

Navy methods. No adverse events occurred, and one report and one presentation were generated from this research. CO approved.

3. New Business

- a) **HRPP #:** NHRC.2007.0029
Title: Evaluation of Young Marines Drug Education Program
PI: Suzanne L. Hurtado, MPH
WU#: 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. This study will use both between-subjects and within-subjects designs to evaluate the Program. 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 the proposal originally indicated aged 8 to 18 years. 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 within-subjects comparison to assess the effectiveness of the program. A between-subjects comparison will be performed using a sample of 500 randomly-selected non-identifiable youth subjects from the “Monitoring the Future” national database, an annual national in-school survey of drug use of adolescents. Further, to examine and describe the process by which the Young Marines Program implement drug abuse prevention education, a representative from each Young Marine Unit will be asked to complete a one-time survey, thereby also involving 325 adult volunteer subjects.

Ms. Hurtado, Ms. Simon-Arndt and Dr. Woodruff were introduced. The Chair distributed 45 CFR §46.401 Subpart D (Additional Protections for Children Involved as Subjects in Research) to researchers and board members for reference. The PI presented a summary of the proposed study. The following items were discussed:

- The Young Marines Program is a program similar to youth scouting programs. Membership is typically associated with a family member in the military service, however, enrollment is open to all youth. There are approximately 10,000 youth enrolled at ~300 units in the United States. Units are not affiliated with a specific military base, however, meeting may be held on a military installation.
- The PI has Young Marines National Headquarters-level support and will provide written documentation of support. There are approximately eight “large” units (100+ participants) in the United States. The PI will recruit and administer the survey in-person at these large units. Participants at other units will be enrolled via the Internet. Use of two-tailed sample size calculations were performed to allow investigators to plan conservatively.
- The Chair questioned the inclusion of subjects 8-11 years old, due to their limited attention span, comprehension, and comparability to the national sample which involves older children. The PI stated that some very young subjects had been administered such surveys in the past but in order to be able to compare results of this study with existing data from other sources, she would amend subject inclusion criteria to 6th to 12th grade children (approximately 11-18 years of age). She reported that existing materials have a readability score of 6th- and 7th grade and the mean age of Young Marines is 12.5 years of age. She also proposed

conducting a pilot study of the survey to assess its understandability and readability.

- The Chair reviewed 45 CFR §46.401 Subpart D. The PI must make provisions for child assent. The PI stated that the cover sheet on the survey will clearly state that completion is optional. Completion of the survey will constitute assent by the child. Signature of the child will not be obtained, as it would be the only information linking subject identity to the research. Parental permission will not be required for Young Marines who have attained the age of consent (18 years of age) and the consent form will be modified accordingly.
- For large Young Marine units (100 or more participants), parental permission will be attained by sending a packet home with the child after an in-person recruitment session at the Unit. The packet will contain a cover letter, parental permission form, and include information regarding how to obtain a gift card (\$4.50) for sending back the request to participate, even if they choose not to participate. Completed parental consents will be returned with child or mailed to the unit leader who will forward to PI.
- For small Young Marine units (less than 100 participants), parents will be informed about the study on the Young Marines website and unit leader announcements. Parents must initiate request for further study information. A link will be provided to the NHRC website and parents can request a packet mailed to them. Consenting parents will be mailed an access code to provide to their child to complete the questionnaire online (via the Internet). Parents must return signed hard copy consents.
- The Board noted that many survey item responses are phrased in the negative (e.g., disapproval of activity). The PI stated that the majority of the questions were taken directly from the Monitoring the Future survey.

The Board found that parents should be provided with an option to view the survey or sample questions to allow for informed decision-making about their child's participation. Additionally, parents should be encouraged to allow child to complete the survey in private. Recommendations are detailed below.

Ms. Hurtado, Ms. Simon-Arndt and Dr. Woodruff were excused from deliberation and voting. The Board discussed that study conduct may be difficult, as active parent and child participation is needed. It was discussed that the main safeguard to subject confidentiality is that information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects. 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. Pending specific modifications outlined below, the Board found 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 will not be required from participants. Completion of the survey by the child will be considered assent. Use of a \$4.50 movie rental gift card was considered to be a nominal inducement for participation and was deemed appropriate. 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 the below-stated issues are addressed. Needed administrative changes are also noted below.

