

NCIPC Determination of Applicability of Human Subjects Regulations, Request to Classify Project as Not Involving Human Subjects or Research

Project Title: Science to Practice: Developing and testing a marketing strategy for preventing alcohol-related problems in college communities

Science Officer(s) Ruth Shults, PhD, MPH Division: DUIP Telephone: 770 488 4638
Ethics verification number: 0083

Project Officer(s) _____ Division: _____ Telephone: _____
Ethics verification number: 83

Proposed Project Dates: Start: Aug 1, 2009 Ending: March 31, 2013

Categories of data collection that do not constitute human subjects research **OR** do involve human subjects but CDC not engaged are listed below. Please check appropriate category:

- I. Activity is not research.** Primary intent is public health practice: disease/injury control, surveillance, improvement of programs or services. Objectives focused on a specific population.
- A. Epidemic/endemic **disease/injury control** activity; collected data directly relate to *immediate* disease control needs.
- B. Routine **disease/injury surveillance** activity; data used for disease control program or policy purposes for a specific health condition/disease in a specific population and setting. (Includes disease reporting)
- C. **Program evaluation** activity; data are used primarily for assessing, monitoring or improving a program in a specific population/setting.

Justification: Please attach project goals/aims, objectives, design, setting and participants, methods, and data sources.

-OR-

II. Activity is research but does NOT involve identifiable human subjects. Primary intent is to develop or contribute to generalizable knowledge.

- A. Activity is research involving collection/analysis of data about health facilities or other organizations or units, which are *not individual persons.... or...*
- B. Activity is research involving data and/or specimens from *deceased persons*.

Justification: Please attach project goals/aims, objectives, design, setting and participants, methods, and data sources.

-OR-

III. Activity is research involving human subjects but CDC – including employees, visiting scientists, fellows, and on-site contractors (but not off-site contractors or other collaborators) - will NOT obtain data by intervening or interacting with participants and will NOT have access to identifiable (including coded) private data or biological specimens.

Justification: Please provide a summary of CDC's role and explain that CDC will not be "engaged" in either obtaining

data by intervening or interacting with participants or have access to identifiable data. Staff can have access to data that have been stripped of the codes that link information to individuals and still be considered to not be "engaged" in human subjects research. Also, please attach a summary of project goals/aims, objectives, design, setting and participants, methods, other data sources and plans for local IRB review.

Once local IRB approval has been obtained please forward a copy (electronic preferred) to the Human Subjects Contact (Natalie Gilles) for records keeping purposes.




Attach project description in enough detail to clarify "non-human subjects", "non-research" or "not-engaged" nature of the product.

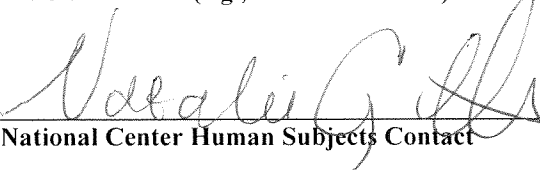
Comments/Rationale:

Although CDC Human Subjects (IRB) review is not required in this instance, investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality and autonomy of participants. All applicable State and Federal privacy laws must be followed.

Additional Comments:

Required Signatures:

	<i>2/11/09</i>
_____	_____
Division Official (e.g., Director or ADS)	Date

	<i>2/18/09</i>
_____	_____
National Center Human Subjects Contact	Date

STATEMENT OF WORK

Title of Project: Science to Practice: Developing and testing a marketing strategy for preventing alcohol-related problems in college communities

C.1 Background and Need – Each year, 1,700 college students die and more than 1.4 million are injured in alcohol-related incidents. Additionally, about 25% of students reporting negative academic consequences due to alcohol. Despite the enormous public health burden of college-age alcohol misuse, there have been few rigorous evaluations of environmental strategies to address alcohol misuse in college settings; environmental strategies typically involve implementing and enforcing policies that change the environments that influence alcohol-related behavior and subsequent harm. Further, studies show that the typical lag time between identifying an effective interventions and obtaining widespread adoption can stretch to well over a decade. There is an urgent need to develop more efficient and timely strategies for moving effective science to widespread practice. This project will address this exact issue by systematically developing a marketing strategy for a comprehensive, community-based environmental prevention program with proven efficacy in reducing intoxication and alcohol-impaired driving among college students.

The *Safer California Universities Project* was designed, implemented, and evaluated by the Pacific Institute for Research and Evaluation (PIRE) with funding from the National Institute for Alcohol Abuse and Alcoholism (NIAAA). This comprehensive community-based program focuses on the first weeks of the academic year and comprises several alcohol control measures (enforcement of underage sales laws; roadside DUI operations; social host party patrols with local ordinances) along with a multi-faceted media advocacy campaign via channels unique to college student audiences. The program was implemented among campuses in the two California university systems (UC and CSU). The purpose of this acquisition is to develop and test a marketing strategy that addresses the variety of barriers and challenges that colleges and universities may face as they consider adopting a program based on the *Safer California Universities Project*.

