Supporting Statement A for

Simulations for Drug Related Science Education (NIDA)

Bethesda, MD 20892

Prepared by:
Robert Levine
Address: 3600 FAU blvd., Boca Raton, FL 33431
Telephone: 305-981-4830
Fax: 305-981-4831
Email: Rlevine@archiemd.com

Submitted By:

Cathrine Sasek, Ph.D., Project Officer

National Institute on Drug Abuse
National Institutes of Health
6001 Executive Boulevard, Room 5230
Rockville, MD 20892
Phone: (301) 443-6071
Fax: (301) 443-6277
Email: csasek@nih.gov

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A.1 Circumstances Making the Collection of Information Necessary

Engaging high school science education materials are needed to improve scientific literacy and increase science based careers. Studies demonstrate that students in the United States have scored poorly on standardized tests relative to their international peers in developed countries. The 2003 ACT college entrance exam reveals that only 26% of high school students taking the test are prepared for college biology. A low level of scientific literacy has a significant impact on the nation as a whole, the National Institutes of Health (NIH) and the National Institute on Drug Abuse (NIDA). The public health mission of NIH and NIDA requires stimulation of a high-level of scientific literacy. It is particularly important to NIDA that all members of society understand the role of science, biology, and technology as they relate to neuroscience, drug abuse, and addiction research.

In following this mission, we propose to develop *ArchieMD: The Science of Drugs*, a computer-generated interactive simulation for drug-related science education based on physiologically and medically rigorous visual models. . The interactive inquiry-based simulation will enable students to explore the science of addiction in a non-linear fashion aimed at maximizing curriculum absorption. The overall objectives are to: 1) increase achievement in science, and 2) reinforce and complement the social influence model of substance abuse prevention with scientific knowledge to support student decision-making processes and skills.

Studies have shown that supplemental materials to curriculum enhance learning. The Pharmacology Education Partnership (PEP) project demonstrated that learning the science behind cocaine, drug testing, and nerve gas can help high school students understand basic biology and chemistry concepts. In Phase I of this project, 47 teachers participated and 3500 students across the U.S. were tested. Students that used the educational modules scored up to 28 percentage points higher in the areas of basic biology and chemistry compared to students who did not have access to the materials. The degree of improvement obtained by using the PEP modules is considerably greater than that reported in several science education studies of standards-based instructional practices. Phase II expands upon the Phase I prototype by including information about additional drugs and more background information on the brain and other

body organs, and by increasing the interactivity by incorporating 3D gaming technology and more exploratory activities.

Aside from enhancing drug related science curriculum, it is important to broaden students' understanding of the nature of addiction as a biologically based brain disorder and the physiological effects of drug abuse. Science curricula should provide a drug prevention benefit while improving scientific literacy and increasing student interest in biomedical sciences. An enhanced drug-related science curriculum will increase students' knowledge on the subject matter, pique students' interests in science, and strengthen negative attitudes regarding drug use. Understanding the underlying science of drug addition serves as a preventive force. The science classroom is an excellent environment to create awareness about this issue and, through the application of an inquiry-based approach, combat the problem.

The Science of Drugs project is authorized under U.S.C. 285o and supports NIDA's mission of 'bringing the power of science to bear on drug abuse and addiction' and "ensuring the rapid and effective transfer of scientific knowledge to …the general public (http://www.nida.nih.gov/about/welcome/mission/NIDA_Movie1.html)."

A.2 Purpose and Use of the Information Collection

Modern computer-simulations have a unique ability to demonstrate scientific information in an easy to understand manner. Technology advances in computer graphics allow opportunities to present higher quality visual models in an interactive fashion that can convey the scientific process in a way that makes learning science fun and interesting for the students.

ArchieMD: The Science of Drugs will combine physiologically and medically rigorous visual simulation models with scientific explanation, delivered in an interactive, non-linear fashion. The product will be designed for use in a traditional classroom environment – as a class or on an individual basis (although it will also be adaptable to run in an online, distributed fashion). The primary target audiences are high school biology and health classes.

