Supporting Statement A for

Simulations for Drug Related Science Education (NIDA)

Bethesda, MD 20892

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Table of contents

A. JUSTIFICATION....4

A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY....4

A.2. PURPOSE AND USE OF THE INFORMATION COLLECTION....6

A.3 USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION....7

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION....8

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES....9

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY....9

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5....9

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE AGENCY 10

A.9 EXPLANATION OF ANY PAYMENT OF GIFT TO RESPONDENTS....12

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS....12

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS....15

A.12 ESTIMATES OF HOUR BURDEN INCLUDING ANNUALIZED HOURLY COSTS....15

A.13 ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS....16

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT....16

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS....16

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE....17

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE....17

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS....17

List of Appendices

1. Appendix 1: Pre-Tests and Post-Tests
2. Appendix 2: Post feedback questions
3. Appendix 3: Memo to parents
4. Appendix 4: Memo- Applicability of the Privacy Act: Simulations for Drug Related Science Education
5. Appendix 5: Demographic Profile of Miami Dade County

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, ArchieMD, Inc. proposes to meet science education needs by developing computer-generated interactive simulations for drug related science education based on physiologically and medically rigorous visual models. This product will be called *ArchieMD: The Science of Drugs*. In Phase II, we will expand upon our Phase I prototype by including information about additional drugs and more background information on the brain and other body organs and increase interactivity by incorporating 3D gaming technology and more exploratory activities. The ArchieMD 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 objective is to increase achievement in science while reinforcing and complementing 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 1 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.

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. It is our belief that by enhancing a drug related science curriculum students will increase their knowledge on the subject matter, along with peak students' interests in science, and strengthen negative attitudes regarding drug use.

Science curriculums should provide a drug prevention benefit, while improving scientific literacy and increasing student interest in biomedical sciences. Attitudes drive behavior and national drug education campaigns over the years may have had an effect on the attitudes of youth toward drug use. However, few curricular materials about substance abuse generally, and drug abuse specifically, are science-based. Rather, they focus on substance abuse awareness and on social influence – the importance of personal self-esteem and on building refusal skills. This health education approach is indeed valuable, but it is not enough. For example, being told in a health education class that drugs can cause cognitive damage is very different from learning the *science*, or the *why* behind this finding. Moreover, "telling" is not always "teaching". The critical thinking skills involved in the methodology of science are learned in science education, not in health education. Critical thinking is an invaluable asset in personal decision-making. Understanding of 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. Teaching practices and topics that arouse student interest help motivate students to learn and increase achievement levels.

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 present a unique ability to demonstrate scientific information in an easy to understand manner. NIDA has funded well-received 3-D computer animations such as "Animated Neuroscience & The Actions of Nicotine, Cocaine and Marijuana in the Brain" for high school biology, psychology or health classes, drug educators, health practitioners, police departments, nursing students, and physician's assistant students. 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 which makes learning science fun and interesting for the students while capturing their enthusiasm for science.

At the core of the concept are physiologically and medically rigorous visual simulation models. The program will incorporate these 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 system encourages inquiry-based exploration of science topics related to drug abuse, and addiction. The primary target audiences are high school biology and health classes.

With the inclusion of different curricular methods for teaching science and reinforcing the social model for drug abuse and prevention, we hypothesize that use of the *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. Three-hundred and sixty tenth and eleventh grade high school students will be enrolled 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 the *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).

An internal evaluation team at Archie MD 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 ArchieMD contacted Elsevier Science, a global health science publisher that has recently contracted with us to license existing visual technology as well as perform developmental work. As an extension of this relationship, we have entered into business discussions with the 6-12 division of Harcourt, 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 us to have the product widely distributed.

A.3 Use of Information Technology and Burden Reduction

ArchieMD proposes to purchase 35-laptop computers for use in the evaluation. This will enable us to preload the prototype onto a computer prior to the intervention at the schools. The evaluation team will be responsible for bringing the laptop computers to each school for the intervention. It enables the study to be carried out in any classroom regardless of existing computer facilities. Basing the study on the availability of existing computers in high schools would likely skew the study away from schools in low-income areas with a high number of at-risk students.

While the method of product delivery and assessment itself involve technological aspects, the information collection will be executed though means of surveys, questionnaires, and assessment tests. A pretest and posttest (Appendix 1) has been developed by ArchieMD and the expert panel. The tests are designed to measure knowledge, attitudes toward science, and attitudes towards drugs use and drug abuse. Knowledge questions are based on the learning

objectives and information in the computer based learning module and the control group materials. Attitudes towards science questions have been adapted from the Science Attitude Inventory (SAI). Additionally, questions regarding attitudes towards drug use and drug abuse have been adapted from the Florida Youth Behavior Risk Survey (YBRS), along with past attitudinal questions developed from a prior alcohol use and abuse evaluation conducted in 2005.

