

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of responses	Average time per response (minutes/hour)	Annual burden hours
Telephone Clients	Customer Service	65,500	1	1/60	1,092
	Demographic Questions	23,580	1	2/60	786
Smoking Cessation Clients	Smoking Cessation "Intake" Questions.	5,707	1	4/60	380
	Demographic Questions	3,995	1	2/60	133
VA Smoking Cessation Clients	Call Backs	1,540	4	1/60	103
LiveHelp Clients	Demographic Questions	6,119	1	2/60	204
Customer Satisfaction Survey	Survey Questions	15,665	1	2/60	522
E-mail Clients	Email Intake Form	1,000	1	10/60	167

Dated: December 16, 2015.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

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Dated: December 16, 2015.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Therapeutics.

Date: January 14, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435-3504, tothct@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

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) 276-1243.

Project: Cross-Site Evaluation of the Minority Substance Abuse/HIV Prevention Program (MAI)—(OMB No. 0930-0298)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) is requesting from the Office of Management and Budget (OMB) approval for the revision of data collection activities for the cross-site evaluation of the Minority Substance Abuse/HIV Prevention Program (MAI), which includes both youth and adult questionnaires. This revision includes the inclusion of 4 cohorts, substantial revisions to the youth and adult questionnaires, updates to the data used to estimate response rates and expected numbers of participants by service duration (see Table 1 below), and addition of two brief forms to collect dosage information.

This cross-site evaluation supports two of SAMHSA's 6 Strategic Initiatives:

Prevention of Substance Abuse and Mental Illness and Health Care and Health Systems Integration. It builds on evaluations of data collected by ten previous cohorts of grantees funded by SAMHSA's CSAP to provide substance abuse and HIV prevention services for minority populations. The first two cohorts were planning grant programs and the rest were service grant programs. The goals for the Cohort 3-10 grants were to add, increase, or enhance integrated substance abuse (SA) and HIV prevention services by providing supportive services and strengthening linkages between service providers and at-risk minority populations. Cohorts 1-3 previously received clearance under OMB No. 0930-0208 and Cohort 6-10 grants previously received clearance under OMB No. 0930-0298. The grant period for Cohort 9 and 10 grants will end on 9/30/2015.

The cohorts of grantees funded by the MAI and included in this clearance request are:

- Minority Serving Institutions (MSI) in Partnerships with Community-Based Organizations (CBO): 29 three-year grants funded at the end of FY 2013 (MSI CBO 2013)

- Minority Serving Institutions (MSI) in Partnerships with Community-Based Organizations (CBO): 21 three-year grants funded at the end of FY 2014 (MSI CBO 2014)

- Minority Serving Institutions (MSI) in Partnerships with Community-Based Organizations (CBO): 34 three-year grants were funded in FY 2015 (MSI CBO 2015)

- Capacity Building Initiative (CBI): 54 five-year grants were funded in 2015 (CBI 2015)

MSI CBO grantees are Historically Black Colleges/Universities, Hispanic Serving Institutions, American Pacific Islander Serving Institutions, or Tribal Colleges/Universities in partnership with community based organizations in their surrounding communities. MSI CBO grantees are required to provide integrated substance abuse (SA),

Hepatitis C (HCV), and HIV prevention services to young adults. The CBI grantees are community-level domestic, public and private nonprofit entities, federally recognized American Indian/Alaska Native Tribes and tribal organizations, and urban Indian organizations. CBI grantees will use grant funds for building a solid infrastructure for integrated SA, HIV, and HCV prevention service provision and implementing evidence-based prevention interventions using the SPF process. The target population for the CBI grantees will be at-risk minority adolescents and young adults. All MAI grantees are expected to provide leadership and coordination on the planning and implementation of SAMHSA's Strategic Prevention Framework (SPF) and to target minority populations, as well as other high risk groups residing in communities of color with high prevalence of SA and HIV/AIDS. The primary objectives of the cross-site evaluation are to:

