

the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46. Participating sites are responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems and study progress to the sIRB. Participating sites must communicate relevant information necessary for the sIRB to consider local context issues and state/local regulatory requirements during its deliberations. Participating sites are expected to rely on the sIRB to satisfy the regulatory requirements relevant to the ethical review. Although IRB ethical review at a participating site would be counter to the intent and goal of this policy, the policy does not prohibit any participating site from duplicating the sIRB. However, if this approach is taken, NIH funds may not be used to pay for the cost of the duplicate review.

Exceptions

Exceptions to this policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.

Effective Date

This policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017. Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application. For contracts, the policy applies to all solicitations issued on or after May 25, 2017. For the intramural program, the policy applies to intramural multi-site studies submitted for initial review after May 25, 2017.

Dated: June 14, 2016.

Lawrence Tabak,

Deputy Director, National Institutes of Health.
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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: Now Is The Time (NITT)—Project AWARE (Advancing Wellness and Resilience in Education) Evaluation—New

SAMHSA is conducting a national evaluation of the Now is the Time (NITT) initiative, which includes separate programs—NITT Project AWARE (Advancing Wellness and Resilience in Education)—State Educational Agency (SEA), Healthy Transitions (HT), and two Minority Fellowship Programs (Youth and Addiction Counselors). These programs are united by their focus on capacity building, system change, and workforce development.

NITT-Project AWARE, which is the focus of this data collection, represents a response to the third and fourth components of President Obama's NITT Initiative: making schools safer and focusing on access to mental health services. The goal of NITT-Project AWARE is to develop a comprehensive, coordinated, and integrated program for advancing wellness and resilience in educational settings for school-aged youth.

SAMHSA awarded NITT-Project AWARE grants to 20 SEAs. Each SEA proposed partnerships between at least three high-need Local Educational Agencies (LEAs) to develop a coordinated and integrated plan of services and strategies to address the Project NITT-Project AWARE-SEA goals and objectives. Project AWARE grantees will plan and implement activities designed to increase the capacity of SEAs in three areas: (1) Increase mental health awareness among school-aged (K-12) youth; (2) train those who work with school-aged children to identify and respond to mental health issues in children and young adults; and (3) connect children, youth, and families with mental health services. The intention is to encourage cross-system

collaboration and use evidence-based strategies to address mental health needs.

The Project AWARE evaluation will examine the process and outcomes of activities by SEA grantees and their LEA and school partners. It will evaluate the capacity of SEAs to effectively involve family and youth, provide a culturally and linguistically competent and family-centered mental health service array, and implement a process for identifying need and delivering services that is informed by data and coordinated across child-serving agencies. Evaluation questions have been developed to understand grantee context, planning, implementation, outputs, and outcomes across each of the NITT priority areas. Data collection efforts that will support the evaluation are described below.

AWARE Planning and Implementation Activities Inventory (AWARE Activities Inventory), to capture information about all activities supported by Project AWARE resources during the grant period. The inventory will be reviewed and updated on an annual basis at the SEA level with the grant project director, at the LEA level with the grant program coordinators, and at the school level with coordinators in each participating school. The questionnaires will guide review and input of additional information as needed for all activities captured in the AWARE Activities Inventory and conducted under Project AWARE. Each questionnaire will be conducted annually to review and update the AWARE Activities Inventory with 20 SEA-level respondents, 62 LEA-level respondents, and 432 school-level respondents.

SEA Collaborative Partner Survey (SEA-CPS), to collect information about collaborative processes and partnerships at the state level to examine the networks involved in successful information sharing and collaborations across child-serving agencies and the families and youth they serve. SAMHSA estimates that there will be 24 collaborative partner respondents at each SEA grantee who will complete the annual SEA-CPS.

Local Educational Agency Collaborative Partner Survey (LEA-CPS), to collect information about collaborative processes and partnerships at the local level to examine the networks involved in successful information sharing and collaborations across child-serving agencies and the families and youth they serve. The survey will be administered twice during the grant period, with 15 respondents in each of the 62 LEAs.

Collaborative Partner Interview Guide, to collect qualitative information about collaborative processes and partner roles. Approximately 160 core staff (8 SEA-level collaborative partners in each SEA grantee) are expected to participate in annual in-person and telephone interviews.

School Information Systems Data Abstraction Protocol, to capture information from existing school information systems about student socio-demographics, school climate, and school safety. The data abstraction protocol will detail the procedure through which the national evaluation team will abstract data from each LEA or school information system. These data will be requested annually to cover school-level measures from the 2014–2015 through 2018–2019 school years. School-level information will be collected at the school level for all sample schools (N = 432), but the number of respondents is calculated based on whether the school information systems are consistent across SEAs and/or LEAs, or whether they vary from school to school. Based on preliminary discussions with the grantees, SAMHSA estimates that five SEA grantees will be able to provide data for all sample schools in the SEA (N = 5 SEA respondents), the data will be provided from LEAs in ten of the

SEA grantees (N = 30 LEA respondents), and the remaining five SEA grantees will have school information systems and surveys that differ at the school level (N = 90 school respondents). Therefore 125 respondents will provide the secondary data that covers the 432 sample schools.

Teacher Mental Health Literacy Survey, to assess the mental health literacy and associated knowledge and skills of teachers in selected schools participating in Project AWARE activities. This survey will be administered twice to a random sample of teachers in selected schools in partner LEAs, stratified by school type and size. An average sample size of approximately 24 teachers will be selected from each of the 432 schools selected to participate in the school-level coordinator questionnaire data collection.

Existing Teacher and Student Survey Data Abstraction Protocols, to compile information from existing surveys to examine school climate and safety. The data abstraction protocol will be customized for each SEA based on the specific data collected by each state. Data from existing teacher and student surveys in selected schools (N = 432) participating in the national evaluation will be provided to the national evaluation on an annual basis. The

number of respondents is calculated based on whether the existing student and teacher surveys are consistent across SEAs and/or LEAs, or whether they vary from school to school. Based on preliminary discussions with the grantees, SAMHSA estimates that 125 respondents will provide the secondary student and teacher survey data that covers the 432 sample schools.

Student Focus Groups Protocol, to collect qualitative information about student perceptions of school climate; ability to identify signs of mental, behavioral, or emotional health issues; and student knowledge of school- and community-level service access. The evaluation team will conduct these focus groups during site visits conducted in 2016 and 2019. The guided discussion protocol will focus on participants' general knowledge of available resources, programs to support AWARE activities, and overall perceptions of school climate and safety. The focus groups will be conducted with approximately 8–10 students in each of four schools from one LEA associated with each SEA grantee, for a total of no more than 800 students participating in focus groups at each of the two site visits. Each focus group will last approximately one and a half hours.

ANNUALIZED BURDEN HOURS

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
SEA leadership questionnaire	20	1	20	1	20
LEA coordinator questionnaire	62	1	62	1	62
School coordinator questionnaire	432	1	432	1	432
SEA-Collaborative Partner Survey	480	1	480	0.5	240
LEA-Collaborative Partner Survey	930	1	930	0.5	465
Collaborative partner interviews	160	1	160	1	160
Teacher mental health literacy survey	10,368	1	10,368	0.5	5,184
Student focus groups	800	1	800	1.5	1,200
School information systems data abstraction	125	1	125	1.5	188
Student survey data abstraction	125	1	125	1.5	188
Teacher school climate and school safety survey	125	1	125	1.5	188
Total	^a 13,377	13,627	8,327

* This is an unduplicated count of total respondents.

Written comments and recommendations concerning the proposed information collection should be sent by July 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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