SUPPORTING STATEMENT A For:

A Generic Submission for Theory Development and Validation

(BRP/DCCPS/NCI)

OMB Number: 0925-0645 Expiry Date :12/31/2014

September, 2014

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ATTACHMENTS

Abstract

This is a revision information request to conduct formative research related to behavioral science theory development and validation for the next three years. Formative research in the area of theory development and validation would provide the basis for developing effective cancer prevention and control strategies, allow for a better understanding of theoretical constructs that influence decisions and actions related to cancer, and ultimately contribute to reducing the U.S. cancer burden. Sub-studies proposed under this generic clearance would involve methodological testing and a standard set of research approaches, including surveys (internet, phone, and paper-and-pencil) and focus groups. Respondents would include individuals in the general public, recruited through established online panels or internet/ newspaper advertisements. Development of each study or survey would involve consulting with NCI scientists as well as experts from the behavioral science research community.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The National Cancer Institute's (NCI) Behavioral Research Program (BRP) is within the Division of Cancer Control and Population Sciences (DCCPS). BRP initiates, supports, and evaluates a comprehensive program of research ranging from basic behavioral research to the development, testing, and dissemination of interventions in areas such as tobacco use, screening, dietary behavior, and sun protection. 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. Specifically, BRP conducts formative research and evaluation in order to:

- Identify psychological, biobehavioral, demographic, and individual difference predictors of behaviors related to cancer prevention and control, including cancer screening, nutrition, physical activity, sedentary behavior, HPV vaccination, tobacco use and cessation, and sun safety behaviors,
- Develop and refine simple and complex theories to explain cancer-related behaviors,

- Extend our understanding of psychological and behavioral constructs important in theoretical frameworks for predicting cancer-related behaviors and outcomes;
- Refine theories and models used to inform cancer communication approaches (involving a wide array of approaches, from patient-physician communication to mass media), including research to elucidate responses to health and risk communications, as well as factors that may moderate such responses (e.g., health literacy, numeracy, emotion, self perceptions, cognitions),
- Observe theoretical and innovative trends in behavioral cancer prevention and control research, and
- Determine feasibility and usefulness of collaborative and multidisciplinary approaches to cancer prevention and control.

Formative research in the area of theory development and validation would provide the basis for developing effective cancer prevention and control strategies, allow for a better understanding of theoretical constructs that influence decisions and actions related to cancer, and ultimately contribute to reducing the U.S. cancer burden. This NCI office is requesting that OMB review this package, which describes a generic OMB clearance for voluntary, low-burden, non-controversial, formative behavioral research 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). Section 410 states, "The general purpose of the National Cancer Institute . . . is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients." The collections under this clearance would contribute to the conduct of behavioral

research with respect to causes, diagnosis, prevention, and treatment of cancer. Further, collections under this clearance may lead to initiatives designed to support this type of research (e.g., funding announcements).

As stated in the OMB document "Questions and Answers When Designing Surveys for Information Collections," under the heading: "What is a generic clearance and when are these useful for agencies?" http://www.whitehouse.gov/omb/inforeg/pmc_survey_guidance_2006.pdf): "A generic clearance is considered only when the agency is able to demonstrate that there is a need for multiple, similar collections, but that the specifics of each collection cannot be determined until shortly before the data are to be collected . . . Individual collections should not raise any substantive or policy issues or go beyond the methods specified in the generic ICR." This generic clearance request is in accordance with this description, as it would house similar collections, where the specifics cannot be determined until shortly before the data are to be collected. Additionally, the collections would be non-controversial in nature and would not contribute to or inform policy changes.

The need for a generic clearance in BRP has been identified based on feedback from scientific staff, internal working groups, and external consultants, and has been discussed in a number of scientific, expert panel, and ongoing working group meetings (discussed in more detail in Section A.8 and in **Attachment 1**). The purpose of the clearance would be to expedite the review of studies that would solidify operationalization of and elucidate associations among theoretical constructs, as well as empirically inform future theory development. BRP is committed to furthering theoretically-driven research, evidenced by a number of initiatives under the Theories Project (http://cancercontrol.cancer.gov/brp/theories_project/index.html). Further, in the strategic

planning efforts in BRP, integrating theory into research undertaken in and supported by BRP remains a key objective that helped to guide the organization of the Program and Branches.

