PHASE II EXAMPLE

INTRODUCTION TO REVISED APPLICATION

This proposal responds to the National Cancer Institute's (NCI) program on Interactive Media Technologies in Cancer Prevention in its Division of Cancer Prevention and Control in the categories of Innovative Alternative Teaching Methods, Internet/World Wide Web Applications, and Cancer Prevention Systems for the Public. This Phase II application is a revision of an earlier proposal (1 R43 _____) submitted in December, 1998. **Changes and additions to the previous proposal are indicated in italics.** Reviewers' recommendations have been addressed to strengthen the original proposal in the following ways:

Uniqueness and Innovation

This application proposes the ninth study in a long-term collaboration between _____, M.A. and _____, Ph.D. to develop effective sun safety educational materials that increase sun protection of children. The centerpiece of these materials is the _____ skin cancer prevention curriculum (SDHW). The first four studies from 1991-99 focused on developing the standard _____containing traditional classroom presentations and activities for use by teachers in elementary schools (Figure 1). In more recent projects, two objectives are being pursued: developing and evaluating a version of the SDHW for teachers and children in middle schools (grades 6-8) and developing multimedia SDHW instructional materials on CD-ROM. This application is the fourth project addressing the latter objective (Figure 1).

As Figure 1 shows, this program of research has been funded by several sources and Ms. _____and Dr. _____have served alternately as principal investigators on the various projects. This was a source of confusion in the original version of this application, especially since Ms. _____ is the principal investigator for the overall application--as an employee of the applicant small business, _____, Inc.--and Dr. _____is the Principal Investigator only for the subcontract to the _____ Cancer Research Center for his time on the project, production of the multimedia _____by _____'s Health Communication Core, and biostatistical support from ____'s Biostatistics Core. To reduce confusion in the revised application, all references to Ms. _____ have been changed to Ms. _____ and all references Dr. _____ have been changed to Dr. _____and he is described as the Subcontract P.I.

Figure 1: Previous Research on SDHW

Title of Study	Principal Investigator	Date	Funding Source	Objective
Mesa Study	P.I	1991	Arizona Cancer Center	Evaluate initial SDHW for grades 4-5
ADCRC Study	Subcontract PI	1992	Arizona Disease Control Research Commission	Evaluate revised SDHW for grades 4-5
Sun Smart Day program and Study	P.I.	1993	Skin Phototrauma Foundation	Evaluate one-day sun safety SDHW health fair
Family Sun Safety 5 and Project parents	Subcontract PI	1994-1999	National Cancer Institute (CA)	Evaluate SDHW expanded to grades K- Together for Sun Safety program for
Middle School Sun Safety Project	Subcontract PI	1998-2002	National Cancer Institute (CA)	Evaluate SDHW for grades 6-8
CRFA CD-ROM CD-ROM Study	Subcontract PI	1998	Cancer Research Foundation of America	Produce and evaluate prototype SDHW for grade 4
SBIR Phase I for multimedia	P.I.	1997-	National Cancer	Produce and test feasibility of SDHW

Elementary schools		1998	Institute (CA)	activities for grades K and 2
SBIR Phase I for multimedia	P.I.	1999-	National Cancer	Produce and test feasibility of SDHW
Middle schools		2000	Institute (CA)	activities for grades 6 and 8
SBIR Phase II for multimedia programs	**P.I.**	***	**National Cancer**	**Produce & evaluate SDHW**
Elementary schools			**Institute**	**for grades K-1, 2-3, and 4-5**
SBIR Phase II for programs	P.I.	***	National Cancer	Produce & evaluate SDHW multimedia
Middle schools			Institute	for grades 6, 7, and 8
***Current application is in boldface type; future application is in italics.				

The long-term programmatic nature of the research on the SDHW may have produced a perception that the present application lacks innovation and is redundant. However, each of our previous projects and the present application have addressed a unique objective(s). At the same time, the literature on the epidemiology of skin cancer, strategies for sun safety education of children, and theories and principles of health behavior change and education have changed slowly. Consequently, each project has been built on a similar conceptual and empirical base, leading to similar descriptions of significance and theoretical approaches. Also, we have developed effective methods for creating and producing curricular materials and evaluating them, which we will apply again in the proposed project. These circumstances provide a sound foundation and increase the potential for success of the proposed CD-ROM programs and the project and will ultimately produce an integrated package of sun safety education materials for K-8 schools.

The relationship of this application to the CRFA CD-ROM Study was specifically questioned. We used a small grant of $32,000 from the Cancer Research Foundation of America to produce our first prototype multimedia SDHW activities. However, the CD-ROM created in that project was short, did not teach all of the principles and skills in the standard SDHW for grades 4-5, and not all features were effective with children, producing improvements only in knowledge (ref). We plan to expand substantially the multimedia program for grades 4-5 in the project proposed in this application to make it a more effective companion or alternative to the standard SDHW classroom materials and to match the format of the CD-ROM programs authored for grades K-1 and 2-3. Also, the limited funds in the CRFA grant permitted us to conduct a very small evaluation in two schools; evaluation of the CD-ROM program for grades 4-5 proposed here will be far superior.

CD-ROM programs continue to be new within school health education and are very innovative in the skin cancer prevention arena. We identified only one other CD-ROM program on sun safety. It was authored in Sweden, contained information specific to the European Union countries, and was designed for an adult audience. Finally, we have added to the application a consultant on educational technology--Dr. _____--who will help us include pedagogical agents in the sun safety CD-ROM programs to tailor information to the learning styles of children. These agents are simple artificial intelligence routines that function as intelligent tutors accompanying children throughout the computer-based application.

Revised Experimental Design

At the suggestion of the reviewers of the original application, we extensively revised the experimental design and its accompanying analysis plan and sample size. We now propose to implement a three-group randomized trial, comparing groups receiving the SDHW CD-ROM only, standard SDHW curriculum and combination of CD-ROM and standard curriculum. In this design, we will test that both the CD-ROM and standard curriculum produces changes from baseline in outcomes, compare the equivalence of outcomes produced by the CD-ROM and standard curriculum to test the relative effectiveness of the two interventions, and evaluate whether they improve outcomes when used in combination. However, this more complicated design involves enrolling a larger sample of schools and children and implementing the standard curriculum, both requiring an increased project budget.

We did not make changes in our plans to conduct a small validity study on children's self-reported sun protection behavior. We have shown in several studies that self-reports and colorimeter measures are positively correlated and we expect the same to occur here, providing an estimate of concurrent validity. Colorimeter measures require a lot of staff and student time (5 min. per student per assessment) and are not a gold-standard measure of solar protection. So, we opted against wide-scale usage of this measure to control costs, but have retained the small cost-effective validity study.

Educational Value of Multimedia Programs

We have expanded review of the educational value of multimedia programs which show that stimulating multimedia activities are effective and that potential distraction can be reduced by combing age-appropriate on-screen text with interactive activities, as we plan to do. Moreover, the addition of pedagogical agents (i.e., intelligent tutors) by project consultant, Dr. _____, will tailor the content to student learning styles, further increasing the program's educational and commercial value.

We provided further information on the value of the multimedia programs in the entire SDHW package. This includes recent data we collected from a national sample of elementary school principals who identified sun safety educational materials on CD-ROM as a highly desirable educational tool. This survey also indicated a high degree of interest in a curriculum like the SDHW. We also highlight marketing successes with the SDHW since the original application.

One reviewer asked what would be suggested as an alternative intervention, if the SDHW CD-ROMs are not effective at improving protective behavior. In such a circumstance, we would suggest linking it into a larger community sun safety program, where sun safety education is directed to parents and adults. We also believe that community programs that promote changes in school and organizational policies that reduce children's sun exposure are warranted. We are currently working on sun safety policy materials with the Environmental Protection Agency. Finally, there is a need for additional products to help children and adults practice sun protection (e.g., inexpensive shade structures, sun protective fabrics, sun safe swimsuits such as those available in Australia). These alternatives are too costly to be added to the proposed project.

We have added a consultant with training and experience in educational theories and educational technology--Dr. _____. He will assist the investigators in grounding the CD-ROM program in current approaches to elementary education. The instructional designer in _____'s Health Communication Core, who will script the program, has nearly 10 years of teaching experience and training in curriculum design.

The interactive multimedia CD-ROMs produced in this project will compliment, rather than copy the content of the written SDHW curriculum. The CD-ROM programs will address each of the SDHW's four lesson areas (i.e., personal risk, limiting time in the sun, wearing protective clothing, and asking for/using sunscreen and lip balm) to be consistent with the curriculum's core concepts. However, the CD-ROMs will present the concepts in new multimedia activities that provide an opportunity for skill-building and practice. Concepts from the SDHW curriculum, which can be illustrated well in the audio-visual computer environment, will be selected for inclusion on the CD-ROMs. Like the SDHW curriculum, the CD-ROM activities will address a variety of curriculum standards.

The Role of School-based Curricula in National Sun Safety Public Education Programs

Currently, there are no large, well-funded, wide-scale national sun safety public education programs in the U.S., despite prominent calls for them (190). The American Academy of Dermatology, American Cancer Society, Centers for Disease Control and Prevention, and Environmental Protection Agency are leading small efforts to promote sun safety, with very limited funds. All of them have recognized the priority of reducing sun exposure by children through health education to children and adults. Currently, these national efforts provide limited sun safety educational activities for children, none of which are as extensive, multi-level, and integrated as the SDHW we are working to create. In recent reviews of the literature on sun safety programs for children, only such extensive programs showed

improvements in actual sun protection behavior; shorter programs did not (191). Thus, the SDHW holds more promise of effectively changing children's sun protection than existing school resources available from these other organizations.

However, school-based sun safety education is only one important element in the community-wide efforts that are required to improve sun protection by the U.S. population. Schools offer many advantages both in terms of coverage of the child population and credibility in the health education arena. But, we acknowledge that it is essential to involve parents, teachers, and other adults in the community to produce large changes. We have already worked to develop effective interventions for these adult populations in our other studies. We are focusing on multimedia SDHW programs, in part because we believe they add another means of introducing the topic. Well-developed educational software is desired by school administrators to effectively use their new computer technologies. Linking sun safety education to school computer technology may help teachers find additional time for this "new" health topic. Finally, the audiovisual and interactive features of multimedia programs can be used to effectively present and model important sun safety principles and skills.

Our work and that by several other groups has clearly shown that children as young as three years old can learn some of the principles and skills needed for sun protection (192,193). While parents do determine some aspects of their sun protection, we teach young children to ask their parents for these products (e.g., sunscreen, hats). We believe that this is a realistic approach. Further, the SDHW may forestall parent-child complaints and conflicts over sun protection. Finally, the value of introducing other health education behaviors at a very young age has been shown, even with behaviors that also rely on parent participation (e.g., nutrition, dental health, car safety, personal hygiene).

RESEARCH PLAN

\VI) SPECIFIC AIMS

Sun protection must start in childhood when we receive more than 80% of our lifetime sun exposure. Childhood provides an excellent opportunity to instill solar protection habits before lifestyle patterns are formed. Schools are likely the most efficacious setting for delivering sun safety training to children. Computer CD-ROM programs are an increasingly effective method of instruction. Thus, the specific aims of this project are to:

1. Produce three comprehensive sun safety CD-ROM programs -- one for students in grades Kindergarten and 1, one for students in grades 2 and 3, and one for students in grades 4 and 5 -- based on the Grade K-5 Sunny Days, Healthy Ways (SDHW) skin cancer prevention curriculum. The CD-ROM programs will integrate with the published SDHW curriculum, be compatible with current health and science curricula, and be implemented by classroom teachers;
2. Evaluate the ability of each CD-ROM to increase children's sun protection skills, their attitudes and perceived norm for sun safety, and their use of sun protection (i.e., limiting time in sun, avoiding daily periods of peak ultraviolet radiation, wearing protective clothing and hats, and using sunscreen on exposed skin).
3. Evaluate satisfaction and acceptance of the CD-ROM programs by elementary school teachers and students.
4. Develop an Instructor's Guide on integrating the SDHW CD-ROM programs in school health and/or science education.

B. SIGNIFICANCE

B.1.Skin Cancer is Epidemic

Although 90% of skin cancers are preventable, they are epidemic in the U.S. Over 1,000,000 cases of non-melanoma skin cancer (NMSC) and 44,200 cases of melanoma will be diagnosed resulting in 9,200 deaths in 1999 (3). Melanoma incidence has doubled since 1973, is increasing 4% per year, and by 2000, the risk of melanoma will be 1 in 75 (3,56). Skin cancer is highest in states with low latitudes, high elevations, abundant sunlight, dry climates with little cloud cover, and outdoor lifestyles which increase ultraviolet radiation exposure. A rule of thumb is that UVR increases by 4-5% for every 1000 ft above sea level (38) making Colorado a high exposure state (38,42,78). Colorado's melanoma incidence rates climbed 17-33% from 1991-95 and are higher than the national average, with cumulative lifetime risk of melanoma 1 in 39 men and 1 in 66 for women (165). Skin cancer is more common among individuals with lightly pigmented skin. Incidence rates are about 20 times higher among whites than among African Americans nationwide and melanoma is the fastest growing cancer among Colorado's non-Hispanic whites.

B.2.Preventing Skin Cancer by Reducing Ultraviolet Radiation (UVR) Exposure

UVR exposure is the most preventable risk factor for skin cancer (48). Total lifetime UVR exposure has been positively associated with development of squamous cell carcinoma and, likely, melanoma skin cancer (5,46,93,132,141). Intermittent, especially severe, exposure (i.e., blistering sunburns) before age 20 is linked to melanoma formation and possibly to NMSC (54,83,94,106,145). The best defenses against UVR exposure are limiting time in the sun, using shade, and wearing protective clothing. Broad-spectrum sunscreens (that absorb or block UVA & UVB) may prevent skin damage and ultimately skin cancer when used to reduce normal exposure rather than to prolong exposure (52,109). However, people inconsistently and infrequently take these precautions (23,61,92,108,121,131). If compliance levels were higher, a large majority of skin cancer (up to 80%) might be prevented (34,57,132). Despite some recent controversy about the efficacy of sunscreen for preventing melanoma, it continues to be an important sun protection practice. By wearing a hat, contribution of UVR to NMSC may be decreased by up to a factor of 100 on some areas of the face (147) and ocular exposure to UVB by almost half (23,35,45,90). Sun safety must be a year-round practice, especially at high elevations where dry air increases UVR at the surface (114) and dry, fresh snow can reflect 85%-95% of UVR, nearly doubling ambient UVR (14,38).

B.3. Preventing Eye Damage by Reducing UVR Exposure

Ocular damage (i.e., photokeratitis, photoconjunctivitis, cataracts, other opacities of the lenses, aging and degeneration of the retina) is associated with exposure to UVB (66,135). Risk of cortical cataracts had an odds ratio of 3.30 when the highest and lowest quartiles of UVB exposure were compared. Damage may be higher in males than females (135). Ocular melanomas are related to sun exposure. Blue-light from the sun can damage the eyes (66). Protective sunglasses reduce UVR exposure to eyes (124,135), yet sunglasses are worn infrequently by children. More persuasive education strategies could promote routine wearing of sunglasses by children, like for seat belts and dental care.

B.4. Childhood Sun Safety in Essential

Behaviors to reduce sun exposure must start in childhood (58,106,139). The majority of lifetime sun exposure occurs before age 20 (46,93,132,141). But, childhood sun safety is not normative: (a) children are inadequately and inconsistently protected from the sun (9,24,64,120), so severe sunburns are a relatively common occurrence before age 20 (18,32,54,83,94,117,145); (b) parents and children infrequently use protection measures that avoid or block UVR altogether (e.g., staying indoors, wearing protective clothing), relying instead on sunscreens that can still permit UVR exposure (23,24); (c) tanning norms that produce intentional UVR exposure develop during childhood (18,91,97,140).

B.5. Strategies for Increasing Sun Safety for Children and Adolescents

Because lifestyle patterns form at this age, there is an excellent opportunity to instill sun protection habits during childhood (27,58,125,137). Schools are potentially the most efficacious setting for delivering sun safety training: (a) nearly all children regularly attend school up through grade 10 (age

15) and are available to an intervention (22,27,58); (b) schools are a credible community channel (24), are responsible for children's well-being, and consider health education an appropriate mission; (c) controlled educational environments in schools facilitate program implementation and repeated presentations to obtain progressive changes (111,149); (d) environmental experiences can be designed into prevention curricula to reinforce desired behaviors; (e) children can be accessed at school for assessment and schools can help track study participants. Despite these advantages, sun safety curricula have only recently been developed for U.S. preschools and elementary schools (22,25,27,89).

Other community channels are less attractive than schools for sun safety programs. Physicians have limited contact with children; most contacts are for acute care, with well-child checkups not recommended after age 7; managed care systems limit time with each patient making it hard to include prevention; and children without health insurance or Medicaid may not visit physicians. Community groups and organizations attract a very selective population of children (e.g., athletes, gregarious children, religious children, more affluent children), may not see health education as their mission, and do not have a central administration. A mass media campaign has high start-up costs, may be hard to sustain, and expose children to messages inadvertently in environments not conducive to learning and persuasion.

