

## A. Justification

1. In order to better address the mental health needs of middle and high school students living on and near military bases, we are evaluating the SOS Signs of Suicide prevention program. SOS is a universal prevention program that consists of a video, other curricular materials and self screening for depression that is implemented by school professionals during school hours. The program has been used by middle and high schools throughout the country in order to educate students about the signs and symptoms of depression and suicidality. Our evaluation involves only the completion of two surveys approximately three months apart. The surveys are aimed at determining the degree to which the SOS program fosters greater knowledge of and more adaptive attitudes toward depression and suicide, increases rates of help-seeking, and reduces rates of suicidal ideation and suicide attempts. Without this data collection schools cannot make evidence based decisions about suicide prevention programming.

The data collection includes both military dependents and civilian dependents living near military bases and attending what are considered to be “high impact” schools. We are evaluating the SOS program using a randomized experimental design, looking in particular at its impact in certain subgroups of students such as those with and without parents on active military duty, those in DoDEA and state schools, and those with and without deployed parents. It is vital that the civilian dependents be included in the data collection. Without their inclusion, we will be unable to report on findings for the subgroups under evaluation. We also risk stigmatizing the military dependents if they are singled out for participation.

Public Law 109-163 Sec. 721 authorizes this collection of data. A copy of Public Law 109-163 Sec. 721 is attached to this statement.

2. The information collected will be submitted to the Department of Defense and will also be submitted for publication in academic journals. Screening for Mental Health will also use the information to improve their program if appropriate. Schools can use the information to make evidence based decisions about suicide prevention programming.
3. This data collection does not involve the use of electronic means for collection, as some schools do not have adequate computer facilities to make this method feasible. It is necessary for schools to receive identical methods of survey presentation; thus electronic means of data collection is not possible.
4. This data collection does not duplicate any current or previous data collections. No other current data collections are collecting similar information and no previous studies have collected identical information. A few studies have previously evaluated the SOS Suicide Prevention Program<sup>1,2,3</sup>. These studies have collected similar, but not identical, information. Previous studies have evaluated the SOS program in high schools with low proportions of military dependents only. This is the first study to evaluate schools with large numbers of military dependents. It is unknown whether previous findings apply to the population in the proposed study. This is also the first data collection to include questions about parental military involvement and deployment. It is unknown whether these factors influence the effectiveness of the SOS Program.

This is also the first study to evaluate the SOS Middle School program in domestic schools. Currently, it is unknown whether the SOS Suicide Prevention Program is effective in middle

school students, particularly among those with parents in the military. Previous findings with high school students may or may not generalize to younger age groups.

5. Not applicable. No small entities will be impacted.
6. Without this data collection, schools on and near military bases will not be able to make evidence based decisions about suicide prevention programming for their students. Students, especially those in middle school and those who are military dependents, may receive insufficient prevention programming. The frequency of data collection cannot be reduced as surveys given both before and after the program administration are required to adequately assess the effectiveness of the SOS Program. There are no legal or technical obstacles to reducing burden.
7. None of the listed special circumstances exist except that respondents are expected to complete the survey in class on the day that they receive the survey. This is necessary to ensure that the surveys are presented to respondents in a consistent manner, to reduce rates of survey non-completion and to ensure that respondents have adequate privacy when providing information.
8. The 60-day Federal Register notice published September 22, 2009 (74 FR 48231). No responses to the posting were received by the Military Liaison to this data collection, Jill Carty, Psy.D., MSPH Executive Officer, Psychological Health Strategic Operations, Force Health Protection & Readiness, Office of the Assistant Secretary of Defense (Health Affairs).
9. There is no plan to provide payment or gifts to respondents for participation in the data collection. We are offering incentives to students for the return of consent forms. All students who return signed consent forms by the date stipulated on the consent form (which will vary by school) will be entered into a drawing for two prizes. One prize is a \$50 gift card and one is an iPod worth approximately \$188. Consent to participate in the evaluation is not required for eligibility in the drawing. Students and their parents may either consent or decline to participate and still be eligible for the incentive. This incentive aims to increase the numbers of students who return their consent forms in time for participation in the data collection.
10. We provide the following statement of confidentiality to respondents and their parents: “The answers your child provides will be kept strictly confidential. This means that no one but the investigator and his study staff will be able to connect your child’s responses with his/her name. Completed surveys will be collected with an assigned identification number and will not include your child’s name or date of birth. The file linking your child’s name to the assigned identification number will never be shared with anyone at your child’s school.” This assurance is provided via the informed consent form which is approved by the Institutional Review Board at the University of Connecticut Health Center (basis of assurance Title 45, Code of Federal Regulations, Part 46) and the Office of the Assistant Secretary of Defense for Health Affairs TRICARE Management Activity, Human Subjects in Research Protection Office (basis of assurance Title 45, Code of Federal Regulations, Part 46; Title 32, Code of Federal Regulations, Part 219; DoD directive 3216.2).