The mission of each Branch within the Behavioral Research Program (BRP) includes advancing theoretically-driven research to elucidate psychological and behavioral factors that contribute to cancer control outcomes (see **Attachment 2**). For example, the Science of Research and Technology Branch (SRTB) leads and supports the development and application of innovative research approaches, theories, methods, measures, analytic tools, and technologies to advance social and behavioral science in the context of cancer prevention and control. The Basic Biobehavioral and Psychological Sciences Branch (BBPSB) advances research in biobehavioral mechanisms and psychological processes to reduce cancer risk and improve outcomes. The Health Communication and Informatics Research Branch (HCIRB) advances research on the processes and effects of communication and informatics across the cancer control continuum. (see http://cancercontrol.cancer.gov/brp/about.html)

Importantly, the expedited review of formative research studies under this clearance would attract research fellows (and scientific staff) to the Program. Currently, BRP houses eight post-doctoral fellows and nine post-baccalaureate fellows. The Program recruits fellows through a variety of mechanisms on an ongoing basis, including the Cancer Prevention Fellowship Program. Thus, the generic clearance proposed herein would benefit BRP twofold, not only by providing a means to request expedited review for important research that would inform Program priorities and initiatives, but also by providing research opportunities for current and future research fellows. Additionally, the expedited review would allow BRP to conduct formative research on timely cancer-related issues. For example, when new cancer screening guidelines are announced, an expedited review process would allow BRP to examine psychological reactions to

these guidelines as they unfold, contributing to theory development in this area. Other clearances have been granted to allow data collection to occur in a timely manner in response to emerging situations (for example, "Centers for Disease Control and Prevention (CDC) Secure Public Health Emergency Response Communications Network (Epi-X)," OMB No. 0920-0636 [expiry date 5/31/2014] covers data collection in the event of disasters and disease outbreaks; similarly, "Real Time Surveys of Consumers' Knowledge, Perceptions, and Reported Behavior Concerning Foodborne Illness Outbreaks or Food Recalls," OMB No. 0910-0711 [expiry 6/30/2014] covers data collection in the event of foodborne illness outbreaks or food recalls).

NCI is requesting a clearance similar to that previously granted to the Centers for Disease Control ("Formative Research and Tool Development," OMB No. 0920-0840, expiry date 2/29/2016). That generic clearance covered, in part, studies aimed to test mental models (psychological theories) of decision-making related to HIV/AIDS and other sexual-risk related conditions. Similar to the generic clearance requested by BRP/DCCPS/NCI described in this submission, the CDC clearance covered studies using a variety of methodological designs, including focus groups and surveys, to examine theoretical constructs related to health behaviors, including attitudes, knowledge, values, perceived stigma, beliefs, and skills (all constructs that would be of interest in the context of the current submission). A related Food and Drug Administration Clearance ("Focus Groups as Used by the Food and Drug Administration," OMB No. 0910-0497, expiry date 06/30/2014) covers qualitative research undertaken with the purpose of understanding theoretical constructs (e.g., emotions and attitudes) in consumer psychology. The National Institute on Aging also holds a (previously approved but not currently active) clearance to examine theoretical constructs (e.g., knowledge, attitudes, behaviors) and develop theories related to health communications ("Testing successful health communications surrounding aging-related

issues from the National Institute on Aging (NIA)," OMB No. 0925-0634, expiry date 3/31/2014). Additionally, other clearances have covered research examining theoretical factors related to health communication processing and decision-making in non-cancer-related domains, such as health literacy (e.g., "Prevention Communication Formative Research," OMB No. 0990-0281, expiry date 11/30/2015 to the Office of Public Health and Science) and attitudes ("Testing Communications on Medical Devices and Radiation-Emitting Products," OMB No. 0910-0678, expiry date 3/31/2017).

BRP/DCCPS/NCI is requesting generic clearance to conduct formative research related to behavioral science theory development and validation for the next three years.

1**A.2. Purpose and Use of the Information**

Data collections that result from this generic clearance would inform and clarify the use of theory in BRP-supported initiatives and funding announcements. For example, formative research empirically examining associations among various risk perception constructs may later inform a funding announcement requesting grant submissions that would validate a model of risk perception in a nationally representative population or that would use the risk perception framework to inform cancer-related behavior-change interventions. Formative research involving empirical development of a multilevel model for cancer prevention behaviors could lead to a funding announcement to support multilevel intervention research in cancer domains.

