
Supporting Statement for
**A Study of Primary and Secondary Prevention Behaviors
Practiced Among Five-Year Survivors of Colorectal Cancer**

PART A. JUSTIFICATION

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A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), Division of Cancer Prevention and Control (DCPC), is requesting Office of Management and Budget (OMB) approval to conduct a study of the prevention and follow-up screening practices of 5-year colorectal cancer survivors. This study constitutes a new Information Collection Request (ICR). The information collection for which approval is sought is in accordance with CDC's mission to conduct, support, and promote efforts to prevent cancer and to increase early detection of cancer, authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). A copy of the legislation is included in **Attachment A** – Legislative Authority.

Colorectal Cancer (CRC) is one of the most commonly diagnosed cancers in the United States. It is the third most prevalent cancer and the second leading cause of cancer death in both men and women. In 2004, there were an estimated 145,083 new cases of colorectal cancer diagnosed and 53,580 deaths (U.S. Cancer Statistics Working Group, 2007). However, due to advances in early detection and effective cancer treatments, many individuals diagnosed with CRC can expect to survive many years beyond their diagnosis. The five year survival rate of CRC is estimated to be between 10.3% and 89.8%, depending on the stage of cancer at the time of diagnosis (Ries et al., 2006) and the five-year relative survival rates of those diagnosed with CRC have been steadily increasing since 1975 (SEER, 2007). As a result, there are now over 1 million CRC survivors in the U.S. and this number is growing (Rowland et al., 2004).

Although the large and growing number of CRC survivors lends optimism to the prognosis for recently diagnosed patients, life after CRC treatment is not risk-free. Cancer survivors are known to be at increased risk for cancer recurrence, second primary cancers, and a number of other health problems after being treated for cancer (Ganz, 2001). Certain groups appear to be at even higher risk than others (Ahmed et al., 2006). For instance, black, male CRC survivors are at elevated risk for prostate cancer and young, female CRC survivors are at elevated risk for uterine cancer. Survivors are also at increased risk for second tumors in the colon/rectum, esophagus, stomach, lung, and urinary tract or kidney (Ahmed, et al, 2006; Tichansky, et al., 2002). Possible reasons for these heightened risks include genetic-, treatment-, and lifestyle-related factors (Bines & Gradishar, 1997; Brown et al., 1993; Li & Stovall, 1998; Weiderpass et al., 1997). It is important, therefore, for survivors to adhere to recommendations for prevention, medical follow-up, and cancer screening practices after cancer (Brown et al., 2003). There is evidence that the long-term health of cancer survivors may be improved through adherence to clinical and public health recommendations for the prevention and early detection of cancer and other chronic diseases (Meyerhardt et al., 2006, 2007). Prevention refers to practices such as engaging in regular exercise, eating a healthy diet, maintaining a healthy bodyweight, and avoiding tobacco, which have been linked with lowering the risks of developing disease. Medical follow-up and screening for early signs of disease is also important so that disease may be detected and treated in its early stages.

The American Cancer Society (ACS), American Society for Clinical Oncology (ASCO), United States Preventive Services Task Force (USPSTF), National Comprehensive Cancer Network

(NCCN), American Gastroenterology Association (AGA), and American Institute for Cancer Research (AICR), have all issued recommendations for regular cancer screening and prevention practices among cancer survivors. Specifically, CRC survivors are advised to undergo regular screening by colonoscopy and CEA testing, and to maintain a regular schedule of routine follow-up visits after treatment ends (ACS & NCCN, 2005; Desch et al., 2005; Rex et al., 2006; Winawer et al., 2003; NCCN, 2006; AGA, 1997; ASCO, 2005a; USPSTF, 2002). Most organizations also recommend that cancer survivors practice an array of preventive health behaviors, including: smoking cessation, limiting alcohol consumption, increasing physical activity levels, ensuring adequate nutrition intake, and maintaining or achieving a healthy body weight (ACS, 2006; AICR, 2006; ACS & NCI, 2002).

