

Proposed Project

Field Test of Communication and Marketing Variables for Health Protection—New—National Center for Health Marketing/Coordinating Center for Health Information Service (NCHM/CCHIS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC does not have a mechanism to assess and monitor the health communication and marketing components of health protection. While CDC does invest in formative and process evaluation of specific health communication and marketing programs and projects, the common elements rooted in communication and marketing theories and constructs are not identified across programs and projects, nor frequently compared after the fact to ascertain the underlying factors and dynamics that inform and shape individual and group behaviors and actions. The purpose of this project is to develop a core set of communication and marketing variables that can be used to inform CDC health protection programs and projects as well as track population-level changes over time.

The proposed data collection is to conduct a field test of the survey

instrument focusing on the core communication and marketing constructs for health protection behaviors. The field test survey will be administered to a purposive sample of 1,925 respondents. Two modes of administration will be tested, telephone (both landline and cell) and self-administration via the Web. The telephone survey will be conducted in five geographical locations. The Web survey will use an on-going national consumer panel.

Rather than randomly sampling from the population, CDC has identified subpopulations of particular interest and interviewers will achieve quotas of completed interviews from each group. This purposive sampling is designed to reach adult persons who are vulnerable from a health protection perspective. It is of particular importance to interview those known to have low health literacy, that is, difficulty accessing and/or understanding health messages so CDC can work to meet their needs. Therefore, included in the target groups are the elderly, who may be somewhat isolated and for whom health messages may be confusing; people of low socioeconomic status (SES), whose level of education can be a barrier to comprehending and following health messages; and persons

not fluent in English, for whom innovative ways of communicating health messages may be necessary. In addition to English, interviews will be conducted in three other languages, Spanish, Cantonese and Vietnamese. Members of the general population will be surveyed as well in order to provide a benchmark for the subpopulations of interest. Demographic variables that will be used to screen respondents into the subpopulations of interest include age, education, and race and ethnicity. Interviewing will continue with specific subpopulations until quotas are reached. Incentives will not be provided to survey respondents.

CDC will use the field test data to assess continuity of response patterns within each of the subgroups and to determine differences in administration time. In addition to subgroup population differences in attitudes, beliefs, and health behaviors, CDC will use the data to examine item-level mode effects, regional differences, and administrative/logistical barriers to guide the design of core measure surveys for other health protection behaviors. There is no cost to respondents other than their time to complete the survey. The total estimated annual burden hours are 1,222.

ESTIMATED ANNUALIZED BURDEN HOURS

| Forms and respondents | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|----------------------------------------|-----------------------|------------------------------------|----------------------------------------|
| Screener | 19,250 | 1 | 2/60 |
| Survey: General Population | 1,000 | 1 | 18/60 |
| Survey: Elderly | 275 | 1 | 18/60 |
| Survey: Low SES | 275 | 1 | 18/60 |
| Survey: Low SES African American | 150 | 1 | 18/60 |
| Survey: Hispanic | 75 | 1 | 18/60 |
| Survey: Chinese | 75 | 1 | 18/60 |
| Survey: Vietnamese | 75 | 1 | 18/60 |

Dated: October 8, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more

information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Regulations To Implement SAMHSA’s Charitable Choice Statutory Provisions—42 CFR Parts 54 and 54a (OMB No. 0930–0242)—Revision

Section 1955 of the Public Health Service Act (42 U.S.C. 300x–65), as amended by the Children’s Health Act of 2000 (Pub. L. 106–310) and Sections 581–584 of the Public Health Service Act (42 U.S.C. 290kk et seq., as added by the Consolidated Appropriations Act (Pub. L. 106–554)), set forth various provisions which aim to ensure that religious organizations are able to compete on an equal footing for Federal funds to provide substance abuse services. These provisions allow

religious organizations to offer substance abuse services to individuals without impairing the religious character of the organizations or the religious freedom of the individuals who receive the services. The provisions apply to the Substance Abuse Prevention and Treatment Block Grant (SAPT BG), to the Projects for Assistance in Transition from Homelessness (PATH) formula grant program, and to certain Substance Abuse and Mental Health Services Administration (SAMHSA) discretionary grant programs (programs that pay for substance abuse treatment and prevention services, not for certain infrastructure and technical assistance activities). Every effort has been made to assure that the reporting, recordkeeping and disclosure requirements of the

proposed regulations allow maximum flexibility in implementation and impose minimum burden.

