APPENDIX C. REVIEW FOR PROTECTION OF HUMAN RESEARCH VOLUNTEERS FROM RESEARCH RISKS

INSTITUTIONAL REVIEW BOARD RECOMMENDATION

INITIAL REVIEW

Date of Review: 06 September 2007 Protocol Number: NHRC.2007.0029

Protocol Title: Evaluation of Young Marines Drug Education Program

Principal Investigator: Suzanne L. Hurtado, MPH

Approximate Dates of the Research: 01 August 2007 to 31 February 2009

Work Unit / Number: Young Marine Evaluation, 60707

The principal investigator submitted this protocol for initial review. The objective of the proposed research is to conduct an evaluation of the effectiveness of the "Young Marines" youth development program to reduce drug use behavior and increase drug-awareness among its youth members. Toward that end, 700 Young Marine participants and 700 young people waiting to enter the Young Marines Program will be recruited. Participants may be male or female, and will be 6th graders through 18 years of age. Parental consent will be sought for subjects under the age of 18. Subjects will complete a survey about their drug use, attitudes, knowledge, self-esteem and personal responsibility. A subset (325 subjects) will be asked to complete a similar follow-up survey approximately three months later for a comparison to assess the effectiveness of the program. The data collected will not include any personal identifiers through which the responses could be tied to a specific individual. Further, to examine and describe the process by which the Young Marines Program implement drug abuse prevention education, an adult representative from each Young Marine Unit will be asked to complete a one-time survey, thereby also involving 325 adult volunteer subjects. These data will not include personal identifiers either.

Per 45 CFR § 46.404, the Board found that adequate provisions are made for soliciting the permission of each child's parents or guardian and that permission of one parent is sufficient for this survey research to be conducted and that adequate provisions are made for soliciting the assent of the children. Procedures for attaining child assent will include description of voluntariness of study on questionnaire cover page. As the only linkage between the Young Marines and the research would be a signed assent form, signed assent was waived (32 CFR § 219.117(c)(1). The Board also waived the requirement for signed consent for Young Marine adult unit leaders and 18 year old Young Marines, as again, the only identifier linking the research to the respondent would be a signed consent form

The Board agreed that all criteria of 32 CFR § 219.111 and 45 CFR §46.401 Subpart D for the approval of research had been met. With a vote of 8 for, 0 against, Chair abstaining, and no member disqualified from the review, the Board classified this protocol as minimal risk. On a vote of 8 for, 0 against, Chair abstaining, and no member disqualified from the review, the Board recommended to approve this minimal risk protocol for a period of 364 days after minor changes were made. Those changes have been made and approval is recommended. The PI needs to provide OMB survey approval documentation, and any web-based screen shots or other subject materials to be used for IRB review before any subject enrollment.

The next scheduled review is on or before 05 September 2008.

Christopher G. Blood, JD, MA
Chair, NHRC IRB

Christopher G. Blood 11/7/08
Signature & Date

****

DETERMINATION OF APPROVING AUTHORITY

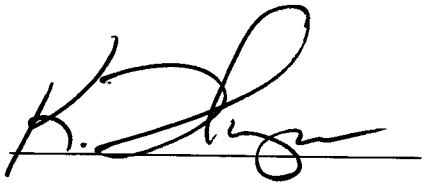
1. I concur with the recommendation of the IRB, and I approve this research.

   Next review is required no later than: 05 September 2008

2. I concur with the recommendations of the IRB, but I require additional modifications or restrictions prior to providing continuing approval (Attach modifications or restrictions required).

   Next review is required no later than:

3. I disagree with the recommendations of the IRB and recommend (Attach statement regarding recommendations and reasons).

	Signature	Date (DD/MM/YY)
CAPT K. R. THOMPSON, MSC, USN Commanding Officer		08 Jan 08

INSTITUTIONAL REVIEW BOARD MEMBERS

Name and Affiliation	Signature	Date
Christopher Blood, J.D., M.A. Naval Health Research Center IRB Chairperson		6 Sep 07
Mr. Walter Leverette Naval Medical Center San Diego Chaplain Representative		6 SEP 07
Joseph Purcell, JD, LLM Space and Warfare Systems Center, San Diego Legal Representative - Alternate		6 Sep 07
LCDR Dennis Faix, MC, USN Naval Health Research Center Medical /Dept 164 Representative		6 SEP 2007
HMC Mark Valencia, USN The Naval School of Health Sciences, San Diego Military Representative Alternate		6 SEP 07
Gerald Pang, M.S. Naval Health Research Center Dept 161 Representative		6 SEP 07
Diane Williams, Ph.D. Naval Health Research Center Dept 161 Representative		6 Sep 07
Linda Hervig, M.S. Naval Health Research Center Dept 162 Representative - Alternate		6 Sep 07
Stephanie Kewley, Ph.D. Naval Health Research Center Dept 163 Representative		6 Sept 07

INSTRUCTIONS: Complete all portions of shaded text in this application, revising text as appropriate. Delete all brackets and shading prior to submission.

HUMAN USE PROTOCOL
ROUTING SLIP

FROM (Principal Investigator): Suzanne L. Hurtado, MPH (TYPED NAME)	(SIGNATURE)

In accordance with NAVHLTHRSCHCENINST 3900.2C, I am submitting the attached human use protocol for consideration.

TITLE OF PROTOCOL: Evaluation of Young Marines Drug Education Program

ABBREVIATED TITLE: Evaluation of Young Marines

PROPOSED DATES OF RESEARCH: 2007AUG01 to 2008DEC31

SUBMISSION (CHECK ONE):
☒ INITIAL SUBMISSION
☐ MODIFICATION OF PREVIOUS SUBMISSION
☐ CONTINUING/ANNUAL REVIEW

PROTOCOL OBJECTIVE (Brief sentence or two): To conduct an evaluation of the effectiveness of the "Young Marines" youth development program to reduce drug use behavior, drug-related attitudes, and knowledge among its youth members.

COMMENTS (e.g., issues, special considerations):

DoD PROTOCOL NUMBER (Assigned by IRB Administrator upon submission for initial review. Be sure to add this number where indicated on the title page): NHRC.2007.0029

Note: You must obtain signatures 1-4 before you submit the protocol to the IRB.		DATE RECEIVED	DATE APPROVED	INITIALS
1	PROGRAM MANAGER			
2	PROGRAM IRB MEMBER			
3	DIRECTOR OF SCIENCE AND TECHNOLOGY			
4	IRB ADMINISTRATOR			
5	COMMANDING OFFICER			

INSTRUCTIONS: Complete all portions of shaded text in this application, revising text as appropriate. Delete all brackets and shading prior to submission.

HUMAN USE PROTOCOL ROUTING SLIP	
FROM (Principal Investigator): Suzanne L. Hurtado, MPH (TYPED NAME)	Suzanne L Hurtado (SIGNATURE)
In accordance with NAVHLTHRSCHCENINST 3900.2C, I am submitting the attached human use protocol for consideration.	
TITLE OF PROTOCOL: Evaluation of Young Marines Drug Education Program ABBREVIATED TITLE: Evaluation of Young Marines	
PROPOSED DATES OF RESEARCH: 2007AUG01 to 2008DEC31	
SUBMISSION (CHECK ONE): ☒ INITIAL SUBMISSION ☐ MODIFICATION OF PREVIOUS SUBMISSION ☐ CONTINUING/ANNUAL REVIEW	
PROTOCOL OBJECTIVE (Brief sentence or two): To conduct an evaluation of the effectiveness of the "Young Marines" youth development program to reduce drug use behavior, drug-related attitudes, and knowledge among its youth members.	
COMMENTS (e.g., issues, special considerations):	
DoD PROTOCOL NUMBER (Assigned by IRB Administrator upon submission for initial review. Be sure to add this number where indicated on the title page): [#####] NHRC.2007.0029	

Note: You must obtain signatures 1-4 before you submit the protocol to the IRB.		DATE RECEIVED	DATE APPROVED	INITIALS
1	PROGRAM MANAGER	8/22/07	8/22/07	JC
2	PROGRAM IRB MEMBER	8/22/07	8/27/07	SBK
3	DIRECTOR OF SCIENCE AND TECHNOLOGY	23 Aug 07	23 Aug	
4	IRB ADMINISTRATOR	AUG 28 2007		
5	COMMANDING OFFICER		08 JAN 08	KT

I. COVER PAGE(S)

1. Protocol Number: NHRC.2007.0029

2. Title: Evaluation of Young Marines Drug Education Program

3. Date of Submission: 2007AUG28

4. Approved Work Unit Title (i.e., the funded research proposal [or also referred to as the work unit] title under which the protocol is being conducted) and Full Work Unit Number:

   Young Marine Evaluation, 60707

5. Approximate Dates of Research: 2007AUG01 to 2008DEC31

6. Principal Investigator: Suzanne L. Hurtado, MPH
   Naval Health Research Center

7. Co-Investigator(s): Cynthia M. Simon-Arndt
   Naval Health Research Center

   Robyn M. Highfill-McRoy
   Naval Health Research Center

   Susan Woodruff
   Naval Health Research Center

   Jerry Larson
   Naval Health Research Center

8. Primary Performing Institution(s): Naval Health Research Center

9. Collaborating Institution(s): N/A

10. Subjects:
    a. Number of Subjects: 2,225
    b. Number of Female Subjects: 1,001
    c. Number of Male Subjects: 1,224
    d. Number of Civilian Subjects: 2,225
    e. Number of Active-Duty Subjects: 0

11. Identification of Medical Monitor: Heidi Kraft, PhD
    Naval Health Research Center

12. Is a JRRA/CRDA/MOU needed? No

II. SIGNATURE PAGE(S)

1. Principal Investigator:
Suzanne L. Hurtado, MPH
Naval Health Research Center

2. Co-Investigator:
Cynthia M. Simon-Arndt
Naval Health Research Center

Robyn M. Highfill-McRoy
Naval Health Research Center

Susan Woodruff
Naval Health Research Center

Jerry Larson
Naval Health Research Center

3. Medical Monitor:
Heidi Kraft, PhD
Naval Health Research Center

4. Key Support Personnel:
NA at present

NA at present

5. Program Manager:
Jerry Larson
Head, Behavioral Science and Epidemiology Program

6. Director of Science:
and Technology
Karl Van Orden

7. Commanding Officer:
K. R. Thompson, CAPT MSC USN

III. RECORD OF CHANGES TO THE PROTOCOL

IV. TABLE OF CONTENTS

V. SCIENTIFIC BACKGROUND AND OBJECTIVES

1. Background

This research is intended to address the serious health concern of drug use among youth. While national youth surveys indicate that the prevalence of tobacco, alcohol, and marijuana use has declined in recent years, usage rates are still quite high and the consequences of use are still quite severe. Among the nation's 12th graders, 22% report smoking and 37% report the use of any illicit drugs within the past year (Johnston et al., 2006). Drug use among middle school children is also alarming, with 9% reporting tobacco use and 15% reporting illicit drug use. Alcohol has been called the *most heavily abused substance by America's youth* by the Surgeon General (US Department of Health and Human Services, 2007). This is evidenced by survey data showing that 30% of high school seniors report being drunk in the last 30 days, as well as 19% of 10th graders, and 6% of 8th graders. Marijuana remains the most widely used of the illicit drugs. In 2005, 12% of 8th graders and 32% of 12th graders reported having used marijuana in the past year.

Despite the downward trend of the use of some substances among youth, the nature of drug use among high school age children in the United States has shifted in recent years. The use of prescription drugs and sedatives, as well as inhalants, has increased somewhat since 2003 (Johnston et al., 2006). The most recent survey data show that 9% of 12th graders reported inappropriate use of prescription drugs during the past year, and 4-7% report inappropriate use of over-the-counter medications. Furthermore, there is heightened concern over the use of inhalants because the survey indicated that young people's perceived risk of the dangers of inhalant use has decreased.

The negative consequences of youth drug abuse are broad and devastating, covering many economic, medical, and social issues. Abuse and addiction to alcohol, nicotine, and illegal substances cost the nation approximately half a trillion dollars a year, when considering the combined medical, social, and criminal impact (NIDA, 2007). The abuse of illicit drugs and alcohol contributes to the death of more than 100,000 Americans each year, while tobacco alone is linked to an estimated 440,000 deaths per year. Youth suffer harmful social and life consequences of drug abuse and addiction such as poor academic performance, dropping out of school, unplanned pregnancies, infectious diseases, violence, poor social behaviors and personal relationships. Thus, making such problems during the formative years far more deleterious and further reaching in their potential consequences.

Drug abuse education and prevention programs have been developed to reduce or prevent drug use, slow the uptake of initial drug use, and to reduce the occurrence of negative consequences. These programs can utilize different approaches and be implemented across family, school, and community domains. The most common approaches to youth drug abuse prevention in recent years include the social influence and skills training approach, risk factors and protective factors approach, and educational and information dissemination. Often, a combination of these approaches is used. Social influence and skills training focuses on teaching life skills which includes decision-making, refusal and resistance skills, communication and assertiveness, and correcting perceived norms. The risk and protective factors approach seeks to modify certain psychosocial concepts that influence behavior, such as drug-related attitudes, peer influence, and self-efficacy; while the traditional educational approach seeks to increase young people's awareness and information that they have on drug use prevention.

In recent years, there has been much interest in addressing youth drug abuse with positive youth development programs. These programs are broad in scope and can be implemented across family, school, and community domains. This type of program seeks to promote a positive developmental pathway for youth, and prevent the occurrence of problems by promoting social, emotional, and behavioral competence or skills, fostering resilience, self-efficacy and social norms, as well as specifically targeting drug prevention and education (Catalano et al, 2002).

Effective prevention programs are critical to guiding the development of adolescents into healthy, productive adults. Many educational programs for youth drug abuse prevention exist; however, their effectiveness in changing drug-related behaviors, attitudes, knowledge, and other factors has varied greatly

among programs. For example, the Drug Abuse Resistance Education (DARE) program, implemented widely across the US, has been evaluated numerous times with varying outcomes. The more rigorous of evaluations with long-term follow-up found that the program did not produce lasting effects in drug abuse related measures among youth (Rosenbaum and Hanson, 1998). Among youth development programs, an evaluation of the Life Skills Training program, a school-based social skills development curriculum, showed significant reductions in cigarette and marijuana use and an increase in substance use knowledge, as well as some long-term positive effects (Botvin, Baker, Dusenbury, Tortu, and Botvin, 1990; Botvin, Baker, Dusenbury, Botvin, and Diaz, 1995). An evaluation of another school-based, refusal and resistance skills development program, Project ALERT, indicated short-term positive effects on behavioral and cognitive risk factors associated with substance use among eighth graders (Ellickson, Bell, and Harrison, 1993). Other youth development programs that address a variety of youth development constructs have been shown to produce varying positive effects among youth including decreased alcohol use, knowledge, and attitudes (Perry, Williams et al, 1996), overall drug use (Tierney, Grossman and Resch, 1995), and drug use in the last month (LoSciuto, Freeman, Harrington, Altman, and Lanphear, 1997).

The United States Marine Corps funds a youth development and drug education program called the Young Marines. Young Marines is the official youth program of the U.S. Marine Corps and is the focal point for the Marine Corps' Youth Drug Demand Reduction effort (MCO 5000.20, 12 July 93). The program focuses on character building, leadership, and promotes a healthy drug-free lifestyle. The mission of the Young Marines is to positively impact America's future by providing quality youth development programs for boys and girls that nurture and develop its members into responsible citizens who enjoy and promote a healthy, drug-free lifestyle (http://www.youngmarines.com, 2006).

Program Description. Young Marine units are organized into local units located across the United States. The Young Marine units are community-based programs run by adult volunteers. Young Marine units meet at various venues such as schools, U.S. Marine Corps bases, and community recreation centers. Upon joining a local Young Marine unit, the youth undergo an orientation program, generally spread out over several weekly meetings. During the orientation program, also called boot camp, the focus is on general Young Marine subjects such as history, close order drill, physical fitness, customs and courtesies, and military rank structure, and drug education is also covered. After graduating from boot camp, Young Marines continue the character building process by continuing to meet and work toward earning ribbons in various subjects, including drug awareness.

Specifically, the orientation class is a 26-hour curriculum usually given 2 hours per week for 13 weeks. Drug resistance and prevention education is included in this curriculum, and required for three hours per quarter thereafter. The Registered Adult (Leader) Manual and the Guidebooks for the Young Marines provide guidelines and basic information on drug resistance and education. Quarterly drug education may include activities such as a discussion on why kids use drugs, information about drug substances, an exploration of resources such as Substance Abuse and Mental Health Services Administration, Centers for Disease Control, Office of National Drug Control Policy, and Partnership for a Drug-Free America, and guest speakers such as police officers who may bring drug-sniffing dogs and discuss drug control and gang-related drug issues. In addition, the organization publishes and distributes to all members a quarterly magazine which highlights drug education topics in each issue. The goal of the Young Marine's drug demand reduction efforts is to promote a healthy, drug-free lifestyle among the youth.