B.6.National Skin Cancer Prevention Guidelines and Healthy People 2000

In 1993, the National Centers for Disease Control and Prevention (CDC) reported to Congress that skin cancer morbidity and mortality could be reduce through prevention efforts to reduce sun exposure. In its own effort to reduce national sun exposure, CDC launched the National Skin Cancer Prevention Education Program. As part of this program, CDC plans to issue national skin cancer prevention guidelines for K-12 comprehensive health education through the Division of Adolescent Health in the U.S. Center for Health Promotion and Disease Prevention in 2000. In theory, the guidelines will be used by all U.S. schools to identify fundamental sun safety skills and to incorporate sun safety in their educational curricula and school safety policies. All U.S. schools will be encouraged to adopt them. The current K-5 SDHW curriculum and its proposed interactive CD-ROM programs will be uniquely poised to help schools fulfill these recommendations with evaluated, comprehensive, effective, sun safety education materials. The CDC's program and the proposed project are aimed at addressing the Healthy People 2000 objective to "increase to at least 60 percent the proportion of people of all ages who limit sun exposure, use sunscreens, and wear protective clothing when they are exposed to sunlight, and avoid artificial sources of UV light" (167).

B.7.Computer Use in Education is Increasing

President Clinton has made computers in the classroom a national priority and described technology as “an engine of our economic growth and has fundamentally changed the ways we learn, how we do business, and the skills students in America need to flourish in the world of work” (118). Children today must master computer skills to be prepared for a lifetime of computer use. The President has challenged states, communities, business, families and teachers to ensure that by the year 2000 every classroom in America is connected to the Internet with high-quality computers, creative software, and well-trained teachers to enrich education. “In some cases, scores on standardized tests of basic skills for children taught with computers rise by 10-15% compared to the scores of those taught using conventional instruction” (118).

The CD-ROM programs proposed in this Phase II project will conform to the President’s national goals and to recent trends in American education. A national survey (154) found that use of computers and telecommunications by students at school is increasing rapidly (from 29% in 1984 to 59% in 1993). Public school access to the Internet also is increasing rapidly (153). On average, 55% of schools have videodisc players, 74% have cable TV, 28% have satellite access, and 70% have Internet connections (95). On average, schools have one CD-ROM multimedia computer for every 21 students (95). In Colorado, the ratio is 20:1 (95). Teachers do use computers for instruction. In a 1997 survey (155), 20% of teachers in all public schools regularly used computers for teaching; 16% for professional growth; and 15% for curriculum development. A majority (54%) of public school teachers give ‘using computers for classroom instruction’ as the #1 or #2 activity that they use computers for at school. The 1998-1999 Colorado District Technology Survey (195) found that 100% of districts have incorporated technology use into student performance standards (includes elementary level). In 1998-99, Colorado districts spent $358,587 on technology, including $44,720 on software. Nationally, more than $570

million was spent by schools on digital content in 1998 (196). Educational technology is in demand.

Educational CD-ROM programs also can be accessed at home--representing a secondary product market. Students' use of home computers rose from 12% to 28% (1984 to 1993) (154). Access to home computers is even higher than use, indicating the potential for growth. In 1993, an average of 33% of homes with children aged 3 to 17 had home computers (150). Parents, educators, and students believe computer skills are necessary for future success (136). One recent study showed even higher penetration rates. Most (78%) parents participating in the Family Sun Safety Project (Dr. _____, P.I.) had access to a computer in 1996, and a large number of these computers had a CD-ROM drive (71%) and/or were connected to the Internet/World Wide Web (43%). Phase I student participants had ample access to computers (Final Report section). All 24 students use computers at school and like using them. Almost 60% of Phase I students (n=14 of 24) use computers at home and 8 students reported that their home computers had a CD-ROM drive. Ninety-two percent (92%) of students said they use a computer at least once per week (42% used a computer every day). Children as young as five were knowledgeable about how to use a mouse and navigate a visual/verbal computer program. With substantial and rising computer access, use, experienced users and need, the market for innovative, quality software will be significant.

B.8. Technology and Multimedia Enhance Children's Comprehension

There is no doubt that education technology positively impacts student learning and achievement. In a 1999 report, the Milken Exchange on Education Technology (194) analyzed over 700 research studies of education technology and concluded that "students with access to computer-assisted instruction, or integrated learning systems technology, or simulations and software that teaches higher order thinking, or collaborative networked technologies, or design and programming technologies, show positive gains in achievement on researcher constructed tests, and national tests (194). Another review of 219 studies from 1990-1997 found that students in preschool through college in technology-rich environments experienced positive effects on achievement in all major subject areas and improved attitudes toward learning and their own self-concept (197).

The attractiveness of multimedia for students has been confirmed by this proposal's Phase I counterpart (see Final Report) and published studies (163,164,166). Students react positively to CD-ROM. The interaction between interactive animation and learning, however, is more subtle and dependent upon other factors such as text level, text type, media-text integration, clear objectives, and non-diffuse use (163,166,194). One study of sixth-graders' ability to recall information from print, text on screen, and multimedia (text with images and animation on CD-ROM) and draw inferences from it found text on screen produced higher recall scores but multimedia produced higher inference scores (166). In a follow-up study (163), animation helped increase understanding of underlying principles even though it did not increase recall. Moreover, the highest comprehension scores occurred in the condition including text plus animation with captions. The authors concluded that multimedia should be selected if the educational objective is to enhance comprehension rather than merely enable recall of information. This may help explain the discrepancy between Kindergartener's pretest and posttest knowledge scores in the Phase I feasibility study (see Final Report).

Other researchers argue that children are exposed to many layers of information outside of school and learn from many different types of media in their everyday lives. Children expect the same layering of information in school, but are limited to only a few types of media in the traditional school setting (164). In today's high tech society, children need to learn from visual and interactive sources as well as traditional text and oral sources. Multimedia is not intended to replace the teacher, but rather to enhance instruction and create avenues for active participation. CD-ROM programs allow students to make their own observations and to gain useful experience through skill-building exercises (198). CD-ROM programs can play a positive role in educating students, as long as effective design criteria are applied.

B.9. Agent-based Interfacing and Information Tailoring

Perhaps one of the best ways of using educational computer technology is to provide adaptable guidance that can help students acquire and transfer general intellectual skills through reflection and inquiry. Pedagogical software agents have many characteristics of such a system. Through the technical expertise of Dr. _____ from Colorado State University, we will integrate this innovative approach into our multimedia production.

In a recent evaluation of agent feasibility with sixth grade students, Dr. _____ designed a computer support environment (SCI-WISE) for learning and inquiry. The system incorporates software advisors that have general, non-domain specific knowledge about a skill, such as hypothesizing. Their knowledge includes concepts, strategies, examples, referrals to other advisors, and criteria for evaluating good products and skills. The advisors offer their advice at context-specific times and can adjust the advice they give based on student user actions. Also, the students control the type of advice the advisors give and when they give advice, as well as modify the contents of advisors' knowledge bases. The system is based partly on a theoretical framework of levels of agency and goal orientation. This framework assumes that giving students higher levels of agency facilitates higher-level goal orientations (such as mastery or knowledge-building as opposed to task completion) that in turn produces higher levels of competence.

A study of 64 sixth-grade science students was conducted. Students took a pretest that included an open-ended inquiry question and a questionnaire that measured their goal orientations for science projects. The students worked in pairs on an inquiry project about memory. They used one of two versions of SCI-WISE, one that was modifiable and one that was not modifiable. After finishing the project, the students took a posttest similar to the pretest, as well as evaluated the system they used. The main research hypotheses were that knowledge-oriented students using the modifiable version would rate the system higher and use it more effectively than task-oriented students. With students using the non-modifiable version, the opposite result should occur. The results supported half of the hypotheses generated from the theoretical framework. Overall, the students rated SCI-WISE on average as "very helpful" in completing their inquiry projects. All students were able to complete their project using the system's advisors. They also rated the system as potentially useful in other classes. Knowledge-oriented students tended to rate SCI-WISE higher, use general purpose and system development advisors more than task-oriented students, and select general advice and hints more than task-oriented students. Overall, the SCI-WISE system showed promising initial results for helping students of a wide range of achievement levels and goal orientations develop inquiry skills.

B.10. Additional Advantages of Interactive Multimedia for Education

This proposal will make the Grade K-5 SDHW curriculum available in an interactive multimedia format on CD-ROM, and eventually, in the Internet environment. "Interactive multimedia programs" denotes two types of computer-based applications: CD-ROM-based and Internet-based. CD-ROM programs have become commonplace in homes and schools. They incorporate a variety of media, including sound, graphics, animation, digital video, and text, to create a free-standing, computer-based learning experience. They visually engage students by allowing them to click on different objects on the screen and by display animations or simulations -- transporting the student to different worlds and world views. Effective learning programs meet educational objectives by presenting valuable, meaningful educational content and demonstrating information that is difficult to present orally or in print. An example of a relevant activity would be the exploration of fabric construction with a "spectroscope" -- an imaginary machine into which students could place fabric samples and have the “scope” zero in on a magnified analysis of the construction, tightness and sun protection of its weave. By receiving points for accurate performance, students can become involved in a competitive learning game, a common device used with almost every well-designed computer-based instructional program.

Internet-based (on-line) programs translate these engaging activities and rich content to a web-based environment so that the programs can be disseminated worldwide. Currently, bandwidth requirements of the Internet impose significant constraints on instructional programs; however, with creative use of streaming technologies (e.g., Realaudio and Realvideo), and the advent of the next generation Internet technologies on the horizon, much of the excitement and engaging attributes of CD-

> *Intelligent tutoring systems have been designed and studied since computers were available (168), including as (a) simple tutors (169), (b) facilitators in a "constructivist" environment as with Papert's (190) LOGO system or other microworlds such as ThinkerTools (170), (c) methods of structuring arguments with feedback (171), (d) ways to reflect on one's work (172), or (e) "partners" in discovery (173). How agents are different from an "object" (as in object-oriented programming) or "programs" in*

ROM based instructional programs can be preserved. We are not committing to Internet-based (on-line) programs in this proposal. However, we will use authoring tools (e.g., Director, Toolbook) which can allow the CD-ROM to be "taken to the web" (for expanding markets) using plug-in technologies and/or html/JAVA solutions in a future project. In summary, interactive multimedia CD-ROM programs are an attractive and effective educational technology and have many advantages for elementary education (see Figure 2).

Figure 2: Advantages of Interactive Multimedia for Cancer Prevention Education

- Overcome many uncontrolled variables found in the traditional classroom setting.
- Provide consistent, reliable information presentation that is thoughtfully designed, based on well-researched content, and grounded in solid instructional design and behavioral principles.
- Do not fatigue with student interaction as the school day progresses.
- Promote greater receptivity, comprehension, and integration of information than classroom instruction (4,98,101,119).
- Increase students' sense of their own capabilities, increase motivation, and boost self-esteem.
- Can cater information to very discrete target populations.
- Demand continual involvement of students (promoting sustained attention and better comprehension [98]).
- Challenge and empower students to make decisions, solve problems, resist peer pressure (e.g., to sunbathe), and practice new behaviors (e.g., how to ask for and apply sunscreen).
- Can provide personally consequential feedback to the user (116), links to tangential data banks with more detailed explanations of interesting or difficult concepts, and increase self-awareness. These attributes make attitudes more salient, accessible (102), and increase knowledge-consistent behavior, self-efficacy expectations, and confidence (29,30,137,138).
- Facilitate acquisition and application of sun safety skills by using attractive, similar peer models and "teachers" to repeatedly demonstrate skills in vivid and fast-paced sequences depicted in contexts relevant to children.
- Promote student attention, skill acquisition, repetitive practice, goal-setting and monitoring, and the formation of positive outcome and self-efficacy expectations, crucial aspects of behavior acquisition as outlined in SCT.
- Can be very cost effective, if computer infrastructure is in place, because they can disseminate information to many users (especially with a site license), save paper and printing expenses for the school, and be updated easily
- Overcome barriers of physical and social distance (123,127,156);
- Engage users in self-paced, user-centered, collaborative learning environments where users can thoroughly explore content with features such as Web-based hypertext links, graphics, digital video, animation, and interactivity (11,55,60,81,128);
- Deliver accurate, consistent, and thorough information (31,50); improve the quality and quantity of information (11,55,60,62);
- Collect data from students to assess learning and to tailor messages and feedback for different needs (6,55,60,100,130, 163);

- Provide private, non-judgmental teaching (6,100);
- Can give easy access through hypertext links to local and national health information and support programs;
- Promote anonymity & honesty when answering questions on personal characteristics, knowledge, attitudes & behavior (10,49,143);
- Overcome literacy problems by using audiovisual and 3-dimensional navigation devices rather than linear printed text only (60,81);
- Can be more effective than printed or spoken instructions (39,50);
- Yield shorter learning times and longer and larger knowledge retention (6,10,110).

Development and implementation of complex interactive multimedia systems is neither trivial nor easier than traditional, well-designed curricula. However, once created, programs are enduring, engage students with age-specific visuals and audio not just text display, encourage shy students by creating a non-threatening, self-paced, private learning environment, improve students' abilities to retrieve complex, rich information matched to their level of understanding, and automate feedback on student performance. Free-standing programs liberate teachers to concentrate on more abstract, individualized, and advanced concepts and instruction in the classroom. When linked to Internet sites (such as the EPA, NOAA, ACS, NCI), the CD-ROM programs can make sun safety instruction available beyond traditional school walls.

B.11. Commercial Opportunities and Significance

B.11.1. National Survey of School Principals. In the spring and fall of 1998, Ms._____(PHS), Dr. _____ Buller (____) and Dr. _____ (_____ University) conducted a telephone survey of a national sample of 411 elementary school principals for the Environmental Protection Agency (EPA) about their schools' sun protection policies and practices, including classroom instruction. Notably, 87% of principals reported that sun protection education was important to them and their school. Also, 21% of the schools had taught sun protection in the last five years (78% of these in the last year); 11% used a written curriculum for sun protection education. And, 35% reported that they plan to teach sun protection in the next three years. When asked to name the types of sun protection education materials they desire at their school, 82% wanted sun safety CD-ROM programs and 78%, written instruction material like the SDHW.

While desired by schools, comprehensive, integrated instructional material for elementary school-aged skin cancer prevention education is not plentiful. The existing SDHW curriculum and proposed interactive CD-ROMs have little or no competition in the marketplace. To date, sun protection interventions have been implemented in school settings either by funded research projects or not-for-profit agencies (see for example Health Education and Behavior, Vol. 26(3), June 1999). None has yielded an evaluated, age-appropriate, effective, comprehensive set of integrated instructional material such as those being created as the SDHW.

B.11.2. Commercial Application and Competitive Advantage. The nation's schools sent $571.3 million on stand-alone software, comprehensive courseware (integrated learning systems), and on-line courseware in 1998--up from $519.1 million in 1997 (196). Despite this, 59% of 1,407 teachers polled in a national survey (1999), said it is somewhat or very difficult to find software to meet their classroom needs, with science teachers reporting the most difficulty (204). The SDHW CD-ROM programs will have commercial application and competitive advantage since they will be introduced into an expanding market, conform to national science and health standards, meet the CDC's skin cancer prevention education recommendations, appeal to science and health teachers, and fill a current void in an area of high demand. The CD-ROMs will be comprehensive, creative, innovative, and effective at increasing student learning, and rated extremely favorably by students and teachers alike. They will be unique, not only because of their content, but also because they will have the companion SDHW classroom curriculum to achieve multi-layered education. Currently, there are no comparable competitors. The

SDHW CD-ROM programs will be marketed along with, and independent of, the SDHW curriculum to meet the needs of two end users—teachers who would use the CD-ROM programs in conjunction with a comprehensive classroom curriculum and teachers who would use the CD-ROM programs independently (Phase I Final Report for results of teacher preferences).

B.11.3. Market Research. A Medline review of academic research literature and an extensive Internet search of multiple education technology publishers and clearinghouses and large computer product retailers [e.g., The Gateway to Education Materials (199), EDUCORP (200), J & R Computer World (201), Hopkins Technologies (202)], netted one adult-level CD-ROM title on skin cancer. No sun safety CD-ROMs for children were identified.

B.11.4. Market Size and Sales Goals. The size of the public elementary school market alone is vast and growing. A preliminary primary market was estimated based on 1990 Census data (157) which showed that there were 32,007,392 children between the ages of 5 and 13 (68.89% of the school age population) in the U.S. Of these children, 28,012,869 were enrolled in public elementary schools (87.52% of the elementary school population). Applying these percentages to the number of K-12 public schools in the nation (81,608), we estimated that there were 56,220 public elementary schools. Based on these figures, we estimated that there were 498 students per elementary school in the U.S. The 1997 Technology Survey (95) found that there was one multimedia computer for every 21 students in U.S. public schools. Thus, we estimate 24 multimedia computers per public elementary school.