- 1) This protocol has been assigned protocol number “NHRC.2007.0029. Please update “Protocol #” to read” “Protocol #NHRC.2007.0029” throughout protocol and in header accordingly.
- 2) Training and Education:
 - a) Provide curriculum vitae (CVs) for Hurtado, Simon-Armdt and Kraft.
 - b) Provide CITI human subjects protection training completion certificates for Woodruff and Kraft.
 - c) Provide completion certificate for HIPAA training, Support Service module, for all study personnel.
- 3) Section II, Signature Page(s)—Submit original signatures.
- 4) GLOBAL:
 - a) Provide written acknowledgement of subject recruitment from participating Young Marine units and support of national headquarters.
 - b) Provide copy of electronic presentation and website screen shots to IRB prior to use.
 - c) As presented at the meeting, revise protocol and accompanying documents to reflect inclusion of subjects in 6th – 12th grade. Briefly discuss involvement of 6th and 7th grade subjects, as Monitoring the Future (MTF) Survey samples only adolescents in 8th grade or above and thus, there is no potential for matching Young Marine respondents to age in the MTF, if younger than 8th grade.
 - d) As presented, describe procedure to pilot survey to assess understandability and readability.
- 5) Section VI(1)(A) Subjects, Parental consent is not required for 18 year old participants. Address this in Informed Consent section of protocol and age verification procedures. And add to bottom of page 3:

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. Otherwise, parent is asked to complete information on next page.

Printed Name of 18 years of age or older Young Marine

Date of Birth of 18 yr old

Signature of 18 years of age or older Young Marine

Email address of 18 years of age or older (to complete internet survey)

Mailing address of 18 years of age or older (to mail gift card to whether you participate or not)

I wish to participate I do not wish to participate

- 6) Section VI(1)(B) Methods and Informed Consent Plan:
 - a) Sampling Strategy—Describe sampling strategy of unit adult leaders (i.e., how will one person per unit be chosen?)
 - b) Procedures:
 - i) Parents should be encouraged to allow child to complete the survey in private. The access code provided will not be unique, however, and the survey should be programmed to ensure participants' privacy. Measures should include use of a statement immediate prior to questionnaire commencement stating in large, bold type that the survey should be completed in private. Also, survey should be programmed to not allow someone to go back into the survey to view previous responses.
 - ii) Para. 2, last line—Provide email text to be sent by the Young Marines Headquarters and Young Marine website announcement prior to use.
 - iii) Per the presentation, it was acknowledged that subjects could be waiting months to start boot camp. The Board recommends that attrition rate during the waiting period prior to start of boot camp be considered in the recruitment strategy.
 - iv) For small Young Marine units who will not undergo a formal recruitment session, the Board recommends that the unit distribute a recruitment flier to children to take home to their parents. If you decide to do so, incorporate into procedures section of protocol and provide a flyer for review.
 - v) Ensure that web version allows parent and/or adult leader to print a copy of the informed consent form for their records.
 - vi) Specifically state in protocol that parental (or 18 year old) written consent will always be received prior to survey administration.
 - vii) Describe survey administration environment (who will distribute surveys? Will unit leaders be present? What will non-participants do during survey administration?)
 - viii) Provide cover letter to be mailed with movie coupon to homes.
 - ix) Describe procedures to ensure participant privacy during completion of survey, i.e. subjects will be provided an envelope to cover their surveys and to place the survey in when completed.
 - x) Provide reminder emails that will be used with follow-up survey.
 - xi) Provide email invitation that will be sent to unit commanders to get leader participation.
 - xii) Per presentation, describe use of "reminders" to unit leaders (how will they be sent? Provide copy of text to be used). The Board recommends deleting unit number from the survey to encourage more open self-report.
- 7) Section VI(2) Sample Size—Provide formula and show calculation used sample size/power calculations.
- 8) Section VII(1) Responsibilities—State who will conduct recruitment sessions.
- 9) Section IX(1) Experimental Data—State where website will reside (e.g., NHRC server?) and describe data transfer of hard copy consents and surveys from unit site to NHRC.
- 10) Appendix A, Consent Document:
 - a) Risks Para. 1, line 6—Ensure description of code matches code creation in protocol (i.e., add child's middle initial and odd or even birth year, and change "your birth month" to child's birth month.
 - b) Risks Para. 1, Change next to the last sentence to: The survey data... will not be given to you, Young Marine unit leaders or anyone else beside the NHRC...."