Two studies of the Young Marine Program have been conducted to date. In 1994, a descriptive study was conducted that examined several military sponsored, drug education programs, including the Young Marines (Caulkins et al., 1994). This study described the program and its community relations at that time in 1993. The researchers concluded that the program was in accord with recommendations in the literature regarding interactive and multidimensional programs; however, the study noted that it did not provide a standardized drug education curriculum. Another study conducted in 2002 compared a sample of Young Marines to two existing databases on youth drug use and related variables (Channing Bete, 2002). While comparisons were made in self-reported drug use and in risk and protective factors, 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.

The Prevention and Intervention Section of the Marine Corps Community Services, Headquarters Marine Corps, has requested NHRC to conduct a scientific evaluation to assess the Young Marines Program's effectiveness to develop a drug free lifestyle among its youth members. This study will add to the body of literature on the effectiveness of broad-based youth development programs to decrease drug use and related factors. Headquarters Marine Corps is the funding sponsor and has provided O&M funding to carry out this research.

2. Objectives

A. Hypotheses to be tested

(1) Youth who participated in the Young Marines will report lower levels of drug use and drug-approving attitudes, higher drug knowledge scores, and higher positive character traits than: (a) a group of peers who has not participated in the Program, and (b) a comparison group from an existing national drug survey database.

(2) Similarly, the posttest scores of youth who will have participated in the Young Marines program for three months will indicate lower levels of drug use and drug-approving attitudes, higher drug knowledge scores, and higher positive character traits when compared to their pretest scores.

B. Other objectives

(1) To examine and describe the drug abuse prevention education activities that the Program implements.

VI. EXPERIMENTAL METHODS

1. Experimental Procedures and Rationale

A. Subjects

The primary subjects for this study will be boys and girls who are enrolled in the Young Marines program. This program already exists and is currently being implemented. The youth's decision to participate in the program was made independently of this protocol. While the Young Marines organization includes children from age 8 to 18, the present study will only include participants in the 6^{th} through 12^{th} grades (approximately 11 to 18 years old). Participants will be currently enrolled in a state-recognized educational institution (e.g., primary school, middle school, or high school). Young Marines participants may be dependents of active duty military personnel, but this is not a criterion for inclusion or exclusion in the study.

To address hypothesis (1) which will be referred to as the comparison group study, a group of Young Marines will be compared to two comparison groups: new enrollees and a national sample. The new enrollees comparison group will be new participants in the YM Program who have not begun their orientation class, or thus been exposed to the intervention. Typically, a child who wants to join the Program is signed up and entered into the YM national database. Their first activity is to complete their orientation class, referred to as "boot camp," that lasts approximately

13 weeks; however, the orientation class is only offered approximately two times per year necessitating that new enrollees wait until the class is offered to officially start the Program.

The other comparison group will be a sample of adolescents drawn from the Monitoring the Future (MTF) survey, an annual national 8th -12th grade in-school survey of drug use based on probability samples of adolescents (web-site: http://monitoringthefuture.org/). MTF is one of the country's main sources of information on trends and cross-sectional patterns of drug use among young people. The 8th through 12th grades from the MTF data and the Young Marine data will be directly compared. In addition, while not a direct match, the 6th and 7th grade student data from the Young Marine sample will be compared to the 8th grade MTF comparison sample. A total of 500 subjects per comparison group (Young Marines, new enrollees, and a national sample) are needed for the comparison group study.

To address hypothesis (2) which will be referred to as the pre- and post-test study, the subjects will be new enrollees in the Program who have not yet started their Program orientation class; 250 subjects are needed for the pre- and post-test study, and they will be randomly selected from the 500 new enrollees already participating in the comparison group study. (The full grade range—6th through 12th—will be utilized here without any comparison concerns since this is the within subjects part of the study.) The survey that the new enrollees complete for the comparison study will serve as their pre-test survey. Those same 250 subjects will be followed-up with a post-test survey.

To address the additional objective—to examine and describe the process by which the Program implements drug abuse prevention education—a one-time survey will be administered to the adult leaders of the Young Marine units (this study will be referred to as the adult leader process survey). These adult leaders are civilian volunteers and include both men and women. There are approximately 325 Young Marine units in the organization, and one respondent is needed to complete the survey for each unit.

B. Methods and Informed Consent Plan

Study design – This study will use both between-subjects and within-subjects designs to evaluate the Program. A comparison group (between subjects) study will be conducted to compare Program participants to other similarly aged youth who have not participated in the Program. In addition, a pre- and post-test group (within-subjects) study will be conducted to assess changes in drug use, attitudes, knowledge, and positive character traits among Young Marines. The pre- and post-test group study utilizes a longitudinal study design which is necessary to accomplish the goals of this program evaluation.

Sampling strategy – For practical and efficiency reasons, large Young Marine units (those with 100 or more youth) will be targeted for in-person subject recruitment. There are approximately 8 units of this size in the organization. The researchers will make an in-person presentation to these units during regularly scheduled unit meetings. Subject recruitment will be open to all other units in the organization through the use of an electronic presentation that can be viewed by units as a group during a unit meeting, or by individuals in their own setting, using the internet. The study will be announced on the Young Marines website through which interested units and individuals may click on a link to get to this evaluation website to view the recruitment presentation. Recruitment will stop when the minimum sample size is achieved.

The 500 subjects needed from the national sample for comparison will be drawn from an anonymous, publicly available micro-database from the MTF study. All personal identifiers have been removed, and other information that might be used to impute identities has been either altered or removed altogether to protect MTF respondents. To compare the responses of the YM participants with the general U.S. adolescent population, we will select 500 adolescents from the

national database matched to study participants by age (within two years) and gender. The 500 matched subjects randomly selected from the national database will not be consented since their data is anonymous, publicly available, and consent is impractical to obtain.

The sampling strategy for the adult leaders surveys is to get as much representation from all of the units as possible. All units will be asked to participate. However, only one respondent per unit is needed. The commanding officer of each unit will be targeted, and that person, or his or her designee (the commanding officer may pass the opportunity to complete the survey to another knowledgeable adult leader in the unit) is needed to complete the survey; only one completed survey per unit is needed (and only one survey response per unit access code will be allowed).

Procedures – A flier about the study will be distributed to all units to give to their Young Marines to take home to their parents. This will be done so that the smaller units who will not undergo a formal recruitment session may find out about the study via another channel (besides viewing the link on the Young Marines website or receiving an email). The flier also serves the purpose of informing the parents that their child may receive study information at an upcoming meeting for the larger Young Marine units.

Subject recruitment will take place using two methods. The first is where the 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). This presentation will take approximately 15 minutes. The main objectives are to tell the children what the study is about and what participation would involve, address common concerns, to emphasize the importance of bringing the study information packet home and discussing it with their parents, and the importance of turning in the signed parent permission/consent form, as well as question and answer time (see Appendix H).

A parallel recruitment method will also be used on the Internet. There will be an electronic subject recruitment presentation available on the internet that can be viewed from a home computer in an individual setting. It will be about 15 minutes in length. 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. The electronic presentation is aimed at the parent and it will emphasize the information contained in the consent form (see Appendix I). The availability of the study recruitment presentation and information will be announced in an email from the Young Marines Headquarters to the parents of Young Marines and Leaders and via an announcement on the Young Marine website. The content of the announcement on Young Marines National Headquarters Website is:

New Research Study Opportunity for Young Marines

There is an important research study going on right now to assess the effectiveness of the Young Marines Program in reducing drug use and promoting a healthy, drug-free lifestyle among its youth members. This study is open to active Young Marines *and newly enrolled Young Marine recruits who have not yet started orientation*, in the 6th grade and up.

Young Marines will get a **FREE movie rental gift card** (a $4.50 value) if they return a signed parent permission form, *whether their parent allows the child to participate in the study or not.*

Please click on the link below to learn more about this study and how you can be involved.

youngmarinesstudy.org

Don't miss out on this chance to ultimately better the Marine Corps sponsored services for youth drug education!

The content of the email from Young Marines National Headquarters to parents is:

From: National Headquarters, Young Marines
To: Parents of Young Marines
Subject: New Research Study Opportunity for Young Marines

Dear parent of a Young Marine,

There is an important research study going on right now to assess the effectiveness of the Young Marines Program in reducing drug use and promoting a healthy, drug-free lifestyle among its youth members. This study is open to active Young Marines *and newly enrolled Young Marine recruits who have not yet started orientation,* in the 6th grade and up.

Young Marines will get a **FREE movie rental gift card** (a $4.50 value) if they return a signed parent permission form, *whether their parent allows the child to participate in the study or not.*

Please visit the website: **www.youngmarinesstudy.org** to learn more about this study and how you can be involved. You can also link to this website from the Young Marines National Headquarters website: **www.youngmarines.com** under Young Marine News.