- Assess the success of the MAI in reducing risk factors and increasing protective factors associated with the transmission of the Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and other sexually-transmitted diseases (STDs).
- Measure the effectiveness of evidence-based programs and infrastructure development activities such as: Outreach and training, mobilization of key stakeholders, substance abuse and HIV/AIDS counseling and education, testing, referrals to appropriate medical treatment and/or other intervention strategies (*i.e.*, cultural enrichment activities, educational and vocational resources, social marketing campaigns, and computer-based curricula).
- Investigate intervention types and features that yield the best outcomes for specific population groups.
- Assess the extent to which access to health care was enhanced for population groups and individuals vulnerable to behavioral health disparities residing in communities targeted by funded interventions.
- Assess the process of adopting and implementing the SPF with the target populations.

Continuing the cross-site evaluation will assist SAMHSA/CSAP in promoting and disseminating optimally effective prevention programs, counseling, health education, and referrals to appropriate medical treatment and/or other intervention strategies. The MAI grantees are expected to provide an effective prevention process, direction, and a common set of goals, expectations, and

accountabilities to be adapted and integrated at the community level. Grantees have substantial flexibility in choosing their individual evidence-based programs, but must base this selection on and build it into the five steps of the SPF. These SPF steps consist of assessing local needs, building service capacity specific to SA and HIV prevention services, developing a strategic prevention plan, implementing evidence-based interventions, and evaluating their outcomes. Grantees are also required to provide HIV and HCV testing and counseling services and referrals to appropriate treatment options. Grantees must also conduct ongoing monitoring and evaluation of their projects to assess program effectiveness including Federal reporting of the Government Performance and Results Act (GPRA) of 1993, The GPRA Modernization Act of 2010, SAMHSA/CSAP National Outcome Measures (NOMs), and the Department of Health and Human Services Core HIV Indicators.

As part of the cross-site evaluation, survey data will be collected through self-report questionnaires administered to program participants. All grantees will use two questionnaires, one for youth aged between 12 and 17 and one for adults aged 18 and older. Participants in services lasting 30 days or longer will complete all three sections of the questionnaires at three time points (baseline, exit, follow-up), taking an average of 37 (youth) or 32 (adult) minutes per survey. However, the average number of responses per participant for both youth and adult surveys is only twice per year due to response rate declines from baseline to exit to follow-up. Participants in services lasting 2–29 days will complete the first two sections of the questionnaires at two time points (baseline, exit), taking an average of 26 (youth) or 23 (adult) minutes to complete each survey. Participants in single-day services will complete Section 1 and 3–5 items from Section 2 at one time point (at exit), taking an average of 13 minutes for both youth and adult questionnaires. The revised youth questionnaire contains 94 questions, of which 24 relate to HIV/AIDS and the revised adult questionnaire contains 79 items, 29 of which relate to HIV/AIDS. This represents a substantial reduction from the current OMB-approved versions of the Youth and Adult Questionnaires (128 and 122 items).

In addition to the shortened versions of the Youth and Adult Questionnaires, SAMHSA is requesting approval for two brief forms for collecting dosage data.

Program staff will complete the Individual Dosage Form after each one-on-one service encounter with every participant to provide information on the types of services delivered during the encounter and the duration of each service type. The form takes approximately three minutes to complete. Program staff will complete the Group Dosage Form after each group-format service encounter to provide similar information, with the addition of a list of the unique identification numbers of all participants attending the session. A typical group session is expected to have approximately 20 attendees and a typical Group Dosage Form takes about eight minutes to complete.

Respondent burden and intrusiveness have been limited to the extent possible while providing sufficient power to fulfill the cross-site evaluation's objectives. Procedures such as the use of unique identification numbers in place of personal identification information, security measures at grant sites for limiting access to completed forms, and analysis guidelines that limit the reporting of outcome results for subgroups with small sample sizes, safeguard the privacy and confidentiality of participants. Every effort has been made to coordinate cross-site data collection with local data collection efforts in an attempt to minimize respondent burden.

The cross-site evaluation results will have significant implications for the substance abuse and HIV/AIDS prevention fields, the allocation of grant funds, and other evaluation activities conducted by multiple Federal, State, and local government agencies. They will be used to develop federal policy in support of SAMHSA/CSAP program initiatives, inform the public of program outcomes and lessons learned, improve existing programs, and promote replication and dissemination of effective prevention strategies.