The timing of this work is critical because the public debate over how best to reduce the burden of alcohol-related problems among college students has recently escalated. A small but vocal group of university administrators are now questioning the merits of the nations' minimum legal drinking age of 21 years. They are recommending lowering the drinking age to 18 years and providing alcohol education. This approach has appeal because it is much simpler to implement and less likely to meet with community opposition than an environmental strategy such as the *Safer California Universities Project* that involves policy change and enforcement. However, education-only approaches such as this have been consistently shown to be ineffective in changing behavior.

C.2 Project Objective –The purpose of this acquisition is to systematically develop and test a strategy to market a comprehensive, community environmental prevention program, the *Safer California Universities Project*, that has demonstrated efficacy in reducing intoxication and alcohol-impaired driving among college students. The Safer Universities project combines alcohol management policies and enforcement with a publicity campaign targeting student drinking at private parties in homes and apartments (including fraternity and sorority houses) in

the college community. The proposed approach for developing and testing the marketing strategy is broadly based on work by the CDC (Sogolow, Sleet, Saul, 2007), the NIH and health communication theorists such as Maibach and Bloodgood, (2006) who argue persuasively on behalf of using a marketing approach to move an evidence-based strategy to adoption by a wide audience.

C.3 Scope of Work –

Independently, and not as an agent of the government, the contractor will furnish all the necessary personnel, facilities, supplies, and equipment required to systematically develop and test a marketing strategy for a comprehensive, community-based environmental prevention program that has proven effective in reducing intoxication and alcohol-impaired driving among college students as described in the Technical Requirements.

C.4 Technical Requirements – An ongoing collaboration between the contractor and CDC program staff is expected, with CDC playing a consultation role in the project, providing technical assistance, and contributing to the preparation of manuscripts for publication.

The contractor shall perform the following tasks:

Task 1

Initiate and schedule quarterly conference calls with CDC staff

Within two weeks of the effective date of the contract, the contractor shall arrange an initial conference call with CDC staff to clarify the scope of work and delivery schedule, delineate roles and responsibilities, and establish communication protocols. The contractor and CDC staff will establish a schedule of quarterly conference calls.

Task 2

Develop a detailed work plan and time line

Within six weeks of the effective date of the contract, the contractor shall submit to the Project Officer a draft copy of the work plan which will include a time line for completing all project tasks and a management and staffing plan. Within two weeks of receipt of the draft work plan, CDC will furnish the contractor its comments and recommendations to be included in the final work plan. Within ten weeks of the effective date of the contract, the contractor shall furnish to the Project Officer an electronic version of the final work plan incorporating CDC's comments and recommendations.

Task 3

Quarterly progress reports

The contractor will submit quarterly written reports. See section C.5 for additional details.

Task 4

Provide materials for obtaining Office of Management and Budget Paperwork Reduction Act clearance for focus groups

The contractor will provide the necessary documentation about the project to complete the Office of Management and Budget Paperwork Reduction Act Clearance package.

Documents will include, but may not be limited to, the justification for information collection; details of statistical design, data collection and analysis; estimates of the hour burden of the collection of information; and copies of data collection instruments.

Task 5

Conduct Focus Groups

The overall objectives of this task are to understand how best to 1) customize the promotional materials to appeal to the different campus and community stakeholders who may lead the project; 2) customize the program materials to meet the needs of these various stakeholders, and 3) identify likely stakeholders and assist them in selecting and implementing the *Safer California Universities Project*, hereafter referred to as the *Safer Universities Project*. The contractor will recruit focus groups from universities in California and at least one other state. The focus groups will be designed to isolate the perspectives of different campus and community stakeholders (e.g., upper-level administrators such as vice-presidents; campus and municipal police; student affairs; judicial affairs; student health; community leaders). Information gathered from the focus groups will be used to: 1) develop customized marketing materials targeting various potential campus and community stakeholders; 2) revise and expand the existing draft program toolkit; and 3) inform strategies for the marketing plan.

Task 6

Develop a program toolkit and marketing plan

Drawing on the results from the focus group discussions, internal expertise, and consultation with experts in the fields of marketing and dissemination of evidence-based community interventions, the contractor will develop a program toolkit and marketing plan for the *Safer Universities Project*. In producing the marketing plan, the contractor will develop marketing and program materials that would appeal to various stakeholder groups that might be in charge of implementing the program. For example, if the program was to be implemented by campus or municipal police departments, the program toolkit would be accompanied by resources heavily pitched toward police agencies and providing “standard operating procedures” for the various enforcement operations (i.e., decoy operations for sales to minors, DUI roadside checks; party patrols). As an alternative, the same basic interventions could be described as a community awareness program with an emphasis on educating students on the limits of acceptable (party) behavior as defined by the community via its state and local laws that the student are subject to. In this orientation, police operations would be described as supporting the campaign (rather than vice versa) by providing the minimum necessary to ensure credibility of the messaging.