Don't miss out on this chance to ultimately better the Marine Corps sponsored services for youth drug education!

The consent form will explain that a potential participant must be a current, active participant in the Young Marines, or a new Young Marine enrollee waiting to begin the orientation class. All participants will be asked to complete an initial survey, and a smaller group may be selected to do a follow-up survey. The parents or guardians of the potential research participants will be given the opportunity and will be encouraged to ask questions about the research before signing the consent document, by calling or emailing the PI directly. An extra copy of the informed consent document will be provided in the study materials packet to the parent. Parental consent will not be required for 18 year old participants; the 18 year old participant can sign the consent form. Age will be confirmed by asking the Young Marines National Headquarters to check age recorded in their database for all participants who indicate they are 18 and who sign the consent form.

The consent form and study materials for the child and parent to review will be obtained in one of three 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); (2) after seeing the study announcement on the Young Marines website then linking to the study website where they 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 (a limited supply will be available from some unit leaders); or (3) the parent may request the packet from the investigators via email to be mailed to their home address.

Also contained in the study information packet will be a prepaid envelope for the parent to return their signed consent form and a cover letter to the parent (see Appendix J).

If the parent or child returns a signed consent form, they will receive a thank you gift for the potential research participant, specifically a movie rental coupon valued at $4.50 (see attached cover letter to accompany coupon mailed to home). 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. The coupon will be mailed to the child provided that the parent gave their mailing address on the consent form as requested.

It will be requested that the signed consent forms be mailed back to the researchers at NHRC (a pre-paid envelope will be provided), or another option will be for the youth to turn their parent-signed consent forms in an envelope into a marked box that will be set up at their next unit meeting. Those forms can be mailed by the adult leader in one large envelope to NHRC.

At a pre-scheduled, subsequent unit meeting, the survey will then 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 survey will take approximately 45 minutes to complete. On the survey cover, it will explain that the youth's agreement to participate will be made known by their completing the survey. Survey participants will be reminded to keep their eyes on their own surveys during completion of the survey. The survey booklet has a cover page (there are no questions and answers on the cover or back page), so answers are private and will be covered when the booklet is closed and when participants place their surveys into the box.

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, not the unit leaders, although they will be present at the facility. Non-participants will likely be separated from the participants and will be kept busy with another low-key unit activity, so as to provide a quiet, distraction-free survey-taking environment. Those Young Marines who are given a survey but decide not to take it, and those who stop before completing it will sit quietly during the time that others are filling out their surveys (as indicated on the front page of the survey).

An internet survey option will also be made available to increase participation, particularly for many of the smaller units where in-person survey administration will not be feasible. Participants will have the option to complete the survey on the internet, in their own individual setting, by logging onto a website. After consent is received by NHRC, parents will be emailed the internet survey link and access information for their children to participate in that manner, if they choose that option. The internet survey will be programmed such that no one (participants, parents, anyone with the access code) can go back into the survey to view previously recorded responses. In addition, the on-line instructions will tell participants to complete the survey in *private* (i.e., without parents observing).

In all cases, parental (or 18 year old) written consent will always be received prior to survey administration, whether it is in-person surveying or the sending of the access code for on-line surveying.

For the 250 randomly selected youth out of the new enrollees group who consented to participate, an email prompt will be sent to those parents asking for their child to participate in the on-line, 3-month follow-up survey for the pre- and post-test study component of this research. The follow-up survey will take approximately 45 minutes to complete. Two reminder emails will be sent to

increase participation in the follow-up (see attached text for the reminder emails).

The surveys will contain a self-generated identification code for matching purposes for the pre- and post-test study. Similar codes have been used in a variety of settings where sensitive information was collected (Kearny, Hopkins, Mauss & Weisheit, 1984; Carifio & Biron, 1978; DiIorio, Soet, Van Marter, Woodring & Dudley, 2000; Grube, Morgan & Kearney, 1989) and have been shown to provide successful rates of matching with children as young as 4th graders. Carifio and Biron found their subjects indicated a 100% willingness to respond to sensitive questions when using a coding technique whereas only 55% would answer sensitive questions when their name was attached to their responses. They also noted that such codes were reported to be easy to use by children as young as 7th graders, and that the majority of survey participants had some affinity for the coding technique. In short, it has been demonstrated that such scales are an optimal way of conducting longitudinal research on sensitive subjects such as alcohol use, drug use, and other risky behaviors among children, young adults and other populations who are likely to fear repercussions from their responses.

The elements for our survey code are middle initial, birth month, whether or not birth year is an even numbered year, sex, and first letter of mother's first name. Each of these elements were used in the studies cited above and produced matching rates of 67% to 74%; and higher matching rates of 88% to 93% were achieved using the *off-one* matching technique (Kearny, Hopkins, Mauss and Weisheit, 1984), which we propose to use. For demographic information purposes, the survey already asks for the participant's sex; the other elements are solely for the purpose of the survey code.

Regarding the adult leader process survey, this survey will be conducted via the internet. An email will be sent to the unit commanders of all YM units (email addresses provided by the National Young Marines Headquarters), inviting them to log onto a website to read about the survey and to provide their consent to participate (see attached text for email). From there, there will be a link to the actual on-line survey. Only one adult leader (the commanding officer or another adult leader designated by the unit commander) is needed to complete the survey; only one completed survey per unit is needed. Respondents will be asked to identify unit characteristics, and information about the drug education activities that they provide, but they will not provide their name on the survey. It should take about 20 minutes to complete this survey. Two reminder emails will be sent to encourage them to complete the unit leader survey (see attached text for reminder emails).

Survey instruments – The youth survey to be used in the comparison group study and for the pre- and post-test study includes sections on background and demographic characteristics, behaviors and use patterns, drug attitudes, drug knowledge and other psychosocial characteristics (see Appendices K and L). In order to permit comparisons with national findings and trends, many of the survey items parallel those with the national study, Monitoring the Future, conducted annually by the University of Michigan Survey Research Center for the National Institute on Drug Abuse (NIDA). The following is a description of the measures.

Background and demographic variables. A number of background variables are measured in the survey, including gender, race, age, grade, parental education (as an indicator of socioeconomic level), urbanicity, and type of household (one or two parent). The variables are important as factors to control for in most multivariate analyses on youth drug use (Brown, Schulenberg, Bachman, O'Malley, & Johnston, 2001; Johnston, O'Malley, and Bachman, 2001a, 2001b). Additional background variables include participation in organized activities (ROTC, Scouts, sports), participation level in the Young Marine program, sibling and family involvement in the Young Marine program, and length of time in the program.

Drug knowledge. The drug knowledge section of the survey consists of 15 items on the dangers and consequences of drug use, drug classifications, and common forms. This section

includes 3 tobacco-related items, 4 alcohol-related items, 3 marijuana-related items, and 5 items on other drugs. The items were developed directly from the drug educational information (Chapter 5) that is contained in the Young Marines Basic Guidebook, and from an existing drug knowledge questionnaire from the American Council for Drug Education (2007).

Drug behaviors and use patterns. The questionnaires cover usage measures for many licit and illicit substances, and other factors relevant to each. The variables include (1) descriptors of the patterns of drug-using behavior, including frequency, quantity, recency, and age at first use; and (2) self-reported reasons for use and intent to quit. The drug categories and specific drugs covered in the survey are: cigarettes, smokeless tobacco, alcohol (specifically flavored alcoholic beverages), marijuana or hashish, LSD, hallucinogens other than LSD, ecstasy, amphetamines, methamphetamines, crystal meth, quaaludes, sedatives, tranquilizers, heroin, narcotics other than heroin, inhalants, anabolic steroids, any drug by injection, non-prescription diet pills, and non-prescription stay awake pills.

A standard set of two questions is used to determine *usage levels* for the various drugs (except for cigarettes and smokeless tobacco). For example, we ask, "On how many occasions (if any) have you used ecstasy . . . (a) in your lifetime? (b) during the last 30 days?" Both questions are answered on the same answer scale: 0 occasions, 1–2, 3–5, 6–9, 10–19, 20–39, and 40 or more occasions.

For the psychotherapeutic drugs (amphetamines, quaaludes, sedatives, tranquilizers, and narcotics other than heroin), respondents are instructed to include only use "on your own—that is, without a doctor telling you to take them." A similar qualification is used in the question on use of anabolic steroids.

For cigarettes, respondents are asked two questions about use: "Have you ever smoked cigarettes?" (the answer categories are "never," "once or twice," and so on) and "During the past 30 days, about how many cigarettes have you smoked per day?" (the answer categories are "not at all," "less than one cigarette per day," "one to five cigarettes per day," "about one-half pack per day," etc.). Parallel questions are asked about smokeless tobacco.

