

Evaluation of Young Marines Drug Education Program

Supporting Statement for Paperwork Reduction Act Submission

A. Justification

1. Circumstances that make the collection of information necessary:

This information collection is necessary for the Naval Health Research Center (NHRC) to carry out the research study “Evaluation of Young Marines Drug Education Program.” The Prevention and Intervention Section of the Marine Corps Community Services, Headquarters Marine Corps, has tasked NHRC to conduct a scientific evaluation to assess the Young Marines Program’s effectiveness in developing a drug free lifestyle among its youth members. The study will evaluate the Program’s efforts in changing drug-specific behaviors, attitudes, and knowledge, as well as factors such as self-esteem and personal responsibility. Youth subjects in this study will be asked to complete a survey about their drug use, and some of these youth subjects will also be asked to complete a follow-up survey about three months later. In addition, the Young Marine unit adult leaders will be asked to complete a one-time survey about the drug education activities that their unit provides to their program members.

2. Purpose:

The information shall be collected by conducting a voluntary survey of Young Marines youth participants and adult leaders. The Naval Health Research Center team will collect this information by administering a paper-and-pencil survey to some of the youth at regularly scheduled Young Marines meetings and by posting an on-line survey that can be completed via the Internet for other youth and adult leaders. The information collected will be used to describe how the Young Marines program is affecting drug behaviors and related measures and will allow recommendations to be made to improve youth drug education.

3. Use of Electronic Collection Techniques:

The collection of information will be accomplished by using both in-person and Internet-based survey administration. Specifically, the survey will be available to all participants by logging onto a website that shall contain the youth survey, follow-up youth survey, and the adult leader survey. The decision to include the Internet as a means to complete the survey was made in order to facilitate widespread participation. It was also a practical decision, as it would not be feasible to visit in-person a large number of Young Marine units across the US.

4. Efforts to Identify Duplication:

This is a specific program evaluation and no other adequate scientific program evaluation data exists for the Young Marine program. While a comparative study was previously conducted by the Channing Bete Company in 2002, the study contained problematic methodological issues such as the absence of significance testing, and an

inadequate description of the sample selection and important sample characteristics such as length of time in the Program. Thus, there is no available information to use for this evaluation, and there will be no duplication of effort in conducting this information collection.

5. Impact on Small Businesses or Entities:

The collection of information will not impact small businesses or other small entities.

6. Consequences if Collection is Not Conducted:

If this information is not collected, the consequences to the Naval Health Research Center are that it will not be able to carry-out the research that it has been tasked to do and it will not be able to fulfill the technical requirements associated with this evaluation that were agreed upon with the study sponsors. Altering the data collection plan or collecting the information less frequently would result in an ineffective program evaluation. This is a one-time project.

7. Special Circumstances:

There are no special circumstances that require the data collection to be conducted in a manner inconsistent with 5 CFR 1320.5 (d)(2).

8. Agency's Notice:

The agency's notice is included in Attachment A.

Date of publication in the Federal Register: March 6, 2008

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Summary of public comments and actions taken: No public comments received.

The following persons were consulted about this project:

- Mr. Cruz Martinez, Headquarters Marine Corps Substance Abuse Prevention Program, Marine Corps Community Services
- Mr. Mike Kessler, National Director, Young Marines

In addition, consultation with representatives of those from whom information is to be obtained was conducted. Two members of the Naval Health Research Center staff for this information collection consulted with approximately 15 Young Marines adult leaders at a conference held in May 2007. Many of the adult leaders are also parents of youth who participate in the organization. Hence, input was received from both leaders and parents, the two groups who must provide their voluntary consent to participate in this data collection. The majority of leaders and parents were in favor of this information collection and supported the data elements to be collected, indicated that both in-person and Internet-based formats were appropriate, and felt that the survey was reasonable and that the results would be beneficial to the organization.