The CD-ROMs will be packaged and sold individually by grade level or as a three-CD set. Based on the above statistics and product packaging plan, we estimate the potential primary target market for the Phase II sun safety CD-ROM programs to be approximately 56,000 schools. We estimate product sales to be between 56,000 and 168,000 units, assuming that each of the 56,000 schools purchases between one (two grades) and three (six grades) CD-ROM programs for teachers to share. This estimate of potential market size and potential product sales is actually conservative because elementary schools typically have enrollments smaller than 498 students per school so there may be more than 56,000 schools and it does not include non-regular public schools (e.g., charter and alternative) or private schools which would increase the market by 14%.

Not every school in the potential primary target market would purchase the product. Market share is a proportion of potential market size and a more realistic estimate of product sales. PHS's conservative first-year goal would be to sell 560 individual units, a 1% share of the estimated potential primary target market (56,000 schools). PHS's goal for Year 5 would be 2,800 units per year, a 5% share of the estimated potential market. We have set conservative initial sales estimates, because schools have a nine-month window in which to conduct business each year, the product has seasonal value, and schools will vary regionally in their interest in this product. Sales should grow with additional promotions and national education campaigns.

The CD-ROMs will be sold individually (two-year grade levels) or as a set of three CDs (all six grades). They will be priced to cover production costs, generate a reasonable profit for PHS, and fit within the boundaries of similar products in the marketplace. It is anticipated each CD-ROM will be in the $15 to $30 range and the three-CD set in the $40 to $85 range. If 1% of the primary market purchased one unit in the first year, PHS would generate $8,394 to $16,794 in revenue assuming a purchase price between $14.99 and $29.99. Our five-year annual sales goal would be a 5% market share or roughly $41,972 to $83,972. Since 65% of public schools in the U.S. have a local-area network (95), site licensing would be an alternative way to market the CD-ROM programs. Another marketing strategy that PHS will explore is Internet delivery. More than 70% of public schools nationally and 82% of Colorado classrooms have Internet access. With this penetration, PHS could sell password-accessed subscriptions to the SDHW program. Customers could benefit from continual updating and upgrading of the programs and reduced shipping costs.

Secondary markets for this product include public, private, charter and alternative schools (U.S., other English-speaking countries), preschools, and after-school programs. The market reaches beyond the traditional school environment as well to tertiary markets of private homes, public libraries, dermatologist offices, and state departments of health, hospital health educators, and managed care corporations.

B.11.5. Commercialization Plan. In order to reach the five-year sales goal, a multi-level strategic marketing plan will be implemented: (1) PHS will contract with one or more multimedia marketing

companies to promote the CD-ROMs through catalogs, publishers, tradeshows, and Internet sites; (2) PHS will promote the CD-ROMs as a “gift with purchase” to sun protection industry partners (e.g., shade structure and UV equipment companies) that market their products to schools; (3) PHS will market the CD-ROM directly to consumers through PHS and AMC channels (e.g., websites, catalogs, direct mail, newsletters, conference exhibits, journals, and educational events; and (4) PHS will market the sun safety CD-ROMs to public health, health care, and managed care organizations for their patient, member, and family education and outreach programs (see below). In many cases, the CD-ROMs will piggyback onto on-going SDHW curriculum commercialization programs.

Currently, PHS is planning the marketing and distribution of the proposed CD-ROM products with two multimedia companies -- _____, Inc. (_____, President) and _____, Inc. (_____ , President). _____Productions (____, a subsidiary of _____International, is a full service interactive multimedia development and marketing firm with success in niche markets. Founded in 1996 and based in Irvine, California, it specializes in CD-ROMs, web-access CD-ROMs and World Wide Web sites. _____offers a unique ability to bring creative products to market quickly. Current CD-ROM productions include "Star Trek Voyager - Missions in Science" with ViaCom/Paramount Studios and Edmark (IBM Subsidiary (pending)) and the educational science CD-ROM "Xenomorphology" with NASA, SETTI and Pyranah Publishing. _____currently markets a breast cancer CD-ROM for _____ Cancer Research Center called “The Personal Guide to Breast Cancer.” In the last year, the Personal Guide has been distributed to participants in _____’s Day of Caring events for breast cancer survivors, purchased by a large national health care corporation, and featured on the QVC home shopping network. Sales in the first year of representation totaled over $17,000. Currently, an advertising agency in Australia is contemplating national licensing of the product. _____would like to expand its representation of multimedia products to include the sun safety CD-ROMs developed by this project (see letter in Appendix A).

_____, Inc. (_____, a Madison, Wisconsin corporation started in 1978, publishes multimedia instructional CD-ROMs for the K-12 education market. Currently, _____ publishes ten health education titles that were originally developed at the University of _____ and _____ University. Under exclusive distribution licenses with these universities, ___ is responsible for packaging, production, pricing, promotion and on going technology development of these titles. ____ has partnered with approximately 25 companies to distribute the CD-ROMs through their catalogs. In addition, they promote their health CD-ROMs each year in 40 national tradeshows and send thousands of CD-ROMs for preview to schools and other organizations involved with health education and prevention. _____is anxious to license the sun safety CD-ROM programs produced by this project

PHS has initiated inventive SDHW product promotions with two sun protection companies: _____Ô , Inc. (_____, President) and _____, Inc. (_____, President). _____ markets large shade structures to schools and day care centers in the southern and eastern U.S. _____ purchases the SDHW curriculum encoded in cross-platform Acrobat Reader 4.0 files on CD-ROM and gives it to customers as a gift with the purchase of a shade structure. _____ had the SDHW curriculum evaluated by the _____ County School District in Florida. Mr. _____, Health and Science Curriculum Advisor, gave the curriculum a very high approval rating and recommended that _____ adopt it for dissemination to Florida schools. _____ is anxious to expand this successful promotion to include the interactive sun safety CD-ROM programs (see letter of support in Appendix A). _____ markets a watch-like ultraviolet radiation detector. Currently, it is packaging their UV detector with the SDHW curriculum for promotion in Fisher Science Education, a national science laboratory education catalog for teachers (see letter of support in Appendix A). This joint promotion will be expanded to include the interactive SDHW CD-ROMs. Additional catalog promotions also are planned.

As it does currently for the SDHW curriculum, PHS also will promote the SDHW CD-ROMs directly to consumers through _____and ____ websites, other educational software websites, a catalog of cancer prevention materials, the _____ quarterly newsletter and Annual Report, national AMC educational events and national clearinghouses of health education materials (e.g., NCI, CDC, ACS). SDHW currently is being promoted on the Internet by _____New Media Information, the most complete listing of multimedia titles in print (203;see Appendix P) and various clearninghouse websites (e.g., National Resource Center for Health and Safety in Child Care, Dr. R. Neil, Director). The CD-ROMs also will be introduced to school administrators through a direct mail campaign, journal ads, and exhibits at educational conferences and curricula trade shows.

B.12. Grade K-5 Sunny Days, Healthy Ways Sun Safety Curriculum

_____(SDHW) is the only skin cancer prevention sun safety curriculum in the U.S. that is integrated across all elementary school grades, fulfills state and national comprehensive health and science education standards, and has been systematically evaluated through progressive field tests and revisions (see published papers in Appendix B). SDHW was honed and evaluated by a project team (NCI Grant #CA_____) led by Dr. _____. Ms. _____ was SDHW's primary author and editor. Several staff, school administrators, teachers, community dermatologists, health communication experts, and curriculum consultants also contributed to its development. A few other researchers have published evaluations of sun safety programs for elementary schools (see e.g., 58); elementary-school sun safety projects are underway in New Hampshire and Chicago; day care sun safety programs are being implemented in Massachusetts and Arizona; and high-school projects are occurring in Chicago (102). None have published a complete curriculum or library of CD-ROM programs.

The printed SDHW curriculum teaches sun safety skills with health, science, mathematics, society and culture, and language arts activities for grades K, 1, 2, 3, 4 and 5. This inter-disciplinary cross-curricular approach is consistent with recent national science education reforms (see e.g., 2) and allows SDHW to be implemented without reducing mandated instruction in these areas. By linking SDHW to science, it is more attractive to schools. It is consistent with the Healthy People 2000 national objectives and the CDC's K-12 comprehensive health education guidelines, including the anticipated skin cancer prevention guidelines, so it can be added to comprehensive health education curricula. Its format follows the Madeline Hunter model (74) of the essentials of effective instruction. (See SDHW sample unit in Appendix C.)

The SDHW was developed following principles of Social Cognitive Theory (SCT; 8,158). According to SCT, sun safety behavior by children is determined by a reciprocal relationship between personal and environmental factors. The SDHW produces sun safety by teaching requisite skills through demonstration and mental and physical rehearsal (e.g., selecting a proper type of hat and other protective clothing, identifying and using shade in outdoor environments, requesting sunscreen and other protective articles from adults). It also creates positive outcome expectations (e.g., avoidance of sunburn, protection of skin) and attempts to reduce barriers to sun safety (e.g., negative outcome expectations like sunscreens are messy, hats are unattractive, pants are too warm). Self-efficacy expectations are improved by teaching children that they are responsible for keeping their own skin healthy and demonstrating ways of doing so. The SDHW addresses these psychosocial variables at age-appropriate levels. Grades K and 1 are comprised of interactive exercises, activities, games, storybooks, and poems in four 60-minute units promoting use of shade, protective clothing, and sunscreen. The curricula for Grades 2 and 3 introduce some didactic instruction along with interactive activities in four units on the sun, human skin, sun safety strategies, and skills for putting sun safety into action. Grades 4 and 5 incorporate science experiments and computer-based activities along with lectures and classroom activities.

Evaluations of SDHW showed that it teaches children at all ages relevant sun safety skills (using protective clothing, shade, and sunscreen), provides older children with the scientific basis for positive outcome expectations (avoid sunburn, healthier skin), reduces perceived barriers to sun safety (sunscreens are messy, suntan is desirable), increases sun safety intentions and actual sun safety, and reduces UVR exposure (measured by colorimeter). The SDHW also provoked parent-child sun safety discussions (22,23,25-27). We anticipate that the CD-ROM version of the SDHW will be equally successful at teaching these skills, improving positive outcome expectations, reducing barriers, and increasing sun safety.

B.13. SDHW CD-ROM Programs

Beginning in July of 1998, Ms. _____ led an NCI Phase I SBIR project (CA_____) to establish the merit and feasibility of producing sun safety CD-ROM program activities for elementary schools to integrate into their science and health education to meet the CDC's national skin cancer prevention guidelines for K-12 comprehensive health education. The project produced two prototype CD-ROM program activities for children in grades K and 2 based upon one unit (i.e., using sunscreen for grade K; and finding shade for grade 2) from the Grade K-5 SDHW sun safety curriculum and demonstrated the feasibility of CD-ROM use by students and teachers. A complete description of project implementation and results is provided below in the Phase I Final Report. Currently, Ms. _____ is leading another

SBIR Phase I project to produce prototype CD-ROM program activities for middle school students (CA_____).

C. PHASE I FINAL REPORT

C.1. Budget Period

The budget period for this Phase I project is from September 15, 1998 through August 31, 1999. However, work on the project actually began on the proposed start date of July 1, 1998. This was necessary to accomplish project objectives within the elementary school academic calendar and complete data collection before the end of fall semester (December).

C.2. Key Personnel

The following key personnel devoted time and effort to this project:

Name	Title	Service Dates	Hours/Week	Hrs on Project
_____, MA	Principal Investigator	7/98 - 12/98	20 hrs/wk	520
_____, MS	Research Assistant	8/98 - 12/98	30 hrs/wk	600
_____, PhD	Contractor; Scientist	7/98 - 12/98	02 hrs/wk	52
_____	Graphic Art Director	7/98 - 12/98	10 hrs/wk	260
_____	Multimedia Developer	7/98 - 12/98	10 hrs/wk	260
_____	Instruct. Design Spec.	7/98 - 12/98	10 hrs/wk	260
_____, PhD	Multimedia Consultant	9/98 - 12/98	N/A	30

C.3. Specific Aims, Progress Toward Their Achievement, and Account of Results

C.3.1. Specific Aim #1: Produce two prototype CD-ROM programs for students in Grades K and 2 based upon two units from the Grade K-5 Sunny Days Healthy Ways (SDHW) sun safety curriculum.

C.3.1.1 Progress Toward Achievement. The AMC Health Communications Core (multimedia development subcontractor) produced two creative 15-minute prototype interactive multimedia (CD-ROM) programs as proposed. Multimedia development began with the selection of activity content (i.e., from SDHW curriculum) and drafting of concept plans. This was followed by scriptwriting; audiotaping narrators, voice-overs, and other sounds; graphic design and illustration; multimedia programming; and beta-testing to produce the two prototype multimedia activities for student and teacher interaction. The CD-ROM programs corresponded with two lessons from the printed SDHW elementary school sun safety curriculum: Using Sunscreen (Grade K, Unit 4) and Finding Shade (Grade 2, Unit 2).

Kindergarten Concept Plans. The proposed main concept for the grade K activity was to depict multiple screens of four different children participating in varied outdoor activities (e.g., soccer, swimming, sledding) and teaching the behavior skills of applying sunscreen on all exposed skin prior to going outdoors. Students would be prompted to "click" on all parts of each character's body that needed sunscreen before they could go out to play to rehearse the skills. When the student would click on an exposed area of skin it would turn a bright color to indicate the application of sunscreen. Fun audio bites would provide feedback for correct and incorrect selections to help students monitor their performance and provide positive reinforcement for correct skill usage and build self-efficacy. The student could not move forward in the activity until all the unexposed areas of skin (e.g., legs, arms, face, neck) were brightly colored. This main concept was approved by Ms. _____, P.I., and the activity was titled "The 5 W's of Sunscreen."

The four children would be illustrated with appearance characteristics of the four major skin types: (1) fair-skinned with blond hair; (2) light-skinned with light brown hair; (3) olive-skinned with dark brown hair; (4) black-skinned with black hair. This concept was proposed to help teach students that everyone, regardless of skin color, needs to protect their skin in the sun. This concept was adopted.

A third adopted concept involved the seasonal nature of the activity each character was doing. Activities common to the four seasons were used to help teach students that sunscreen should be worn all year round, not just in the summer.

A forth concept was to provide students with lesson content and instruction before they proceed with the interactive activity and attempt to put sunscreen on the characters. The proposed concept for the lesson presentation was to present the 5 W's of Sunscreen: (1) what you should use; (2) who should use it; (3) where you should use it; (4) why you should use it; and (5) when you should use it. This format would provide a simple way to present to the students the fundamental skills and outcomes expectations related to sunscreen use. Based on this content (especially the "where" you should apply it), students could make decisions needed to apply the skills into the activity. Concepts and information presented would be simple and direct for this young age group. More complex topics (e.g., SPF values, UVA/UVB, broad spectrum sunscreen) would be avoided. This concept of providing age-appropriate lesson content at the beginning of the activity was adopted. In addition, a summary of content learned was added to the end of the "painting" activity.

A fifth concept was to provide students with a color printout of their work "painting" the characters with sunscreen to provide immediate performance feedback and "proof" of their ability to make correct choices. It also could be used as an assessment tool by teachers. This concept was not adopted due to technology and resource limitations of the schools.

Grade 2 Concept Plans. The proposed main concept for the grade 2 activity was to depict multiple screens of four different, yet common, sources of shade (e.g., house, tree, beach umbrella, ramada). For each shade source, student would "click" on five times of day from early morning to late afternoon. When a student would "click" on each time of day (i.e., early morning, late morning, noon, early afternoon, late afternoon), the program would show where the sun was positioned and what size shadow, or shade, was made by the shade object. Being able to predict the presence of shade and it's relation to time of day is an essential component of the shade use skill. It is hard to illustrate in classroom presentations. In addition to the graphic illustration, a narrator would provide important information about how to choose shade at each time of day. Fun moving graphics would "reward" activity completion and the student could not move on to the next shade object until all five times of day were chosen. The proposed title was "The Shade Show." This main concept was adopted.

As with the Kindergarten program, this activity addressed providing students with effective lesson content and instruction before they would proceed with the interactive activity and investigate different sources of shade. The proposed concept for lesson text (with graphic illustration) was to show the sun moving across the sky from sunrise to sunset over a shade object and show in fluid motion how shade changes in size throughout the day – from big to small to big again. This format would provide a straightforward way to present the fundamental information about how shade changes throughout the day, when it is best to play outdoors, and when it is best to play indoors are important skill components and outcome expectations. Thus, the four shade object activities provided students with an opportunity to investigate what they learned in the introduction and see shade in action throughout the day for several sources of shade. Concepts and information presented would be simple and direct for this young age group. This concept of providing age-appropriate lesson content at the beginning of the activity was adopted and a summary of content presented was added to the end of the shade activity.

A third adopted concept was to emphasize reading clocks and telling time – an important skill that is being developed at this age and is necessary for proper shade use. As often as possible and appropriate, screens would include the face and hands of a clock, with the time of day depicted, on the face of the sun. The intent was to teach students that (1) the sun's rays are strongest between 10 am and 3 pm; (2) shade is also smallest during these hours; (3) this is when you should play indoors; and (4) if you have to be outside between 10am-3pm, play in the shade. For students not yet able to tell time, verbal and visual cues would link time of day with a common activity such as waking up, eating lunch, or catching the bus. A concept proposed for both the Kindergarten and second grade programs involved using children as narrators and voice-overs. To examine a variety of voices and narration styles, the Kindergarten program would use a female child's voice and two adult voices (male and female), and the second grade program would use the voice of a male child and a female adult. It was proposed that students may respond more favorably to a voice similar in age to their own age. The concept of using a variety of voices was approved.