Alcohol use is measured using the two questions just illustrated above for ecstasy. A parallel set of two questions asks about the frequency of "being drunk." In order to assess binge drinking, two additional questions are included..."On a typical day when you drank during the last 30 days, how many drinks do you have?" and for the prior two-week period, "How many times have you had five or more drinks in a row?" One additional question asks about the use of flavored beverages during the last 12 months.

Drug attitudes. Aspects of the immediate social environment likely to contribute to respondent's use (and attitudes about use) of various drugs, including extent of exposure to use, friends' use, availability, perceived attitudes of friends and exposure to drug education are also included. Additional items include various attitudes and beliefs regarding drugs, including the perceived harmfulness of various drugs and personal disapproval of their use.

Perceived risk is measured by a question asking, "How much do you think people risk harming themselves (physically or in other ways), if they . . ." ". . . try marijuana once or twice," for example. The answer categories are "no risk," "slight risk," "moderate risk," "great risk," and "can't say, drug unfamiliar."

Disapproval is measured by the question "Do you disapprove of people doing each of the following?" followed by "trying marijuana once or twice," for example. Answer categories are "don't disapprove," "disapprove," "strongly disapprove," and "can't say, drug unfamiliar."

Perceived availability is measured by the question "How difficult do you think it would be for you to get each of the following types of drugs, if you wanted some?" Answer categories are "probably impossible," "very difficult," "fairly difficult," "fairly easy," "very easy" and "can't say, drug unfamiliar."

Other relevant psychosocial characteristics. Other variables include views of global satisfaction, self-esteem, susceptibility for drug use/behavioral intentions, self-efficacy/personal responsibility, and life goals.

Self-esteem is measured using 12 questions that were modified from the Rosenberg Self-Esteem Scale (Rosenberg, 1965). The question asks, "How much do you agree or disagree with the following statements," (such as "I take a positive attitude toward myself" and "Life often seems meaningless"). Answer categories are "Disagree," "Mostly Disagree," "Neither," "Mostly Agree," and "Agree."

Susceptibility for drug use/behavioral intentions is measured using four items that ask "Do you think you will do the following things in the next two months" (smoke a cigarette, use alcohol, use marijuana, use other drugs). Answer categories are "Yes," "Probably," "I don't know," "I don't think so," and "No, definitely not."

Self-efficacy and personal responsibility are measured using a ten item scale that asks "How much do you agree or disagree with the following statements?" Items include, "I'm confident I can avoid drinking alcohol," "I'm confident I can set goals and achieve them," and "I have a responsibility to make the world a better place." Answer categories are "Strongly Agree," "Agree," "Disagree," and "Strongly Disagree."

Life goals is measured by the question "How likely is it that you will do each of the following things after school?" Answer categories are "Definitely Won't, Probably Won't, Probably Will, Definitely Will."

Participant satisfaction. Twelve additional items ask about the participant's level of satisfaction with the Young Marine program. For example, the survey asks if they would recommend the program to their friends, if the knowledge and skills learned are useful, and if they like participating in the program. This section also asks which program components the participants like the most.

Piloting the youth questionnaire - the youth questionnaire will be pilot-tested for understandability and readability by asking a local Young Marine unit to assist with this task. A small group of 20 Young Marines in the 6th grade and up will be given the 15 minute in-person study presentation at a regularly scheduled unit meeting. As with the subject recruitment process, they will be provided information about the study and a hard copy of study materials including the parental consent form for the youth to take home to discuss with their parent. The Young Marines that return to a subsequent unit meeting with a signed parental permission form and also give their assent to participate will be given the questionnaire. The amount of time it takes for each of them to complete the survey will be recorded. In addition, the researchers will ask them to comment on any questions or items that they do not understand. Any questions that are brought up will be reexamined by NHRC researchers and feedback will be considered for revisions to the questionnaire.

Adult leader process survey – The adult leader survey asks about the availability, frequency, duration, and percent attendance of various drug demand reduction activities. The survey also asks for some unit characteristics, and reasons for not being able to provide any drug education activities. (See Appendix M.)

2. Sample Size Determination With Statistical Power Calculation (and related data analysis plans)

Based on the primary hypotheses, the main outcomes of interest are drug use, drug related attitudes, drug knowledge scores, and positive character traits. Power calculations were based on expected effect sizes for differences in drug use behavior (specific drug behaviors such as alcohol, cigarettes, marijuana, or any illicit drug use, past month or lifetime), which are typically more difficult to achieve than other outcomes such as changes in knowledge. Two sets of calculations were conducted: one for the comparison group study (hypothesis 1) and one for the pre-post study (hypothesis 2). Computational methods are described in Machin & Campbell (1987), Fleiss, Tytun, & Ury (1980), Cohen (1988), and Hsieh (1989).

Hypothesis 1. For the comparison group study, (hypothesis 1), current Young Marine participants will be compared to two groups: (a) newly enrolled Young Marines who have not yet participated in the program, and (b) age- and sex-matched respondents from a national database. Five hundred Young Marines participants, 500 young people waiting to enter the Young Marines, and 500 subjects from a national database are proposed, for a total number of youth subjects of 1,500. (However, see over sampling needs below.)

A primary outcome variable is past-month drug and alcohol use. The two comparison groups are expected to be statistically equivalent to one another, while the Young Marine participants are expected to be lower than those two groups. Estimates for program and comparison group differences in rates of use, mean frequency of use, attitudes, and knowledge come from several drug prevention/youth development studies (LoSciuto et al., 1999; Aseltine et al., 2000; Ellickson et al., 1993; and Grossman & Tierney, 1998).

The adequacy of our proposed sample size is based on the following formula:

$$n \geq \frac{2(Z_\alpha + Z_\beta)^2 S^2}{d^2}$$

$n =$ minimum sample size--438
$Z_\alpha =$ Using $p = 0.05$ for a two tailed test, $Z_\alpha = 1.96$
$Z_\beta =$ Using a power level of .80, $Z_\beta = 0.84$.
$S^2 =$ Variance estimate is .1369, based on LoSciuto and colleagues study of lifetime alcohol and drug use from the Woodrock Youth Development Project evaluation.
$d =$ Difference is estimated to be .074 based on LoSciuto and colleagues reported means of 1.21 and 1.28 in an experimental and control group participating in the Woodrock Youth Development Project evaluation.

Based on estimates from the Aseltine (2000) study of mentoring effects on youth, we will have 80% power to detect program-comparison differences in self control, alcohol use, marijuana use, problem behavior, and attitudes toward drugs. A power calculation, using the same formula, is shown below. The calculation is presented for marijuana use because it had the weakest effect in the Aseltine study.

$$470 = \frac{2(1.96 + .84)^2 .60^2}{.11^2}$$

To assess power to detect group differences in drug-related knowledge and attitudes, estimates were taken from Project ALERT (Ellickson et al., 1993), a school-based program for 7th and 8th graders aimed to curb cigarette and marijuana use. Because measures are dichotomous rather than continuous, sample size/power formulas are somewhat more complex, and were performed using nQuery Advisor®, a respected and

popular sample size and power software package. The formula used by nQuery Advisor to determine power to detect group differences in independent proportions is shown below.

$$n = \left[\frac{Z_{\alpha}\sqrt{2\pi_1(1-\pi_1)} + Z_{\beta}\sqrt{\pi_1(1-\pi_1) + \pi_2(1-\pi_2)}}{\pi_1 - \pi_2} \right]^2$$

Based on Project ALERT, we assume anti tobacco-related beliefs to be .55 in the intervention group compared to .45 in the control group. A two-sided chi-square analysis with alpha set to .05 would have excellent power (close to 90%) to detect these expected group differences with our proposed sample size. One final power calculation was based on a dichotomous measure (initiated drug use over an 18 month period—yes versus no) from an evaluation study of the Big Brothers Big Sisters program (Grossman & Tierney, 1998). Based on estimates from the study, we assume initiation rates of 11.5% for the control group and 6.2% for the intervention group. Again using nQuery Advisor, we find that a chi-square test with a .05 two-sided significance level will have 80% power to detect these differences with our proposed sample size.