9. Gifts to Respondents:

Youth respondents they will receive a thank you gift if their parent returns a signed consent form. The gift is a movie rental coupon valued at \$4.50. This will be given to the child whether or not the parent allows the child to participate; it will be given only

for returning a signed consent form. Such incentives are offered to encourage participation yet not introduce undue inducement to participate in the research.

10. Confidentiality:

As stated in this study's approved NHRC Institutional Review Board (IRB) Protocol (# NHRC.2007.0029, see Attachment B), respondents and parents of respondents are provided assurance of the privacy of their information as stated in the informed consent document. All information provided by respondents will be considered privileged and kept private, to the extent permitted by law and will be used only by Naval Health Research Center research personnel. A respondent's privacy on surveys will be protected by the use of unique participant codes rather than personal names. Regarding data collected via the Internet, the web application and transmission procedures will utilize Secure Socket Layering (SSL), to ensure that only encrypted data will flow over the Internet. Consent forms were modified to reflect OMB's suggestion that the term privacy be used rather than confidentiality.

The study's Principal Investigator, Suzanne Hurtado, is responsible for storing all information during the study. This information will be protected by keeping all paper copies of the information in a locked file in Building 328 at the Naval Health Research Center. Electronic data will be stored in password-protected files on secure computer servers at Naval Health Research Center. Access to all data will be limited to staff involved in this study and will not be given to parents, Young Marine unit leaders or anyone else besides the NHRC investigators. The information that individual respondents disclose will not be used by or released to another institution. The results of this study may be published in Department of Defense technical reports, scientific journals, or presented at scientific meetings; however, no publication or presentation will reveal any respondent's identity.

Lastly, individuals from official government agencies, such as the Department of Defense and the U.S. Navy, may inspect individual respondent's research records to ensure that the rights and safety of all research participants are protected.

11. Questions of a Sensitive Nature:

The survey asks about youth respondents' use of tobacco, alcohol, marijuana and other illicit drugs, drug-related knowledge, perceived pressures to use drugs, disapproval of drug use and other similar sensitive questions. It is necessary to ask these questions to measure the impact of the drug education program on individual behavior. Several other large studies on the sensitive issue of drug use have been conducted with youth (i.e., Monitoring the Future and Youth Risk Behavior Surveillance System), as this is an important area for study with implications for effective drug abuse prevention programs for young people.

As previously described earlier, the information collected will be used to describe how the Young Marines program is affecting drug behaviors and related measures and will allow recommendations to be made to improve youth drug education. The purpose of the information collection, participation, risks and benefits, risk

mitigation, and privacy are explained to the respondents and parent in the consent form (please see Attachment B). Per 45 CFR 46.404, this collection of information requires the solicitation of permission (or consent) from both the parent of the youth, and the youth's assent to participate in the study. The consent form and study information materials for the youth and parent to review will be obtained in one of two ways: (1) hard copies of consent form and study materials will be given to the child during the in-person presentation at a Unit meeting for the child to take home and discuss with their parent (for the large units only); and (2) after seeing the study announcement on the Young Marines website and linking to the study website where they can view the electronic study recruitment presentation, the parent may request a hard copy of the study materials packet from the unit leader at the next unit meeting, or the parent may request the packet from the investigators via email to be mailed to their home address. After returning a signed consent form, the youth provide their assent by either completing the survey or not, when it is administered or available to them on-line. The adult leaders are given their consent information on-line and indicate their consent to participate by clicking the appropriate box and either completing the survey or logging off the website.

12. Estimates of Hour Burden:

The total number of respondents to this information collection is 1,325. This is made up of 1,000 youth respondents and 325 adult leader respondents. The frequency of response is once for the baseline survey for all 1000 youth respondents, twice for a subset of 250 youth respondents for a follow-up survey, and once for survey of 325 adult leader respondents, totaling 1,575 annual responses. The youth surveys require 45 minutes to complete and the adult leader survey requires 20 minutes to complete. Together, all of the surveys will require 1,046 hours to complete. The estimate of 45 minutes for the youth survey is consistent with other youth surveys of similar length on drug use conducted by other organizations. The collection of information or the completion of surveys by the youth (aged 11 to 18) does not have any cost associated with the hour burden. The wage burden for the adult leader survey has been estimated using the most recent average national wage of \$18 per hour, provide by the Bureau of Labor Statistics (U.S. Department of Labor, December 2007, <http://www.bls.gov/news.release/empstat.nr0.htm>).