The marketing plan will include a strategy for how best to reach the various audiences. Potential strategies include media advocacy via publications read by college personnel (e.g., Chronicle of Higher Education); presentations at professional conferences (e.g., Student Affairs Administrators in Higher Education – NASPA; American College Health Association); and a web site with materials from the toolkit, more details on evidence for its efficacy, and testimonials from professional staff at the campuses that have already (and successfully) implemented the program.

Task 7

Provide materials for Obtaining Office of Management and Budget Paperwork Reduction Act clearance for post-marketing survey

The contractor will provide the necessary documentation about the project to complete the Office of Management and Budget Paperwork Reduction Act Clearance package. Documents will include, but may not be limited to, the justification for information collection; details of statistical design, data collection and analysis; estimates of the hour burden of the collection of information; and copies of data collection instruments.

Task 8

Execute the marketing plan

The contractor will execute the marketing plan with a national sample of about 150 4-year colleges and universities. Some marketing activities may not be limited to the sampled institutions (e.g., giving presentations to professional organizations), but having the sample will allow the contractor to dedicate resources such as direct mailings or even, for instance, live web-based presentations to a small audience of one campus' personnel.

Task 9

Post marketing key informant survey

The contractor will follow up that marketing effort with a survey of key informants from the sampled institutions who would most likely play a major role in whether the *Safer Universities Project* was adopted by their campus. A key goal of the survey will be to identify where the marketing efforts were successful and where they may have met resistance (which members of the focus groups would have only anticipated). In reporting results of this survey, the contractor will include potential campus-level factors (e.g., size of student population; urban vs. rural setting; whether the campus has sworn law enforcement officers vs. security personnel; level of activity among Greek organizations; and level of collegiate athletic program). These results will be incorporated into the final marketing plan that will be included in the final report of the project.

Task 10

Final report on findings

The contractor will summarize and present findings in a final report. The report will include the program toolkit and a proposed marketing plan for widespread adoption of the *Safer Universities Project* that draws on the conclusions from the project.

C.5 Reporting Schedule –1. Quarterly Progress Reports

The contractor will submit a quarterly progress report in electronic format to the CDC Project Officer.

The quarterly **progress report** will include:

- A description of activities during the prior quarter
- Copies of any materials developed
- A summary of conference call and e-mail communication with CDC
- Challenges and suggestions for solutions
- Activities planned for the next quarter
- Activities by project staff

- Changes in project staff
- Changes in budget
- Other information as requested by the Project Officer

2. Final Report

The contractor shall provide a final report that includes final copies of all materials developed; a summary of activities, study results and a summary of major challenges encountered and solutions identified. A list of any published, prepared or planned manuscripts from the project will be included.

C.6 Special Considerations –N/A

C.7 Government Furnished Property – N/A

C.8 References –

Maibach EW, Van Duyn MAS, Bloodgood B. A marketing perspective on disseminating evidence-based approaches to disease prevention and health promotion. *Prev Chronic Dis* [serial online] 2006 Jul [4 Feb 2009]. Available from: URL: http://www.cdc.gov/pcd/issues/2006/jul/05_0154.htm.

Sogolow, E S, Sleet, DA, Saul, J. Dissemination, implementation and widespread use of injury prevention interventions. In Doll L, Bonzo S, Mercy J, Sleet D (Eds). *Handbook of injury and violence prevention*. New York: Springer, 2007. p. 493-510.

Deliverables – The contractor shall furnish the CDC Project Officer the following items in the quantities and during the time periods indicated.

Task	Description	Deliverable	Due Date (as of Effective Date of Contract)
1	Schedule regular conference calls with CDC staff	Participation as required	2 weeks
2	Work Plan and Timeline	Final work plan and time line	2 months
3	Quarterly Progress Reports	Progress reports	quarterly
4	Provide materials for OMB Paperwork Reduction Act Clearance	Required documentation for conducting focus groups	4 months
5	Conduct Focus Groups	Plan for incorporating focus group results in to toolkit and marketing plan	20 months
6	Develop a program toolkit and marketing plan	Draft toolkit and marketing plan	24 months
	Provide materials for OMB Paperwork Reduction Act	Required documentation for conducting post-marketing survey	

7	Clearance		24 months
8	Execute marketing plan	Summary of marketing activities and results	42 months
9	Post marketing key informant survey	Summary of results and plan for incorporating results in to final toolkit and marketing plan	42 months
10	Final report on findings	Final report	44 months