Despite the availability of guidelines for healthy living after cancer, there is limited information on the extent to which long-term survivors follow such recommendations after CRC. Of the studies that have investigated health behavior among survivors, the majority have focused on lifestyle changes that are made during or immediately following treatment of cancer. Such studies have found that cancer survivors often make positive changes in their diet or exercise habits after diagnosis and up to two years later (Demark-Wahnefried et al., 2005; Pinto, Eakin, & Maruyama, 2000). Survivors' eating and exercise habits have been the most studied behaviors and, incidentally, appear to be the behaviors that survivors most commonly report changing after cancer (Satia et al., 2004; Maunsell et al., 2002; Patterson et al., 2003; Humpel, Magee & Jones, 2007). Findings have been limited and inconsistent regarding changes in alcohol and tobacco use; however, it seems that reduced alcohol consumption and cigarette smoking are especially common when survivors have been diagnosed with cancers that are attributable to these habits (e.g., lung cancer; Demark-Whanefried et al., 2005; Pinto et al., 2000). With regard to survivors' adherence to recommended medical follow-up, studies have found substantial variability. Some studies have found overuse of follow-up visits (Trask et al., 2005; Rulyak et al., 2004; Mahon et al., 2000), while others have found that survivors commonly receive insufficient follow-up after the completion of cancer treatments (Elston-Lafata et al., 2005). Adherence to recommended follow-up cancer screening appears to be greater for gender-specific cancer screenings (e.g., mammography) than non-gender-specific screenings (Trask et al., 2005). While the results of the aforementioned studies provide some insight into the health practices of cancer survivors, limitations of this newly emerging body of research are noteworthy. To date, the vast majority of studies on the health practices of cancer survivors have been based upon reports of behavior that occurs two years post-diagnosis or less. Few studies have focused on the practices of survivors farther in time from the completion of cancer treatments. Thus, there remain important questions about adherence to recommended prevention behaviors among longer-term survivors. Long-term behavior change is important for cancer survivors given that most recommended lifestyle changes require sustained practice over months and years to achieve the benefits of improved health and reduced risk of disease.

Additional limitations of the current literature include a disproportionate focus on breast cancer survivors, small sample sizes, and inadequate representation of ethnic and racial minority groups, thus limiting the generalizability of study findings (see Demark-Whanefried et al., 2005 and Pinto, Eakin, & Maruyama, 2000, for reviews). Most studies have focused on a small number of lifestyle behaviors--most often physical activity, nutrition, and smoking--leaving questions about other recommended behaviors, such as achieving a healthy body weight and limiting alcohol use,

unanswered. Importantly, previous research has also lacked an in-depth examination of the facilitators and barriers to practicing recommended prevention and screening behavior after cancer. There is a wealth of theoretically-based research on the predictors of health behavior and behavior change in non-cancer populations, but these relationships have not been clearly demonstrated in a cancer survivorship context. Although it is likely that demonstrated predictors of health behavior in general models of health behavior show similar predictive value in the context of survivorship, there is also reason to suspect that there may be important differences. For instance, constructs such as risk perception, perceived severity of health threat, and perceived efficacy of prevention behavior may be construed differently among cancer survivors, and thus may show different relationships with health behaviors.

Through the proposed information collection, we will address the following research questions:

Primary Research Questions

1. What proportion of CRC survivors are adherent with clinical and public health guidelines for medical follow-up, cancer screening, and prevention behavior 5 years after cancer?
 - a. What proportion of survivors practice prevention strategies (e.g., smoking cessation, regular moderate/vigorous exercise, healthy bodyweight) as they are specified by public health guidelines?
 - b. What proportion of survivors adhere to clinical guidelines for medical follow-up of CRC and screening for other cancers?
2. Which characteristics are associated with greater adherence to recommended health behaviors?
 - a. Sociodemographic: In what capacity is adherence to health behavior recommendations associated with gender, education, race/ethnicity, marital status, insurance coverage, age, and employment status?
 - b. Psychosocial: In what capacity is adherence to health behavior recommendations associated with awareness of recommendations, perceived risk of cancer recurrence, perceived severity of cancer recurrence, perceived benefits of behaviors, perceived barriers to behaviors, self-efficacy, and perceived support from others?
 - c. Physical/medical: To what extent is adherence to health behavior recommendations associated with cancer history (stage at diagnosis, treatments received), current health, comorbidities, and satisfaction with previous cancer care?