A post feedback questionnaire will be given to students that participated in the computed based learning module. This post feedback questionnaire (Appendix 2) will ask questions regarding the students' satisfaction with the *ArchieMD: The Science of Drugs (*i.e. questions regarding user friendliness, whether they enjoyed using the computer based learning module, etc.)

The privacy act does not 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". (Appendix 4).

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

Technology advances in computer graphics present opportunities to present higher quality visual models in an interactive fashion that can convey the scientific process in a way which makes learning science fun and interesting for the students while capturing their enthusiasm for science. There is anecdotal evidence that traditional animation materials, such as "Changing Your Mind: Drugs in the Brain"- an interactive CD-ROM that teaches the neurobiology underlying drug use, abuse, addiction and depression, are effective in attracting an audiences' interest.

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, ArchieMD and the

proposed project break new ground in modeling human physiology behaviors in a medically rigorous 3D computer simulation. We believe this will be the first project that develops 3D simulations of the effects of drugs on a virtual patient.

Throughout these simulations, we journey inside this virtual human body which literally "comes alive" with a beating heart, flowing blood, breathing lungs and a thinking brain. The virtual patient provides a complete human body heretofore impalpable, allowing a user to navigate throughout the human body, observing the organs in simulated motion during both normal and pathological physiology, while demonstrating the internal effects of drugs on these organs.

Aside from the programs pioneering efforts to simulate drug effects, the program's effectiveness is also to be considered. 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. Our virtual patient model, complete with fully dynamic organ systems, and an ability to view the body internally from the tissue to the molecular level is the ideal educational vehicle to simplify this complex subject matter. Our visual technology would tap into the visual learning capacity of students, conveying the material more efficiently and with longer retention based on deep understanding, rather than simple rote memory.

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

We have developed a data collection schedule that minimizes the number of times that data needs to be collected. We are collecting data at 3 points (pre-test, post-test, post-test). If we were to collect data any less frequently, we would not be able 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

Michael Lang will serve as a consultant on this effort. 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. Throughout his career Mr. Lang has taken a leadership role in science education, including:

Dr. Leslie Miller will serve as a consultant on this effort. 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 will be a consultant on this effort. 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 Principal Investigator for the Center for Research on Treatment and Prevention of IV Drug Abuse. Dr. O'Brien is the author of over 400 peer-reviewed publications

Charlie J. Parsons will serve as a consultant on this effort. 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).

While with the FBI, Mr. Parsons served in a number of prestigious training, field and management positions. From 1991 until joining D.A.R.E. America, he was Special Agent in Charge of the FBI's Los Angeles Division. In Los Angeles, he led the agency's successful efforts to reduce bank robberies and violent street gang activities while strengthening relations with local law enforcement agencies in the region. The Los Angeles Division is the Bureau's second largest, with more than 1000 staff serving a population of 15.9 million in seven Southern California counties.

Mr. Parsons joined the FBI in 1969, shortly after receiving his law degree from Bates College of Law at the University of Houston. He also has done post-graduate work at Harvard University and taught at the Baylor University College of Medicine. He is a past president of the Peace Officers Association of Los Angeles County and has served on the Board of Directors for the California Peace Officers Association.

Over the years, Mr. Parsons has been honored with numerous awards and citations. Among them was a Presidential Award for his leadership during the 1992 Los Angeles riots. In 1993, he was the first recipient of the Anti-Defamation League's national Jefferson Award for "exemplary law enforcement work."

Dr. Eden Evins will serve as a consultant on this effort. Dr. Evins is a Director of the Addiction Research Program at Massachusetts General Hospital and is an assistant professor of Psychiatry at Harvard Medical School.

Dr. Evins completed her residency in adult psychiatry at the Massachusetts Mental Health Center and Longwood Psychiatry Residency Training Program, where she was Chief Resident. She conducted a fellowship in molecular biology at the Mailman Research Center of McLean Hospital and a second fellowship in clinical schizophrenia research at the Massachusetts General Hospital. She is currently completing a Masters in Public Health at the Harvard School of Public Health.

Dr. Evins research interests include pharmacotherapy for negative symptoms and nicotine addiction in schizophrenia and treatment for cognitive dysfunction in schizophrenia and bipolar

disorder. She has authored articles, book chapters, and reviews concerning topics in this field. She is currently supported by a career development award from the National Institutes of Drug Abuse for her work on nicotine use in schizophrenia. Dr. Evins served as the head of the Expert panel during Phase I.

A.9 Explanation of Any Payment of Gift to Respondents

Our goal is to recruit 360 participants in grades 10 or 11. Initially, ArchieMD will recruit the assistance of high school principals and science teachers in the south Florida regions. Classrooms of 10th and 11th grade science classes will be enrolled in the evaluation. Teachers will receive a $750 dollar gift card to purchase school supplies/science materials for their classrooms for participating in this evaluation. Prospective teachers will be asked to contact the study coordinator, who will collect classroom information (i.e. what grade students are in, in the science class) and explain the commitment and evaluation procedures to the teacher at this time.