- c) What Health Information—No protected health information is used in this study. As such, strike “health” from section heading and:
 - i) Strike para. 2.
 - ii) Para 3 – Strike “health” in front of “information” in two places.
 - iii) Para. 3, line 2—Change “your information” to “your child’s information.”
- d) Questions, Para. 3—Change to NHRC-IRB@med.navy.mil and change last line to “protect your rights and the rights of your child.”
- e) Change text after text box to “I am the parent or legal guardian of the below-named child and I give permission”
- f) Change text after text box to “I am the parent or legal guardian of the below-named child and I DO NOT give permission”
- g) It is recommended that parents be provided with sample questions or a copy of the survey for review as part of the consenting process. Suggested methods include providing a hard copy in information packet to parents, provide unit leaders a copy for parental viewing, or provide a link to a NHRC website to allow parents to view a PDF file.
- h) Privacy Act Statement, Purpose—Insert protocol number.
- 11) Appendix B, Investigator Assurance Agreement—Submit original signatures.
- 12) Appendix C(5)(f)—Provide OMB survey approval, when available.
- 13) Appendix H, In-Person Subject Recruitment Presentation:
 - a) Revise to account for subjects 18 years of age that do not require parental permission.
 - b) Inform subjects that their assent will be required.
 - c) Add study risks.
 - d) Pg. H-1, Last line—Change “you will get a free movie rental gift card” to “you will be mailed a free movie rental gift card.”
- 14) Appendix I, On-Line Subject Recruitment Presentation:
 - a) Make all requested changes to Consent Document to this document as well.
 - b) Provide CD-ROM copy of final PowerPoint slideshow with voice over.
 - c) Risks, line 6—Correct listed survey code prompts to match protocol.
 - d) Questions, Para. 3—Change to NHRC-IRB@med.navy.mil and change last line to “protect your rights and the rights of your child.”
 - e) Page I-4, para. 2—Correct numbering.
- 15) Appendices K (Youth Questionnaire) and L (Follow-Up Youth Questionnaire):
 - a) ADD to beginning of last paragraph on survey cover sheet: **NOW IT IS YOUR TURN TO DECIDE IF YOU WANT TO PARTICIPATE. EVEN THOUGH YOUR PARENT AGREED TO ALLOW YOU TO PARTICIPATE, IT IS YOUR DECISION. If you decide not to fill out”**
 - b) Add a statement immediate prior to questionnaire commencement stating in large, bold type that the survey should be filled out only by the Young Marine and in complete privacy
 - c) The board noted the below-listed formatting issues. It is recommended that the questionnaire be *carefully* reviewed prior to final submission.
 - i) Review Question #67 of the Youth Questionnaire and #60 of the Follow-Up Youth Questionnaire for consistency. Question involves use of marijuana or hashish. Last response item states “I feel that I have to drink.”
 - ii) Edit needed in paragraph 5 of cover letter to questionnaire. See page K-1 and L-1. First sentence should read “If you decide not [to] fill out the questionnaire...” Recommend adding the complete mailing address for NHRC.
 - iii) Text errors occur in the instrument questions.
 - Q2: 3 is missing from item 1. Grade 3 (Page K-3, L-3). Delete all inappropriate grades.

- Q24: Sentence is past tense. Edit to read "...how many drinks [did] you have?"
(Page K-6 and Item 20 on Page L-5)
- iii) Include full mailing address on cover letter to Adult Leaders. Text errors occur in the Adult Leaders Questionnaire.
 - Q2: What region [is] your Unit in? (M-4)
 - Q13: Should read "...did [your] unit participate..." (M-6)
 - Q18: Should read "...did [your] unit use drug demand reduction..." (M-8)
- 16) Appendix M, Adult Leaders Questionnaire with Consent Form:
 - a) Cover Page, Privacy Act Statement—Insert protocol number.
 - b) Page M-2, Risks—Line 3 states that "all paper copies of your information" will be kept. Clarify and/or correct statement, as protocol states adult leaders will complete surveys online and information will be anonymous.
 - c) Health Information:
 - i) Make appropriate changes to this section requested for parental consent form.
 - ii) Para. 1, Line 5 states that "all paper copies of your information" will be kept. Clarify and/or correct statement, as protocol states adult leaders will complete surveys online and information will be anonymous.
 - d) Questions, Para. 3—Change to NHRC-IRB@med.navy.mil.
 - e) Change consent to "click here" to consent or state by completing questionnaire, they consent to participate.
 - f) Provide screen shots of final consent and questionnaire.

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- 4) The meeting adjourned a 1500. The next meeting was scheduled for Thursday, 11 October 2007 at 1300.
 - 5) These minutes were distributed for review to IRB members and consensus was obtained that they accurately reflect the proceedings of the 06 September 2007 IRB meeting.

Christopher G. Blood 9/18/07
Christopher G. Blood, J.D., M.A.

APPROVED

K. Thompson
CAPT K. R. THOMPSON, MSC, USN

26 Sep 07
DATE