Secondary Research Questions

3. How do 5-year CRC survivors perceive of their risk for CRC recurrence and second primary cancers?
 - a. Do African American male CRC survivors know of their heightened risk for prostate cancer?
 - b. Do other CRC survivors know of their heightened risk for CRC recurrence and other cancers?

4. What proportion of 5-year CRC survivors recall receiving guidance (including written instructions or reminders) from their doctors, nurses or other medical care providers regarding:
 - a. the recommended frequency for getting routine medical check-ups after completing cancer treatment?
 - b. the recommended frequency for getting screened by colonoscopy and CEA blood tests to screen for cancer recurrence?
 - c. undergoing other cancer screening tests (i.e., mammography, Pap, PSA and DRE) after completing treatment for CRC?
 - d. specific prevention behaviors and healthy lifestyle practices (e.g., exercise, nutrition, weight management, alcohol intake, smoking cessation) to maintain and improve health and quality of life after cancer?

Privacy Impact Assessment

Overview of the Data Collection System

A mailed survey will be the primary form of data collection for this study. Participants will receive a survey in the mail and be asked to complete and return it in a provided postage-paid envelope. As a means of limiting non-response, those who have not responded to the survey will receive a phone call and given the opportunity to take the survey over the phone using a CATI (Computer Assisted Telephone Interview) protocol. We estimate that the study will be in data collection for approximately 6 to 8 months.

All data will be collected by Macro International, the contractor carrying out the study. They will be responsible for sending out all study mailings, conducting the necessary CATI interviews, designing the database files, and performing data entry and management tasks.

All response data collected from surveys will be housed in a de-identified database. Once the survey data has been abstracted and entered into the database and the data collection period has ended, the physical copies of the survey will be destroyed. CDC will receive only de-identified data. Macro will securely delete/destroy all identifying information in their possession.

Items of Information to be Collected

The study survey contains questions on primary and secondary prevention behaviors (e.g., physical activity, nutrition, smoking, alcohol consumption, weight management, routine medical visits, and cancer screening) and current health (e.g., quality of life, cancer history, and co-morbidities). In addition, there are also questions that address satisfaction with overall medical care, knowledge of behavior recommendations, and information considered to be IIF or demographic information (e.g. age, gender, race and ethnicity, marital status, education level, and employment status). These variables will be used as covariates in the multivariate analysis planned for this study. A more thorough description of survey questions and domains can be found in **Attachment C**, Technical Supplement.

The study will utilize Information in Identifiable Form (IIF) to facilitate recruitment. IIF is being provided by the California Cancer Registry and the Public Health Institute for recruitment purposes. This includes each patient's name, mailing address, phone number, and information on their cancer diagnosis. IIF provided by the registry will only be used to facilitate recruitment of the participant, and procedures are in place to limit the linkage of identifiable contact information to response data, and thus to prevent inadvertent disclosure of identifiable response data. Only de-identified response data will be transmitted to CDC; please see section A.10 for further description of the process for de-identifying data.

Study staff also utilize IIF (name, address) to contact the physician of record for each potential study participant. The purpose of this contact is to identify patients who should not be recruited and to obtain the physician's permission for study staff to approach the remaining eligible patients about study participation. No personal information is collected from the physician of record.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

This study does not involve web-based data collection methods. Respondents are referred to the website of the CDC's Division of Cancer Prevention and Control (www.cdc.gov/cancer) if they would like more information on cancer. The CDC website provides health information to the general population and does not use cookies. No website content is being directed at children less than 13 years of age.