Sub-studies proposed under this generic clearance would involve methodological testing and a standard set of research approaches, including surveys (internet, phone, and paper-and-pencil) and focus groups. Respondents would include individuals in the general public, recruited through established online panels or internet/ newspaper advertisements. Development of each study or survey would involve consulting with NCI scientists as well as experts from the

behavioral science research community. Some examples of sub-studies that have already, and could again be submitted under this generic clearance include:

- A survey study to elucidate the association between two theoretical constructs: 1) health perceptions (e.g., risk perceptions, affective responses to risk, beliefs about curability or preventability of cancer) that arise as the result of reading or watching real news stories on cancer and 2) behavioral intentions for cancer prevention behaviors (Attachment 5),

- A mixed-methods study that utilized surveys and eye tracking software to examine attention to and perception of information on clinical trial consent forms and their association with perceptions of risks and potential benefits of the clinical trial,

- A survey study to disentangle different types of risk perceptions (e.g., comparative risk perceptions, numerical risk perceptions, intuitive "feelings" of vulnerability) in order determine whether these are empirically distinct and valid constructs,
- A focus group to assess mental models or lay perceptions of various cancers (e.g., whether people believe different types of cancer are common, severe, aggressive, controllable),

- A survey to examine whether messages framed in terms of gains (e.g., screening will reassure you that you are at low risk for cancer) or losses (e.g., not screening could result in not catching cancer that would be easily treatable) is most associated with intentions to screen,

- A survey study to validate novel theoretical frameworks that involve constructs on multiple levels (e.g., organizational, environmental, dyadic, social, and personality-level influences),

- A retrospective study examining major innovations in tobacco control research through bibliometric techniques as well as the Delphi technique (a qualitative research technique where experts in the field answer a series of polls to come to consensus in answering this type of research question). This could lead to the development of a multilevel theory for focusing tobacco cessation efforts. By identifying the most salient contributions to tobacco control, one might envision a theoretical perspective that identified similarities and connections among these contributions from a multidisciplinary theoretical perspective. For example, if such a study identified major innovative contributions such as warning labels (risk communication and behavioral economics), medications to break addiction (medical), and counseling approaches (psychological), these could be combined into an overarching theoretical model that might predict a successful tobacco control approach, and

- A study to examine whether risk tools (e.g., risk calculators on the NCI website) influence theoretical constructs such as risk perceptions and attitudes towards cancer and prevention.

Results would be analyzed using standard statistical analyses commonly employed in survey research. Weighted analyses would not be undertaken in data obtained under this clearance, as the sub-studies would be formative in nature and not intended to be representative. Results from studies would be disseminated to a specialized scientific audience, through publication in methodological and behavioral scientific journals. The ability to publish the data collected under this generic clearance is important, because such results could inform not only BRP theory-related initiatives, but also theory development and validation done by other behavioral scientists. Additionally, it is possible that data collected under this clearance would be made publicly available for scientists to use for their own hypothesis testing, a type of dissemination that has been approved for other questionnaire generic clearances (e.g., OMB No. 0920-0237 expiry date 10/18/2013, to the CDC for the National Health and Nutrition Examination Survey studies,; not currently active but previously approved).

Other information that may be gathered on respondents includes demographic information (e.g., gender, age, educational attainment, income, race/ethnicity, family medical history) may provide a basis for evaluating whether theoretical associations differ by demographic characteristics.

A.3. Use of Information Technology and Burden Reduction

Information collection for sub-studies under this generic clearance may be conducted using a variety of methodologies and technologies, such as interviews, focus groups, or questionnaires, depending upon the research question addressed by the study and the population of interest. All efforts will be made to use technology to reduce respondent burden. For example,

collecting data in surveys or online focus groups via the Internet has the potential to reduce time burden for respondents, as well as for data collectors. Through the Internet, respondents can access surveys wherever is most convenient for them, and at whatever time is most convenient. This eliminates the need to travel for in-person or group interviews, or to mail surveys back to NCI. Internet surveys and focus groups also eliminate the need to enter, and often clean, data, which reduces the burden on researchers. NCI anticipates that the majority of data for collections approved under this generic clearance will be collected electronically.

Online surveys are particularly convenient for both participants and researchers. As stated, they can be completed at the convenience of the participant and reduce researcher burden. Data is submitted electronically, reducing the potential for data entry error.