We hypothesize that use of *ArchieMD: The Science of Drugs* by high school students will increase knowledge about the science of addiction, reinforce or instill positive attitudes toward science, and reinforce or instill negative attitudes toward substance abuse. Information collected will be in the form of a pre-test/post-test/post-test that will gather information on the students'

knowledge of science (cardiac, respiratory and neurological systems), attitudes towards science, and their attitudes towards drugs use and drug abuse. We plan to enroll 360 tenth and eleventh grade high school students in the evaluation. The study will occur in a school environment. A control group will receive text-based intervention, while the intervention group will use the product. Participants will commit four school periods over a school semester to the study. During the first visit to the school, the evaluation team will administer a pre-test (one to two weeks before the intervention or control) to the participating students. During the second visit, the evaluation team will administer the intervention. The student will receive either *ArchieMD: The Science of Drugs* or the control material. One to two weeks after using the test or control material, the participants will receive a post-test to measure short-term knowledge retention and changes in attitudes (the third visit to the school). The final post-test questionnaire will be administered six months after the first post-test (the fourth visit to the school).

Data collected during this study will be used to modify and improve the educational module as determined by the participants' responses. Additionally, data collected will be used for final reporting purposes for NIDA in program improvement. Additionally results will be written for a peer reviewed publication submission in the area of technology in education.

To ensure objectivity, the evaluation will be conducted by external evaluators: a statistics faculty member and a professional staff member from the University of Miami. Both are unaffiliated with the development of the product.

An evaluation team (that are independent consultants hired directly by ArchieMD, and have no involvement in product development) will evaluate the efficacy of the *ArchieMD: The Science of Drugs* with respect to knowledge, attitudes toward science, and attitudes towards drug use and abuse. A 2 (intervention, control) X 3 (pretest, 1st posttest, 2nd posttest) ANOVA analysis will be used to assess the efficacy of the *ArchieMD: The Science of Drugs*.

On the commercialization side, representatives of the developer have contacted Elsevier Science, a global health science publisher that has recently contracted to license existing visual technology as well as perform developmental work. As an extension of this relationship, business discussions with the 6-12 division of Harcourt are in-process, (a Reed-Elsevier company), regarding the publishing and distribution of an expanded product that would include additional

content in the form of other drugs and some enhancement of the interactivity. A publishing and distribution partnership with a company of this size and scope would enable wide distribution of the product. Results from this evaluation may be used for marketing purposes if the evaluation suggests an increase in knowledge. If the evaluation results suggest that there is no benefit to this learning mode, it is anticipated that this will not be used for marketing purposes, but will still be written up for a peer reviewed publication submission.

A.3 Use of Information Technology and Burden Reduction

While the method of product delivery and assessment itself involve technological aspects, the information collection will be executed through paper surveys. We will use paper-based surveys for data collection due to the costs of developing an electronic survey tool and providing computers for over 350 students to input their responses for this project.

We have minimized the respondents' burden by limiting response requests to only necessary information for the evaluation. Additionally, staff will be present to disseminate and collects all surveys used and bring all materials necessary for the project so that teachers and students will spend the minimum amount of time participating in the evaluation. No personnel time will be required of participants for this project.

The privacy act does apply to this submission as determined by the NIH Privacy Act Officer. The data collection is covered by NIH Privacy Act Systems of Record 09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD". (Attachment 4). A Privacy Impact Assessment will be conducted once the study obtains clearance and annually thereafter as required.

A.4 Efforts to Identify Duplication and Use of Similar Information

The potential of using computerized representations of anatomy for health related training has long been recognized. Virtual reality based on 3D graphics was targeted at human anatomy instruction over a decade ago with the Vesalius Project. Hoffman et al's Anatomic VisualizeR project is perhaps the most significant project dedicated to anatomy instruction, although there are numerous other projects. To date, there is no major effort to apply this technology to addiction curriculum for science education. Furthermore, the proposed project breaks new ground in modeling human physiology behaviors in a medically rigorous 3D computer

simulation. This will be the first project that develops 3D simulations of the effects of drugs on a virtual patient.

Since this is a new program, this collection is necessary to assess its effectiveness. Time constraints exist in high school classrooms and there is a limit to how much material students can learn and retain from conventional didactic teaching with static slide presentations and written material. The virtual patient model, complete with fully dynamic organ systems and an ability to view the body internally from the tissue to the molecular level, may be an effective educational tool to simplify this complex subject matter.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

A data collection schedule has been developed that minimizes the number of times that data needs to be collected. Data will be collected at 3 points (pre-test, post-test, post-test). If data were to be collected less frequently, it would not be possible to measure any changes in knowledge and attitudes.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection fully complies with all guidelines of 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult

The 60 day FRN was published on 06/26/08 (Vol. 73, No. 124, page 36337). No comments were received.