A2. Purpose and Use of the Information Collection

The purpose of this study is to examine adherence to recommended follow-up screening and prevention behavior among 5-year colorectal cancer survivors, and to identify the demographic, physical/medical, and psychosocial correlates of such adherence. Based upon previous research and theoretical models of health behavior, we hypothesize that a combination of psychosocial, physical/medical, and demographic factors serve to influence survivors' perceptions of the benefits and barriers to prevention behavior, which, in turn, influence actual prevention behavior. The primary prevention behaviors to be examined as outcome variables in the proposed study include exercise, nutrition, weight management, smoking cessation, and moderate alcohol consumption. The medical follow-up and screening behaviors to be examined include routine medical check-ups and colonoscopy screenings for CRC recurrence, as well as screening tests for cancers of the breast (mammography), cervix (Pap testing), and prostate (PSA and DRE testing). Physical/medical factors that will be examined as independent variables include general physical health and comorbidities, cancer history and treatment, and satisfaction with cancer care; sociodemographic factors include race and ethnicity, age, gender, marital status, insurance, employment and educational attainment; and psychosocial factors include awareness of recommendations, perceived risk and worry about cancer recurrence, perceived severity of recurrence, self-efficacy, social support, and perceived benefits and barriers to behavior. **Attachment C**, Technical Supplement, provides additional information on the conceptual models underlying the proposed research and their relationship to the principal information collection instrument.

Our goals are to advance research, inform public health efforts, and provide information to healthcare providers on the facilitators and barriers to practicing medical follow-up and prevention behaviors after cancer. The proposed study will address several gaps in the literature on cancer survivorship. Specifically, it will answer important questions about how closely colorectal cancer survivors follow recommendations for engaging in medical follow-up, screening for subsequent cancers, and practicing other recommended behaviors for cancer prevention. It will also examine adherence to these behaviors as they are related to demographic, physical/medical and psychosocial variables. Examining adherence in this way will allow us to identify factors that are most and least likely to result in practicing recommended prevention behaviors. Increased understanding of the factors that motivate or hinder colorectal cancer survivor's participation in important prevention behaviors can facilitate the development of effective interventions to increase healthy behaviors among cancer survivors. Study results will be disseminated through presentations for health professionals and publications in peer-reviewed scientific journals.

Privacy Impact Assessment Information

Information considered to be IIF is being provided to us by the California Cancer Registry and PHI. This information will be used for the purposes of recruitment. This identifiable information will be kept in a controlled access database available only to senior study staff. Each participant's response data will be stored according to a unique respondent ID code. The only linking factor between the survey response database and participant database will be this unique identifier. Safeguards are in place to make sure linkages only happen when necessary and to ensure that the link is destroyed as soon as practicable after data collection has been completed. All interviewers are trained in privacy issues and sign non-disclosure agreements.

Information considered to be IIF is also being collected through the study survey. Specifically, we are collecting information on respondents' age, gender, race and ethnicity, marital status, education level, and employment status. These variables will be used as covariates in the multivariate analysis planned for this study. If the sample sizes within categories becomes too small, we will collapse across categories to avoid indirect identification through IIF, while maintaining statistical power. The survey response data are not considered to be highly sensitive, however, the diagnosis of cancer may be considered sensitive by a portion of respondents. Recruitment procedures have therefore been designed to ensure that the physician of record assists in identifying appropriate individuals for recruitment, and the mailed study materials are designed to avoid inadvertent disclosure of information about cancer diagnosis. The proposed information collection and management procedures have been successfully employed by the CCR, PHI and Macro and have received IRB approval.