Scriptwriting. Based on the approved activity content and concepts, _____, Instructional Design Specialist in the _____Health Communications Core drafted scripts for the two prototype

programs (see Appendix D for complete scripts). Scripts were reviewed by _____project staff and revised to produce the final scripts.

Audiotaping. Four different individuals were recruited to provide the voices and narration for the programs: two adults (male and female) and two 8-year-old children (male and female). Four audiotaping sessions were conducted at _____the Multimedia Developer, and captured on a Macintosh computer. Each session lasted one to three hours.

Graphic Design and Illustration. The Core's Graphic Designer, drew each of the characters and other illustrations by hand and then scanned each item into Adobe Photoshop. The artwork was then transferred to Macromedia Freehand where it was colorized. Screen backgrounds were created using Freehand, Photoshop, or a combination of both programs.

Multimedia Programming. Graphics were given to the Core's Multimedia Developer to program activities, content and audio. The introductory presentation, interactive activity, summary and posttest were developed using rough graphics. Voice-overs and sound effects were created using Macromedia SoundEdit 16. Specular Infini-D was used to develop 3D graphics which were touched up and manipulated with Adobe Photoshop 5. Graphics were filtered with Equilibrium Debabelizer 3. Ideas, concepts and final components were developed using Macromedia Director.

Beta-Testing. The prototypes were beta-tested on computers that would most likely be in school computer labs today, and on computers that would most likely be in computer labs 2+ years from now (Phase III). The lower end computers were PowerPC Macintoshes and Pentium Windows computers. The higher end computers were G3 PowerPC Macintoshes, and Pentium II Windows computers. Although the programs ran a bit slow on the lower end machines, they were of sufficient speed for the students in grades K and 2.

C.3.1.2 Results. The first specific aim of this Phase I project was to produce two prototype CD-ROM programs for students in Grades K and 2 based upon two units from the Grade K-5 Sunny Days Healthy Ways sun safety curriculum. Working with the AMC Health Communications Core, this objective was successfully met. Two 15-minute CD-ROM programs were produced. Production was completed on schedule in four months time at a cost of $23,000.

C.3.2 Specific Aim #2: Evaluate the capability of Grade K and 2 teachers and students to use the prototype sun safety CD-ROM programs.

C.3.2.1 Progress Toward Achievement. The purpose of the Phase I project was to demonstrate that delivering sun safety education to Kindergarten and second graders on CD-ROM format is feasible, not to show that such a program would change children's knowledge, opinions, or behaviors related to sun safety which is the aim of this proposed Phase II project. The feasibility study aimed to show that children react favorably to, a prototype and that they can use it either with teacher guidance or on their own. It also aimed to show that teachers can utilize the product in their normal course of instruction and that they too react favorably to it. If achieved, these outcomes would show that an interactive multimedia SDHW is a feasible and desirable educational product. To achieve Specific Aim #2, it was necessary to recruit schools, teachers and students to participate in the project, have teachers and students interact with the CD-ROM programs, interview them, and analyze their responses. Achieving these aims did not require a pretest-posttest design.

Recruitment and Consenting. Upon notification of funding, the Principal Investigator re-contacted Mr. _____, Curriculum and Instruction Coordinator for the _____ County School District (_____). Mr. _____ facilitated the WCSD's formal review and approval of the project. In September, Mr. _____ contacted the 14 WCSD elementary school principals to determine their ability to participate in the project. Project staff had already interviewed the WCSD Technology Management Information Services Coordinator, Mr. _____Gilbreth, by telephone in August, and determined that all schools were eligible to participate based on technology requirements (e.g., Macintosh computers with CD-ROM drives). Four schools quickly agreed to participate and two of these were randomly selected by the Principal Investigator to participate. The Principal Investigator then contacted the principals and the teachers at these two schools to introduce the project and outline its requirements. Each principal recruited four teachers to participate in the project. All teachers at each school participated in teacher interviews. Students were recruited from two of the teachers' classes at each school. As planned, parental consent forms were obtained for 24 students. Dates for computer interaction and interviews were scheduled. Student assent was obtained from all 24 students before they used the computer program.

Instrument Development. Several forms and instruments necessary for project implementation and data collection were developed by project staff based on materials from previous related investigations detailed in the original Phase I proposal (e.g., Family Sun Safety Project, Body Fun Evaluation). These included: (1) a parent consent form; (2) a student assent form; (3) a teacher consent form; (4) a computer technology survey; (5) teacher interview questions on CD-ROM satisfaction and teaching format; (6) a brief 6-item student pre/post test for each grade to assess knowledge, attitude, behavioral intention; and (7) a student survey for each grade on satisfaction with the activity. Copies of Phase I consent forms and surveys are included in Appendix E and Appendix F. All were approved by the AMC Institutional Review Board (Peter Raich, MD, Chair) prior to use.

Computer Interaction and Interviews. Computer interaction and interviews were conducted in each school's computer lab with at least one teacher present. Interviews were conducted by PHS project staff and AMC Health Communications Core staff. Staff attended a two-hour training program on interviewing procedures lead by the Principal Investigator. Each interviewer followed a standard protocol obtaining student assent, pretesting, directing the student to play the CD-ROM activity, posttesting, and conducting the interview. The protocol for teacher interviews included obtaining consent, directing the teacher to play the CD-ROM activity, and conducting the interview. As students were playing the CD-ROM activities, staff recorded observations of their ability to navigate through the activity, follow instructions, make selections, and their reactions to playing the activities. Student interviews lasted 15-20 minutes; teacher interviews lasted 20-30 minutes. All students were interviewed with a teacher present (teachers were not involved in the interview session). The Multimedia Developer attended interview sessions to install programs, handle technical difficulties, and download computer-stored data.

C.3.2.2 Results. Evaluation methods included primarily qualitative, not quantitative, measures of product feasibility. Consequently, analysis was based on summarizing mostly open-ended responses by students and teachers, not on statistical analyses of numerical data. Qualitative results of all student, teacher, and technology coordinator interviews are reported, as well as some quantitative results from student pre/post tests, student and teacher computer recorded test scores (posttest only), and observations of student computer interaction patterns. In general, tables report items that were given as responses by two or more participants in the sample (by grade).

Computer Technology Survey. _____County School District (_____) has over 2,800 computers (Windows 95/98 and Macintosh platforms) for student and teacher use. School computer labs and classrooms are equipped with multiple computers and available during regular school hours and via remote access. Typical platforms are Mac Power PC, iMac, and mid-range IBM-compatibles. About half of these machines have CD-ROM capabilities. Each school has Macintosh computers in either a classroom, library, or computer lab setting. Some classroom and library computers did not have CD-ROM drives or sufficient memory and speed to run the CD-ROM programs. (These Phase I CD-ROM programs were developed using technology and equipment that will become the standards 2 + years from now). Fortunately, the computer labs had excellent Macintosh equipment including several brand new iMac computers. Every classroom has access to the Internet, with T-one connections. In (____), $850,000 a year is allocated to technology support and programs, and 18,000 hours of computer training are offered each year for teachers. Training includes Internet use, troubleshooting, e-mail, multimedia, and integration of technology into classroom lesson plans. The (_____) technology goals for the future consist of integrating technology into instruction, focusing on district standards with reading, writing, science and math and improving graduation rates. In summary, (_____) and participating schools had more than adequate equipment and technical support for implementation of the Phase I feasibility test. Their commitment to continued technological expansion and teacher training bodes well for their Phase II involvement and adoption of more educational multimedia.

Student Sample. Of the 24 students, 12 (50%) were Kindergarteners and 12 (50%) were second graders. We interviewed 11 girls (46%) and 13 boys (54%). The average age for grade K was 5.25 years and for grade 2 was 7.24 years. Nearly two-thirds (62.5%) of students in the sample were white and 37.5% were Hispanic. Students' hair color (8% red, 29% blond, 13% light brown hair, 33% dark brown hair, and 17% black), eye color (21% green, 17% blue-green, and 54% brown eyes; one case was missing), and skin tone (17% fair with freckles, 33% fair with no freckles, 21% light brown skin, and 29% dark brown skin) varied. When asked how their skin reacts to the sun, 29% said they always burn

and never tan, 58% said they burn and then tan, and 13% said they never burn. Students were evenly split on physical risk factors for sunburn and skin cancer (i.e., skin type, hair and eye color).

Student Interviews. Students had very little difficulty using the CD-ROM programs. All 24 students use computers at school and like using them. Fifty-eight percent (58%) of student participants use computers at home and 8 students reported that their home computers had a CD-ROM drive. Ninety-two percent (92%) of students said they use a computer at least once per week (42% used a computer every day). Children as young as five were knowledgeable about how to use a mouse and navigate a visual/verbal computer program. Minimal assistance was needed by these very young children. In fact, 58% of students described the activity as "very easy" to play. See Table 1 for responses to computer use questions.

Table 1: Student Computer Use (n=24)

	Grade K	Grade 2	Total
Like To Use Computers:			
Yes	12	12	42
No	0	0	0
Use Computer At Home:			
Yes	6	8	14
No	6	4	10
Home Computer Has CD:			
Yes	4	4	8
No	1	3	4
How Often Use a Computer:			
A Lot (once/day)	4	6	10
Sometimes (once/wk)	6	6	12
A Little (once/month)	2	0	2

C.3.2.3 Observations of Student CD-ROM Use Patterns. Kindergarteners and second graders had minimal difficulty with program mechanics. Some Kindergarteners had trouble figuring out where the cursor arrow was at times, had difficulty exiting the screen by clicking on the door, and could not remember which characters had already been chosen during the sunscreen game. Kindergarteners and second graders seemed to have some mechanical difficulty with the posttest questions. The answer choices seemed to be too slow for the computer-saavy students and they had to wait for the next prompt or started clicking before the narrator finished presenting the question and answer choices. These students are capable of handling a fast-paced program. Kindergarteners had trouble knowing when to click "yes" or "no" because of the quiz design. Verbal feedback on correct or incorrect answers and the ability to repeat instructions or questions would have been helpful to reduce confusion. Second graders had some trouble remembering which "time of day" buttons they had already clicked on. It would be helpful to have the buttons of completed items turn a different color, for example, to solve this problem. A few students tried to click and drag on inappropriate items, had trouble waiting for the directions to begin the activity, or clicked all over the screen looking for things to happen. In general, Kindergarteners were excited by the sights and sounds of the CD-ROM activity, especially the various voices and Spanish words. However, this excitement distracted some of them from concentrating on the content. They seemed to enjoy the activity, did not mind applying sunscreen to all four characters, and often asked to play a second time. Second graders' interest was held by the first two to three of the four shade objects but appeared to wane on the last object. All said they liked playing the CD although some seemed inattentive at times.

One technical difficulty was that one school's computer lab did not have headphones. Thus, the noise level of multiple CD-ROMs playing at the same time could easily distract or disturb students' concentration. We will recommend that teachers use headphones whenever possible.

Teacher sample. The sample (n=8) consisted of four Kindergarten teachers and four second grade teachers. All teachers were female, six were white and two were Hispanic.

Teacher Interviews. Teachers expressed very little difficulty using the CD-ROM programs without instruction. All of the teachers reported understanding how to play the CD-ROM activity. All said directions given in the activities were clear enough for their students to follow. On a scale from 1 to 5, with 1 being the easiest, the Kindergarten teachers' mean score was 2.0 and the second grade teachers' mean score was 2.25, indicating that the activity was easy for them to play. Several teachers expressed that the activity was "appropriately" easy for their students. Only one student (grade 2) thought it should be harder. In total, 87.5% of the teachers reported the CD-ROM programs were very

age-appropriate for their respective students. See Table 2 and 3 for teacher responses to CD-ROM use questions.

Table 2: Teacher Ease of CD-ROM Use (N=8)

	Grade K	Grade 2	Total
(Scale:1=easy; 5=hard)			
Mean Score	2.0	2.25	2.12
Age appropriate			
Yes	4	3	7
No	n/a	1	1

	Grade K	Grade 2	Total	Did yo
How easy was activity?				
Yes	4	4	8	
No	0	0	0	

Teachers were asked how the CD-ROM programs best fit into their method of instruction. Kindergarten teachers reported they would utilize the CD-ROM activity with computer lab sessions or as an individual center activity. Second grade teachers believed they would use the CD-ROM activity integrated with other lessons in the classroom or in computer lab with the entire class indicating use of more didactic instruction at this age. Individual teachers (K and 2) reported they would use the CD-ROM activity with "individual or pairs of students". When asked how teachers prefer to teach about sun safety issues, 100% of second grade teachers and 75% of Kindergarten teachers reported they would use a teacher-directed comprehensive set of classroom materials and a student-directed CD-ROM program together. One Kindergarten teacher would rather use the CD only. All of the teachers believed the CD-ROM activity was an effective health education tool for teaching children about sunscreen or shade. Collectively, second grade teachers reported this CD-ROM activity would strengthen science, vocabulary, and auditory learning skills. Individual Kindergarten teachers reported it strengthened direction-following skills, hand-eye coordination, and reading comprehension. Individual second grade teachers reported it strengthened telling time, math, and social studies. The majority of both Kindergarten and second grade teachers reported the CD-ROM activity could help them teach difficult concepts that are hard to get across in other ways. Individual teachers stated the CD-ROM activities could do this because they appealed to a variety of "learning styles" (e.g., visual learners and those who do best at their own pace), used simple language and directions, promoted listening skills, and used the same vocabulary as parents do at home.

When asked if teachers could adequately assess student learning from the CD-ROM program, 100% of the second grade teachers and 50% of the Kindergarten teachers indicted they could. The majority of second grade teachers believed they would give an individual post-quiz to assess student learning in the classroom. Individual Kindergarten teachers liked the idea of using "pictures better than words, " and would "like to hear positive noises for correct answers and negative noises for incorrect answers." A full 75% of the Kindergarten and Grade 2 teachers liked the computer-generated quiz, but would like it to give feedback (i.e., on correctness of the answer) to the students. This feature could be added easily.

Table 3: Teacher Ability to Use CD-ROM for Instruction (N=8)

	Grade K	Grade 2	Total
Curriculum & CD-ROM	3	4	7
CD-ROM only	1	n/a	1
Effective health education tool			
Yes	4	4	8
No	0	0	0
Strengthens other skills			
Auditory learning	1	2	3
Vocabulary	1	3	4
Science	1	2	3
Could assess learning?			
Yes	2	4	6
Ask quiz	2	3	5

	Grade K	Grade 2	Total	Method of i
How would use CD				
Computer lab	2	2	4	
With other lessons	1	3	4	
Teaches difficult concepts				
Yes	3	4	7	
For some kids	1	n/a	1	
Reflects real-life situations				
Yes	4	2	6	
No, more detail	1	n/a	1	
Some	1	n/a	1	
Liked computer quiz				
No	1	1	2	
Yes, needs feedback	3	3	6	

Sun safety is important				Will teach sun safety			
Yes	4	4	8	Yes	4	4	8
No	0	0	0	No	0	0	0

C.3.3 Specific Aim #3: Evaluate Grade K and 2 students' and teachers' satisfaction with and acceptance of the prototype SDHW sun safety prototype CD-ROM programs.

C.3.3.1 Progress Toward Achievement. Procedures for achieving this aim were the same as those for Specific Aim #2.

C.3.3.2 Results. Evaluation methods included analysis of primarily qualitative measures of students' and teachers' satisfaction with, and acceptance of, the prototype SDHW sun safety CD-ROMs. Analysis was based on coding, content-analyzing and summarizing mostly open-ended responses by students and teachers to the post-interaction interviews.

Student Interviews. Students were very satisfied with the CD-ROM activities. Response frequencies are listed in Table 4. Overall, 83% of participants liked the activities "a lot" (10 grade K students; 10 grade 2 students). Only one student reported liking the activity "not at all" (grade K). Most students (92%) said that this was a CD-ROM they would like to play again (10 grade K students; 12 grade 2 students), even though 71% of students thought that the game could be faster (8 grade K students; 9 grade 2 students).

Table 4: Student Satisfaction with CD-ROM Activity

	Grade K	Grade 2	Total
How Liked CD Activity			
A Lot	10	10	20
Some	0	0	0
The Kids/Characters	3	1	4
A Little	1	2	3
Not At All	1	0	1
Liked Them	20	28	48
Didn't Like Them	2	0	2
Sounds/Voices *			
Liked Them	10	19	29
Didn't Like Them	0	0	0
How Easy Was It To Play			
Very Easy	7	7	14
Kind of Easy	2	3	5
Kind of Hard	3	2	5
Very Hard	0	0	0

	Grade K	Grade 2	Total
What Liked Best *			
Putting Sunscreen on Kids	10	20	
Learning About Shade	n/a	9	9
What Didn't Like *			
Characters/Pictures/Colors *			
Girl in Swimsuit	2	0	2
What Would Make It More Fun *			
Nothing	3	4	7
More Falling Objects	n/a	2	2
Speed/Pace of Game			
Too Fast	4	2	6
Too Slow	8	9	17
Just Right	0	1	1
Would Play Again			
Yes	10	12	22
No	2	0	2

When asked specifically about the visual features (i.e., characters, pictures, colors, sounds and voices), project staff counted 29 positive responses and only 2 negative responses (multiple responses per student were allowed). Students mostly liked the characters, the girl characters, the indoor and outdoor pictures, and the colors of the activity. Individual second graders liked the "bouncing ball" and "the buzzing bee." When asked specifically about the audio features (i.e., sounds, voices), project staff counted 29 positive responses and no negative responses (multiple responses per student were allowed). Students mostly liked all the sounds, especially laughing, the narrators' voices, and Spanish words. Three Kindergarteners liked the female child narrator's voice and one liked the adult female voice. Individual second graders liked the female adult narrator's voice, the bus "beep-beep" sound, and the way the title was announced. Two second graders liked the male child narrator's voice and one did not like the adult voices.

