	3,457		99,203		4,796,465.05

The instruments have been revised to reflect comments received during the 60-day **Federal Register** comment period and cognitive testing. Changes include adding/updating instructions for clarification, added skip patterns, adding/revising definitions, standardizing language, collapsing of response items, and removal of measures. This will ease burden on respondents. Additionally, adjustments have been made in the language related to reporting race/ethnicity and sexual orientation and gender identity.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

Alicia Broadus,
Public Health Advisor.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

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Project: Revision of Mental Health Client/Participant Outcome Measures and Infrastructure, Prevention, and Promotion Indicators (OMB No. 0930–0285)

SAMHSA is requesting approval from OMB for a revision to extend the expiration date for the previously approved instruments and data collection activities for the Center for Mental Health Services Mental Health Client/Participant Outcome Measures and Infrastructure, Prevention, and Promotion Indicators (OMB No 0930–0285) that expires on March 30, 2025.

To be fully accountable for the spending of Federal funds, SAMHSA requires all programs to collect and report data to ensure that program goals and objectives are met. Data are collected and used to monitor and

improve performance of each program and ensure appropriate and thoughtful spending of Federal funds.

SAMHSA requests to continue using and extend the expiration date for the currently approved Client-level Mental Health Client/Participant Outcome measures and Infrastructure, Prevention, and Promotion indicators and to extend the expiration date.

These two data collections maintain capacity and requirements to report qualitative performance and quantitative outcomes for all Center for Mental Health Services discretionary grant programs, including: demographic characteristics of clients served; social determinants of health of clients served before, during, and at end of services; numbers of clients served; and process measures, outputs, outcomes, of grant program required activities.

Currently, the information collected from these data collections is entered and stored on SAMHSA’s Performance Accountability and Reporting System (SPARS), which is a real-time, performance management system that captures information on mental health and substance abuse treatment services delivered in the United States through discretionary grantees. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 (GPRMA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs, which are consistent with OMB guidance.