A3. Use of Improved Information Technology and Burden Reduction

We have proposed a mixed-mode data collection method (i.e., self-administered paper survey plus computer-assisted telephone interview) with priority on self-administered surveys in order to maximize the study response rates while minimizing the likelihood of bias in data collection. Previous studies that have recruited cancer survivors from cancer registries have found that offering a mixed-mode data collection method yields higher response rates than either telephone

interviews or mail-based surveys alone (Smith et al., 2007). Our priority on self-administered surveys is based on research showing that social desirability bias, or the inclination to present oneself in a way that will be viewed favorably by others, is less common in self-administered surveys than in interviews (Dillman et al., 2001). Self-administered surveys can also be completed when it is most convenient for respondents. However, to improve response rates, we will use a telephone-based CATI system to conduct interviews with participants who have not responded to the survey after several mailings. Telephone interviewers will ask the same survey questions using the CATI system that will be included in the paper survey. Responses will be entered directly into a data file, without additional data entry required.

Efforts have been made to design a survey instrument and CATI script that are user-friendly and easy to follow and comprehend. The research team has carefully considered the content, appropriateness, and literacy level of questions. Cognitive interviews were also conducted with nine individuals to ensure comprehension of the content and ease of working through the survey. Feedback from participants of the cognitive interviews informed our revisions of the survey content, including elimination of extraneous items and response categories. Furthermore, this process helped us revise the survey to be the least burdensome for respondents.

A4. Efforts to Identify Duplication and Use of Similar Information

Based on an extensive review of the literature, a review of the scientific projects described in the National Institutes of Health database of funded projects (“CRISP”), attendance at national conferences, and personal communication with experts in the field, CDC has determined that the planned data collection efforts do not duplicate any other current or previous data collection efforts.

Existing studies assessing the health behaviors of cancer survivors have failed to assess the full array of recommended primary and secondary health behaviors and have lacked an in-depth examination of the facilitators and barriers to adherence to recommended prevention behaviors among CRC survivors (e.g., Satia et al., 2004; Maunsell, et al., 2002). In addition, previous studies have suffered from small sample sizes and lack of racial and ethnic diversity, thus limiting the generalizability of study findings (Demark-Whanefried et al., 2005; Pinto, Eakin, & Maruyama, 2000). This study is proposed to assess a more comprehensive representation of primary and secondary health behaviors and to examine more closely the array of physical/medical, psychosocial, and sociodemographic factors that may act as facilitators or barriers to engaging in those behaviors. Several previous studies have shown that cancer survivors commonly make certain positive health behavior changes such as increased physical activity, improved nutrition, and decreased smoking and alcohol consumption (Satia et al., 2004; Maunsell et al., 2002; Demark-Whanefried et al., 2005; Pinto et al., 2000) and that they are mostly undergoing screenings and attending follow-up medical visits (Trask et al., 2005; Ruyalk et al., 2004). However, it is unclear whether these reported behaviors are in line with published recommendations and there is a paucity of information to answer questions about “why” cancer survivors do or do not follow recommendations.

A search of the National Institutes of Health CRISP database reveals a growing number of studies dealing with the health behaviors of cancer survivors. These include studies that have

assessed the health behaviors and family histories of colorectal cancer survivors, cancer worry and health-protective behaviors, breast cancer survivors' physical activity levels and quality of life, long-term health outcomes in breast cancer survivors, healthy weight management for breast cancer survivors, health and quality of life among long-term lung cancer survivors, health behavior change in cancer patients and their families, social support and quality of life in women with advanced ovarian cancer, and preventive health care use in elderly cancer survivors. Our study covers some aspects addressed in these investigations, specifically measurement of primary and secondary prevention behaviors after cancer. However, our main focus on elucidating the facilitators and barriers to engaging in healthy behaviors after colorectal cancer, extends the existing body of research. We will delve deeper into this topic by investigating both the health behaviors most and least commonly practiced by 5-year colorectal cancer survivors as well as the factors that motivate survivors or deter them from participating in recommended behaviors. These include assessing survivors' nutrition practices, exercise routines, smoking and alcohol consumption, and screening practices. Additionally we will assess knowledge of recommendations, social support, perceived barriers and benefits, perceived risk and severity, physical health, and sociodemographic characteristics. To our knowledge, these particular psychosocial variables have not been used to assess long-term colorectal cancer survivors' adherence with health behavior recommendations.