The following table displays estimates of the annualized hour burden for data collection using the Youth and Adult Questionnaires and the Individual and Group Dosage Forms. The expected numbers of participants by service duration and the numbers of completed dosage forms were estimated based on analysis of the data submitted by Cohort 7–10 grantees. The numbers are adjusted for expected response rates, also estimated based on data analysis. Program staff will complete an Individual Dosage Form for each one-on-one service encounter with every participant, spending an estimated three minutes per form. A typical grantee is expected to complete 1,316 Individual

Dosage Forms per year. A group Dosage Form will be completed for each group session held by the funded programs,

and will take approximately eight minutes to complete. A typical grantee

is expected to offer approximately 26 group sessions per year.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Type of respondent activity	Number of respondents	Responses per respondent*	Total responses	Hours per response	Total burden hours
Youth Questionnaire/Single-day service duration	64	1	64	0.2167	14
Youth Questionnaire/2–29-day service duration	240	2	480	0.4333	208
Youth Questionnaire/30-or-more-day service duration	1,136	2	2,158	0.6167	1,401
Adult Questionnaire/Single-day service duration	1,040	1	1,040	0.2167	225
Adult Questionnaire/2–29-day service duration	4,314	2	8,628	0.3833	3,307
Adult Questionnaire/30-or-more-day service duration	19,150	2	38,300	0.5333	20,425
Individual Dosage Form	138	1,316	181,608	0.0500	9,080
Group Dosage Form	138	26	3,588	0.1333	478
Total	26,220	235,980	35,139

Written comments and recommendations concerning the proposed information collection should be sent by January 21, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,
Statistician.

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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

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Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Performance Monitoring for Partnerships for Success (PFS)-NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA)'s Center for Substance Abuse Prevention (CSAP) aims to address two of SAMHSA's top substance abuse prevention priorities: Underage drinking (UAD; age 12 to 20) and prescription drug misuse and abuse (PDM; age 12 to 25) through the Strategic Prevention Framework Partnerships For Success (SPF-PFS) program. The program is scheduled through September 2018 to systematically collect and maintain community sub-recipient information, quarterly progress reports (QPR) and outcomes data submitted by the PFS grantees through the online Program for Evaluation in Prevention Contract (PEP-C) Management Reporting Tool (MRT). This data collection will place a new emphasis on the SPF-PFS impact on outcomes related to Prescription Drug Misuse, including the prevalence of prescription drug misuse and related consequences such as prescription drug poisonings and overdoses. SAMHSA is requesting approval for data collection through the PEP-C MRT using the instruments listed below:

- Contact Information: This instrument includes sections for Grantee Information, Grantee Staff, Sub-State Information, Community Subrecipient information, and Subrecipient Staff
- QPR: This instrument will gather data related to implementation of the SPF-PFS grant based on the SPF steps

(Assessment, Capacity, Planning, Implementation, and Evaluation).

- Outcome Data: this instrument includes 4 separate sub-instruments that grantees will complete in varying time frames dependent on requirements.

- Grantee Target Outcome Data
- PFS Selected Grantee-Level Outcome Data
- Community-Level Outcome Data for Subrecipients
- Substitute Data Source Request

These SPF-PFS performance monitoring measures will primarily be tools for SAMHSA project officers to systematically collect data to monitor grant program performance and outcomes along with grantee technical assistance needs. In addition to assessing activities related to and progress through the SPF steps, the performance monitoring instruments covered in this statement collect data to assess the following grantee required specific performance measures:

- Number of training and technical assistance activities per funded community provided by the grantee to support communities;
- Reach of training and technical assistance activities (numbers served) provided by the grantee;
- Percentage of subrecipient communities that submit data to the grantee data system.

The instruments also collect data to provide information for the following PFS required Government Performance and Results Act (GPRA) measure:

- Number of sub-recipient communities that improved on one or more targeted NOMs indicators (Outcome)