SUPPORTING STATEMENT A For:

A Generic Submission for

Theory Development and Validation

(BRP/DCCPS/NCI)

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ATTACHMENTS

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,
- Refine theories and models used to inform cancer communication approaches, including research to elucidate responses to health and risk communications, as well as factors that may moderate such responses (e.g., health literacy, numeracy),
- 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 collective. 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 recent strategic planning efforts in BRP, integrating theory into research undertaken in and supported by BRP remained a key objective that helped to guide the reorganization of the Program, and one of the key objectives of the new branch that emerged during strategic planning (the Science of Research and Technology Branch) is to provide infrastructure and resources for testing theory (see **Attachment 2**).

Importantly, the expedited review of formative research studies under this clearance would attract research fellows (and scientific staff) to the Program. Currently, BRP houses seven post-doctoral fellows as well as a number of post-baccalaureate fellows, and BRP 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).

NCI is requesting terms of clearance similar to that previously granted to the Centers for Disease Control ("Formative Research and Tool Development," OMB No. 0920-0840, expiry date 1/31/2013). 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 (previously approved but not currently active) related Food and Drug Administration Clearance ("Focus Groups as Used by the Food and Drug Administration," OMB No. 0910-0497, expiry date 02/28/2011) 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 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 5/31/2014). Additionally, other clearances have covered research examining factors related to health communication processing and decision-making, such as health literacy (e.g., "Prevention Communication Formative Research," OMB No. 0990-0281, expiry date 4/30/2012 to the Office of Public Health and Science).

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

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 could 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,
- 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.
- 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 to the CDC for the National Health and Nutrition Examination Survey studies, expiry date 11/30/2012).

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) 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) and communication pretesting (OMB No. 0925-0046). 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 prior to initial submission to OMB was published August 2, 2011 (76 FR 46307) and no public 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. Levels of remuneration depend on a variety of factors, difficulty in recruitment and estimation of costs incurred to participants.

Incentives can also improve response rates and improve data quality. [1,2] Additionally, similar incentives for participation have been approved under many OMB clearances (e.g., sub-studies in OMB Nos. 0925-0589, 0925-0046).

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. 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

[1] E. Singer, J. Van Hoewyk, and M. P. Maher, "Experiments with Incentives in Telephone Surveys," *Public Opinion Quarterly*, Vol. 64, No. 2, Summer 2000, pp. 171-188; A. H. Church, "Estimating the Effect of Incentives on Mail Survey Response Rates: A Meta-Analysis," *Public Opinion Quarterly*, Vol. 57, No. 1, Spring 1993, pp. 62-79.
[2] W. D. Mosher, W. F. Pratt, and A. P. Duffer, "CAPI, Event Histories and Incentives in the NSFG Cycle 5 Pretest," *American Statistical Association, 1994 Proceedings of the Section on Survey Research Methods,* Vol. 1, 1995, pp. 59-63.

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 confidentiality and safeguarding collections will be specified by each sub-study submitted under this clearance.

Data collection activities covered under this clearance are generally 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). If a contractor is involved in the collection, the sub-study may need to be reviewed under that contractor's IRB.

A.11. Justification for Sensitive Questions

Depending on the research question and study design, data collections may require sensitive questions (e.g., PII). For example, if the sub-study seeks to develop or validate theories in hard-to-reach populations, PII related to race/ ethnicity, income, education, or health status may be required in eligibility screening. Additionally, PII may be collected to code multilevel 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 research is difficult to estimate, although we can estimate the number of studies based on conversations with scientific staff, fellows, working groups, and consultants. We estimate the need for 15-25 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 annual number of respondents will be 3833 (11,500 over three years). As such, we are requesting 2,000 annual burden hours over the course of three years, for a total of 6,000 burden hours during that period. The proposed data collection methodologies are described in more detail in Supporting Statement B.

Table A.12-1 Estimates of Burden Hours for Three Years (Generic Study)

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Total Burden Hours
General Public Physicians Health Professionals Researchers	2,000	1	15/60 (0.25)	500
	6,000	1	30/60 (0.5)	3,000
	1,000	1	60/60 (1)	1,000
	1,000	1	90/60 (1.5)	1,500

TOTAL	11,500			6,000

Table A.12-2 presents the approximate cost to respondents over the three year span of this generic clearance. Annual cost is one third of this figure, or $75,750. The general public's hourly rate was estimated at $22/hour, consistent with the mean hourly wage in May 2010 (http://www.bls.gov/oes/current/oes_nat.htm#00-0000). Physician's hourly rate was estimated at $84 per hour (http://www.bls.gov/oes/current/oes291062.htm). Non-physician health professionals and researchers' hourly rate was estimated at $35/hour and $31/hour, respectively. (http://www.bls.gov/oes/current/oes_nat.htm).

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 For Three Years (Generic Study)			
Type of Respondents	Total Burden Hours	Hourly Respondent Wage Rate	Cost
General Public	1,750	$22.00	$38,500.00
Physicians	1,000	$84.00	$84,000.00
Health Professionals	1,000	$35.00	$35,000.00
Researchers	2,250	$31.00	$69,750.00
TOTAL	6,000		$227,250.00

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 $352,979, which amounts to a total estimated cost of $1,058,937.00 over the duration of three years. Table A.14-1 contains estimated annualized 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	0.25 FTE	$20,000
	Professional	0.50 FTE	$60,000
	Support	0.50 FTE	$20,000
	Fellow	0.50 Fellow	$25,000
Payment of participants (see section A.12)			$49,979
Payment, under contract, for assistance with activities/research			$175,000
Travel costs (mainly local travel):			$1,000
Recruitment materials: (flyers, newspaper advertisements):			$2,000
TOTAL			$352,979

*All costs are estimates based on costs for past research conducted under previous NCI generic submissions (OMB Nos. 0925-0589 and 0925-0046).

A.15. Explanation for Program Changes or Adjustments

This is a new generic clearance request. .

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 such as, but not limited to, *Health Psychology, Annals of Behavioral Medicine*. Findings may also be presented at meetings of national and international professional organizations. For example, but not limited to, *Society for Behavioral Medicine, Association for Psychological Science*. Formative research conducted by NCI may also be summarized in publications such as the *NIH Record*.

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

Not applicable

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

Not applicable; NCI is in full compliance with the provisions contained within the Certification for Paperwork Reduction Act.