Along with our extensive literature review and search of scientific projects in the CRISP database, we have sought the existence of other possibly similar studies through discussions with experts in the field. Over the last several years, members of the study team have attended conferences, such as the American Psychosocial Oncology Society Conference, the Biennial Cancer Survivorship Conference, the Society of Behavioral Medicine Conference, the American Psychological Association Conference, and the American Public Health Association Conference, and attended oral and poster sessions dealing with similar topics. We have found no evidence of ongoing data collection efforts comparable to the proposed study through our attendance at these meetings or through our conversations with conference presenters and attendees.

A5. Impact on Small Businesses or Other Small Entities

We will be sending letters to the physician of record for each potentially-eligible participant in order to seek their permission to allow contact with their patient(s). Although the majority of physicians contacted are expected to be affiliated with hospitals and cancer centers, it is possible that some physicians from smaller practices may be contacted. To minimize burden to all physicians contacted, we have designed this part of the consent process to be as streamlined as possible, while meeting registry and human subjects requirements. The Public Health Institute will mail letters to the physicians of record, informing them about the study and indicating the name(s) and date(s) of birth of their patient(s) selected for recruitment into the study. The letter will explain that physicians have three weeks from the date on the letter to give or decline permission to contact their patients. Permission is presumed ("passive permission") and physicians only need to take action by contacting PHI if they believe that recruitment of their patient(s) would be inappropriate or inadvisable. Contact information for PHI will be clearly labeled on the letter. This procedure for physician permission is recommended and approved by the California Cancer Registry to minimize physician burden. The letter to be used was drafted to

be comprehensive while providing easy-to-follow instructions. The burden on the physician is estimated in Section A12.

A6. Consequences of Collecting the Information Less Frequently

In the proposed data collection effort, a single, self-administered survey will be administered via mail. A single telephone interview will be offered as an alternative for those who do not respond to the paper survey. This study is cross-sectional and, therefore, data will be collected only once. If the proposed study is not conducted, interventions to improve healthy behaviors among colorectal cancer survivors will not be informed by a clearer understanding of barriers and motivators. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Comments in Response to the Federal Register Notice

A notice for public comments on the proposed data collection activities required by 5 CFR 1320.8 (d) was published in the Federal Register on July 30, 2008 (Vol. 73, No. 143, pages 44268 – 44269). CDC received one comment in response to this notice. A copy of the notice is included as **Attachment B**; the public comment and a summary of CDC's response are included as **Attachment B2**.

The public comment was an expression of opinion questioning the value of the proposed approach to cancer prevention work and urging additional support for studies about human exposure to potentially carcinogenic substances. While we agree that research to identify the primary causes of cancer is important and should continue to receive government funding, we believe that behavioral studies and interventions are an important component of cancer prevention and control efforts in public health.

Protecting and improving the health of cancer survivors is considered an emerging issue in the public health arena and is of increasing importance to the health of our nation. We are now able to detect and treat cancer much more effectively than in the past, which has resulted in cancer becoming a chronic, rather than an acute, deadly condition. Survival rates for colorectal cancer are reaching 90% in patients diagnosed with early stage cancer (current estimates predict that there are over 12 million cancer survivors in the United States alone). However, cancer survivors are at an increased risk for secondary cancers and other co-morbidities. Therefore, it is important to place emphasis on protecting and improving the health and well-being of cancer survivors, and to assess which factors affect a cancer survivor's practice of recommended behaviors. With the information collected from this study, we will be able to design interventions and inform programs to encourage positive health behavior change, thus improving cancer survivors' length and quality of life.

Efforts to Consult Outside the Agency

The study protocol, data collection plan, identification of a partner cancer registry, data collection instrument and analysis plan have been discussed with individuals inside and outside the study team. The project has benefited from input from a variety of individuals with varying expertise. Several consultants outside the core study team are listed below.