Students were asked what they liked best about the CD-ROM activity that they played. Collectively, Kindergarteners liked the characters in the program (i.e., Natalie, CJ, Raymond, Josh) and putting sunscreen on them. Individual Kindergarteners liked "the sunscreen bottle," "the big hat," "the things they say," and that the activity "showed what the kids were wearing." Second graders liked learning about shade and things that make shade. Individual second graders liked the "poem at the end" of the activity, the "dropping hamburger," "kids talking and laughing," "picking shade things," "the clock on the sun," "the questions and answers," "the tree," and "information about the sun." When asked what they did not like about the activities, 14 of the 24 students said there was nothing they did not like. Two

Kindergarteners said they didn't like the girl character in the swimsuit. This may have been because she was the least sun safe character in the activity. Individual Kindergarteners did not like "the soccer girl," "putting sunscreen on," "the sun," and the "questions at the end" of the activity. One second grader did not like that the slide makes small shade.

Students were asked what would make the activity more fun to play. Of the 9 responses to this question, 7 students said "nothing" would make it more fun to play, and 2 said "more falling objects" (grade 2). Individual Kindergarteners said that the following would make the activity more fun: eating, rainbows, more sun, Barney, animals, longer length, more choices, more pictures, and making it harder to play. Individual second graders suggested rainbows, more choices, more falling objects, running, putting a person in the shade, more interaction, making it faster, harder questions, and more numbers on the sun clock. When asked if they had any other ideas about the activity, one Kindergarteners suggested "making it so you can play with a friend." One second-grader said he didn't know what a ramada was.

Teacher Interviews. Overall, teachers were very satisfied with the CD-ROM activity (Table 5). When asked on a scale from 1-5, with 5 being the best, how much they liked the game, teachers' mean score was 4.25. When asked if there was anything they liked or disliked about the CD-ROM, teachers reported liking the age-appropriateness and the ethnic diversity of the characters in the CD-ROMs. Teachers disliked "nothing" in the CD-ROM activity. All teachers said that sun safety is an important issue and warrants attention in the classroom, and plan to teach it in the classroom this spring.

Table 5: Teachers Satisfaction with CD-ROM Activity (N=8)

	Grade K	Grade 2	Total
(Scale: 1=worst; 5=best)			
Mean score	3.75	4.75	4.25
Liked the colors	23	5	

	Grade K	Grade 2	Total
How did you like the activity?			
Sound & Voices			
Voices were clear/liked voices	3	2	5
Combo child/adult voice	2	n/a	n/a
Was there anything you liked?			
Culturally/age/appro	5	8	13
Liked winter/seasons			
Content	2	4	6
Format			
Was there anything you dislike?			
Reinforcement & repetition		3	n/a
3			
Nothing	1	2	3
Format was good			
Character, pictures &colors			
Length			
Ethnicity of characters	2	n/a	2
Just right			
Liked it was simple			
		2	1
3			
Too short			
What would make more fun?			
More activities & characters		1	2
3			

When asked about the characters, pictures, and colors, 38% of teachers liked that the graphics were simple. Sixty-three percent (63%) liked the bright colors used in the activity. Two second grade teachers said they liked the ethnic variety of the characters. Sixty-three percent (63%) of teachers liked the voices and thought they were clear and easy to follow. Half of the Kindergarten teachers said they liked the combination of the child and adult voices (narrators).

Teachers liked the content of the CD-ROM very much. Seventy-five percent (75%) of teachers felt the information was important, and 37% liked that winter use of sunscreen was presented. Seventy-five percent (75%) of Kindergarten teachers liked the way the CD-ROM reinforced and repeated key concepts. Fifty percent (50%) of all teachers reported the format was good. Three of the eight teachers thought the program had good repetition and reinforcement (grade K). All of Kindergarten teachers and 87% of all teachers reported the length was just right. One Kindergarten teacher said it was too short. Most teachers believed that the CD-ROMs reflected real-life situations.

When asked what could be done to make the CD-ROM activity more fun 38% of teachers suggested " more activity" and "having characters do more things". Indicating that the activities could be even more interactive. Two of the Kindergarten teachers suggested we produce the CD-ROM in Spanish.

C.3.4 Supplemental Specific Aim: Assess student learning and evaluate the ability of the CD-ROMs to increase students' sun safety knowledge, attitudes, sun protection skills, and intentions to practice the desired sun safety behavior.

C.3.4.1 Progress Toward Achievement. A pretest-posttest and accompanying analyses to show change were not necessary to achieve the specific aims of this project. The test of the full program's effectiveness in a pretest-posttest design will be the goal of Phase II. However, Phase I included a posttest on student knowledge in the CD-ROM program, as the final activity, to determine whether this type of testing is feasible. Students also answered interviewed-asked pretest and posttest questions for comparison to the on-screen version. Phase I did not presume to affect students' sun safety knowledge, attitude change or behavior with a single brief interaction with a 15-minute CD-ROM activity.

C.3.4.2 Results. From a feasibility perspective only, student learning and the ability of the CD-ROM activities to increase students' sun safety knowledge, attitudes, sun protection skills, and intentions to practice sun safety behavior were assessed with a 5-item multiple choice pretest/posttest and one open-ended interview question.

Student Pretest/Posttests. Results from pretest to posttest and computer posttest varied. Due to the small sample, the results should be taken as suggestive only. The purpose of the pre/posttests was to learn more about the feasibility of this method of testing, rather than as determinants of knowledge, attitude, and behavior outcomes. In general, students were knowledgeable of sunscreen and/or shade at pretest. Kindergarteners scored 50-92% correct at pretest; second graders scored 75-92% correct at pretest on knowledge items. Sun-safe attitudes and behaviors were less established at pretest and left room for improvement in most cases (Grade K favorable attitude toward sunscreen = 67%; behavior = 50%; Grade 2 favorable attitude toward shade = 67%; behavior = 83%).

Kindergarten knowledge from pretest to both posttests increased and decreased. Students did better with information from the interactive activity than the introductory lesson, probably because they spent more time on the activity, its inter-active nature held their attention, it provided an opportunity to practice sunscreen application, and provided feedback. Kindergarteners fared better on the interviewer posttest that the computer posttest. This was likely due to the design of the computer posttest (i.e., the way "Yes" and "No" would flash before you could click on them) rather than the questions (which were identical). From pretest to posttest, attitude and intention to use sunscreen increased favorably in Kindergarteners. Second graders scored better from pretest to computer posttest indicating the value of two additional years of computer experience over Kindergarteners. All second graders scored 100% correct on the knowledge items at computer posttest. Intention to play in the shade did not increase and attitude toward playing in the shade became more favorable with the interviewer posttest only. This method of testing (i.e., built into a CD-ROM program) is feasible, especially with second grade students.

Table 6: Percent Correct Answers on Pretest and Posttests (Kindergarten)

	Pretest (n=12)	Posttest (n=6)	Computer Posttest (n=11)	Content Covered
Item 1	50	67	73	Knowledge from Activity
Item 5	67 (n=6)	67	64	Knowledge from Activity
Item 2	92	100	82	Knowledge from Introduction
Item 3	50	83	73	Behavior
Item 4	67	83	54	Attitude

Table 7: Percent Correct Answers on Pretest and Posttests (Grade 2)

	Pretest (n=12)	Posttest (n=12)	Computer Posttest (n=12)	Content Covered
Item 1	92	83	100	Knowledge from Introduction
Item 2	75	58	100	Knowledge from Activity
Item 5	83 (n=6)	83 (n=6)	100	Knowledge from Activity
Item 3	83	67	75	Behavior
Item 4	67	75	67	Attitude

Student Interviews. The student interview included one open-ended question to assess learning. Students' answers indicate that they did learn the intended lessons. When Kindergarten students were asked what they learned from the CD-ROM program, 67% said they learned to put sunscreen on when

they go outside. Sixteen percent (16%) of Kindergarten students said they learned that the sun can hurt your skin, and 16% (n=2) reported learning nothing. Fifty percent (50%) of second grade students said they learned that the sun can hurt your skin. The 12 second-graders gave 10 accurate responses about shade indicating that they learned the main lesson. Students could give multiple responses to this question; only responses given by two or more students are listed in the tables.

Table 8: What Students Report Learning From the CD-ROM Activity

What You Learned *	Grade K	Grade 2	Total
To Put Sunscreen On	6	n/a	6
Use Sunscreen Everyday	2	n/a	2
Sun Can Hurt Your Skin	2	6	8
About Staying in Shade	n/a	3	3
More Shade in a House	n/a	2	2
Shade Protects You	n/a	2	2
Nothing	2	0	2

* multiple responses per child were allowed

C.4 Importance of the Findings

All eleven indicators of success set at the outset of the Phase I project (listed below in boldface) were realized based on the analysis of interviews with computer technicians, teachers, and students. This evaluation found that:

\a. **Schools had sufficient technology to run the sun safety CD-ROM programs.** The participating schools were more than adequately equipped with computers powerful enough to run our CD-ROM programs.

\b. **The CD-ROM programs were easily installed and ran on school computers with minimal problems.** We experienced no difficulties installing or running our programs on the schools' computers.

c. SDHW curriculum content was easily translatable into CD-ROM computer-based activities. The AMC Health Communications Core had no difficulty achieving this outcome of success.

d. Teachers believed skin cancer prevention to be an important health or science topic to address. 100% of the teachers believe skin cancer prevention is an important health/science concept that warrants annual classroom attention (especially year-round sun protection in Colorado).

e. Teachers could easily integrate the CD-ROM activities into their health and/or science lesson plans. All teachers said they could easily integrate the CD-ROM activities into their lesson plans. Most Grade K teachers would utilize the CD-ROM activity with computer lab sessions or as an individual center activity. Grade 2 teachers said they would integrate the CD-ROM activity with other lessons in the classroom or in computer lab.

f. Teachers found the CD-ROM programs to be an effective health education tool. All of the teachers said that the CD-ROM activity was an effective health education tool for teaching children about sunscreen or shade.

g. Teachers believed the CD-ROM programs could help them teach difficult or complex concepts. The majority of both Grade K and 2 teachers said that the CD-ROM activities could help them teach concepts that are hard to get across in other ways, largely because they accommodate a variety of learning styles.

h. Teachers felt that they could assess student learning using the CD-ROM prototypes. 100% of the Grade 2 teachers and 50% of the Grade K teachers said they could adequately assess student learning from the CD-ROMs.

i. Students were able to navigate through all features of the CD-ROM prototypes. Students had very little difficulty using the CD-ROM programs. All 24 students use computers at school frequently and like using them.

j. Students scored over 80% correct on items assessing learning of the sun safety content. All second graders scored 100% correct on the knowledge items at computer posttest. Kindergarteners scored 64-82% on the knowledge items. They scored better on information from

the interactive activity than the introductory lesson, probably because they spent more time on the activity, its inter-active nature held their attention, it provided an opportunity to practice sunscreen application, and provided feedback.

k. Students liked the features and content of the sun safety CD-ROM prototype programs. Students were very satisfied with the CD-ROM activities. 83% of the students liked the activities "a lot."

These findings are important because teaching young children about sun safety (i.e., skin cancer prevention) via interactive multimedia is both feasible and desirable to educators and students. Teachers considered the prototype CD-ROM programs to be an effective health education tool that could be integrated easily into their lesson plans. They are eager for us to develop the full CD-ROM programs and address all aspects of sun protection behavior. Nearly all of the teachers prefer to use a classroom curriculum with an accompanying CD-ROM. One Kindergarten teacher would rather use the CD-ROM alone. These represent the two most likely ways of using multimedia sun safety instructional programs. Teachers need flexible strategies and resources for educating students. The CD-ROM programs help meet the needs of a variety of learning styles and provide needed repetition, reinforcement, and practice of concepts and skills. Students liked the features and content of the sun safety CD-ROM prototype programs, were able to navigate through all features of the CD-ROM activities, and learned the main lessons of the programs even with only a brief encounter with new content (i.e., sun safety). Computer-based instruction is not only feasible, but inevitable. Schools are equipped with computer technology, are training their students to be computer proficient, and are seeking high quality educational multimedia.

C.5 Changes in the Specific Aims

No changes have been made to the Specific Aims since the Phase I project was initiated.

C.6 Publications, Patents, and Other Materials (e.g., CD-ROMs)

This project produced two copyrighted (O 1998 PHS, Inc.) prototype CD-ROM activities to complement, supplement, and expand the printed SDHW grade K-5 sun safety curriculum. The Kindergarten CD-ROM activity is titled "The 5 W's of Sunscreen." The Grade 2 CD-ROM activity is titled "The Shade Show." Disk copies of the activities and color copies of several screens are included in Appendix G to show the quality of the graphic design and animation.

D. EXPERIMENTAL DESIGN AND METHODS

In Phase II, PHS project staff and AMC collaborators will complete timetable of activities outlined in Appendix O to produce and evaluate the comprehensive set of SDHW CD-ROM programs for grades K -5.

D.1 Target Population

The target population is students enrolled in grades K-5 in 12 schools in participating public school districts in Colorado. All students enrolled at the time of the pretest (February 2001) will be eligible to participate in the evaluation of the interactive multimedia sun safety educational programs.

D.1.1 Ethnicity of Eligible Students. White, non-Hispanic individuals are at substantially higher risk for developing skin cancer than other ethnic groups with darker skin complexions. Thus, the primary target of the interactive multimedia programs is students of white, non-Hispanic ethnicity, the largest ethnic group in participating school districts (59%-85%). However, all enrolled students, regardless of ethnicity, will be eligible to participate to achieve school cooperation and to be ethical. We have not been required to translate sun protection education into Spanish in previous evaluations, but we will translate informed consent forms into Spanish, using techniques from previous nutrition education for multicultural adults (Dr. _____, CA_____) and web-based tobacco cessation for adolescents (Dr. _____, CA_____), if needed.

D.1.2 Participating School Districts. The _____ County School District (WCSD) in Colorado has agreed to participate in this Phase II SBIR project (see letter of support in Appendix H). This district participated in the Phase I feasibility trial and contains a total of 14 elementary schools, all of whom have sufficient computer equipment and facilities for conducting the evaluation of the interactive multimedia SDHW programs (see Final Report on Phase I). Given our past experiences from our previous school-based projects, we are confident that we can obtain 12 participating elementary schools from this district. However, to provide a broader sample of schools, we will secure the participation of the _____County School District and _____Creek School District to access and recruit additional elementary schools. Both of these districts are currently participating in a project to develop and test the middle school (grade 6-8) components of the SDHW curriculum (Dr. _____ CA_____), and the web-based tobacco cessation program for adolescents (Dr. _____ CA_____). Combined, these districts contain 127 elementary schools and are located in the suburban _____ metropolitan area. In the WCSD schools, none of the students who participated in the Phase I SBIR feasibility test will be eligible to participate (i.e., pre/posttesting) in this Phase II trial; however, they will be able to receive the multimedia sun safety instruction if they are in classes randomized to receive it.

D.2 Production of Interactive Multimedia SDHW Programs (Months 01-16)

D.2.1 Instructional Format and Content. An interactive multimedia version of the _____ curriculum for grades K-5 (SDHW) will be developed in Months 01-16. Like the current SDHW that relies on classroom presentations and activities, the instructional goals of the multimedia version of SDHW will be to promote behaviors by students that reduce sun exposure by (a) limiting time in the sun and avoiding sun exposure during daily hours of peak UVR, (b) wearing protective clothing (e.g., long-sleeved shirts, long pants, shoes, sunglasses, hats), and (c) applying sunscreen lotion and lip balm with a sun protection factor (SPF) of 15+ to exposed skin areas. Strategies for teaching these behavioral skills will be based on Social Cognitive Theory (8) and aim to (a) improve self-efficacy and outcome expectations related to sun safety, (b) change attitudes to create a sun safety norm, and (c) increase sun safety skills, through role modeling and rehearsal. Interactive multimedia will facilitate the application of principles from SCT. Students' attention will be enhanced by attractive, animated, similar child models and voices and vivid and fast-paced sequences within a still-novel multimedia environment. Key behaviors will be demonstrated and time allocated to students for rehearsal. Skills will be decomposed into components of behavior and shown repeatedly. Performance feedback will be provided through the interactive features of the programs. Contexts relevant to children will be modeled to improve self-efficacy expectations. Positive reinforcement for sun safety behavior by models will be illustrated to increase outcome expectations.