The primary analysis for Hypothesis 1 will use intent to treat, although additional analyses will examine differences among participants who got a "meaningful" dose of the program. Initial analysis will include analysis of variance with post-hoc tests to test for group differences, although multivariate analyses (i.e., logistic regression for dichotomous outcomes or linear regression for continuous level outcomes) will be the final approach so that important covariates (e.g., site, age) and potential confounders can be adjusted for. Sample size calculations (conducted in nQuery Advisor) for multivariate models (both logistic and linear) with 5 covariates in the model (including group as the primary one of interest) will have 80-99% power to detect even small group effects (R-square of 5%; odds ratio of 1.3) with our proposed sample size. Subgroup analysis (e.g., males only, those with a higher baseline level of use) and possible interaction effects will also be examined in an exploratory manner, although statistical power may be lacking for some of these exploratory analyses because of reduced sample size.

Hypothesis 2. For the pre- and post-test study (hypothesis 2), a cohort of 250 subjects is proposed. These 250 subjects will be randomly selected from the 500 newly enrolled Young Marines mentioned above as a comparison group in the comparison group study. Thus, the 250 subjects required for this pre- and post-test study are included in the required number of subjects for the comparison group study, and are not additional. Using longitudinal effect sizes for past-month and lifetime use of drugs reported in the Woodrock study (LoSciuto et al., 1999), nQuery Advisor indicates that this sample will provide adequate power (80% or greater), assuming two sided tests and an alpha level of .05. 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 or confounders. The SAS procedure PROC MIXED is a useful regression approach for this type of longitudinal data since there can be a variable number of observations per subject and the interval between observations can vary somewhat. Fixed effects variables, such as sex and site, can be easily controlled for in the model. When the sample size is 250, a regression test with 5 variables in the model will have 80% power to detect an r-square as low as 5% or an odds ratio as modest as 1.3.

The total number of youth subjects needed for the 2 studies is 1,500. However, 500 of the youth subjects will be randomly selected from the national database, and they will not have to be actively recruited through the study recruitment procedures. Considering only the other 1,000 youth subjects that are needed, 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).

(Note that for the longitudinal part of the study, it is anticipated that for the 250 subjects needed for the pre- and post-test group (which will be drawn from the 500 original new enrollees), approximately 50% of that group will attrite by the 3-month follow-up survey. Hence, 375 subjects will be targeted for this part of the study (250 subjects plus 125 additional to account for attrition); however, all of these 375 subjects needed for this part of the study will be drawn from the original 500 new enrollees for the first part of the study, so they do not represent additional overall subjects. In addition, an attrition analysis will be conducted for the pre-post study to examine the characteristics of drop-outs and those who remained in the study.)

Considering the total needed number of youth subjects, 500 are needed from the national database, and 1,400 are needed for both the comparison and pre- and post-test studies to account for non-participation rates, which totals 1,900 youth subjects needed for the research.

In addition, 325 adult subjects are needed to complete a one-time survey about the drug education activities that their Young Marine unit provides. This descriptive survey is intended for one adult leader to complete per unit to capture the activities of the entire organization. All available units will be surveyed and there are 325 units, hence 325 adult subjects are required.

The youth subjects needed (1,900) plus the adult subjects needed (325) is a total of 2,225 subjects. Approximately 55% of the youth and adult members of the Young Marines are male, hence the number of male subjects is 1,224; the number of female subjects is 1,001.

3. Justification for Exclusion of Specific Groups

No specific groups will be excluded.

4. Required Equipment and Supplies

No special equipment and supplies are needed for this study.

VII. ORGANIZATION OF RESEARCH EFFORT

1. Duties and Responsibilities

The Principal Investigator, Suzanne Hurtado, will oversee the study and coordinate the subject recruitment, data collection, analyses and all activities.

The co-investigators, Cynthia Simon-Arndt, Robyn Highfill-McRoy, and Susan Woodruff, will conduct subject recruitment sessions, collect the survey data, build the database, analyze the data, and write reports.

2. Chain of Command

All of the co-investigators (Cynthia Simon-Arndt, Robyn Highfill-McRoy, Susan Woodruff, and Jerry Larson) will report directly to the Principal Investigator, Suzanne Hurtado.

VIII. RISKS AND DISCOMFORTS TO RESEARCH VOLUNTEERS

1. Risk to the Volunteer and Means of Mitigation

Inappropriate disclosure of survey data - Subjects could potentially suffer negative social risks and discomforts and legal risks if their survey responses regarding drug use and related attitudes and knowledge were inappropriately disclosed. However, rather than asking the participant's name or other personal identifier, youth participants will create their own unique code based on several prompts. Such procedures for creating a unique code for research among adolescents have been successfully utilized in other studies (Kearny, Hopkins, Mauss & Weisheit, 1984; Carifio & Biron, 1978; DiIorio, Soet, Van Marter, Woodring & Dudley, 2000; Grube, Morgan & Kearney, 1989). Subjects will write this code on their surveys which will allow the researchers to match the pre- and post-test surveys for data analysis, while protecting the identity of the subject's data. Also, it will be emphasized to the subjects that their surveys will not be looked at by their Unit leaders, parents, or anyone else, besides the approved NHRC investigators. Furthermore, other procedures for the safe handling and storage of the study data, both hard copy and electronic, will be strictly followed, as described in Section IX. Description of the System for Maintenance of Record, Experimental Data.

Subjects might also encounter feelings of discomfort just based on the sensitive subject matter of drug use. Completing the survey on drug use may cause some subjects to feel anxious or uncomfortable. To minimize this possible discomfort, subjects will be told that they may skip any survey questions that they do not wish to answer and that they may stop at any time before completing the survey. In addition, if any subject has feelings of discomfort related to participating in this study and feels that they should seek clinical/psychological attention, they or their parent may contact the study medical monitor, a clinical psychologist; this is indicated on the consent form.

Large studies on drug use have been conducted with children (i.e., Monitoring the Future, Youth Risk Behavior Surveillance System), and specifically longitudinal studies on the effectiveness of drug education programs for adolescents (Rosenbaum and Hanson, 1998; Botvin, Baker, Dusenbury, Tortu, and Botvin, 1990; Botvin, Baker, Dusenbury, Botvin, and Diaz, 1995; Ellickson, Bell, and Harrison, 1993; Perry, Williams et al, 1996; Tierney, Grossman and Resch, 1995; LoSciuto, Freeman, Harrington, Altman, and Lanphear, 1997), as this is an important area for study with implications for effective drug abuse prevention programs for young people. The researchers anticipate an immediate impact from the intervention as seen in an increase in knowledge and decrease in drug use behavior and related attitudes among study participants, similar to other youth drug program evaluations which found effects immediately and at 3 months after their interventions (Ellickson, Bell, and Harrison, 1993; Botvin, Baker, Dusenbury, Tortu, and Botvin, 1990). The scientific knowledge gained from the proposed longitudinal investigation is anticipated to be valuable and is a worthwhile endeavor to better youth drug education programs, even considering the unlikely, aforementioned risks.

There are no risks associated with the adult unit leaders completing a survey about the drug education activities that their unit offers to the Young Marines. Name or other personal identifier will not be collected on this adult survey; however, their Young Marine Unit number is requested. The unit number could be used to identify a group of individuals who could have filled out the survey. The survey, however, does not ask about personal health information, only the activities that their unit conducts. The procedures for the safe handling and storage of this study data, will be strictly followed.

2. Special Risks to Pregnant Women

Participation in the study does not pose any reproductive risks to women, a developing fetus, and a male who might father a baby. There are no contraceptive requirements and procedures for confirming that the subject is not pregnant. A pregnant woman may participate in this survey research.

3. Safety Precautions and Emergency Procedures

The surveys will be conducted at the sites where the Young Marine units (youth and their adult leaders) usually meet, or via their own personal internet access site. Existing safety precautions and emergency procedures that are in place at those sites shall continue. This study is not providing any additional safety precautions.

4. Assessment of Sufficiency of Plans to Deal with Untoward Events or Injuries

The use of standard civilian medical procedures has been deemed sufficient to deal with any untoward events and/or injuries. These procedures include calling 911 for emergency medical treatment if needed and asking the Young Marine adult leader present to engage in the organization's emergency procedures, if not already in progress, which includes contacting the youth's emergency contact name and taking the youth to the nearest medical treatment facility for emergency treatment, as indicated on the required, signed authorization for medical treatment (Young Marine Form 12). This signed form is required by the Young Marine organization before the youth can attend any Young Marine activity. All of the in-person surveying procedures for this study will occur during the youths' regularly scheduled Young Marine activity/meetings, or on the youth's own time using, for example, their own personal computer to complete the internet-based survey. While the Principal Investigator is not aware of other NHRC surveys conducted with youth, the Principal Investigator is aware of numerous other NHRC health behavior survey studies and these have never met with untoward events to the Principal Investigator's knowledge.