Other Consultants					
Name	Degree	Position	Institution	Phone	E-mail
Kevin Stein	PhD	Director, Quality of Life Research	American Cancer Society	404-982-3640	Kevin.stein@cancer.org
Tenbroeck Smith	MS	Director, Survivorship Research	American Cancer Society	404.327.6442	Tenbroeck.smith@cancer.org
David Brown	PhD	Behavioral Scientist	CDC, Division of Nutrition, Physical Activity & Obesity	770-488-5526	Dbrown@cdc.gov
Heidi Blanck	PhD	Epidemiologist	CDC, Division of Nutrition, Physical Activity & Obesity	770-488-5638	hblanck@cdc.gov

Funding Sources

Project activities will be supported by CDC Task Order Contract 1 200-2002-08562, Task 21, 1 A Study of Primary and Secondary Prevention Behaviors Practiced among Five-Year Survivors of Colorectal Cancer.

A9. Explanation of Any Payment or Gift to Respondents

The survey packet mailed to respondents will include a \$10 cash incentive and a pen/highlighter. Incorporating modest incentives to aid in recruitment is considered justifiable in order to increase participation, especially when recruiting specialized populations. In addition, monetary and non-monetary incentives are associated with higher response rates in questionnaire study design (Whiteman et al., 2003; Dillman, 2007). Previous research that has recruited cancer survivors from state cancer registries has shown variable response rates. To achieve the highest possible response rates from this specialized population, we propose to include an unconditional monetary incentive along with a pen/highlighter pre-printed with the CDC logo to facilitate ease of completing the survey. High response rates are essential to ensure that study findings are representative of the study population.

A10. Assurance of Confidentiality to Respondents

Procedures for data collection have been designed to keep patient information as secure as possible. As explained earlier, participants for this study will be recruited through the California Cancer Registry and the Public Health Institute. After obtaining physician permission for participation, PHI will provide to Macro, the data collection contractor, an electronic file to support recruitment of participants who are eligible for the study. Information given to Macro will include: name, phone number, mailing address, and details of their cancer diagnosis. The contact and eligibility information will be maintained in a secure manner. Macro will assign a

unique identification code to each eligible patient, and the ID code will be printed on each mailed survey. In order to prevent inadvertent disclosure of identifiable information, response data will be maintained in a separate database that contains the respondent ID code but does not include identifiable contact information. Additional information on relevant data management procedures is provided below in section A.10-B, Safeguards.

The temporary capacity to re-link the respondent ID code to their contact information is necessary to enable targeted follow-up with non-respondents. If a participant does not respond to the mail survey, they will be contacted via phone and asked to participate through a CATI protocol. The proposed script includes language that addresses consent and participant privacy. Identifying information for CATI participants will be available to interviewers. However, all interviewers will be trained in the importance of maintaining patient information in a secure manner and will also sign a non-disclosure agreement (see **Attachment G**).

All paper versions of the survey will be destroyed after data collection has been completed and survey information has been entered into the study database. The electronic contact file with identifying information will not be sent to CDC and will be destroyed by Macro at the end of the data collection period. The survey response database, which contains no identifying information, will be sent to CDC, as the data is property of CDC. CDC will only analyze data in the aggregate and will not have access to the identifiable file used for recruitment and follow-up. More information on these procedures can be found below, in sub-section B, under Privacy Impact Assessment Information.

IRB Approval

The study has been approved by the IRB's of the State of California, Public Health Institute, Macro International and CDC (see **Attachment H** for the approval letter from CDC).

Privacy Impact Assessment Information

A. Privacy Act Determination. The Privacy Act will apply to the identifiable information maintained by the data collection contractor, Macro. The applicable system of records is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. The Privacy Act will not apply to the de-identified information transmitted to CDC.