No changes are being made to the regulations. This revision is for approval of the updated estimate of burden on respondents to provide the information required to be reported by 42 CFR part 54a.8(d) and 54.8(e), respectively, and to ascertain how they are implementing the disclosure requirements of 54a.8(b) and 54.8(b), respectively. Information on how States comply with the requirements of 42 CFR part 54 was approved by the Office of Management and Budget (OMB) as part of the Substance Abuse Prevention and Treatment Block Grant FY 2008–2010 annual application and reporting requirements approved under OMB control number 0930–0080.

| 42 CFR Citation and purpose | Number of respondents | Responses per respondent | Total responses | Hours per response | Total hours |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------------|-----------------|--------------------|-------------|
| Part 54—States Receiving SAPT Block Grants and/or Projects for Assistance in Transition From Homelessness | | | | | |
| Reporting: | | | | | |
| 96.122(f)(5) Annual report of activities the State undertook to comply 42 CFR Part 54 (SAPT BG) | 60 | 1 | 60 | 1 | 60 |
| 54.8(c)(4) Total number of referrals to alternative service providers reported by program participants to States (respondents). | | | | | |
| SAPT BG | 7 | *68 | 476 | 1 | 476 |
| PATH | 0 | 5 | 50 | 1 | 50 |
| 54.8(e) Annual report by PATH grantees on activities undertaken to comply with 42 CFR Part 54 | 56 | 1 | 56 | 1 | 56 |
| Disclosure: | | | | | |
| 54.8(b) State requires program participants to provide notice to program beneficiaries of their right to referral to an alternative service provider. | | | | | |
| SAPT BG | 60 | 1 | 60 | .05 | 3 |
| PATH | 56 | 1 | 56 | .05 | 3 |
| Recordkeeping: | | | | | |
| 54.6(b) Documentation must be maintained to demonstrate significant burden for program participants under 42 U.S.C. 300x–57 or 42 U.S.C. 290cc–33(a)(2) and under 42 U.S.C. 290cc–21 to 290cc–35 | 60 | 1 | 60 | 1 | 60 |
| Part 54—Subtotal | 116 | | 818 | | 708 |

Part 54a—States, local governments and religious organizations receiving funding under Title V of the PHS Act for substance abuse prevention and treatment services

| | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------|-------|-------|-------|
| Reporting: | | | | | |
| 54a.8(c)(1)(iv) Total number of referrals to alternative service providers reported by program participants to States when they are the responsible unit of government | 25 | 4 | 100 | .083 | 8 |
| 54a(8)(d) Total number of referrals reported to SAMHSA when it is the responsible unit of government. (NOTE: This notification will occur during the course of the regular reports that may be required under the terms of the funding award.) | 20 | 2 | 40 | .25 | 10 |
| Disclosure: | | | | | |
| 54a.8(b) Program participant notice to program beneficiaries of rights to referral to an alternative service provider | 1,460 | 1 | 1,460 | 1 | 1,460 |
| Part 54a—Subtotal | 1,505 | | 1,600 | | 1,478 |

| 42 CFR Citation and purpose | Number of respondents | Responses per respondent | Total responses | Hours per response | Total hours |
|-----------------------------|-----------------------|--------------------------|-----------------|--------------------|-------------|
| Total | 1,621 | | 2,418 | | 2,186 |

* Average.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7-1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at summer.king@samhsa.hhs.gov. Written comments should be received within 60 days of this notice.

