DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: ***July 22, 2013***

To: Office of Management and Budget (OMB)

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Subject: Generic Sub-study, **Patient Perspectives and Simulated Clinical Interactions** 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 plans to refine and validate a theory regarding patient-provider interactions, genetic and behavioral risk information about being overweight, and emotion during the clinical encounter. The study will take place online, and will involve several survey conditions. Participants will write about a time they felt angry (or fearful), or to write about a room in their house (neutral emotion condition), and then will participate in a hypothetical interaction (simulated by video; **Attachment 5A**) with a virtual doctor. Finally, they will answer a series of questions about the encounter, trust in the provider, their risk perceptions for breast cancer (as a co-morbid condition associate with being overweight), and intentions to engage in behaviors that would help them to achieve and maintain a healthy weight (**Attachment 5B**). This research will help to develop and validate a health behavior theory concerning the potential role of emotional influences on different types of patient-provider communications, and lead to further theory refinement.[1]

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 behavior, emotion, and communication in the context of informed patient-provider interactions, which is an emerging scientific priority not only in DCCPS, but also in the National Human Genome Research

1 For selected readings on emotion and patient-provider communication, see **Attachment 5C**.

Institute (NHGRI). This research will be conducted in collaboration with an intramural scientist in NHGRI. 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).

This data is collected through the TESS project, an opportunity for researchers to collect free data to examine psychological theories and hypotheses. A proposal was submitted for this study to TESS, and it was peer-reviewed by two reviewers, who recommended that it be accepted for fielding. Thus, data has been collected free of charge. TESS fields research through Knowledge Networks, an internet survey company. All data will be collected online. The project will be conducted as a collaborative effort between NHGRI and NCI. Recruitment and incentives for the project will be provided by TESS.

While some standard methodology for this proposed sub-study is shared with other sub-studies approved under this clearance **(Sub-studies 1-3)**, the underlying theoretical questions are quite different. As such, this sub-study will not duplicate current federal efforts.

Patient-Provider Communication and Emotion

This project examines patient reactions to introduction of genomic information into weight-related primary care encounters. We focus particularly on how this information will affect patients' health-related attitudes and intentions, and patient perceptions of stigmatization. Several types of emotions are commonly elicited in the medical care context. These emotions have great capacity to influence the way patients think about, feel about, and respond to the information they are given by providers. Given previous findings with respect to the effect of emotion on judgment and decision making, it is likely that patients' emotional state will moderate the relationship between the receipt of weight-related genomic information and their health and stigma-related attitudes and beliefs. This moderating effect may explain some of the previous conflicting findings in the literature assessing the influence or lack of influence of genomic information on behavior motivation. We will assess whether experiencing emotion in conjunction with receiving weight-related genomic information will influence patient motivation to achieve a healthy weight.

Perceived control is expected to increase with anger, decrease with fear. The uncontrollable nature of genetic causes are expected to reduce self-efficacy as a main effect, and attenuate increases in self-efficacy for those who are in the anger/genetic information condition. Breast cancer risk perception (a co-morbid condition related to obesity) is expected to decrease with anger, increase with fear. The 'personalized' risk associated with genomic information is expected to increase risk perception overall, and magnify the influence of fear in heightening risk perception. Trust is expected to decrease with anger and be unchanged by fear. Provision of weight-related genomic information is expected to increase trust in the doctor, but may increase trust less among those in the anger condition.

Participants, Methodology, and Research Instrument

An internet sample (N = 700), will be drawn from a standing Knowledge Networks panel, and

respondents will receive a maximum of $10 for completing this survey. They also receive an incentive of $4-6 per month for being on the internet panel and completing other surveys. Panelists will be eligible if they are overweight (BMI > 25), as determined by standing data on panelists available to Knowledge Networks. Participants will complete a standard Knowledge Networks Consent Form (**Attachment 5D**). The survey (**Attachment 5B**) will be fielded entirely online. Analyses will not yield results that can be generalized to the overall population. Personally identifying information (PII) will not be collected for this study; although Knowledge Networks maintains PII on members of the standing panel, these PII will not be transmitted or available for this study.

Respondents will be randomly assigned to one of three between-subjects conditions: anger, fear, or neutral. They will then participate in a virtual doctor encounter, where pre-tested videos of a virtual doctor will present information about the risks of being overweight (including increased risk of breast cancer), emphasizing either behavioral or genetic causes of weight gain/ being overweight. Finally, they will complete a questionnaire, assessing impressions of the encounter, trust in the provider, risk perceptions for breast cancer (as a co-morbid condition associate with being overweight), and intentions to engage in behaviors that would help them to achieve and maintain a healthy weight. All materials are included in Attachment 5B.

Analyses will involve examining correlations among study condition and questionnaire outcome measures (e.g., intentions, risk perceptions, and perceptions of the virtual encounter). 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 complex patient-provider interactions.

Other Considerations

The NHGRI IRB approved this project on May 30, 2013 (**Attachment 5E)**. The IRB protocol includes a pair of two studies; however, one of these studies is being conducted in the NIH clinical center, and has been granted a clinical OMB exemption. As such, we are requesting approval for only one study included on the IRB protocol under this generic clearance. Both studies are necessary to develop and refine this theory, and these are not duplicative.

Burden

A total of 700 participants will complete the study, which has an anticipated length of no more than 30 minutes altogether; thus, the total burden is estimated to be 350 hours. To date, a total of 812 burden hours have been used of the 6,000 hours that were requested. Estimated cost to the Federal Government is $1500 for staff (estimated based on 3 FTE hours per week for 10 weeks).

Estimates of Burden Hours

Form Name	Type of Respondents	Number of Respondents	Frequency of Responses per Respondent	Average Burden (in hours)	Total Hour Burden
Questionnaire (Attachment 5B)	General Public	700	1	30/60	350

List of Attachments

4A: Virtual Doctor Video Descriptions
4B: Questionnaire – Screenshot Versions
4C: Selected Readings
4D: Consent Form
4E: IRB Approval