Additionally, to protect the confidentiality of student responses we include no names or other identifiers on the surveys. Each student is identified by a six digit identification number which is printed on the survey booklet. Surveys are placed inside sealed envelopes with have student names printed on the outside. This ensures that students get the correct surveys. The key

connecting names to ID numbers is kept on a password protected computer in a locked office at the University of Connecticut Health Center. School personnel are never allowed access to this information, thus only study staff are able to connect student responses with their names. Students are instructed on the survey that they should receive a sealed envelope, which they should discard after opening, and return only the survey booklet.

11. Our surveys include no questions about current thoughts or behaviors. They do contain questions about past thoughts and behaviors that may be considered private and that concern depression and suicidal thought or behaviors. These questions are necessary as this study is evaluating a suicide prevention program. The nature of the survey questions and the uses of the information collected are described to respondents and their parents in the informed consent form. Copies of the survey are available for parents to view at the school and online.

This study uses an active consent form on which parents can indicate their consent and students their assent to participate. Consent forms are sent to parents by the school counselor who is available to answer any questions that students and parents may have. Contact information for the principal investigator and study coordinator at the University of Connecticut Health Center are also provided on the consent form.

12. We expect to have approximately 2,200 respondents, roughly 840 of which are expected to be civilian respondents. Respondents will complete surveys at two points in time, one pretest and one post test survey. Based on our experience administering the surveys in previous years, administration of the pretest and posttest are expected to take approximately 30 minutes each. Thus the total hour burden on civilians for the pretest is 420 hours and for the posttest is 420 hours. There is a total burden of one hour per respondent, or 840 annual hour burden for the total evaluation.

There is no cost to respondents. Respondents are minors attending school and surveys are presented during normal school hours.

13. There are no costs to respondents.

14. The total costs to the Federal Government for the study are \$324,750. Please see budget line items below. The project covers a two year period, thus the annualized cost is \$162,375. There are a total of 2200 expected respondents with 840 civilian respondents. Thus the civilian component represents 38% of the total award, or \$61,703 of the annualized award. Details are listed in Table 1 below.

Table 1. Total Costs to Federal Government

Category	Total Award	Annualized Amount	Civilian Proportion
<b>Direct Costs</b>			
Personnel	\$104,746	\$52,373	\$19,902
Fringe	\$40,580	\$20,290	\$7,710
Travel	\$145,327	\$72,664	\$27,612
Incentives	\$18,200	\$9,100	\$3,458
Supplies/Printing	\$8,350	\$4,175	\$1,587

<b>Subtotal Direct</b>	\$210,877	\$105,439	\$40,067
<b>Facilities and Administration</b>	\$113,873	\$56,937	\$21,636
<b>TOTAL</b>	\$324,750	\$162,375	\$61,703

15. This is our first submission to OMB.

16. Reports will be provided to participating schools providing school profiles. Plans for publication include submission to peer reviewed academic journals. In both cases all results will be presented so that no individual information can be identified. Data analysis will be accomplished using standard techniques for analysis of clustered randomized data.

Timetable for Project Completion (State School Component)

March 1-May 31, 2011	Recruitment of schools
August 2011	Consent process
September 1, 2011 – May 31, 2012	Pretest and posttest data collection and data entry
June 1, 2012 – September 30, 2012	Data analysis and report generation
September 30, 2012	Submission for publication

17. Not applicable. We are not seeking approval to not display the expiration date for OMB approval.

18. Not applicable. No exceptions were identified.

**B. Collections of Information Employing Statistical Methods**

1. The potential civilian respondent universe consists of students attending grades 6-12 in 24 high military impact schools (schools with 20% or more military dependents) who are receiving the SOS Signs of Suicide Program in the Fall semester of 2011 through the Military Pathways Program. Schools are identified for potential participation by their request of program materials from Screening for Mental Health. All schools are approached for participation. The decision to accept or decline participation in the data collection is voluntarily made by principals and counselors at each school.

Students and their parents in the grade receiving the program are approached for participation in the data collection by the use of an informed consent form that is approved by the Institutional Review Boards at the University of Connecticut Health Center and the Department of Defense. The expected response rate, based on previous years of data collection, is 60%<sup>2,3</sup>.

