ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
School Officials	35	1	60/60	35
Police Officials	35	1	60/60	35
Total			70	

Dated: June 11, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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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) 276–1243.

Project: Garrett Lee Smith Campus Case Studies Funded Through the Garrett Lee Smith Memorial Suicide Prevention and Early Intervention Programs—New

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) is conducting up to six campus case studies with Garrett Lee Smith Memorial (GLS) Suicide Prevention and Early Intervention Campus Program grantees. The GLS Campus Case Studies (CCS) build upon campuses' existing local evaluation being implemented and funded through the GLS grant program. The goal of the CCS is to understand how a public health approach is successfully applied as a model for campus suicide prevention efforts, and will explore, in a systematic manner: The suicide prevention related infrastructures and supports (*e.g.,* clinical and non-clinical) that exist on up to six selected GLS-funded campuses; the various student-level factors that are related to suicide prevention efforts (*e.g.,* protective factors, coping strategies, social norms, and facilitators and barriers to student access and receipt of behavioral healthcare); campus interdepartmental collaboration and the relationship between various efforts to promote student mental health and wellness; and the extent to which the campus infrastructures and supports promote and address these factors.

The data collected through this project will contribute to the knowledge base regarding a successful model for suicide prevention that integrates multiple prevention programs targeting risk and protective behaviors which place students at risk for a host of negative mental and physical health outcomes correlated with suicide, including violence, stress, untreated depression and mental illness, and academic failure. The strategies targeting various populations on campus will also be discussed, as well as the campus policies and procedures which facilitate campus efforts related to mental health promotion and crisis response. The CCS design includes three data collection strategies: (1) Case study key informant interviews (CSIs); (2) focus groups with students, faculty, and staff; and (3) an Enhanced Module to the OMB-approved Suicide Prevention Exposure, Awareness and Knowledge Survey—Student Version (OMB No. 0930–0286) administered to a sample of students. Data collection is planned to commence in fall 2008. CCS activities will be implemented on up to six GLS-funded campuses.

The following describes the specific data collection activities and the data collection instruments to be used, followed by a summary table of the number of respondents and the respondent burden:

- *Enhanced Module for the SPEAKS.* The Enhanced Module will be added to the OMB-approved Suicide Prevention Exposure, Awareness, and Knowledge Survey (SPEAKS)—Student Version (OMB No. 0930–0286). The Enhanced Module examines coping strategies, help-seeking behaviors, awareness of available mental health services, and risk and protective factors across the student population. Questions include the availability of resources to provide assistance to those at risk for suicide; the types of coping strategies they use when experiencing stress; from whom, if anyone, they would seek help; if they have dealt with mental health issues, sought help, and experienced trauma; and their use of protective factors. The Enhanced Module is Web-based and includes multiple-choice, Likert-scale, and yes/no questions. The Enhanced Module includes 16 items and will take approximately 10 minutes to complete. The Enhanced Module will be administered at each campus once in conjunction with the SPEAKS—Student Version to a random sample of 200 students.
- *Student Focus Group Moderator's Guide.* This component will assess student risk and protective factors related to mental health, help-seeking behaviors, and knowledge of prevention activities on campus and their perceived effectiveness. This will help researchers more fully understand student-level factors in relation to population-level factors addressed by the Enhanced Module for the SPEAKS. Questions address stressors that different groups of students face while in college, barriers to seeking help, attitudes and stigma related to seeking help, and the accessibility of the campus counseling center. Six of the following seven groups of students will participate in focus groups on each campus, as decided by the campus: (1) First-year students, (2) athletes, (3) international students, (4) Lesbian, Gay, Bisexual, and Transgender (LGBT) students, (5) Greek life students, (6) graduate students, and (7) residential advisors/peer educators. Recruitment will be conducted by campus project staff. Focus groups will include a maximum of 9 students. Thus, the total number of student focus group participants will not exceed 324. Groups will last approximately 90 minutes.
- *Faculty/Staff Focus Group Moderator's Guide.* The faculty and staff focus groups will assess the campus' approach to prevention, attitudes and stigma around student mental health and wellness on campus, campus infrastructure supports for students who need mental health help, and the

general campus climate around mental health and wellness. Faculty and staff will also describe their knowledge of prevention activities on campus and their perceived effectiveness of these efforts. Local campus staff will recruit appropriate respondents for the faculty and staff focus groups to include a maximum of 9 respondents per group. The total number of participants will not exceed 162 and groups will last approximately 90 minutes.

• *Case Study Key Informant Interviews (7 versions).* The Case Study Key Informant Interviews (CSIs) include 7 qualitative interview versions: (1) Administrator, (2) Counseling Staff, (3) Coalition Member—Faculty, (4) Prevention Staff, (5) Case Finder, (6) Campus Police, and (7) Student Leader. Local project staff will be responsible for identifying appropriate respondents for each CSI version and scheduling the interview to occur during site visits by the case study team. A total of 14 interviews will be conducted during each campus site visit (a total of up to 192 interviews). The case study team from Macro International Inc. will be responsible for administering the interviews and is trained in qualitative interviewing. Fourteen individuals from each of the campus sites will be selected as key informants to participate in the CSIs in the first and third stages of the GLS Campus Case Studies, for a total of 64 respondents. Questions on the CSIs include whether respondents are aware of suicide prevention activities, what the campus culture is, related to suicide prevention, and what specific efforts are in place to prevent suicide among the campus population. Items are formatted as open-ended and semi-structured questions. The CSIs include 16 to 21 items and will take approximately 60 minutes to complete. On the second site visit, the case study team will incorporate preliminary findings from the case studies in the interviews, which may be modified to some extent to collect more comprehensive information and gather feedback from local key informants surrounding the context of the preliminary findings. The CSIs for the second site visit will last 60 minutes.

The average annual respondent burden is estimated below. This project is scheduled to be completed in 12 months; thus, the table reflects the total burden for one year, the project length. The estimate reflects the total annual respondents for the project (at which time the CCS would conclude), the average annual number of respondents, the average annual number of responses, the time it will take for each response, and the average burden.

TOTAL AND ANNUAL AVERAGES: RESPONDENTS, RESPONSES AND HOURS

Measure name	Number of respondents	Number of responses per respondent	Hours/ response	Response burden
Enhanced Module	1,200	1	0.17	204
Focus Group—Student Version	324	1	1.5	486
Focus Group—Faculty Version	108	1	1.5	162
Focus Group—Staff Version	54	1	1.5	81
Interview—Student Leader Version	12	1	1	12
Interview—Case Finder Version	6	1	1	6
Interview—Faculty Version	12	1	1	12
Interview—Campus Police Version	12	1	1	12
Interview—Counseling Staff Version	12	1	1	12
Interview—Prevention Staff Version	18	1	1	18
Interview—Administrator Version	12	1	1	12
Total	1,770			1,017

Written comments and recommendations concerning the proposed information collection should be sent by July 17, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: June 8, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–14218 Filed 6–16–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0648]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; PDUFA Pilot Project Proprietary Name Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 17, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and the title ''PDUFA Pilot Project Proprietary Name Review.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.