Consultants

Expert Panel Information:

Michael Lang ; He has served on the National Committee for Science Education Standards and Assessment. Mr. Lang is the Director of Science Programs, Office of Public School Programs, Maricopa Community Colleges District in Tempe, Arizona. He holds a Masters of Educational

Leadership from Northern Arizona University and a Bachelors of Science in Biological Sciences and Secondary Education from the University of Wyoming.

Dr. Leslie Miller: Dr. Miller is the Executive Director, Center for Technology in Teaching and Learning, Rice University. She holds a PhD in Communication from the University of Texas at Austin, an M.S. in Communications from Florida State University, and a B.S. in Speech/Political Science from the University of Texas at Austin. Dr. Miller's current research focuses on the use of technology in education, in particular, envisioning new ways to use multimedia to improve learning among adolescents. This includes a NIDA funded R25 project "*The Reconstructors Investigate Club Drugs*". This grant is focused on teaching about Club Drugs in the RECONSTRUCTOR format. Based on the original OPIOID-focused series, this grant begins three episodes weaving the story about the effects of drugs such as MDMA on the brain and the body.

Dr. Charles O'Brien : Dr. O'Brien holds both an M.D. and a PhD in Neurophysiology from Tulane University. He is a Professor and the Vice-Chairman of the Department of Psychiatry at the University of Pennsylvania. He is the Principle Investigator for the Center for Research on Treatment and Prevention of IV Drug Abuse.

Charlie J. Parsons: Mr. Parsons is the CEO of D.A.R.E. America. As CEO of D.A.R.E. America, Charlie J. Parsons oversees the day-to-day operations of the world's largest and most effective drug and violence prevention organization. He joined D.A.R.E. in 1996, following a distinguished 27-year career with the Federal Bureau of Investigation (FBI).

Dr. Eden Evins: Dr. is a Director of the Addiction Research Program at Massachusetts General Hospital and is an assistant professor of Psychiatry at Harvard Medical School.

Consultant contact information:

LESLIE MILLER
lmm@rice.edu
713-348-5352

MICHAEL LANG
Director of Science Programs, Office of Public School Programs
Maricopa Community College District, Tempe, Arizona 85281
TEL: (480) 731-8057
mike.lang@domail.maricopa.edu

Evins, Eden A
Director, Addictions Research Program, Massachusetts General Hospital
Assistant Professor of Psychiatry, Harvard Medical School
Freedom Trail Clinic: 25 Staniford Street Boston, MA 02214
617 912-7832 Fax 617 723-3919
a_eden_evins@hms.harvard.edu

O'Brien, Charles P.
Vice Chair of Psychiatry
University of Pennsylvania
3900 Chestnut Street
Philadelphia, PA 19104-6178
(215) 222-3200 fax (215) 386-6770
obrien@mail.trc.upenn.edu

DR. SHIMI K. KANG
Faculty Member, Mental Health Education and Communication Consultation Unit
University of British Columbia
5929 Dumfries Street
Vancouver, BC
Canada V5P 3B1 Tel: (604) 961 7351
Email: shimi.kang@ubc.ca

PATRICK G. O'CONNOR, MD, MPH
Professor of Medicine,Yale University School of Medicine
Chief, Section of General Internal Medicine
333 Cedar Street, PO Box 208025
New Haven, CT 06520-8025
(203) 688-6532 (203) 688-1198
Patrick.oconnor@yale.edu

A.9 Explanation of Any Payment of Gift to Respondents

No monetary incentives will be used for recruitment or participation in this study. Schools and teachers will be given the software application for use as an incentive for participation.

A.10 Assurance of Confidentiality Provided to Respondents

The current project will fully comply with the Privacy Act, *Federal Register*, September 26, 2002, Vol. 67, No.187, pages 60765-60768, Privacy Act Systems of Record Notice 09-25-0156 entitled "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD."