In order to make the multimedia programs attractive and acceptable to teachers and curriculum specialists, presentations and activities will be designed that fit existing health and science curricula, and increase students' understanding of the scientific principles behind health concepts related to skin cancer prevention. Like the SDHW, the multimedia programs will incorporate presentations and activities in the areas of health, science, mathematics, society and culture, and language arts, and be consistent with national science education reforms, Healthy People 2000 national goals, and CDC's anticipated guidelines for K-12 comprehensive health education. Finally, lesson and activity formats will conform with two common models of instruction (learning theory)—behavioral and cognitivist. Behaviorists believe that learning results in a change in the learner's behavior and cognitivists believe that learning occurs when learners are able to recognize a relationship between what they know and what they are learning (7,53). This instructional formatting will facilitate the commercialization of the multimedia programs at the conclusion of this Phase II project (Phase III).

Grade-specific programs will be authored for grades K-1, 2-3, and 4-5, based on information and experience obtained from SBIR Phase I project on grades K and 2 and from a pilot test of a multimedia program for grade 4-5 funded by the Cancer Research Foundation of America (CRFA). Budget restrictions prohibit creating a separate programs for each K-5 grade level. An instructor's guide will be written to accompany the multimedia programs. Each two-grade-level program will contain four units, each with 2-3 instructional presentation or activities, for a total running time of approximately 100 minutes. This format mirrors the units in the current SDHW curriculum and permit teachers to break up the content into manageable instructional periods. It is anticipated that few teachers will use the entire 100 minutes in a single day, so sun safety instruction will be repeated over several days, which should further promote skill acquisition. Following SCT, the units within each grade-level multimedia program

will be organized to create, initially, positive outcome and self-efficacy expectations and motivation to practice sun safety and, then, teach behavioral skills with rehearsal and goal setting and self-monitoring methods to implement and maintain sun safety behavior. Self-efficacy expectations will be developed and reinforcements delivered for sun safety in all lessons. Currently, the SDHW classroom curriculum contains interactive exercises, activities, games, and a storybook in 4 units promoting the sun, use of shade, protective clothing, and sunscreen for grades K and 1; didactic instruction, a storybook, and interactive activities in 4 units on the sun, skin, geography, sun safety strategies, and skills for putting sun safety into action for grades 2 and 3, and didactic presentations and interactive activities in 4 units on the sun, skin type and personal risk for sun exposure, and sun safety strategies along with science experiments for grades 4 and 5. This provides a tentative lesson organization for the Phase II CD-ROM programs.

D.2.2 Multimedia Production by AMC's Health Communications Core. Multimedia production will be completed by AMC's Health Communications Core's professional media developers under the direction of Dr. _____. He will serve as P.I. for the _____Subcontract on this project. The Core possesses several production facilities, including graphic design and multimedia authoring labs, computer demonstration lab, and digital video/audio production studio, for producing print, video, audio, and interactive multimedia disease prevention messages for children and adults. Core services comprise (a) writing and editing, graphic design, technical illustration, and production of age-, developmentally-, and literacy-appropriate health education materials; (b) project management from initial design to final printing and production; and (c) procurement of outside vendors (photographers, talent, animators). Current interactive multimedia projects include producing the sun safety programs for elementary school students (NCI Phase I SBIR, Ms. _____, PI, CA_____) and middle school students (NCI Phase I SBIR, Ms. _____, PI, CA_____), collaborating on the development of a web-based multimedia smoking prevention and cessation program for adolescents (NCI, Dr. _____, PI, CA_____), creating an interactive multimedia program on obesity prevention for fourth graders (USDA #98-00663), and creating and administering the _____website. The Core also is involved with the design of components for a new Grade 6-8 SDHW curriculum (NCI, Dr. _____, P.I., CA_____).

Multimedia production will be completed by _____'s Health Communications Core's professional media developers—_____, Core manager and graphic designer, _____, instructional design specialist, _____, production coordinator, and _____, multimedia programmer—under the direction of Dr. _____. Broad goals and specific instructional and behavioral objectives and content will be developed by the investigators. Messages and graphic design elements from our previous computer-based health education projects (see Relevant Experience) and reactions of teachers and students to multimedia prototypes of our activities in the companion SBIR Phase I project will be reviewed and incorporated in our production. Revisions will be made to the initial user interface design by the graphic designer and multimedia programmer based on the results of the SBIR Phase I project (e.g., in the overall look and feel of the sun safety programs and appropriate graphics, video scenarios, animations, other interactive components). Design ideas and scripts for additional multimedia features will be created in written form, combined into flowcharts and story boards, and reviewed by project investigators before creating the actual images and authoring multimedia programs. Communications Core staff will create a preliminary version of all components, and each component will be thoroughly tested for ease-of-use, graphic appeal, platform stability, and code error trapping.

Each program will provide multiple options and multiple levels of detail to students in a straightforward manner in four 25-minute units of guided instruction. The two activities tested for feasibility in the Phase I project will be revised based on the results of this project and incorporated into the K-1 and 2-3 programs. Additional activities and multimedia content will be authored for these programs. The multimedia program for grade 4-5 authored and tested for feasibility in the CRFA project contains about 60 minutes of content. This prototype program will be expanded by the Health Communications Core to contain a total of 100 minutes of content. Its organization will also be improved to better parallel the SDHW curriculum and integrate seemlessly with the K-1 and 2-3 programs. The overall look and feel of the 100-minute multimedia programs will be based on results from the Phase I SBIR research and the feasibility test on the grade 4 program funded by CRFA. These tests showed that students, even in early grades, are computer literate, frequently use computers in the school setting, and are familiar with many other commercial software for children. Thus, our applications must be sophisticated to maintain their interest.

To prolong “shelf-life,” we will use language, graphics, and video depictions that have "timeless" features. The interactive multimedia instructional programs will use near-peer instructors (children and child voices), to which students reacted positively in the Phase I feasibility study (see Final Report). The programs will deliver curriculum concepts and provide demonstrations of the behavioral, scientific, and health skills in realistic settings with adolescent role models. Programs will integrate digital video, voice-over narration, music, graphics and animation to form age-appropriate activities. Those activities will include simulations, decision-making roleplays, and brief informational presentations and documentary videos. Interactive activities will be used more than presentations, as students reacted most favorably to the interactive activities in the Phase I feasibility test. For example, an exploratory activity to learn lesson content (e.g., what are sun-safe clothes) will be followed by an activity giving students the opportunity to put the content and skills they’ve learned into practice (e.g., choosing sun-safe clothes and dressing a character appropriately). However, activities will be simplified and opportunities to replay the activities will be designed into the computer programs, as many very young students needed to interact with the activities more than once in the feasibility test to achieve full understanding of its content. Programs will provide opportunities for students to express attitudes by responding to questions about sun safety and to practice sun safety behavioral skills. Log files will be created to note each object the student explores as well as the length of time spent on each activity to guide revisions of computer programs.

Modules will be authored progressively (see Phase I procedures in Final Report). Interface design ideas will be created in written form, combined with the scripts into flowcharts and storyboards, and reviewed by the investigators and project consultants, Dr. _____ and Dr._____ (see below), before creating the actual images and authoring multimedia programs. Communications Core staff will create a preliminary version of all program components, and each component will be thoroughly alpha-tested in-house for ease-of-use, graphic appeal, platform stability, and code error trapping by having experienced computer users at AMC use the program in the demonstration lab at the Health Communications Core. Revisions will be made and components will be "wrapped" inside the "user shell"—program interface including audio introduction, help files, navigation devices, and data collection code—to assemble a prototype of the module. Prototype modules will be tested in-house for code stability and final modules will be tested for usability and reviewed the project consultant. Finally, the multimedia units will be pressed on CD-ROMs for application in the schools.

Intelligent software agents will be authored for each program by Dr. _____ in collaboration with Ms. _____ and the Health Communications Core. First, the functions and actions agents will perform will be specified, e.g., provide directions and hints for using the program features, seek information from users, add additional information on a topic, show connects between information taught by different program features. Next, a knowledge base for each agent—the information the agents need to know to do their job—will be created. In programming the agents, we will specify the communication that occurs between the user and the agent. The agents will have limited natural language understanding, so this step will involve establishing syntax and semantics the agents can work with and providing appropriate interfaces so that children can easily understand and communicate with the agents. The gents will serve as tutors and guides for students. For the youngest grades, this communication will rely primarily on audio channels, because of their inability to read and write. For example, these young children will primarily send messages to the agent by responding to simple questions spoken to them by the agent. For older grades, agent-user communication will rely more on text which is easier to program. There will also be some adaptability programmed into the agents, which allow children to adjust agent actions (e.g., choose to have agents provide information without user requesting it or provide information only when user requests it) and permit agents to modify their knowledge base. The interface for the software agents will be a cartoon face that appears in a dialogue box on the screen. The agents will be given names to personalize them.

D.2.3 Software Considerations in Authoring Multimedia Program. In our current multimedia projects, including the Phase I SBIR project, we are creating programs to run on both Macintosh and Windows-based PC machines, with UNIX work stations being a less dominant requirement. Such program delivery uses html-based (hypertext markup language) instruction for content delivery, incorporating digital video and audio. We are using the Macromedia Suite of authoring software, along with Adobe Photoshop and Freehand for graphics, which have cross-platform compatibility. The investigators and project consultants are well aware of the changing nature of

computer, digital video, audio, and graphic technology, so it is unreasonable to specify the final form of the multimedia components at the end of production in 2000.

D.2.4 Instructor's Guide. An Instructor's Guide will be written by the Principal Investigator and research assistants and produced by _____'s Health Communications Core. It will contain a description of each unit in each grade-specific multimedia program, identify the content area that each presentation and activity fulfills (e.g., math, science, language arts), show the relationship between the multimedia program and the print version of the SDHW, provide instructions on how to install and run the programs on Windows-PC and Macintosh systems and handle potential technical difficulties, and provide a schedule for program implementation. It will provide instructional plans for using the multimedia programs both in free play and directed use formats. Similar instructional plans were used in an earlier project evaluating the Body Fun with Helga Health'nstein CD-ROM for the Cancer Research Foundation of America (Dr. _____ & Ms. _____, Co-PIs; see Appendix I). Computer technical support will be available by telephone from the Research Assistant I to help teachers with interactive multimedia implementation.

D.2.5 Teacher Training Sessions. Participating teachers will complete training sessions on implementing the SDHW curriculum and/or multimedia sun safety programs. Training will be conducted at each school by the P.I. and project staff, during regularly scheduled in-service days or after school in January and February 2001. Training procedures from previous SDHW evaluations will be modified (see Appendix J) and include a discussion of the importance of sun safety for skin cancer prevention and why sun safety is important for children, a description of the implementation, consenting, and data collection procedures, a review and demonstration of the interactive multimedia sun safety programs, an opportunity for teachers to navigate through the CD-ROM programs for their grade (in small groups), and a review of the Instructor's Guide. Each training session will last 2-3 hours. Teachers will receive all the curricular materials needed to implement the a classroom curriculum and/or the CD-ROM for their grade and a copy of the multimedia Instructor's Guide. To date, we have trained over 200 teachers in methods of implementing the SDHW in previous studies.

D.3 Evaluation of Interactive Multimedia SDHW Program Effectiveness (Months 16-27)

D.3.1 Experimental Design for Evaluation of Program Effects. The effectiveness of the interactive multimedia SDHW programs for grades K-5 will be evaluated in a randomized pretest-posttest controlled trial. Twelve schools will be matched into triplets (groups of three) and each school will contribute classrooms to three groups: (a) classrooms assigned to receive the interactive multimedia program (CD-ROM group), (b) classrooms assigned to receive the standard classroom SDHW curriculum (Curriculum group), and (c) classrooms assigned to receive both CD-ROM and standard curriculum (Combination group). For each of the four triplets of schools, determination of how classes will be assigned to treatments will be performed via the following scheme: one of the three schools will be randomly assigned to Group A in which 2 classes each from grades K and 3 will receive the CD-ROM instruction, 2 classes each from grades 1 and 4 will receive the curriculum and 2 classes each from grades 2 and 5 will receive the combination; the second school of will be randomly assigned to Group B in which 2 classes each from grades 1 and 4 will receive the CD-ROM, 2 classes each from grades 2 and 5 will receive the curriculum and 2 classes each from grades K and 3 will receive the combination; and the third school will be randomly assigned to Group C in which 2 classes each from grades 2 and 5 will receive the CD-ROM, 2 classes each from grades K and 3 will receive the curriculum, and 2 classes each from grades 1 and 4 will receive the combination. The two classes from each grade within a school will be selected at random within grade strata. Ultimately, class will be the unit of analysis (see Statistical Analysis and Sample Size sections).

The contribution of classes from each school to all three conditions maximizes the efficiency of the design, by controlling for sociodemographic characteristics of children attending each school, thus requiring the use of fewer schools and reducing the project budget. One threat to validity of this design is the possibility of treatment diffusion from classes in different conditions within a school. It is our experience from numerous school-based evaluations of the SDHW that team teaching and therefore sharing of course content is more common within grades rather than across grades. Process evaluation at the training sessions will verify this, and even if it exists, it is unlikely to exist in many schools. Also, classes within a grade, rather than across grades, are usually scheduled to attend recess and lunch periods together where students can interact. Thus, we believe that the possibility of

cross contamination in schools is reduced by sequencing treatment assignment across three grade levels within a school.

Twelve schools from the two districts will be randomly selected from eligible schools (see eligibility criteria below) in Spring 2000. Principals from selected schools will be contacted and their participation in the 2000-01 school year will be secured. In September 2000, principals will meet with research staff and help secure participation by teachers in randomly selected classes. In October-December 2000, students within the selected classes will be recruited to participate in the evaluation of the interactive multimedia programs and SDHW curriculum. School districts will designate the SDHW materials as pilot curricula and informed parental consent will be required only for the testing of student performance on the pilot curricula since this is potentially over and above usual evaluation (see Informed Consent Procedures below). This procedure permits all students to receive sun safety instruction. Using similar procedures in previous SDHW evaluations, we have enrolled 2,038 students in 27 schools in previous community trials.

Of 35 elementary schools approached to participate in previous SDHW evaluations, 27 participated; non-participating schools declined because of too many other special projects or new construction. Participation rates by parents and children varied by school (39%-78%), based mainly on the culture of parental participation and staff enthusiasm. In the Phase I SBIR project, all elementary schools recruited in the WCSD participated and 24 students were recruited from four classes. Higher participation rates could be achieved with passive informed consent procedures, but they are is not permissible under DHHS regulations and our IRB. Thus, we anticipate that 60% of students in the selected classes will participate fully (i.e., 2,160 at posttest of the 3,600 consent packets distributed).

All consented and assenting students will be pretested in February 2001 in their classrooms during school hours (O_1). Teachers will receive training in January and February 2001 (T). The various curricula (either interactive multimedia SDHW, standard SDHW curriculum, or the combination) will be implemented in grades K-5 in the spring semester in March and April 2001 (X_1). Students will be posttested at the end of the spring semester in May 2001 (O_2). Comparison of changes in outcome measures from pretest (O_1) to posttest (O_2) will evaluate the particular method's success. Sun intensity in the spring is high enough in the high altitudes of Colorado to burn the skin in a short period of exposure by May, so students should be practicing sun safety at the posttest. We will track students from initial recruitment, through pretest and implementation, to posttesting in the 2000-01 school year using cohort tracking and maintenance procedures from previous evaluations of the SDHW. In these previous trials, 96%-99% of consented students completed the pretest and posttest, sufficient to maintain statistical power. Figure 3 shows the evaluation design timeline.

Figure 3: Experimental Design & Project Timeline

D.3.2 Informed Consent Procedures. Active voluntary informed consent from teachers and parents and active voluntary informed assent from students for testing will be secured using procedures employed in previous SDHW evaluations. Teacher consent will be obtained at school; parent consent will be obtained by mail; student assent will be obtained at school at the beginning of the pretest sessions. Parent consent and student assent for each student will be required. Packets will be mailed to parents containing informed parental consent forms and a postage-paid return reply envelope. Research staff will perform all tasks for obtaining informed consent. School districts will provide mailing lists or affix mailing labels to packets prepared by the staff in ways that protect parent privacy. To improve participation, teachers will distribute flyers to parents and articles announcing the project will be included in school newsletters, and reminder postcards will be mailed to parents. All forms and procedures will be approved by the AMC IRB who provides oversight for PHS (see Human Subjects section). These procedures have produced sufficient sample sizes and participation rates in previous SDHW evaluations. Examples of Phase I consent and assent forms are in Appendix E.

D.3.3 Process Evaluation. Process evaluation is crucial to ensure intervention integrity and correct problems. For the CD-ROM intervention, a course management system incorporated in the

multimedia programs that creates log files noting each object the student explores and length of time spent on each activity will simplify process evaluation. Unique passwords will be given to each student so that their use of various activities in the multimedia program can be captured in a database (e.g., number of times an the program itself and individual activity within it are played/viewed, duration of use, tracking of selection of branches in activities by each student). For CD-ROM and curriculum interventions, aequate training of teachers to implement the programs will be monitored by (a) recording attendance, (b) assessing acquisition of key knowledge, (c) assessing perceived self-efficacy to teach the lessons, and (d) certifying that teachers are ready to implement it at the training session. Knowledge and self-efficacy is assessed in a brief self-administered test. Implementation process evaluation will include (a) detailed tracking of consents and tests and (b) fidelity checks of teacher implementation of the CD-ROMs and/or curricular activities in instruction (see Teacher Checklist in Appendix K).

