

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)