5. Qualification of Medical Monitor and Medical Support Personnel

Dr. Heidi Kraft, a clinical psychologist and NHRC member, will serve as the medical monitor for this protocol. Dr. Kraft holds a PhD in clinical psychology/behavioral medicine from the UCSD School of Medicine and she conducted her internship in clinical/medical psychology at Duke University Medical Center. Dr. Kraft has over 12 years of experience as a clinical psychologist including 10 on active duty in the Navy. She has served on the Family Service Center family violence review board and the hospital bioethics committee at Naval Air Station Jacksonville. Dr. Kraft is licensed as a clinical psychologist in California (CA, Psychology #21370) and currently sees patients two days a week. As an active clinician and advocate for family health and well-being, Dr. Kraft's duties while serving as medical monitor for this study include being available and responsive to phone calls and inquiries regarding anxiety or other discomforts of participants due to their participation in the study, which entails responding to surveys on drug use and attitudes. Dr. Kraft will assist participants/their parent or guardian with locating appropriate counseling services in their area, if further services are needed.

IX. DESCRIPTION OF THE SYSTEM FOR MAINTENANCE OF RECORD

1. Experimental Data

The experimental data collected for this study will include both paper questionnaires and electronic data forms collected via the internet from the Young Marines participants (they will have the option to complete the surveys in one form or the other). The comparison data from the national youth drug use database will also be electronic. The data collected from the adult leaders will be electronic data forms via the internet.

The experimental data for the study (both paper questionnaires and electronic data) will not use Protected Health Information (PHI). This data will be anonymous and will not be combined with any other data that can be linked to one's identity such as name, complete birth date, or social security number. While the surveys will contain a self-generated identification code in order to match surveys longitudinally, this code will not use PHI and will not be combined with any other data that can be linked to one's identity. The experimental data collected from the adult leaders will also be anonymous and it will not use PHI.

Subject privacy and data confidentiality will be maintained by not collecting name or other individual identifiers on the survey forms. Rather, a self-generated identification code will be used. Specifically, the subjects' data will be labeled only with this identification code. Subjects will not be identifiable directly through their data. In addition, the paper questionnaire data will be stored in locked file cabinets in Bldg 328, NHRC. The electronic data sets will be stored in password-protected files on secure computer servers at NHRC. The data will remain protected for five years using the locked file cabinets with limited access and secure servers at NHRC. Only approved investigators will have access to the data.

Data will be used for immediate analyses conducted by the researchers at NHRC. No data will be shared or released outside of NHRC.

2. Research Protocol, Consent Forms, and Related Documents for Protection of Human Research Volunteers

The principal investigator will keep the research protocols and consent forms in a locked file in NHRC Building 328, Room 205A.

3. Individual Medical Records

No official medical records will be accessed.

4. Conflict of Interest

No person involved in the design, conduct, or reporting of this research has a financial or other interest that could reasonably appear to be affected by the carrying out or the results of this research.

X. APPENDICES

PERMISSION/VOLUNTARY CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Evaluation of Young Marines Drug Education Program

You are being asked to allow your child to participate in a research study. Before you give your permission for your child to participate, it is important that you read the following information and ask as many questions as necessary to be sure you understand what your child will be asked to do.

**** Why is this study being done?***

This research is being conducted to better understand educational programs that might be effective in reducing alcohol and drug use among youth. This research is being conducted by researchers from the Naval Health Research Center (NHRC) in San Diego, California, and it is being conducted at the request of Marine Corps Community Services. About 1,000 young people will be recruited from several Young Marine units throughout the US to take part in this study. To participate in this study, your child must be an active participant in the Young Marines, or a new Young Marine enrollee waiting to begin the orientation class.

**** What will my child's participation involve?***

This project will assess the effectiveness of the Young Marines program in bringing about changes in attitudes and behavior related to drug use. If you agree to allow your child to participate:

* Your child will be asked to complete a survey either in-person at a Young Marines meeting, or on a secure Internet website.
* Your child may be asked to complete a second survey about 3 months after the first survey. This survey needs to be completed on a secure Internet website.

The maximum amount of time your child will be involved with the study is a total of 1½ hours (45 minutes for the first survey and if asked to participate in the second survey, another 45 minutes) over a 3 to 4 month period. Participation in the in-person surveys will take place during regularly scheduled Young Marine unit meetings. If your child chooses to complete the surveys on a secure Internet website, this will occur during the child's own time using a computer resource that your child has access to.

**** What are the risks involved in this study?***

You or your child may feel some anxiety as to the privacy and confidentiality of completing drug and alcohol surveys, either on paper or on the Internet. The survey will ask about your child's use of tobacco, alcohol, marijuana and other illicit drugs, drug-related knowledge, perceived pressures to use drugs, disapproval of drug use and other similar questions. For example, we ask questions like, "On how many occasions (if any) have you used ecstasy during the last 30 days?" and "During the past 30 days, about how many cigarettes have you smoked per day?" Another example question on drug behavior is "On how many occasions (if any) have you been drunk or very high from drinking alcoholic beverages?" Your child's confidentiality will be protected by the use of a unique code, rather than personal name. Your child will create his/her own unique code for their survey based on prompts such as what is your child's middle initial, child's birth month, whether or not his/her birth year is an even numbered year, child's sex, and first letter of his/her mother's first name. Surveys completed using the Internet option are done using Secure Sockets Layer (SSL) data transmission lines. SSL encrypts, or scrambles, all the survey data sent over the Internet. The data will only be understandable when it reaches the investigator's database. If your child begins to feel uncomfortable at any point in the study, he/she may refuse to answer any question that disturbs him/her, or he/she may discontinue participation in the study, either temporarily or permanently. The survey data (both paper and internet surveys) will not be given to parents, Young Marine unit leaders or anyone else besides the NHRC investigators. The results of this study may be published in technical reports or articles, but only group

information will be presented and no individual's identity can be revealed.

**** What happens if my child gets upset or has psychological discomfort due to this study?***

If your child is upset or has psychological discomfort due to the sensitive subject matter of this survey on drug use, you may contact the study psychologist, Dr. Heidi Kraft at (619) 553-9142 or heidi.kraft@med.navy.mil. Dr. Kraft is a clinical psychologist and can provide guidance and information regarding any discomforts caused by this study. She may also assist you with locating appropriate counseling services in your area, if further services are needed. No formal compensation is available to you or your child. By signing this consent form, you will not be giving up any legal rights.

**** What are the benefits of the study?***

Your child is not expected to receive direct benefit from taking part in this study. However, this study could benefit children and society in general by contributing to a better understanding of how effective youth development programs are in decreasing drug use and related factors.

**** What information will be collected from my child and will it be kept confidential?***

Your child will be asked to fill out a survey of their drug use, knowledge, and attitudes. Your child's answers to these questions will be used to study the effectiveness of the Young Marines drug education efforts. This information will be used only by NHRC study personnel and will be maintained until all analyses are completed. All information obtained about your child on the survey will be considered privileged and held in confidence. His/her confidentiality on surveys will be protected by the use of unique participant codes rather than personal names (described previously). Suzanne Hurtado is responsible for storing your child's information during the study. This information will be protected keeping all paper copies of your child's 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 NHRC. Access to all data will be limited to staff involved in this study. The information your child discloses 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 about the research study described above will reveal your child's identity. Lastly, individuals from official government agencies, such as the Department of Defense and the U.S. Navy, may inspect your child's research records to ensure that the rights and safety of all research participants are protected.

**** Does my child have to participate?***

No, your child does not have to participate. Participation in this study is completely voluntary. Your decision about whether to allow your child to participate will not prejudice his/her future relations with the Young Marines program or the U.S. Marine Corps. If you decide to allow your child to participate, you are free to withdraw your consent and discontinue his/her participation at any time without penalty or loss of benefits to which you are otherwise entitled.

**** If you have questions about this study***

If you have questions about the research, you may contact Suzanne Hurtado, at (619) 553-7806 or Suzanne.Hurtado@med.navy.mil.

If you have questions about your child's health and safety in this study, you may contact Dr. Heidi Kraft, a clinical psychologist, at (619) 553-9142 or heidi.kraft@med.navy.mil.

If you have questions regarding your child's rights as a human subject and participant in this study, you

may contact Christopher Blood at (619) 553-8386 or NHRC-IRB@med.navy.mil. He is the Chairman of the Naval Health Research Center Institutional Review Board, a group of people who review the research to protect your rights and the rights of your child.

**** Thank you gift***

If you or your child returns a signed parent permission form *whether or not you participate or allow your child to participate in the study*, you or your child will be mailed a free movie rental gift card (a $4.50 value) from us.