Computer-assisted personal interviewing (CATI): capabilities include random respondent selection; automated dialing; scheduling unanswered or interrupted calls for callbacks; automated questionnaire skip patterns; and automated generation and population of databases. Computer-assisted personal interviewing (CAPI) has similar capabilities. Audio and computer-assisted self-interviewing (ACASI) is similar, but does not require a human interviewer. These types of technology are useful when Internet surveys are not practical (e.g., for hard-to-reach populations without access to the Internet).

Videoconferencing is a particularly useful tool for conducting focus groups. It allows individuals from diverse geographic locations to participate in a synchronous discussion, while seeing each other on a monitor, and eliminates the need for travel. Internet conferencing is an option available through a variety of websites and providers, and has similar benefits. Internet conferencing options vary, and can include video, audio, and/ or “chat rooms” where typed discussion takes place. Teleconferencing is an audio-only option for remote focus groups

facilitated by technology, where participants dial into a conference call.

Eye-tracking hardware and software (located in the NCI's Office of Communications and Education, Office of Market Research & Evaluation) is a new technology that can be employed to maximize data collection involving processing of stimuli. Eye-tracking involves a freestanding monitor with integrated eye-tracker camera, which does not require the user to wear glasses. The user simply sits roughly two feet in front of the monitor, and once the tracker is calibrated, the stimulus (pamphlet, website, document, photo, etc…) is displayed. Eye movement data (from both eyes, including eye position, gaze time, pupil and diameter) are recorded and stored linked to the stimulus on the screen to allow for detailed analysis at the level of less than 10 milliseconds. This allows researchers to gather a great amount of rich data linked directly and precisely to a visual stimulus that does not require a large number of participants, or self-report of psychological processes.

If Personally Identifying Information (PII) is collected in a sub-study that implements an information technology (IT) system, the submitter will contact the NCI Privacy Act Coordinator to see if a Privacy Impact Assessment (PIA) is necessary, and to coordinate the PIA, if applicable.

A.4. Efforts to Identify Duplication and Use of Similar Information

The types of research questions and procedures (as described in Section A.2. above) to develop and validate theories related to behavioral cancer prevention and control are generally similar. However, the fields of behavioral and psychological sciences are diverse, and as such, there are many theoretical questions related to various constructs that may predict cancer-related behaviors. Additionally, cancer is a diverse field, and theories of cancer prevention and control may differ by type of cancer, as well as by population. Each sub-study submitted under this

generic clearance will involve a comprehensive search of the literature in the area to determine whether the research question has adequately been addressed elsewhere, in addition to consultation with experts (listed on this submission) and a review of currently approved OMB protocols for data collection.

Additionally, NCI will continue to assess other active generic submissions that may be related to this submission, including those submitted by other NIH ICs as well as other relevant Agencies (e.g., National Science Foundation). Currently, the most similar active clearance (CDC generic clearance to examine mental models of HIV, tuberculosis, and hepatitis prevention, OMB No. 0920-0840, expiry date 2/29/2016) examines theoretical issues related to behaviors that are qualitatively different from cancer prevention and control behaviors; as such, duplication of research is not an issue. Other active cancer-related generic submissions are focused on cognitive testing (OMB No. 0925-0589, expiry date 4/30/2014) and communication pretesting (OMB No. 0925-0046, expiry 5/31/2016). At this time, the above-listed generic clearances listed would not be able to accommodate the research appropriate for clearance under the current submission.

A.5. Impact on Small Businesses or Other Small Entities

It is possible that individual employees or representatives of small non-profit or independently owned businesses may be participants in this generic submission. Small businesses representatives may include physicians and other healthcare providers, who may be necessary to provide data for theory development and validation (e.g., theories concerning physicians' attitudes towards shared decision-making or patient communication). For these interviews, the small business will be approached in the same manner as individuals who are recruited, where the small business is asked to identify representatives to participate in the

research. All efforts will be made to reduce burden on small businesses by using short questionnaires or study materials and including fewer small businesses than larger ones.

A.6. Consequence of Collecting the Information Less Frequently

For the most part, formative research and theory development research will involve one-time data collection activities only. However, some studies may require contacting participants with requests to participate in follow-up studies if they have originally granted consent for this type of procedure. Also, some research studies may require pre- and post-testing to assess changes in outcomes predicted by theories.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The 60-Day Federal Register notice soliciting comments on this study was published on July 14, 2014 (79 page 40763). No comments were received.