Dated: October 8, 2009.

Elaine Parry,

Director, Office of Program Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

B-cell Surface Reactive Antibodies for the Treatment of B-Cell Chronic Lymphocytic Leukemia

Description of Technology: B-cell chronic lymphocytic leukemia (B-CLL) is a cancer characterized by a progressive accumulation of functionally incompetent lymphocytes. Despite high morbidity and mortality, the only available potential cure is

allogeneic hematopoietic stem cell transplantation (alloHSCST). However, there is less than a 50% chance of finding a matching bone marrow or blood donor for B-CLL patients. Other clinically tested targeted therapies such as rituximab and alemtuzumab target both malignant and normal B cells, resulting in immunosuppression.

Available for licensing are fully human monoclonal antibodies that were selected from the first human post-alloHSCST antibody library. The library was generated from a time point after transplantation at which antibodies to B-CLL cell surface antigens peaked, thus indicating its therapeutic value. Utilizing phage display, the investigators generated a panel of fully human monoclonal antibodies that strongly bind to the same epitope on a B-CLL cell surface antigen. Weaker binding to normal B cells, but not to other lymphocytes, was observed. These fully human monoclonal antibodies provide readily available treatment that selectively targets malignant B cells.

Applications:

- B-cell chronic lymphocytic leukemia therapeutics.
- Method to inhibit the growth of malignant B-cells.
- Method to detect B-cell tumors.

Advantages:

- Selective targeting of malignant B-cell surface antigens that are minimally non-damaging to non-diseased cells.
- Readily available therapeutics without the need for bone marrow or blood transplantation.

Development Status: The technology is currently in the pre-clinical stage of development.

Market:

- Monoclonal antibody market has the potential to reach \$30.3 billion in 2010 largely driven by technological evolution from chimeric and humanized to fully human antibodies.
- In the U.S., there is annual incidence of an estimated 15,000 newly diagnosed cases of B-CLL and the disease is responsible for an estimated 4,500 deaths.

Inventors: Christoph Rader *et al.* (NCI)

Publication: S Baskar, JM Suschak, I Samija, R Srinivasan, RW Childs, SZ Pavletic, MR Bishop, C Rader. A human monoclonal antibody drug and target discovery platform for B-cell chronic lymphocytic leukemia based on

allogeneic hematopoietic stem cell transplantation and phage display. Blood, in press. Epub ahead of print, 2009 Aug 10.

Patent Status: U.S. Provisional Application No. 61/178,688 filed 15 May 2009 (HHS Reference No. E-163-2009/0-US-01).

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301-435-4633; wongje@mail.nih.gov.

Collaborative Research Opportunity: The Center for Cancer Research, Experimental Transplantation and Immunology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize fully human monoclonal antibodies selected from post-alloHSCST antibody libraries. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

CXCR4 and CCR10 Expressing Cells: Useful for the Study of Cancer Cell Survival and Metastasis

Description of Technology: The chemokine receptor CXCR4 functions in normal cells, but has been shown to be the most common chemokine receptor expressed on cancer cells, including melanoma, colon, breast, and lung cancers. It plays roles in angiogenesis and cancer cell survival as well as metastasis. CCR10 has also been shown to be expressed by melanoma cells. Like CXCR4, expression of CCR10 can enhance cancer cell survival and block immune recognition of cancer cells. Antagonists of CXCR4 and CCR10, under various conditions, have decreased metastasis or prevented tumor formation after implantation of cancer cells in mice.

These cell lines are based on the widely used B16 murine melanoma cell line. The cell lines were transduced with retroviral vectors encoding cDNA for either CXCR4 or CCR10 under control of a TET-dependent promoter. Both lines achieve greater than 10 fold induction of the respective genes (proteins), which has been confirmed by surface antibody staining using flow cytometry. These cell lines are ideally suited for studying the effect of these chemokine receptors in tumor growth or metastasis. They are also useful for