Table 1. Estimated Respondent Burden

Form	Number of Respondents	Number of Responses per Respondent	Total Number of Responses	Response Time (Minutes)	Total Response Burden (Hours)	Average Hourly Wage (Dollars)	Total Average Wage Burden (Dollars)
Youth baseline survey	1,000	1	1,000	45	750	N/A - \$0	\$0
Youth follow-up survey	250*	1	250	45	188	N/A - \$0	\$0
Adult Leader survey	325	1	325	20	108	\$18	\$1,944
Total	1,325	-	1,757	-	1,046	-	\$1,944

Note. * = These 250 respondents will be drawn from the 1000 Youth Baseline survey respondents so they do not represent additional total respondents.

13. Estimates of Cost Burden to Respondents:

Not applicable; there are no capital or start-up costs, or operation and maintenance costs to respondents for this information collection.

14. Estimates of Cost to Federal Government:

The cost estimate to the Federal government for this information collection is \$108,050 over 12 months. The cost to the Federal government for this effort includes personnel time, contract costs, travel costs to collect data, and indirect costs. Personnel hours expended for this effort are approximately 500 hours. When referenced to a base rate of \$40/hour, this results in an estimated \$20,000 in personnel time incurred by the government. Contract costs are approximately \$33,550. Travel which includes 4 trips at \$1,500/trip equals \$6,000. Including overhead of \$48,500, the total annualized cost to the government for this data collection is approximately \$108,050.

15. Program Changes:

This is a new project so no changes need to be reflected.

16. Plans for Publication and Time Schedule:

The results of this information collection are planned to be published in a Department of Defense technical report. The results may also be published in scientific journals,

or presented at scientific meetings. However, no publication or presentation about this research study will reveal any respondent’s identity. Analysis of this information will include both between-subjects and within-subjects techniques to evaluate the Program.

The time schedule for the entire project is February 2007 through September 2008. The beginning date for information collection is June 2008 and the ending date for information collection is approximately August 2008. The completion of the Department of Defense technical report is expected in September 2008, and publication dates for journal articles are unknown at this time but are anticipated in 2009.

Table 2. Study Time Schedule

Task	Start Date	Finish Date
Summarize literature, document current program, develop and finalize research methodology	2/07	5/07
Finalize questionnaires	5/07	8/07
Obtain NHRC IRB approval	9/07	1/08
Obtain OMB clearance	1/08	6/08
Develop web site for Internet-based questionnaires	2/08	5/08
Collect data	6/08	9/08
Write reports	8/08	9/08

17. Display of Expiration Date:

Not applicable; not seeking approval to not display expiration date.

18. Exceptions to Certification Statement:

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods:

The potential respondent universe is approximately 10,000 boys and girls who are enrolled in the Young Marines program. While the Young Marines organization includes children from age 8 to 18, the present study will only include participants in the 6th through 12th grades (approximately 11 to 18 years old). To meet the minimum sample size requirements for this study, 500 Young Marines are needed and an additional 500 new enrollee Young Marines are needed, for a total of 1,000 youth participants for the survey. It is conservatively anticipated that 40% of the 1,000 needed subjects (or 400 subjects) may refuse to participate, which includes not returning the consent form, not being present the day of the survey administration, and non-participation for other reasons. Other studies on drug use behavior among children have reported baseline participation rates ranging from 68% to 96%