A number of scientific experts at the National Cancer Institute were directly consulted in developing this generic clearance (see **Attachment 3**). In addition, a number of external investigators with expertise in behavioral sciences were consulted. Their comments and suggestions have been incorporated into the data collection plans proposed herein. These consultants will continue to provide guidance and advice in the development of sub-studies for this clearance. A number of internal and external investigators contributed to the ideas and rationale described in this OMB package, although they were not directly consulted in its development (see **Attachment 1**). These individuals may be called upon for guidance and advice in the development of sub-studies for this clearance.

A.9. Explanation of Any Payment or Gift to Respondents

It is possible that information collection activities may involve small incentives or gifts. Participants generally receive some sort of incentive for research activities.

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. As such, an incentive or a reimbursement for costs is appropriate for participation. 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. Incentives can also improve response rates and improve data quality; a recent study of Surveys conducted by a local contractor (Westat) for federal agencies in Montgomery County (MD) indicates that incentives can, in some instances, substantially reduce cost to the federal government by reducing the amount of contractor recruitment hours and the cost to recruit participants (**Attachment 4**). Additionally, similar incentives for participation have been approved under many OMB clearances (e.g., sub-studies in OMB Nos. 0925-0589, expiry 4/30/2014; and 0925-0046, expiry 5/31/2016), as well as under the current clearance.

Levels of remuneration depend on a variety of factors, difficulty in recruitment and estimation of costs incurred to participants. We anticipate that sub-studies will propose higher incentives when:

- The study takes place in person;
- The study targets or oversamples a population that is hard to recruit or retain (e.g., ethnic minority, sub-setted group such as cancer survivors or

- The study takes place after hours and no meal/ childcare is provided;
- The study takes place during working hours and participants need to take time away from work;
- Questions are sensitive in nature;
- Questions are repetitive (often necessary in formative survey research)

We anticipate that proposed incentives will be lower when:

- The study takes place in the participants' homes (e.g., online study, phone interview, mail survey);
- The study uses a convenience sample rather than targeting a specific group;
- The study is very short.

The previously referenced study of Surveys conducted by a local contractor (Westat) for federal agencies indicates that the average hourly incentive was $34 (**Attachment 4).** These averages are consistent with (but lower than) recommendations from local survey and focus group research companies, also included in Westat's study (**Attachment 4**).

The mean incentive rate is anticipated to be $22 per hour. However, as stated in Section A.9, incentives will vary substantially depending on the characteristics of the study and target study population. For example, under this generic clearance, the hourly rate for an internet survey targeting a convenience sample of individuals who regularly engage in surveys via Amazon's mTurk was $0.50/ hour; the hourly rate for an in-person study during the work-day that involved reading a lengthy and complex clinical trial consent form while eye movements were tracked (and targeted a sample of local adults that targeted a specific mix of all socioeconomic statuses, race/ ethnicities, genders, and occupations) was $50/ hour.

While physicians may participate in surveys at no cost, it is customary to reimburse them at the average rate of $84 per hour for taking part in focus groups

A.10. Assurance of Confidentiality Provided to Respondents

Information collected in sub-studies approved under this clearance may include PII in the form of names and contact information. All PII will be collected voluntarily. Data will be kept private to the extent allowable under the law. Reasons for collecting PII may include: 1) creating panels; 2) linking multilevel data; and 3) conducting follow-up interviews. Under purpose 1, PII will be destroyed immediately after the panel is created and data collection efforts have begun. Under purpose 2, address data may be used to link to other data sources to include multilevel variables. For example, zip code can be used to generate a UV exposure score, or a score for the availability of public parks (for exercise) or grocery stores with high quality produce. Under this purpose, PII will be destroyed immediately after a score for multilevel variables is generated. Under purpose 3, PII will be destroyed immediately after follow-up.

Prior to being stripped from individual records and destroyed, PII will be kept secure or private, except as otherwise required by law. This will be communicated to participants in introductory letters or scripts as well as in consent forms. Participants will also be informed about the purpose and use of the data collected, NCI sponsorship, and the continuing voluntary nature of their participation. Participants will be assured that there will be no penalties if they decide not to provide any PII (or decline to answer any other questions). Additionally, the NIH Privacy Act Officer will be asked to review the sub-study submission protocols to ensure that NCI adheres to privacy requirements.