D.3.4 Measurement Instruments

Primary Outcome Measure. For children in grades K and 1, the primary outcome of the evaluation of the interactive multimedia SDHW programs will be improved knowledge, comprehension, and application of sun safety behaviors and skills. In previous SDHW evaluations, this has been measured with a series of visual items on which children either select sun safe behavior from two photographs of children performing a sun safe skill or not, or identify sun safety products and items (e.g., sunscreen bottles, sunglasses, shade, hats). The testing involves showing young children photographs of sun safe scenes and asking structured questions about them (90). Pre-literate K-1 students require using visual question formats and can answer only a small number of items. This test will yield numerical data on proportion of correct items. We will compare the statistical properties (distribution, intraclass correlations, effect sizes) of scores for K-1 students with those from longer tests for grades 2-5 to determine if they are comparable and permit pooling into the same analysis.

For children in grades 2-5, the primary outcome of the evaluation of the interactive multimedia programs is increased use of solar protection behaviors from pretest to posttest. This primary outcome variable will be measured using self-report items from previous evaluations of the SDHW on which students report their frequency of using sun safety behaviors taught in the curriculum—hats, protective clothing, sunscreen, lip balm, sunglasses, avoiding mid-day exposure, avoiding sunburn, not tanning, asking parents for sunscreen. A summed sun safety score provides an estimate of overall sun safety (alpha=.65-.75). Also, individual items can be employed to make statements about use of specific sun safety behavior to diagnose what behavior(s) is changed by the curriculum (23,25,27). Response options are 3-point frequency scales (23, 24; see Appendix L). We will also add an item measuring whether the child has been sunburned and if so how severely (red, red and painful, red, painful and blistering) since the pretest.

All measures of sun safety have potential problems. Self-report measures may overestimate actual behavior (10) and may suffer from memory or social desirability errors, particularly with young children, although positive correlations with colorimeter measures of UVR exposure (a colorimeter is a non-invasive, portable device that measures color of objects in three dimensions , light-dark L*, blue-yellow (b*), and redness (a*))have occurred in the SDHW evaluation (16,19; Preliminary Studies section) and with actual behavior in other studies (58,59,67). However, Mayer et al. (159) found only a few correlations between the Girgis et al. (58,59) prospective sun safety diary by parents and colorimeter measures of UVR exposure on children. Also, it is almost impossible in the visual measure of clothing use to determine with certainty that clothing is being worn for sun protection and not to protect the body from other climate features (e.g., lower temperatures) or for fashion reasons and to which class each child belong. Children may be incapable of accurately reporting on protection during specific periods in previous days. However, to provide an estimate of concurrent validity the self-reports of sun protection behavior, a random sample of 100 students will be selected at the pretest and posttest and their skin tone will be measured using a colorimeter. Two dimensions of color measurements from the colorimeter measure darkening (L*) and reddening (b*) due to sun exposure. Correlations between reported increases in sun protection and darkening of the skin associated with suntanning will be calculated to verify the self-reports. A colorimeter is available for use from AMC.

Measures of Secondary Mediating Variables. In addition, several secondary outcome measures will be evaluated that theoretically act as mediators of behavior change in SCT. These include (a) opinions in support of sun safety, (b) self-efficacy expectations, and (c) positive outcome expectations about sun safety. Opinions will be measured with 11 3-point agree-disagree items used in previous

SDHW evaluations (alpha reliability=.66-.71) that constitute subscales on attitude in favor of tanning (alpha=.62-.83) and barriers to sunscreen use (alpha=.61-.77), and have face validity (i.e., reflect attitudes addressed in the curriculum). Construct validity was established in previous evaluations on elementary school students (23,25,27). Items assessing self-efficacy beliefs will be taken from our current NCI-funded project developing grade 6-8 components of the SDHW (Dr. _____, PI, 89). Outcome expectations in previous SDHW evaluations were measured by 35 items assessing knowledge acquired from the SDHW. These items had face-validity (i.e., measure curri-culum concepts) and construct validity (i.e., repeatedly detected predicted increases in knowledge following curriculum implementation). "True," "false," and "don't know" responses are converted to correct/incorrect scores and summed (alpha reliability=.69 - .86; 23,25,27). Items will be selected from these previous scales which assess opinions, self-efficacy expectations and outcome expectations taught in the interactive multimedia programs. See Appendix L for sample items.

Measures of Potential Moderating Variables. Finally, potential moderating variables ¾ skin sun sensitivity and demographic characteristics (sex, grade, and ethnicity) ¾ will be assessed. Skin sun sensitivity was measured in previous SDHW evaluations by having students report color of the natural scalp hair, color of the untanned skin, and how the skin changes when exposed to for the first time to the summer sun at midday, without sunscreen, for 15 minutes. These items are based on Weinstock's (144) validity test and reflect four dermatologic skin types (Type I-always burn, unable to tan; Type II-usually burns, can tan if work at it; Type III-sometimes mildly burns, tans easily; Type IV-rarely burns, tans easily) (see Appendix L). Responses to these hair, eye, and skin items are a more accurate determinant of risk for skin cancer than race or ethnicity. Skin tone is related to ethnicity, however, and this correlation will be discussed, but the variables of skin tone and race/ethnicity will not be confused with each other. Teachers and interviewers will help students complete these personal characteristic items if they have difficulty understanding them. All measures will be in the pretest and posttest surveys, which will take about 30 minutes for students to complete.

D.3.5 Data Collection and Data Management Procedures. Data will be collected by trained interviewers and project staff at each school following procedures used to collect data in prior curricula evaluations. Hiring and training of interviewers will be supervised by Ms. _____, PI and on-site work will be supervised by the two Research Assistants. Interviewers will be trained together using procedures from previous SDHW evaluations (see sample interviewer training procedures from the Family Sun Safety Project in Appendix M).

Student self-report test will be conducted in groups in each participating class, with teachers present. According to _____ IRB requirements, consented students will be separated from non-consented students in each class for assenting and testing (e.g., moved to the library) unless the entire class has been consented to participate. After obtaining assent (pretest only) and introducing the test, an interviewer will read each question aloud to provide structure. Another interviewer will be available to answer students' questions. Group sessions will take approximately 45 minutes to complete.

Students selected for colorimeter measures will be sent to a location outside the classroom (e.g., hallway, library) where an interviewer trained to operate the colorimeter will conduct the colorimeter measures. Again, school personnel will be present. Colorimeter measures will occur after the written testing is completed and take about 5 minutes per child.

Data management support insures quality of the design, implementation, analyses, and reporting of results. Experienced staff in AMC's Biostatistics Core will provide central data processing and management. Sophisticated data entry and data editing procedures will be implemented along with quality assurance procedures, including both manual and computerized audits. Data will be structured into a functional database format for easy data management and access, accompanied with carefully designed and documented information-processing protocols (Figure 4).

Figure 4: Project Data Management

\A. **and De velo pment Pretesting of Forms**	A major data management task is development and pretesting of forms. Many forms already are developed or can be easily modified from previous SDHW evaluations. Development and pretesting will continue including logistical pretesting for timing and subject burden and reviewing the wording of the questions to prevent bias and ensure responses are expected and analyzable. Some principles to be followed in the form construction and interviewer training are: \A.all relevant information will be precoded on data forms, rather than allowing open-

	ended responses (open ended responses will be noted on forms and abstraction or coding conducted); \B.specific instructions for completion will be written on the form itself ; \C.standard coding conventions will be uniform (i.e., 0 = No, 1 = Yes); \D.pretest data will be reviewed and missing responses and skip patterns will be studied to assess usefulness of forms, quality of reporting of dates, and other problems as they might arise; and \E.time to completion and problems faced by those completing the forms also will be documented.
Database and Data Entry Screen Development	Customized SAS FSEDIT data entry programs will be developed. The SAS files will be maintained in a relational data base. Standard database structure will link data over time for all students in the trial. The data management system will be on a microcomputer network server for data entry, management and analyses. While there are numerous relational data management systems available, we have chosen SAS FSEDIT for data entry because: 1) data analysis will be performed using SAS and this will eliminate an extra data transfer step (or avoid excessive sql coding at analysis time), 2) SAS provides extensive tools that can be utilized to monitor the timeliness and quality of data submission and produce the Data Expectation Reports, Data Queries and Accrual and Follow-up Reports and 3) variable labels and value formats can be incorporated into the data entry system and will already be an established component of the database when analysis begins.
Selection and Training of Interviewers	Interviewers must be personable and skilled at communicating with children. A data collection manual, developed for surveying children, will outline procedures for administering surveys, responding to ques-tions, assenting students, reviewing forms for completeness, supervising data collection staff, and submitting completed forms to the ___ Biostatistics Core for processing. Training will be based on procedures from previous SDHW evaluations. They include an introduction to the project, description of forms, supervised practice and role-playing, data management procedures and performance feedback.
Data Flow	All on-site data forms will be checked immediately by interviewers to insure completeness. If items are missing, staff will try to insure that the question was not intentionally skipped and all missing responses will be identified. Once data collection forms are received at the ___ Biostatistics Core, centralized data editing will be conducted to review completeness and readability of forms and provide feedback to the managers to insure quality. Following edit checks, data will be coded and entered into the master database for tracking throughout the project. Interviewers will be trained to reduce error rates.
Tracking Panel Samples	To improve response rates, we will prepare a tracking database similar to that used in one of our previous community-based nutrition education projects (see Appendix N), using information from informed consent/assent forms and pretest/posttest questions to link student surveys in the trial cohort.

D.3.6 Outcome Analysis Plan. The proposed study is designed to measure the effectiveness of the SDHW interactive multimedia CD-ROM and the standard classroom curriculum at increasing sun safety behaviors (primary outcome), attitudes, self-efficacy expectations, and outcome expectations (i.e., knowledge) (secondary outcomes) as measured by student responses to pretest and posttest questions. Composite scores for each measure will be created from responses to appropriate questions, based on analyses conducted in previous SDHW evaluations. Changes in these scores will be compared across groups. The analysis will be performed using a mixed-effects analysis of variance (ANOVA) appropriate for repeated measures data (SAS Proc Mixed)(84,87). The groups factor will be considered fixed with three levels, CD-ROM, Curriculum, and Combination. Matching of schools will be taken into account in the model. The pretest and posttest scores will be treated as repeated measures for each individual. The covariance structure will be modeled to account for the correlation between students within classrooms and classrooms within schools as well as the correlation between repeat tests on each student. This procedure is conceptually identical to multivariate analysis of variance (MANOVA) but avoids case-wise deletion of subjects with missing assessments. It relaxes the restrictive assumption that data are missing completely at random (MCAR) and provides unbiased estimates under the less restrictive assumption of missing at random (MAR) (88). All analyses will be

performed on an intent-to-treat basis. They will be conducted by ___'s Biostatistics Core, directed by Dr. ___ and assisted by Ms. ____. Contrasts will test the effect of the intervention on hypothesized changes in sun-safe behaviors, knowledge, and attitudes (see Figure 5). In planning other analyses, we will balance the hazards of fishing expeditions with the benefits of exploratory analyses (see Figure 5).

Timing of Analyses. Two major analyses are planned. First, we will describe the student samples, checking assumptions such as expected recruitment rate, analysis of process variables, and relationship among pretest measures. Analysis will be performed within 3 months of the completion of the pretest survey. The second analysis will focus on impact of inter-ventions on primary and secondary outcomes, which will be completed within 3 months of the completion of posttest survey by the end of the project period. Analyses of primary outcomes will not be released before completion of the interventions.

Figure 5: Planned Hypothesis Tests and Other Analyses

H1: Each group will demonstrate a significant change in the outcome over time. This will be demonstrated by testing whether the change in outcome from pretest to posttest for each group is significantly different from zero, using a two-tailed significance level.

H2: The CD-ROM instruction is equivalent to the Curriculum within a prescribed tolerance limit. This will be demonstrated by designating a null hypothesis stating that the CD-ROM performs more poorly than the curriculum by X units. That is, CD-ROM is inferior to the standard condition by at least X units. This is tested against a one-sided alternative that the CD-ROM is as effective as or more effective than the curriculum.

H3: Assuming that hypothesis #2 can be rejected, we predict that there will be an added benefit of combining the CD-ROM and Curriculum instruction. A test of the combination instruction method versus the pooled CD-ROM and Curriculum conditions will be performed, using a two-tailed significance level.

Other Analyses:

\A.Descriptive data on all subjects at pretest, with comparisons by treatment group to examine distributional characteristics. Data transformation procedures will be considered if non-normal distributions are found. (Type I errors associated with testing multiple endpoints will be minimized as described below.) The potential meaning of non-normality will be examined, i.e. excessive skewness potentially identifying key subgroups and the likely transform would be a square root transformation. Alternatively, we could perform the PROC MIXED results on the ranks, but we believe the transformations preserve more of the inherent information.

\B.Homogeneity of dropouts within treatment group with respect to selected outcomes will be examined to assess group-specific problems, although the expected small numbers may make conclusions as to similarities or differences difficult. We do not expect differential dropout, because treatments will be adopted as pilot curricula.

\C.Factor analysis (160) will be conducted on the attitudinal variables and the factor loading can be incorporated as weights for constructing scales that will be assessed using ANOVA for change attributable to the intervention. Internal consistency (coefficient alpha) of multi-item scales (i.e., attitude measures) will be computed to establish reliability and validity and provide comparisons in relevant populations.

\D.ANCOVA to test whether skin sun sensitivity or demographic variables moderate the effects.

\E.Analyses on potential mediating variables to determine whether changes in sun safety are a product of precursor variables in SCT, such as attitudes, self-efficacy beliefs, and outcome expectations.

Missing Data Considerations. Every effort will be made to reduce attrition and obtain post-treatment data on all students enrolled in the trial even if they do not complete the interventions. To avoid missing data, we will train interviewers, design forms to easily and correctly guide interviewers and students from question to question, supervise data collection, and make follow-up contacts with students as necessary to obtain complete responses. Even with these efforts, two types of missing data can occur: (a) non-response to follow-up assessment and (b) failure to gather specific items of information within data collection instruments. Although data collection will occur in classes in the schools, we can realistically expect attrition over time and have increased our initial pretest sample by 10%. The final analysis will be done on data collected from students who are successfully assessed, but we will try to estimate types and amounts of biases that could have occurred as a result of loss to follow-up. Baseline demographic characteristics and other variables of drop-outs will be analyzed to identify important predictors of dropout. Any non-representativeness will be characterized on univariate

and, if possible, multivariate basis, using MLE analysis for incomplete repeated measures, which relaxes assumptions about missing data from missing completely at random (MCAR) to missing at random (MAR) (162). While unlikely in this setting, data may not be missing at random (NMAR). If exploratory analyses suggest NMAR, the range of the potential effect or impact can be estimated by assigning all lost individuals to extreme category of the variable, in either direction. Multiple imputation methods (161) will both explore the sensitivity of the results to drop-out and correctly estimate precision of treatment differences. From results of exploratory analyses and experience, various plausible distributions will be tried, including distributions estimated for responders with similar demographic characteristics to the use of extreme cases, to estimate robustness of treatment differences from responses obtained from responding student segment.

D.3.7 Sample of Schools and Students

Selection Criteria and Matching Procedures. Principals of the elementary schools in the participating districts will be contacted to solicit their interest in the project and to obtain information on the school's computer equipment. Schools, with grades K-5, principals who express an interest in the project, and a minimum of a computer lab or library with at least 15 Windows-PC or Macintosh computers with CD-ROM drives or at least 5 such computers in each classroom will be eligible for inclusion in the study. Twelve (n=12) schools will randomly selected and recruited to the study. If a selected school declines to participate, another school will be selected at random to replace it. Schools will be matched into groups of three based on percent of white, non-Hispanic students (which is associated to elevated skin cancer risk and to a limited extent to skin sun sensitivity) and number of students enrolled in the school. Matching information will be available from the school districts prior to the pretest. We have found in previous school-based interventions that information on other potential matching variables, like socioeconomic status, is often not collected or released by school districts.

Sample Size Determination. The primary hypothesis in this study is the equivalence of the CD-ROM instruction to the standard curriculum in promoting sun-safe behaviors among students. A CD-ROM method for content delivery that is at least as effective as curriculum in promoting sun-safe behaviors, knowledge and attitudes imparts benefits in it may easier and more flexible to implement in school curricula, require less time and effort from teachers, and facilitate enhanced learning in combination with the standard curriculum.

We propose that the CD-ROM produces a change in sun-safe behavior in students that is no more than 0.06 units less than that produced by the standard curriculum. Thus we have, H_0: CD < Curriculum by 0.06 units; H_1: CD $\geq$ Curriculum. In the feasibility test of the grade 4 multimedia program funded by CRFA (_____, PI), students who received the curriculum had an average increase in self-reported sun-safe behavior score of 0.07 over the students who received the CD-ROM instruction. We feel that the mean change for the CD-ROM will be much closer to the curriculum change in the proposed study since students will interact with the programs longer and in more than one session.