(Woodruff, Conway, Edwards, Elliot and Crittenden, 2007; Orlando, Ellickson, McCaffrey and Longshore, 2005; Sussman, Dent, Stacy and Craig, 1998; Dent, Sussman, Hennesy, Galaif, Stacy, Moss and Craig, 1998). We have anticipated a slightly lower rate due to the combination of in-person and internet methods of data collection, where other studies have shown that internet survey rates of participation are lower than in-person surveys (Lozar Manfreda, Bosnjak, Hass and Vehavar, 2005). In addition, because consent will not be given at the same time as survey participation, (i.e., child needs to bring home consent form), we expect a lower response rate. Hence, for this part of the study, 1,400 initial subjects will be targeted (1,000 subjects plus the 400 additional needed for the anticipated non-participation rate).

There are slightly more than 300 Young Marine units in the respondent universe. Units range in size from 1-115 members, with an average size (median) of 20 members. Because members in small, mid-size, and larger units may differ in important ways, our goal is to recruit participants from various sized units to ensure adequate representation. Researchers will be targeting the largest (i.e., “major”) units (approximate size of 100 members) for in-person subject recruitment for practical reasons in order to reach the most participants. There are approximately 4 major units and considering a 60% recruitment rate, approximately 17% (n=240) of the initial 1,400 subjects needed are expected to be recruited from these major units.

A stratified random sample of additional Young Marine units will be targeted for web-based subject recruitment. Our strategy for web-based sampling of the non-major, relatively smaller sized units is based on our estimates that about one-third of the units are very small (i.e., 15 or fewer members, average of 10); one-third are mid-size units (16-25 members; average of 20); and one-third are larger sized units (25-99 members; average of 37). There are approximately 100 units within each of these size strata; 20% of the potential sample is concentrated within the very small units, 30% are within mid-size units, and half are within larger units. Within each of the 3 size strata, 30% of the units will be randomly selected. The selected units will be contacted by email and will follow the recruitment procedures described in the section below. Assuming a 60% recruitment rate across units, we expect to recruit 180 members, 360 members, and 666 members from the very small, mid-size, and larger sized units, respectively, for a total of 1206 subjects. The addition of these 1206 subjects to the 240 recruited in-person at the major units will ensure our sample size of at least 1,400. We believe this sampling plan will provide excellent representation of units.

2. Procedures For the Collection of Information:

Procedures for the collection of the information include procedures for subject recruitment and survey administration. Subject recruitment will be accomplished in two ways. Researchers will make an in-person presentation to the youth at a regularly scheduled unit meeting to give information about the study and provide hard copy study materials including the parental consent materials for the youth to take home to discuss with their parent. In-person presentations will be an efficient means to present

brief study information to the youth in the larger units (i.e., those units that have more than 100 youth participants). A parallel recruitment method will use the Internet. The smaller selected units, identified by the random sampling methods described above, will be contacted by email and they will be requested to show the downloadable, on-line recruitment presentation to their members. A packet containing the parent letter, parental consent form, a copy of the PowerPoint presentation, and return envelope will be provided. Unit leaders will receive follow-up phone calls to discuss recruitment, and in the event that logistical problems occur such that internet access is not available for consented potential participants, they will be given the option of receiving paper versions of the surveys to provide. Pre-addressed stamped envelopes will accompany these surveys so that participants can return them directly to the researchers. This method will be a more practical means to recruit youths who belong to smaller units, where travel for an in-person presentation is not feasible, and for new enrollees who would not be in attendance yet at regularly scheduled unit meetings.

New enrollee recruitment will be handled at the unit level due to variability in the start dates of their boot camps/orientations and unit procedures. The researchers will work with individual unit leaders on the best way to get the study information packet (described above) to their new enrollees. Instructions will be provided to the unit leaders on how to accomplish this; in some cases the leader will send the study information to the new enrollee and in other cases, the information packet can be provided to the new enrollee if they are in attendance at a unit meeting prior to beginning their boot camp training. In either case, the subject recruitment PowerPoint presentation can be viewed by the new enrollee and their parent or guardian via the Internet, or it can be shown to the unit by the leader at a unit meeting (as we are requesting they do for the regular members).