Individual-level data will be accessible only to NCI staff, fellows, and contractors who are conducting the information collection. All project staff will sign a confidentiality agreement, and all electronic and hard-copy data will be maintained securely throughout the duration of the information collection, data analyses, and data storage. This means that electronic data will be in locked files on password secured computers housed in secure building facilities, whereas hard-copy data will be in secure building facilities in locked filing cabinets. If PII is collected, the submitter will contact the NCI Privacy Act Coordinator to coordinate a PIA on the IT system (if applicable). Reports and publications of data will present data in aggregate form only, with no links to individuals. Reports and publications will be used exclusively for research purposes and to inform NCI initiatives. If data are made available in public use data sets, PII will be stripped from the dataset. Detailed plans for assuring privacy and safeguarding collections will be specified by each sub-study submitted under this clearance.

Data collection activities covered under this clearance are often considered to be exempt from IRB review at NIH (in accordance with Exemption Category 2, http://intranet.dceg.cancer.gov/committees/nci-special-studies-institutional-review-board-ssirb/ohsr-exemption-from-nih-ssirb-review/exemption-from-nih-ssirb-review). When required, IRB approval will be obtained prior to the data collection.

A.11. Justification for Sensitive Questions

variables or conduct follow-ups (see Section A.10). No PII will be retained once these purposes have been fulfilled. If a sub-study will collect PII, the submitter will contact the NIH Privacy Officer to determine whether the Privacy Act applies to the information, and will also contact the NCI Privacy Act Coordinator to coordinate a PIA of an IT system, if applicable.

Questionnaires used in data collection under this clearance will generally not contain questions that are highly sensitive in nature. However, note that sensitivity to a question cannot always be anticipated, and as such, some participants may perceive some questions to be of a sensitive nature. For example, asking a participant about worry related to cancer or perceived risk of a disease may be perceived as sensitive to some who worry excessively or feel they are at high risk. However, these questions will be carefully worded, and consistent with standard questions related to these constructs used in this scientific field. Participants will be informed of the risks and benefits of participating, and assured that their answers to all questions are voluntary and will be kept confidential.

A.12. Estimates of Annualized Hours and Costs

The number of participants included in each sub-study will vary according to the goals of the research and scientific research questions. Samples could be large or small, and burden per participant could range from several minutes to 90 minutes. For example, a focus group study could involve 30 participants, each participating for 90 minutes, for a total of 45 burden hours. Alternately, a survey could involve 200 participants, each participating for 30 minutes, for a total of 100 burden hours. It is anticipated that the majority of burden hours will be allocated to cross-sectional data collection. However, on occasion, participants may give permission for a follow-

up survey or interview. Sub-study submissions will indicate when NCI anticipates follow-ups with a given number of respondents.

The number of sub-studies required for NCI behavioral theory testing and validation were estimated based on previous utilization of this generic clearance, as well as on ongoing conversations with scientific staff, fellows, working groups, and consultants. From December 12, 2011 through April 1, 2014, a total of 1,790 burden hours have been used under this clearance. This number is substantially lower than the 6,000 hours that were initially requested, largely because initiating the research infrastructure necessary to carry out research (e.g., establishing recruitment and incentive processes with contractors; navigating NIH Office of Human Subjects and NCI Special Studies IRB submissions; allocating funds for studies; training research fellows to conduct studies) was necessary before sub-study submissions could be generated and executed. However, we are requesting a renewal with 6,000 hours, given that this research infrastructure is now in place. Conversations with scientific staff and fellows indicate that we are likely to need a 6,000 burden hour allowance to accommodate all planned research activities over the next 3 years.

We estimate the need for 10 sub-studies per year. Since it is difficult to ascertain the exact number of respondents who will complete surveys versus focus groups or some alternate methodology, the number of respondents may change within the rows; however it is estimated that the total number of respondents will be 5,668. As such, we are requesting 2,000 annual burden hours over the course of three years, for a total of 6,000 burden hours.

Table A.12-1 Estimates of Annual Burden Hours				
Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Total Burden Hours
General Public	667	1	15/60	167
Physicians	2,000	1	30/60	1,000
Health Professionals	333	1	1	333
Researchers	333	1	90/60	500
TOTAL				2,000

Table A.12-2 presents the approximate cost to respondents over the three year span of this generic clearance. These estimates are based on the following data from the Bureau of Labor Statistics: the physician wage rate was obtained from http://www.bls.gov/oes/current/oes_nat.htm#29-0000 occupation code 29-1069; the wage rate for researchers was obtained from http://www.bls.gov/oes/current/oes_nat.htm#19-0000 with the occupation title "Life Scientist", occupation code 19-1099; the health professionals wage rate was obtained from http://www.bls.gov/oes/2013/may/oes_nat.htm#29-0000 occupation title "Healthcare Practitioners and Technical Occupations", occupation code 29-0000; and the general public rate was obtained from the http://www.bls.gov/oes/2013/may/oes_nat.htm#00-0000 occupation title "All occupations" occupation code 00-0000.