Since the primary outcome is the change in behavior from pretest (O_1) to posttest (O_2), a consideration is the correlation between repeat tests within student. If the treatment comparison is based on the change in the outcome from O_1 to O_2, the variance of the change in outcome is $2ss^2(1 - rr)$ where ss^2 is the variance of the outcome measure and rr is the correlation between measurements at O_1 and O_2. When rr=0.5, the variance of the change reduces to ss^2 and the standard sample size calculation for differences at a single time point applies. As rr increases from 0.5, the required n falls, so calculations based on rr=0.5 over-estimates the required n if the correlation is larger than 0.5. In the CRFA project, rr was 0.56, so a sample size determination based on an assumed correlation of 0.5 is reasonable and conservative. Therefore, if we assume that rr is close to 0.5, we can use the baseline ss^2 in our sample size calculations.

Another consideration is the correlation between students within classes. Donner (40) proposes a method which inflates the sample size value determined by standard methods to account for the correlation between units within clusters. A correction factor is employed which is equal to [1 + (k-1)rr], where k is the average cluster size and rr is the intraclass correlation coefficient for units within a cluster. In this study, the cluster refers to the classroom so that the average cluster size completing this study is expected to be 15. An estimate of rr is obtained from the CRFA study in which the intraclass correlation coefficient for students within classrooms was 0.07. The correction factor determined from these values is 1.98. The sample size required to achieve 720 per group (a proposed 2,160 students divided into three groups) after applying the correction factor (720/1.98) is 364 n per group. Calculating power for a two-mean comparison for a difference in means of 0.06, a common standard deviation of

0.29 (estimated from CRFA pilot data), and a type I error rate of 5% with a one-sided alternative hypothesis, we arrive at a power estimate of 87% for this sample size.

Given the proposed sample size, the effect sizes that can be detected with 80% power for the secondary hypotheses outlined above were determined. For Hypothesis #1, the test of significant change in outcome over time within CD-ROM and Curriculum groups, the size of the change in behavior score that can be detected with 80% power and a two-tailed alpha of 5% is 0.043. For hypothesis #3, the comparison of the combination instruction method with the pooled CD-ROM and Curriculum conditions, the size of the difference in behavior score change that can be detected with 80% power and a two-tailed alpha of 5% is 0.05. If we cannot pool the CD-ROM and Curriculum conditions, individual comparisons between these conditions and the Combination group will detect a difference of 0.06 with 80% power and 5% two-tailed alpha. Based on previous SDHW evaluations, we anticipate that there will be a loss of approximately 10% of students from pretest to posttest but no loss of classes or schools. Thus, we will strive to recruit 16-17 students per class for a total pretest sample of 2,376 to yield a final sample of 2,160 students at posttest.

E. HUMAN SUBJECTS

E.1 Selection Criteria

Students. Students enrolled in grades K through 5 in the spring semester of the 2001-02 academic year at 12 public elementary schools randomly selected from the _____ County School District, and two metro _____ school districts. Anticipated number: 2,160 students. Anticipated age range: 5-11 years. Anticipated health status: good health. There are no criteria for inclusion or exclusion of any sub-population of students. Recruitment procedures will be designed to obtain a sample of students that matches the overall student population in the districts. No one will be excluded from participating in this project due to race, color, ethnicity or gender. The large proportion of white, non-Hispanic students in this population is a plus for the proposed research. Epidemiological evidence shows that the incidence of skin cancer is many times higher among white, non-Hispanic adults than among all other minority groups such as Hispanics, Asian-Americans, and African-Americans, who typically have darker skin tones which provide natural protection (i.e., melanin) against UVR damage. Students of white, non-Hispanic ethnicity are at greatest risk for developing skin cancer and hence are the primary target of the proposed CD-ROM skin cancer prevention curriculum. Schools may request that materials be available in Spanish for Spanish-speaking students. Although such a request has not occurred in previous SDHW evaluations, the project will use translation methods from previous studies, if needed.

Teachers. Classroom and computer teachers instructing classes in grades K through 5 in the spring semester of the 2001-02 academic year at 12 public elementary schools randomly selected from the ____County School District and two metro _____ school districts. A monetary incentive of $50 will be paid to each participating teacher. Anticipated number: 144 teachers (i.e., 48 CD-ROM, 48 Curriculum, and 48 CD-ROM and Curriculum). Anticipated age range: 22-70 years. Anticipated health status: good health. There are no criteria for inclusion or exclusion of any sub-population of teachers.

E.2. Source of Research Materials

Data (for CD-ROM program evaluation) in the form of group-administered standardized questionnaires will be collected from students by staff. In addition, the CD-ROM programs will record students' responses and choices in the interactive activities to provide a measure of learning. A sum of student scores (number of correct and incorrect responses/choices) will be computed from the CD-ROM computer files. Process data in the form of self-completed checklists of CD-ROM use in instruction will be collected from intervention teachers to verify fidelity. Measures of skin color will be obtained from a small subsample (n=100) of participating students using a Minolta Chroma Meter CR-200 colorimeter. Data are stored directly into portable laptop computer files and printed out on paper tapes as back-up. All data will be obtained specifically for research purposes.

E.3. Recruitment and Consent Procedures

a. Identification of eligible students will be made by PHS staff working with district and school administrators.

b. PHS staff will contact administrator(s) of schools and school districts and make an oral presentation to the administrator(s) describing the purpose of the study, recruitment of students and teachers, research procedures, selection criteria, risks, and benefits of study. We will distribute written descriptions to school administrator(s).
c. All grade K-5 teachers from the participating schools randomly-selected for participation will be asked to participate by the project staff. Participating teachers will be contacted by PHS staff by telephone or in person and invited to participate. PHS staff will describe the purpose, procedures, risks, and benefits of the CD-ROM program to teachers. Two teachers (classes) per grade per school will be needed. Teachers will be randomly-assigned to either intervention or control depending on whether they are from a Group A or Group B school (see research methods). Teachers will receive a written description and oral presentation of the project from project staff. The communications will include what will be expected of participating teachers and students in terms of time and effort. Any questions will be answered. If 12 participating, consented teachers are not obtained at the first eight schools, another school will be randomly-selected and the process will be repeated there and at subsequent schools until the full sample is recruited and consented.
d. The recruitment of students will be conducted in each classroom of the consenting/participating teachers at the eight schools randomly-selected for participation. The parents of all students will be mailed a consent packet by project staff, including a letter of introduction describing the study. If the target number of participating, consented students are not obtained at the eight schools, another school will be randomly-selected and the process will be repeated there and at subsequent schools until the full sample is recruited and consented.
e. PHS staff will make an oral in person presentation to teachers at schools selected for recruitment of students. PHS staff will describe the project research procedures, selection criteria, risks, and benefits, and distribute written descriptions to teachers.
f. Active, voluntary parental informed consent will be obtained for each participating student. Parents will be mailed a consent packet by PHS. The school may provide parent addresses to PHS or it may affix mailing labels to packets prepared by PHS to protect parents' confidentiality. Packets will contain (a) letter of introduction from the school principal endorsing the project, (b) informed consent letter from the PI at PHS, Ms. _____, describing the project, (c) informed consent form on which parents indicate whether they give consent for their child and sign the form, and (d) postage-paid return-addressed envelope addressed to PHS. To improve participation, teachers will distribute flyers; school newsletters will contain articles; and reminder postcards will be mailed to parents. All consent forms will conform to DHHS regulations on the protection of human subjects and be approved by _____ Institutional Review Board.
g. Student assent will be obtained by reading an informed assent statement aloud to all students as they read along with their own copy. Students will be asked to indicate whether they assent to participate in the project by marking the “yes” box and signing their name on the form. Student assent statement will conform to DHHS regulations on the protection of human subjects and be approved by ____ IRB. Only students for whom PHS receives <u>both</u> parental consent and student assent will participate in the project.
h. Teachers will read and sign a consent form before the implement the CD-ROM programs with their students.

<u>E.4 Potential Risks</u>

Potential risks posed by the proposed research are minimal and mainly psychological and social. Participating students may be embarrassed or feel uncomfortable reporting their computer skills, use of and experience with educational computer software, and their sources of health information on a questionnaire. Participating students may be embarrassed or feel uncomfortable reporting their knowledge, opinions, and behaviors related to sun safety. They may desire to please their teachers and the research staff and feel disappointed if they do not report frequent sun safety. Focus groups, telephone interviews, and face-to-face interviews are alternative methods of data collection. However, focus groups may tend to sway students responses away from their true answers and the participants may be afraid that the other students will react unfavorably to their answers. Telephone interviews would be very time consuming and virtually impossible with the young people in grades K-5. Also, face-to-face interviews in the home would be highly intrusive and probably unacceptable to parents. Each alternative method would be very time consuming relative to the small reduction in risk obtained

through these two methods. Also, face-to-face interviews would be disruptive to the educational process at schools and be unacceptable to teachers and administrators; school districts will not release students' home telephone numbers; and parents would find telephone interviews at home highly intrusive.

E.5 Procedures for Protecting Against or Minimizing Potential Risks

All student questionnaires will be completed by the students in group sessions, where they will be separated enough to insure that students cannot view each other's responses to the standardized questionnaires. Kindergarten and first grade students, because of their limited test-taking and reading skills, will be asked survey questions in a small group settings. Trained professional interviewers and project staff will be present at all group testing sessions to provide structure and insure that students answer each question on their own. School personnel will be present at all data collection sessions. To protect the privacy and confidentiality of student data, completed student questionnaires will be stored and entered into computer data files at the PHS offices in _____, _____ with access limited to investigators, senior project staff, and biostatisticians. Student responses will only be reported to teachers and school administrators as an aggregate of all students participating in the entire project. No responses from an individual student will be reported to any teacher or school administrator.

E.6 Reasonable Risks to Subjects

The minimal risks posed by this project are reasonable because the participating students will receive a great deal of information, aid, and support from the investigators and project staff to improve their sun safety to lower their exposure to ultraviolet radiation and ultimately lower their risk of developing melanoma and NMSC. The students will provide a great deal of information to investigators and project staff that will result in a collection of CD-ROM programs that improve the sun safety of children. At the conclusion of the interviews, participating children and their parents and participating teachers will receive information on how to adequately protect themselves from the sun to lower their exposure to UVR and ultimately lower their risk of developing melanoma and non-melanoma skin cancers.

The project will yield an understanding of how to design successful school-based CD-ROM curricula to increase sun safety among children enrolled in grades K-5. This age is a period when lifelong health habits, personal decision making about health, and even tanning norms arise in children that can produce more UVR exposure and substantially increase lifetime risk of melanoma and NMSC development. This project will produce interactive multimedia activities that integrate with an existing, successful sun safety curriculum for elementary school students to provide another means of performing sun safety instruction in busy educational environments. Also, the CD-ROM programs will conform to current health and science education standards, including anticipated national guidelines on skin cancer prevention for schools from the CDC. The CD-ROM programs will be compatible with existing health education and science curricula in grades K-5 in the U.S.

F. VERTEBRATE ANIMALS Not applicable.

G. CONSULTANTS

_____, Ph.D.
Assistant Professor

Department of _____and _____
_____State University
_____, ____ 80523

_____, Ph.D., Assistant Professor, Department of _____ and _____, _____State University, _____, ____ will serve as a consultant to this project in Years 1 and 2 for developing and testing agent-based, knowledge-construction interfaces. (See letter of agreement to serve following the Literature Cited.) _____ has a Ph.D. in Science and Mathematics Education (emphasis in cognitive science) from the University of _____, _____ and a M.S. in Technical Communication from _____ State University. He is a member of the Cognitive Science Society, International Communication Association, American Educational Research Association, and is a Registered Professional Engineer, State of Colorado.

Dr._____developed SCI-WISE (Social and Cognitive Improvement Within an Inquiry Support Environment), an agent-based, multimedia, advisory system that supports reflective inquiry. He developed the Scientific Inquiry Assessment Environment, an interactive assessment website and computer-based ThinkerTools that support students' metacognitive development. The ThinkerTools curriculum is a computer-based, inquiry approach to teaching physics to middle-school and upper elementary students. He also wrote, taped, and edited the video "Metacognition: The Movie." He has published and presented in the areas of:

\B. Student goal orientation in learning inquiry skills with modifiable software advisors.
\C. Enabling students to construct theories of collaborative inquiry and reflective learning with SCI-WISE: An approach to facilitating metacognitive development.
\D. Acquiring and transferring intellectual skills with modifiable software agents in a virtual inquiry support environment.
\E. Perspectives from middle-school education: Conceptual tools for learning through inquiry and reflection.
\F. Individual roles and group dynamics in a neurobiology problem-based learning classroom.
\G. Effective use of computers in psychology laboratory courses.

_____, Ph.D.
Associate Director

Department of _____
_____ Health Sciences Center
_____ of Arizona
_____, ___ 85724

_____, Ph.D., Associate Director, _____ Communications, _____Health Sciences Center, University of _____, _____, AZ will serve as a consultant to this project in Years 1 and 2 for instructional design multimedia development, software beta-testing, and final CD-ROM revisions and refinement. (See letter of agreement to serve following the Literature Cited.) Dr. _____ leads the Interactive Multimedia Design (IMD) Team in _____Communications. He and his IMD team have nine years of experience creating and evaluating interactive multimedia instructional computer programs. They author interactive multimedia programs on the Windows 3.1/Win95 platform using Asymetrix Multimedia Toolbook CBT Version, a suite of multimedia authoring tools. Experience and skills of this team include: (a) Script writing and storyboarding for multimedia productions; (b) Recording, editing, post-production of high-quality narration, sound effects and music (8- and 16-bit audio); (c) Production and post production of high quality video (3/4" SP format within an A-B roll production facility); (d) Digital capture and compression of video for computer display employing all popular codes; (e) High quality graphic design and palette management to ensure faithful display of photorealistic images; (f) Database interface design using multimedia front ends (Paradox and Dbase III); (g) Extensive programming experience to ensure in-depth error trapping and user feedback; (h) Human-machine interface design to ensure cognitive consistency and ergonomic efficiency; (i) API hooks so that Web browsers can be configured to download and automatically execute finished titles via the Web which allow central updating of titles for wide distribution, if desired; (j) Thoroughly tested setup programs to make installation easy for the end user; (k) Thorough understanding and experience creating CD-ROM masters; all titles can be mastered in-house; (l) Creation of direct calls to URL's on the network so that Web browsers can be automatically executed and search for a World Wide Web location to present to the user, which allows users to be directed to interesting Web sites of relevance for additional information; (m) Packaging of finished titles for distribution. The Division's 45 media professionals provide scientific/medical illustration, graphic design/publication, medical photography, multimedia program development, broadcast television production, and media technical support.

In the Human Growth and Well-being Project (NICHD), Dr. _____ supervised the development of an HIV/AIDS prevention curriculum for grades 3-8 delivered on 36 interactive multimedia instructional programs to a multicultural student population in Arizona and New Mexico. He currently is directing the development of the SDHW grade 4 CD-ROM programs in the project funded by the Cancer Research Foundation of America (Dr. _____, P.I.). He also is a consultant on Ms. _____'s Phase I SBIR to develop sun safety CD-ROM prototypes for grades K and 2. Dr. _____provides consultation on multimedia development and beta testing to Asymetrix Corporation (Toolbook), IBM, AT&T,

Environment Canada, and the Institute for Academic Technology. He is an Asymetrix Advisory Board member. See the attached letter from Dr. _____ confirming his commitment to this Phase II project.

H. CONSORTIUM ARRANGEMENTS

_____ Cancer Research Center
_____ Street
_____, ____80214

Consortium Investigators: _____, Ph.D., Chair, _____ for Health Communication
_____, Ph.D., Chair,_____Center for Research _____and _____

A subcontract will be drawn between _____and ____ Cancer research Center (____) to cover costs incurred by (1) the _____Communication Core for CD-ROM design and production and (2) the Center for Research _____ and _____ for statistical design, data processing and analysis. _____ is a not-for-profit research institute dedicated entirely to the prevention and control of cancer. In 1995, the American _____ was incorporated as a holding company for _____, ____ and the _____Cancer Research Foundation. Currently, ____has 116 scientists and staff working in the areas of biostatistics, behavioral science, community studies, and laboratory science. ____is funded by profits from _____, federal and private grants, and contributions. ____ was first incorporated in 1904 as the Jewish Consumptives Relief Society - a tuberculosis treatment facility. With the control of tuberculosis, ____shifted its mission to cancer treatment in the 1950s. In 1989, _____ refocused its mission exclusively to cancer prevention and control research.
Subcontract fees have been negotiated with ____ (see budget pages). ___and ___ are prepared to establish in writing the required contractual agreement when this application is funded. Ms. _____ (P.I.) will administer the contract for ____ and Dr. _____, Director of ____ and Dr. _____, Director, Health Communications Core, will administer the contract for ____. See attached letter from Dr.____ and Dr. _____ (following Literature Cited) confirming AMC's intent to enter into such a contract.

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