**** Consent for your child to take part in this research study***

Your signature below indicates that you have read the information in this form and have had a chance to ask any questions you have about the study and its procedures and risks. All of your questions have been answered to your satisfaction. If you check the "I give permission" box below, your signature also indicates that you agree to allow your child to be in this research study and have been told that you can change your mind and withdraw your consent to allow your child to participate at any time. You authorize the use and disclosure of your child's survey information to the persons listed in the health information and privacy section of this consent for the purposes described above. You have been given a copy of this agreement and a statement informing you about the provisions of the Privacy Act.

If you, the Young Marine, is 18 years of age or older and want to complete this form, parental consent is not needed and 18 year old may complete it. ***Otherwise, parent is asked to complete the information on the next page.***

_____ _____

Printed name of 18 years of age or older Young Marine (First Last) **Date of Birth of 18 yr old**

_____ _____

Signature of 18 years of age or older Young Marine **Date**

_____

Email address of 18 years of age or older Young Marine (to alert you when the Internet survey is available)

_____

Mailing address of 18 years of age or older Young Marine (to mail your free thank you gift if you return this signed form *whether or not you participate*)

What is your Young Marine Unit name:_____

Please check one:

☐ **I wish to participate in this research study.**

☐ **I do not wish to participate in this research study.**

(This section is to be completed by the Young Marine 18 years of age or older.)

PARENT PERMISSION/VOLUNTARY CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Evaluation of Young Marines Drug Education Program

For the parent:

Please check one:

☐ **I am the parent or legal guardian of the below-named child and I give permission for my child to participate in this research study.**

☐ **I am the parent or legal guardian of the below-named child and I DO NOT give permission for my child to participate in this research study.**

_____

Printed name of child (First Last)

_____ _____ _____

Printed name of parent/guardian **Signature of parent/guardian** **Date**

_____

Email address of parent/guardian (to alert you when the Internet survey is available)

_____

Mailing address of parent/guardian (to mail your free thank you gift if you return this signed form *whether or not you give permission for your child to participate*)

What is your child's Young Marine Unit name: _____

(This section is to be completed by the parent.)

_____ _____ _____

Printed name of person conducting consent discussion **Signature of person conducting consent discussion** **Date**

(Leave this line blank – for research staff to complete)

Evaluation of Young Marines Drug Education Program

PRIVACY ACT STATEMENT

Authority. 5 U.S.C. 301

Purpose. Medical research information will be collected in an experimental research project #NHRC.2007.0029, titled "Evaluation of Young Marines Drug Education Program," to enhance basic medical knowledge, or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or performance impairment.

Routine Uses. Medical research information will be used for analysis and reports by the Departments of the Navy and Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Navy Surgeon General following the provisions of the Freedom of Information Act or as may be indicated in the accompanying Informed Consent Form.

Disclosure. Provision of information is voluntary. There are no penalties for not providing the requested information but failure to provide the requested information may result in failure to be accepted as a research volunteer in an experiment, or in removal from the program.

Attached: Parent permission/Consent form for this experiment, signed by the parent or guardian.

Announcement on Young Marines National Headquarters Website about the study:

New Research Study Opportunity for Young Marines

There is an important research study going on right now to assess the effectiveness of the Young Marines Program in reducing drug use and promoting a healthy, drug-free lifestyle among its youth members. This study is open to active Young Marines *and newly enrolled Young Marine recruits who have not yet started orientation*, in the 6th grade and up.

Young Marines will get a **FREE movie rental gift card** (a $4.50 value) if they return a signed parent permission form, *whether their parent allows the child to participate in the study or not.*

Please click on the link below to learn more about this study and how you can be involved.

youngmarinesstudy.org

Don't miss out on this chance to ultimately better the Marine Corps sponsored services for youth drug education!

Email from National Headquarters to parents announcing the study:

From: National Headquarters, Young Marines
To: Parents of Young Marines
Subject: New Research Study Opportunity for Young Marines

Dear parent of a Young Marine,

There is an important research study going on right now to assess the effectiveness of the Young Marines Program in reducing drug use and promoting a healthy, drug-free lifestyle among its youth members. This study is open to active Young Marines *and newly enrolled Young Marine recruits who have not yet started orientation,* in the 6th grade and up.

Young Marines will get a **FREE movie rental gift card** (a $4.50 value) if they return a signed parent permission form, *whether their parent allows the child to participate in the study or not.*

Please visit the website: **www.youngmarinesstudy.org** to learn more about this study and how you can be involved. You can also link to this website from the Young Marines National Headquarters website: **www.youngmarines.com** under Young Marine News.

Don't miss out on this chance to ultimately better the Marine Corps sponsored services for youth drug education!

B. INVESTIGATOR ASSURANCE AGREEMENTS(s)

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled Evaluation of Young Marines Drug Education Program, have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), DoD Instruction 6025.18-R (Privacy Rule), SECNAV Instruction 3900.39C (Protection of Human Subjects), BUMED Instruction 3900.6B (Protection of Human Subjects), and NAVHLTHRSCHCEN Instruction 3900.2C (Committee for the Protection of Human Subjects), Title 21 Code of Federal Regulations Part 50 if applicable (clinical investigations regulated by the FDA) and all relevant local instructions. I have disclosed all potential and actual conflict of interest(s) related to the design, conduct, analysis, or reporting of this research. I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates: (DD/MM/YY)

Jerry Larson — 27/08/07
[Head, Behavioral Sciences and Epidemiology Program

Suzanne L. Hurtado, MPH — 27/08/07
Principal Investigator

Cynthia M. Simon-Arndt — 8/16/07
Co-Investigator

Robyn M. Highfill — 8/27/07
Co-Investigator

Susan Woodruff — 8/11/07
Co-Investigator

Jerry Larson — 27/08/07
Co-Investigator

C. REVIEW FOR PROTECTION OF HUMAN RESEARCH VOLUNTEERS

1. Recommendation(s) of the Institutional Review Board (IRB)
2. Minutes of the Meeting of the IRB
3. Recommendation of the Convening Authority
4. Action of the Approving Authority
5. Other Documentation (as required)
    a. Unlabeled use of approved drugs or licensed biologics

        Provide documentation from the Food and Drug Administration (FDA) authorizing exemption from the requirement for Investigational New Drug Application (IND)

    b. Experimental drugs, biologics or devices
        i. Documentation of approved IND or Investigational Device Exemption (IDE) from the FDA
        ii. Approval of the Naval Investigational Drug Review Board (NIDRB)
    c. Documentation of review and action taken by all collaborating institution(s)
        i. Acceptable results of review are: approval, exemption from review, joint review, or other formal review agreement
        ii. Certification by the principal investigator that protocol submitted for review is the same final copy approved or under simultaneous review by collaborating institution(s)
    d. Host Government Approval if Research Is Performed in a Foreign Country
    e. Legal Issues
        i. Sufficiency of third party permission
            1. Citation of statutory authority
            2. IRB determination regarding requirement for assent
        ii. Citation of statutory authority for compensation of volunteers
        iii. Other
    f. OPNAV Form 5214/10 (if required for questionnaire survey include CNO approval document)
    g. Request for waiver of requirement(s) for protection of human research volunteers
    h. Documentation of exemption from compliance with regulations for the protection of human research volunteers (State authority and criteria for exemption)
    i. Other – OMB approval pending

D. POSTAPPROVAL DOCUMENTATION

1. Change of investigator(s), medical monitor, or collaborating institution(s) (addition or deletion)
2. Significant modification(s) to the protocol
3. IRB continuing review (annually)
    a. Reviewed by BUMED activity
    b. Review by collaborating institution(s)
    c. Modification of IRB recommendations
4. Documentation of all official action since initial submission and review

E. SPECIAL REPORTS

1. Unanticipated complications or problems
2. Reports of noncompliance with requirements for protection of human research volunteers
3. Adverse IRB action
    a. Recommendation for suspension
    b. Recommendation for termination
4. Resulting action by convening and approving authorities

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G. NONTECHNICAL SYNOPSIS

While tobacco, alcohol and illicit drug use have declined in recent years among teens, rates are still high and the need for effective substance abuse prevention programs is critical to guiding the development of adolescents into healthy, productive adults. This study will assess the effectiveness of a Marine Corps sponsored youth development program—the Young Marines—in reducing drug use and promoting a healthy, drug-free lifestyle among its youth participants. The study will assess 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 complete a survey about their drug use, attitudes, and knowledge, and some of these youth subjects will also complete a similar follow-up survey about three months later. The Young Marine adult unit leaders will be asked to complete a one-time survey about the drug education activities that their unit provides to their Program members. From this study, the researchers will be able to describe how the Program is affecting drug behaviors and related measures and make recommendations about the Program to ultimately better the Marine Corps sponsored services for youth drug education.