2. *Statistical methodology for stratification and sample selection:* Schools agreeing to participate will be matched based on student demographic characteristics and randomly assigned to control

and treatment groups. Five to six classrooms with total enrollment of 150 students per school will be randomly selected to participate. Students and their parents within these selected classrooms will then be approached about participation via an informed consent form. Participation in the data collection is entirely voluntary and only those students who assent and whose parents give consent will participate.

*Estimation procedure:* Because students will be nested within school, estimation procedures will be performed with software that accounts for clustered sampling designs such as SUDAAN. [[Research Triangle Institute. SUDAAN, 9.0.1. Research Triangle Park, NC: Research Triangle Institute; 2005.]] Prior to estimation, bivariate analyses will be performed to assess the comparability of the intervention and control groups in terms of relevant descriptive characteristics. The intervention effect will be estimated in a generalized linear model that controls for any characteristics that are statistically different between the groups. Although random assignment should limit such differences between the treatment and control groups, controlling for differentiating characteristics will account for differences in composition between these groups and carries the further benefit of improving the efficiency of estimates. Differences between treatment and control groups in knowledge and attitude attainment will similarly be assessed. Finally, if a statistically significant treatment effect is demonstrated, mediation models will assess the role of attitudes and knowledge in explaining this effect.

*Degree of accuracy:* The items that assess suicidal thoughts and behaviors are taken from the CDC's Youth Risk Behavior Survey (YRBS) [[<http://www.cdc.gov/HealthyYouth/yrbs/pdf/questionnaire/2009HighSchool.pdf> accessed on November 25, 2009]]. Item rationale with references is included in the CDC website [[<http://www.cdc.gov/HealthyYouth/yrbs/pdf/questionnaire/2009ItemRationale.pdf> accessed on November 25, 2009]]. Thus, the items used in our survey are established items used in large-scale, longitudinal national studies in the high school population to assess suicidal behaviors.

Regarding the accuracy of conclusions obtained from our study, our design provides power to evaluate intervention effects at the .05 alpha level.

Unusual problems requiring specialized sampling techniques: None.

Use of less than annual data collection cycles: Not applicable. Data will be collected at two points in time only, three months apart.

3. School personnel are engaged to help with respondent recruitment and retention. School points of contact include school counselors and school nurses. These school personnel will inform students and parents of the data collection and offer students participation through the use of the informed consent form. An incentive program is utilized to maximize the return of the consent forms. Students who return their forms by the specified date (which will vary by school) are entered in a drawing for two prizes, a \$50 gift card and an iPod. Students do not need to participate in the data collection to be eligible for the drawing. Additionally, in order to minimize non-responses the surveys are administered during school hours. One make up time is provided to minimize non-responses due to student absence during the initial presentation. These method has been used in schools during similar collections in previous years and has been shown to provide an approximate 60% response rate<sup>2,3</sup>. This level of response is considered acceptable by peer reviewed academic journals.

Additionally, non-response will be addressed in the statistical analyses. Analyses will be performed to determine whether experimental condition (treatment and control) is associated with attrition at post-test. Then, to account for both participant attrition and item non-response in the analyses, standard multiple imputation procedures will be employed<sup>4</sup>. Multiple imputation is a simulation-based approach that generates multiple plausible values for each missing element in order to represent the inherent uncertainty in the missing data.<sup>5</sup> Multiple imputation is an appropriate technique to address missing data when the missing data can be accounted for by variables measured in the study, a situation we expect in the current study based on previous similar studies<sup>2,3</sup>.

4. No formal testing of surveys is planned with this data collection because surveys have been tested and accepted by peer reviewed journals <sup>2,3</sup> in previous years of data collection. However, reliabilities will be calculated for attitude and knowledge scales in order to establish their utility with students in high military impact schools.
5. Ofer Harel, PhD. (860) 486-6989.

#### Citations

<sup>1</sup>Aseltine RH: Evaluation of a school based suicide prevention program. *Adolesc Family Health*. 2003,3:81-88

<sup>2</sup>Aseltine RH, DiMartino, R: An outcome evaluation of the SOS suicide prevention program. *American Journal of Public Health*, 94, 3, 446-451

<sup>3</sup>Aseltine, R. H., Jr., James, A., Schilling, E. A., & Glanovsky, J. (2007). Evaluating the SOS Suicide Prevention Program: A Replication and Extension. *BMC Public Health*, 7: 161

<sup>4</sup>Rubin DB (1987) *Multiple imputation for nonresponse in surveys*. New York: John Wiley & Sons.

<sup>5</sup>Schafer JL, Graham JW (2002) Missing data: Our view of the state of the art. *Psychological Methods* 7:147-177.