Supporting Statement B for

**CLINICAL MYTH-TERIES: A VIDEO GAME ABOUT CLINICAL STUDIES**

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## **LIST OF ATTACHMENTS**:

There are no attachments for Supporting Statement Part B

## B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

### B.1 Respondent Universe and Sampling Methods

The respondent universe for the video game assessment is based on age – 8 to 14 years old – and attendance at one of our recruiting institutions during the study period including:

1. The Newton Boys and Girls Club, Newton MA where 1500 members attend on a regular or daily basis;
2. The Watertown Middle School, Watertown MA where 425 students attend on a daily basis;
3. The Adolescent Center, Primary Care Services for youth at the Boston Medical Center, Boston MA. The pool of adolescents includes approximately 7500 children; or
4. Boston After School Programs. The pool of adolescents can exceed 5000 children.

The primary objective of this study will be to show a greater improvement in knowledge in the group who play the serious video game compared to the group assigned to standard of care. A sample size of 250 will be targeted. Participants will be randomized in a 2:1 ratio of intervention (N=167) to control (N=83) in order to provide greater power for secondary analysis within the intervention group. Assuming 20% attrition, this leaves 134 participants assigned to video game and 66 to standard of care. This sample size provides 80% power to detect an effect size of 0.4 standard deviations using a one-sided t-test at level 0.05, or 90% power to detect an effect size of 0.5. These are considered moderate effect sizes. A 0.5 effect size is equivalent to a difference of one-half of one standard deviation in the change in the number of questions answered correctly by participants in the two groups. A difference of this size is large enough to be considered of practical importance. A much smaller difference would be considered of lesser importance.

### B.2 Procedures for the Collection of Information

Each of the participating institutions (above) is willing to support our collection activities and have expressed a willingness to assist and support our efforts. For each of the collections, users will be approached via a letter with information about the study to be sent home for parents. An informed consent and assent document will accompany the letter. If a parent or approved guardian provides consent and adolescent provides assent, they will be enrolled into the study. For the focus groups (Development Phase), participants will be asked to attend a focus group held at the institution where they enrolled in the study. For the Randomized trial (Evaluation Phase),

they will be asked to complete a basic demographic survey electronically, from which point they will be randomized into the study.

Conducting this survey online will ensure that participants are stratified and randomly assigned regardless of which study site they are being recruited from. As consent is received, participants will complete online demographics and will be scheduled for a time that is convenient for them to attend a game playing session during their study period, or outside of school time. Participants will attend a session during which they will be asked to take a pre-test online, and then either review standard materials or play the serious video game for 30-45 minutes. After they play the serious game, they will complete a post-test online.

An open-ended set of qualitative questions will be asked to gather more detailed information about game experience and recommendations. This qualitative activity will inform any changes to the game. We will carefully monitor recruitment to ensure that participants are relatively balanced across the three sites (balance is not a study factor but we will want to ensure, for example, that all participants of a particular gender are not from one site). The computers will be stationed at the three organizations throughout the evaluation so that users can login to complete the surveys as necessary.

Trained NERI staff will conduct information collection. NERI has a great depth of experience in collecting information in the field. All staff having interactions with participants are trained on proper interviewing techniques and have completed the appropriate training.

Participants will be randomized in a 1:2 ratio to learn about clinical trials using either standard written materials or the video game. Randomization will be carried out using randomly permuted blocks of size 2 and 4 within each of three strata (children aged 8-9, children aged 10-11, and children aged 12-14). Based on findings from the Phase I focus groups that perceptions differ more by age group than by gender, we will stratify by age. This will enable us to capture significant differences particularly between the 12-14 age group and the 8-9, and 10-11 age group. We hypothesize that there may not be differences in knowledge by age group, but that we may see differences in game play preferences.

## B.3 Methods to Maximize Response Rates and Deal with Nonresponse

The NERI team will work with our study sites to assist with recruitment through their sites to minimize the burden on the respondents and their parents. Information will be made available at each site with the opportunity to contact NERI if interested. Focus groups will be scheduled after school, during study periods and other convenient times and at the locations where the adolescents are most likely to be, eliminating need for travel. In order to be a participant in the evaluation, the adolescent will have expressed an interest to a parent or guardian before they are enrolled and completed required consent and assent. Because data is collected at one time point, and will be gathered online, there is low likelihood of non-response. We have factored into our analysis the attrition for participants who choose not to complete the game or the post-survey in the Evaluation Phase.

## B.4 Test of Procedures or Methods to be Undertaken

The content of the focus group information collection is derived from the video game, concerns from the adolescents collected during the Phase I study as well as the learning objectives approved by the Scientific Advisory Board. The goal is to make sure the game is developed in a manner consistent with their interests.

The content for the Pre- and Post- tests are aimed to assess learning during game play. We will use validated study instruments where applicable, and will work with a trained education designer on staff who is familiar with appropriateness of wording question for adolescent audiences.

A trained moderator from NERI's Center for Qualitative Research (CQR) will lead the focus group. The randomized trial will be led by the Study PI. CQR staff use a variety of systematic

## B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The statistical design and all statistical analysis will be performed at:

New England Research Institutes (NERI)
9 Galen Street
Watertown, MA 02472

Contact information for the NERI statistician:

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