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To: Office of Management and Budget (OMB)

Through: Darius Taylor, Report Clearance Officer, HHS
Seleda Perryman, Program Clearance Officer, NIH
Karla Bailey, PRA OMB Project Clearance Liaison, NCI

From: Heather Patrick, Health Scientist Administrator
Division of Cancer Control and Population Sciences
National Cancer Institute (NCI)/NIH

Subject: Generic Sub-study #7, **Goals and Values in Physical Activity**, under
“A Generic Submission for Theory Development and Validation (NCI),”
(OMB No. 0925-0645, Expiry Date 12/31/2014)

Background/ Need and Use for Information

This proposed sub-study request involves formative research to develop and preliminarily validate a theory regarding motivation for physical activity. Research is needed to better understand the nature of people’s broader goals and values and to elucidate how people’s existing goals may be better harnessed through more appropriately-targeted health communication efforts. The study will involve a screener, a brief survey and a series of focus groups, differentiating physically inactive women along key demographic characteristics (ethnicity, age) that are known to be predictive of physical activity and along which broader goals and values may differ. Overall, this project aims to examine motivation for engaging in physical activity, guided by self determination theory as a framework for understanding this motivation.

The National Cancer Institute’s (NCI) Behavioral Research Program (BRP) is within the Division of Cancer Control and Population Sciences (DCCPS). The goal of BRP is to increase the breadth, depth, and quality of behavioral research in cancer prevention and control. BRP conducts varying programs of formative research to develop and validate cancer-related behavioral theories. This project will serve to examine motivation for physical activity, which is a scientific priority at the NCI. This NCI office is requesting that OMB review this sub-study, which describes a voluntary, low-burden, non-controversial, formative behavioral research project related to theory development and validation. Data collection for this project is authorized under 42 USC § 285 and 285a-1 (Section 410 and 412 of the Public Health Service Act).

To date, interventions based on two different but complementary perspectives – Motivational Interviewing (MI) and Self-Determination Theory (SDT) – have shown the most promise for

sustained behavior change in the absence of ongoing intervention.¹ One element that is common to these two approaches is the incorporation of a “goals and values exercise” within the intervention. The purpose of this exercise is to elicit from the individual his or her broader goals and values and to guide the individual to consider (1) how his or her current way of being (e.g., physically inactive) supports or impedes achievement of these broader goals and values and (2) how making a behavior change (e.g., becoming more physically active) may support or impede the achievement of these broader goals and values. By aligning a health goal (e.g., becoming more physically active) with broader goals and values (e.g., spending more time with my kids), MI- and SDT-based interventions support the process of internalization whereby people develop greater self-congruency and more sustained forms of motivation. Thus, the “goals and values exercise” is an important active ingredient of know-efficacious interventions and, importantly, could be modified to have broader public health impact via public health messaging.

Participants, Methodology, and Research Instrument

A convenience sample ($N = 63$) of women, ethnically and racially representative of the local area in Rockville, MD will be recruited, both through a government contractor’s database, of potential respondents and also through newspapers and craigslist (**Attachment A**), and will include mixed ages of adult women. 100 potential participants will be screened (**Attachment B**) in order to achieve a targeted representation across ages and race/ethnicity to ensure the participants are scheduled to the appropriate focus group (stratifying focus groups based on race/ethnicities).

Participants will be reminded of their appointment via phone (**Attachment C**). The study will be completed at Westat. When the participants arrive they will be consented for the study (**Attachment D**). Participants will then be handed a brief survey (**Attachment E**) to complete and the focus group will begin shortly thereafter (**Attachment F**). Participants will engage in focus groups of 7-9 individuals.

The survey includes similar demographic questions that were posed during the screener to ensure that each focus group is accurately described in terms of the demographic composition - and not just the study participants as a whole. Additionally, the survey includes a brief set of items to assess typical exercise behavior patterns of respondents and their level of interest in being physically active on a regular basis. These items will serve to inform analyses of focus group responses vis a vis participants' typical behaviors and attitudes toward exercise.

The full generic states that, incentives will be provided for:

“Research studies, including surveys and interviews, require mental resources and time, as well as transportation and parking expenses. Other costs to participants include time away from jobs and childcare....Additionally, when eligibility criteria for studies are specific (e.g., hard-to-reach populations or minorities, depending on the subject matter and context of the study), it may be difficult to recruit participants; incentivizing participants aids in recruitment. Levels of remuneration depend on a variety of factors, difficulty in recruitment and estimation of costs incurred to participants.” (Supporting Statement A, October 2011, OMB No. 0925-0645, p. 13).

Taking all these factors into consideration, the program staff plans to give respondents \$30 as an

¹ See Attachment G for selected readings.

appreciation for their time and other study-related expenses. This incentive is consistent with the full generic and can be justified to account for:

- The travel time since NCI is not located near a Metro stop,
- Women of child-bearing age who will not be provided with child-care, and
- Difficulty in recruiting a majority of the respondents who include African-American women, Latina/Hispanic women, and mixed race/ethnicity (i.e., a mix of African-American, Latina/Hispanic, and/or white women).

Analyses will involve qualitative analyses of themes in focus group transcripts, and examining correlations among these themes, demographic characteristics, and physical activity status. Findings will be disseminated to relevant audiences –health psychologists/ public health researchers who capitalize on basic psychological science advances to understand real world phenomena such as weight management.

Other Considerations

A request for human subject's exemption was approved by the NIH Office of Human Subjects Research Protection (OHSRP) (**Attachment H**).

Personally identifying information (PII) will be collected by the contractor during the recruitment process; specifically, name, address, and telephone number will be collected in order to facilitate recruitment and reminders. PII will be stored on a password protected file on a password protected computer in a locked office. After a participant completes the study, PII will be destroyed.

Burden

A total of 63 female participants will complete the study (and 100 will complete the screener), which has an anticipated length of no more than 100 minutes; thus, the total hour burden is 108 burden hours. To date, a total of 1,436 burden hours have been used of the 6,000 hours that were requested. Estimated cost to the Federal Government is approximately \$16,000 for NCI FTE/Project PI (estimated based on 10 FTE hours per week for 9 weeks for a GS14-7 (\$61.10/hour * 10 hours * 9 weeks = \$5,499)), contractor staff (estimated based on 12 FTE hours per week for 9 weeks (\$61.10/hour * 12 hours * 9 weeks = \$6,599), and Cancer Research Training Award Fellow (estimated based on 15 hours per week for 9 weeks (26.92/hour * 15 hours * 9 weeks = \$3,634)), \$10,000 for recruitment; and \$2,363 for survey incentives which amounts to a total of \$29,850 to conduct this study.

Estimates of Burden Hours					
Types of Respondents	Instrument	Number of Respondents	Frequency of Response	Average Time Per Response (in hours)	Total Hour Burden
General Public	Screener (Attachment B)	100	1	5/60	8
	Consent (Attachment D)	70	1	2/60	2
	Survey (Attachment E)	63	1	3/60	3
	Focus Group (Attachment F)	63	1	90/60	95
Total					108

List of Attachments

- A: Participant advertisement
- B: Screener
- C: Phone Reminders
- D: Consent form
- E: Survey
- F: Focus Group Protocol
- G: Selected Readings
- H. OHSRP Exemption