The $750 gift card is to attract and encourage teachers for participation. Teachers in the education system are under high workloads during the academic year, suffering under budget cuts and maintaining disciplined behavior among the students is not an easy task at all times. Even though this may be an educational and informative exercise for students, it still constitutes a deviation from the normal school day and poses a burden for teachers. The gift card is an incentive to teachers for them to be able to offset some of the costs associated with purchasing supplies and items for the classroom. It is anticipated that some incentive to augment/complement the work of teachers will contribute to the successful implementation of the intervention in the classroom.

A.10 Assurance of Confidentiality Provided to Respondents

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.

We are requesting a waiver of signed consent for this study. An informational memo (Appendix 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 on 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. We do not need to nor will we identify individual students participating in this evaluation.

Pre-tests and post-tests will be confidential and will be coded so that no names are associated with responses. The questionnaires will ask for participants to include full date of birth (as proof of age), 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 and as proof of age. 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 has been successful in gathering and matching student responses, and not having to collect student names.

Once all recruitment has been completed, a schedule of dates and times to implement pre/post-tests and the intervention will be coordinated with the science teacher to ensure that the project is non-disruptive to the teachers planned educational activities and fits into their lesson plans. Once this has been determined, the evaluation team will go to the classroom to administer pre-tests to the classroom of students. All pre-tests will be administered and collected by the evaluation team. The pre-test will take approximately 25 minutes to complete by the students.

Once collected they 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.

One to two weeks later (exact time depending on the teachers schedule and lesson plans), the evaluation team will return to administer the intervention. At this time, preloaded laptops will be given to classrooms of students to participate in the learning module (intervention group) or standard reading materials will be handed out (control group). Both the intervention and control groups will utilize their given materials for the 50 minute classroom time period. At the end of the class, the research team members will collect the computers or reading materials. At this time, students who used the computer based learning module will be given a brief (3-5 minute) anonymous questionnaire regarding their opinion of the computer based learning module (i.e. Did you like the graphics? Was the sound clear? Suggestions for improvement?, etc). Evaluation team members will collect this feedback form from students before they leave the room for their next class.

Approximately 3-4 weeks later, the evaluation team will return to the classrooms to administer the first post-test. The first post-test will take approximately 25 minutes to complete, and will be administered and collected by an evaluation team member. Once collected the first post-test will be placed in a sealed manila envelope and delivered to the lead evaluator. The lead evaluator will enter the first post-test into the database. After all participating classrooms have completed the post-test, data analysis will begin to determine if there are any differences between the intervention and control groups in the areas of knowledge acquisition and attitudes towards science education and drug use.

A final post-test will be administered 6 months after the initial post-test to collect data. At this time, the evaluation team member will return to classrooms to administer and collect this attitudinal post-test. This post-test will take approximately 25 minutes to complete and will be administered and collected by the team member. Once collected they will be placed in a sealed manila envelope and delivered to the lead evaluator. The lead evaluator will enter all responses from the final post-test into the database. Data analysis will examine if there are any longer term

differences between the intervention and control group. Final results will begin to be written up for the final report to the funding agency (National Institutes of Health's National Institute on Drug Abuse)

A.11 Justification for Sensitive Questions

No personal identifiable information is being collected.

A pretest, post-test and follow-up questionnaire will be created by ArchieMD and the expert panel. The tests 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 the *ArchieMD: The Science of Drugs*. We are not asking any question regarding self reported behaviors regarding drug use.

It is important for us to ask questions regarding attitudes pertaining to drugs as it will aid in demonstrating the efficacy of the program with regard to the knowledge and content absorption as well as if 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 in new modern age and innovative fashion.

Respondents will be made aware of the anonymity of their answers and the following procedure will be explained to them to help reinforce the manner of confidentiality by the ArchieMD evaluation team members. Students will not be required to give their names, as entire classrooms of students will be completing the information. We have 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

Our goal is to recruit 360 participants in grades 10 or 11. Participants will commit four school periods over a school year. *Affected Public:* High school students engaged with the *ArchieMD: The Science of Drugs* program. *Type of Respondent:* Participants will include high school students enrolled in the tenth and eleventh grade. *Estimated Total Annual Number of Respondents:* 360. *Estimated Number of Responses per Respondent:* 4. *Average Burden Hours per Response:* One high school period lasting 50 minutes. *Estimated Total Annual Burden Hours Requested:* 1199.95.

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. The estimated annualized burden is summarized below.

Estimates of Hour Burden Including Annualized Hourly Costs Table				
Type of Respondents	Number of Respondents	Frequency of Response	Average Burden Hours per Response	Estimated Total Burden Hours Requested
Participants-High School Students	360	4	.8333	1199.95
Total	360	4	.8333	1199.95

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 1 year total project costs are thus $72,000, with annualized cost of $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."