Note that it is difficult to estimate the number of each type of participants that will complete different survey methods. As such, the costs may increase or decrease over the duration of the three years.

Table A.12-2 Cost to Respondents				
Type of Respondents	Total Burden Hours	Hourly Respondent Wage Rate	Annual Cost	Three Year Cost
General Public	167	$22.00	$3,674	$11,022
Physicians	1,000	$90	$90,000	$270,000
Health Professionals	333	$36.00	$11,988	$35,964
Researchers	500	$38	$19,000	$57,000
TOTAL	6,000		$124,662	$373,986

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

No costs to respondents are anticipated; payments are designed to compensate participants for expenses and effort. There are no anticipated costs to record keepers.

A.14. Annualized Cost to the Federal Government

The estimated annualized cost to the federal government is approximately $355,000, which amounts to a total estimated cost of $1,058,936.00 over the duration of three years. Table A.14-1 contains estimated costs by category of cost.

Table A.14-1 Annualized Costs to the Federal Government			
Annual costs for NCI staff to plan, conduct, and analyze the outcomes of the questionnaire development activities:	Managerial	0.10 FTE GS-14/3 ($113,346)	$11,000
	Research Staff	0.50 FTE GS-14/1 ($106,263)	$55,000
	Fellow	0.50 Fellow GS-12/1 ($75,621)	$37,000
Incentives to participants (see section A.12)			$75,750

Payment, under contract, for assistance with activities/research	$175,000
Recruitment materials: (flyers, newspaper advertisements):	$2,000
TOTAL	$355,000

*All costs are estimates based on costs for research conducted under this generic clearance (2009-2011), as well as past research conducted under previous NCI generic submissions (OMB Nos. 0925-0589, expiry 4/30/2014; and 0925-0046, expiry 5/31/2016).

A.15. Explanation for Program Changes or Adjustments

This is a revision. Changes are noted throughout in yellow highlighter. These changes include clarifying the nature of research questions (based on activities that have been conducted under this generic clearance previously); updating the justification for data collection based on the updated Behavioral Research Program Branch missions and initiatives; and elaborating on incentive rates, variations, and justifications. The burden hours for this request is substantially lower than the previous approved hours, largely because initiating the research infrastructure necessary to carry out research (e.g., establishing recruitment and incentive processes with contractors; navigating NIH Office of Human Subjects and NCI Special Studies IRB submissions; allocating funds for studies; training research fellows to conduct studies) was necessary before sub-study submissions could be generated and executed.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Plans for tabulation and publication, and associated project time schedule, will differ depending on the sub-study. Estimates of projected time schedule are provided below (Table A.16); however, these may change with the scope and nature of the project, and research staff

will fully evaluate the time schedule for each sub-study. Specific plans for tabulation, publication, and project time schedule will be submitted with each sub-study.

The majority of the focus group studies will be examined qualitatively, while the majority of the survey studies will be examined quantitatively. Occasionally, a study will employ mixed methods analyses.

The primary purpose of each study is to inform NCI initiative planning; however, publication of data to selected scientific audiences in specialized journals is necessary in order to further the science of theory development and validation, and to avoid duplication by other researchers. Thus, while information collected will be analyzed and presented to NCI scientific staff in briefings and reports, it may also be published in scientific journals (e.g., *Health Psychology, Annals of Behavioral Medicine*). Findings may also be presented at meetings of national and international professional organizations (e.g., *Society for Behavioral Medicine, Association for Psychological Science*). Formative research conducted by NCI may also be summarized in publications such as the *NIH Record*.

A.16 Project and Publication Timeline

Activity	Timeline
Review of research questions and design	1-2 weeks after OMB approval
Collection of data	3-11 weeks after OMB approval
Analysis of data	12-16 weeks after OMB approval
Write report of findings	4-5 months after OMB approval
Develop manuscript (if seeking publication)	6-7 months after OMB approval
Submit for publication	8-9 months after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement are required by this information collection.