The evaluation team will recruit participants by soliciting support from school principals and science teachers. The President of the Florida State Association of Science Teachers has agreed to help in the recruiting effort. This study will be completed in a school environment.

A waiver of signed consent will be requested for this study. An informational memo (Attachment 3) notifying parents that their students will be participating in an educational evaluation and an explanation of the computer based learning module and the data collection methods will be sent home with students to their parents. It will also be stated in the memo that participation is voluntary and that neither their child's grades nor standing in the class or school will be impacted by whether they choose to participate in the evaluation. This will also be reiterated each time the evaluation team goes to the school to administer the pre-test, intervention and post-tests.

A waiver of signed consent is being requested because, (1) This is a minimal risk study, (2) the waiver of signed consent will not adversely affect the participants welfare or rights, (3) it would be impractical to request parental consent for an educational evaluation when standard instructional practices are being used (computer based learning and reading), (4) signed informed consents and assents would be the only manner to students who are participating could be identified. It will not be necessary to identify individual students participating in this evaluation.

Pre-tests and post-tests will be coded so that no names are associated with responses. The questionnaires will ask for participants to include full date of birth and last four digits of their current home phone number. If no phone is available, students will be given the option to use their locker number and day of birth as an alternative. These numbers will only be used for the purpose of code numbers to match pre- and post- intervention questionnaires. Students' names are not being collected and will not be matched with any responses. The intervention and questionnaires will be completed during school hours, and the students will not be asked for any time outside of school. This method has been used in past educational evaluations we have conducted, and it has been successful in gathering and matching student responses without collecting student names.

Questionnaires completed in the classroom will be placed in a sealed manila envelope and delivered to the lead evaluator. The lead evaluator will enter all responses to the pre-test into the database. All paper-based data collected will be kept the evaluation team's office, in a locked file cabinet, and all electronic data will be stored on a hard drive that is password protected. NIDA will only have access to the aggregated data used in analysis.

A.11 Justification for Sensitive Questions

No personal identifiable information is being collected.

A pretest, post-test and follow-up questionnaire measure students' knowledge, attitudes toward science and attitudes towards drug use and drug abuse. The post-test will also include questions to measure satisfaction with *ArchieMD: The Science of Drugs*. No questions are being asked in regards to self reported behaviors regarding drug use.

It is important to ask questions regarding attitudes about drugs to assess whether the program assisted in changing attitudes towards drug use and abuse. This program is aimed at not only educating but also shaping attitudes towards drugs in a negative manner by conveying the harmful effects.

Students will not be required to give their names, as entire classrooms of students will be completing the information. There is no way to match the last four digits or date of birth to an individual student.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Recruitment of 360 participants in grades 10 or 11 is planned. Participants will commit four school periods over a school year. The estimated annualized burden is summarized below.

Estimates of Hour Burden Table

Type of Respondents	Number of Respondents	Frequency of Response	Average time per Response	Annual hour burden
Participants-High School Students	360	3	.417	450
Total	360	3	.417	450

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

No capital, start-up or operational and maintenance costs are incurred by study participants in this information collection activity.

A.14 Annualized Cost to the Federal Government

Total costs associated with the project are estimated to be approximately $70,000 over a 1 year contract performance period. These costs cover all aspects of survey design, testing, computer equipment, data collection and analysis and report generation. In addition, it is estimated that one full time equivalent NIDA staff member will spend 2 % of his/her time (40 hours) to manage and administer the project. Assuming an annual salary of $100,000, government personnel costs will be $2,000 over a 1 year period. The annual project costs are thus $72,000.

A.15 Explanation for Program Changes or Adjustments

This is a new information collection request.

A.16 Plans for Tabulation and Publication and Project Time Schedule

A.16 - 1 Project Time Schedule	
Activity	**Time Schedule**
Recruitment and coordination of science classrooms	1 month after OMB approval
Send home informational memo	1-2 months after OMB approval
Administer pre-test	2 months after OMB approval
Intervention	2-3 months after OMB approval (1-2 weeks after pre-test)
Post Test	3 months after OMB approval (1-2 weeks after intervention)
Second Post test	9 Months after OMB approval (6 months after initial post test)
Analysis	10 Months after OMB approval
Final report	11 Months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed on all documents.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the "Exceptions to Certification for Paperwork Reduction Act Submissions."