The in-person surveys will be administered by NHRC staff to the youth (whose parents allowed their child to participate and signed a consent form) in the units where the in-person presentation was made by NHRC researchers. The in-person survey administration environment will be the Young Marines regular unit meeting place (typically a school, military base, or community facility). NHRC research staff will administer the surveys, be available for questions, and collect the surveys. Other participants in many of the smaller units where in-person survey administration will not be feasible will have the option to complete the survey on the internet, in their own individual setting, by logging onto a website. As stated in the previous paragraph, unit leaders will be given the option to request paper surveys with return envelopes for their members.

The youth follow-up survey will be conducted via the study web site; however, there will be the option of mailing the follow-up survey to participants if they indicated that was their preference on the baseline survey. These two modes of data collection are anticipated to increase the response to the follow-up survey.

The survey content is largely based upon an existing data collection instrument that is used in the large national survey of youth drug use, Monitoring the Future Study. Recent changes to the survey based upon discussions with OMB staff include:

- (1) The initial survey will ask participants that if they are selected to receive the follow-up survey, what is their preferred mode (Internet or mail) to receive the follow-up survey.
- (2) Two items on race/ethnicity were added to the youth surveys.
- (3) The PRA burden statement was added to all surveys.

The sampling strategy for the adult leader surveys is to obtain as much representation from all of the units as possible. There are approximately 325 units and all units will be targeted for the survey. The adult leader survey will be administered via the Internet.

3. Methods to Maximize Response Rates:

Response rates shall be maximized by using in-person, Internet-based, and mailed data collection methods. Internet access to the survey allows many potential subjects to be able to participate. The use of a thank you gift for returning a completed consent form is also used to encourage responses. Emailed reminders will be used for the follow-up survey and the adult leader survey to further maximize response rates.

The accuracy and reliability of the information is expected to be high as the vast majority of the youth survey is based on an existing data collection instrument used in the national Monitoring the Future study conducted annually by the University of Michigan Survey Research Center for the National Institute on Drug Abuse (NIDA), and is highly appropriate for this study's intended uses.

4. Testing:

Analysis of this information will include both between-subjects and within-subjects techniques to evaluate the Program. A comparison group (between subjects) analysis will be conducted to compare Program participants to other similarly aged youth who have not participated in the Program. Current Young Marine participants will be compared to: (a) newly enrolled Young Marines who have not yet participated in the program, and (b) grade- and sex-matched respondents from an existing national database on youth drug use.

For the comparison to the national youth drug use database, the national data set will be standardized to reflect the socio-demographic characteristics of our Young Marines sample. The factors to be weighted will include grade, gender, and race. We will use all of the available data from the national database for the comparison as to increase precision and power of the comparison. Use of all of the available data from the national dataset will reduce bias to make the comparison more robust.

In addition, a pre- and post-test group (within-subjects) analysis will be conducted to assess changes in drug use, attitudes, knowledge, and positive character traits among Young Marines. Simple, unadjusted changes will be assessed by paired t-tests for

continuous level variables and McNemar tests for correlated proportions for dichotomous variables. Multivariate analysis will also be conducted to assess the significance of the change after adjusting for important covariates.

5. Statistical Consultants and Data Collection Staff:

The following is a list of Naval Health Research Center staff that will collect and/or analyze the information:

- Suzanne Hurtado, (619) 553-7806; responsible for statistical aspects of design
- Susan Woodruff, (619) 553-6934; consulted on the statistical aspects of design
- Cynthia Simon-Arndt, (619) 553-0131
- Robyn Highfill-McRoy, (619) 553-3535

Attachments:

Attachment A – Agency Notice

Attachment B – Approved NHRC IRB Protocol # NHRC.2007.0029 (Protocol appendices have been placed in separate documents)