B. Safeguards. At Macro, two databases will be created to facilitate mailing, tracking, and following up with patients: (1) a patient contact and recruitment tracking system, which will contain information regarding the mailing of surveys, consent, and reminders; receipt of completed surveys; and number of eligible patients who refused or are unable to participate; and (2) a survey response database, into which data from the completed surveys will be entered. To improve data security, response data sets will contain no directly personally identifying information about the respondents. Each respondent's answers will be identified solely through a unique master identification number that is unrelated to social security number, phone number, or other personal information. Macro's offices maintain controlled access at all times; sensitive or identifiable hard copy project information will be kept in locked files and electronic data will be stored on a password protected computer, with access limited to members of the project

management team. CDC will only have access to de-identified information from the questionnaires. The participants' names and other information that could identify them as study participants will not appear in study presentations or publications.

All personnel who will be engaged in conducting follow-up CATI interviews and/or interacting with participants during the data collection periods will be thoroughly trained on-site at Macro. Project-specific interviewer training will address privacy and security issues particular to the project. Written protocols will be provided that will outline the necessary steps for the study. Staff who are selected to conduct interviews specifically for this project will attend a half-day training session that will include a review of the study's background, study protocols, and a review of the survey. Role-play scenarios will be used to illustrate various situations, and emphasis will be placed on the importance of consent procedures and maintaining privacy. Interviewer training will familiarize interviewers with resources for assistance, should a respondent indicate a need for such services. Macro project management will develop a project-specific training manual to be used at the training sessions. CATI interviewers will keep completely secure the names of respondents, all information or opinions collected in the course of the survey, and any information about respondents learned incidentally during the survey.

Additionally, Macro will provide standard security safeguards for protecting the collected data. All contractor staff working on the project will sign a non-disclosure agreement (**Attachment G**) that emphasizes the importance of safeguarding respondent privacy, outlines staff obligations, and prohibits the disclosure of identifiable information and states specifically that the data will be treated in a confidential manner and that researchers will not use the information for anything other than data analysis consistent with the study purposes as presented to the IRBs. Data will be treated in a confidential manner, and will not be disclosed unless otherwise compelled by law.

The data files delivered to CDC will exclude personal identifiers. The survey data will be analyzed in the aggregate, and no individual respondents will be identified. At the end of the study (i.e., after data have been analyzed and findings disseminated), Macro staff will destroy all electronic files and hard copy documents providing the linkages between respondents' unique identifiers and participants' assigned study identification numbers and all electronic and hard copy documents containing names and contact information for participants that were provided by PHI.

C. Consent Procedures. Before the Public Health Institute (PHI) releases any identified information about eligible participants to Macro International, it will first seek physician permission for contacting each of the eligible participants. All physicians of record will receive a letter (**Attachment D2**) notifying them of the nature and purpose of the study and of Macro's request to contact their patient(s) to invite them to participate. If physicians of record do not want their patient(s) to be contacted for this study, the physician must call PHI at the provided phone number and ask that their patient(s) be removed from the list. If they approve of their patient(s) receiving an invitation to participate, they do not have to act. CCR policies allow for this system of passive physician permission for patient contact and direct recruitment of participants.

Once permission to contact patients is granted by the physician, the participant will receive an advance letter (**Attachment E1**) about the study and an informational brochure (**Attachment**

E2) about the CCR via mail. This mailing will inform the eligible participants of the study and of the impending invitation for participation as well as offer a way to decline participation in the current and/or all future research studies offered through the CCR.

Those who do not decline participation will subsequently receive the study packet, which includes the consent form (**Attachment E4**) that addresses the following issues:

- a) Purpose of the study
- b) Study procedures
- c) Survey question topics
- d) Estimated time required to participate
- e) Disclosure of incentive
- f) Potential risks and benefits
- g) Statement about participation being voluntary
- h) Telephone numbers of persons to contact with further questions

In addition, all participants will also receive the California Patient's Bill of Rights for Non-Medical Research, as required by the State of California (see **Attachment E4**). If participants complete the survey and return it to Macro, they will not be contacted further unless they also request to receive a brief summary of the study findings after data collection concludes. If they do not respond and are contacted via phone and participate via CATI, they will be read the consent form over the phone.

D. Voluntary Nature of Response. All respondents are informed through the consent form (**Attachment E4**) and survey instructions that their responses are voluntary.

A11. Justification for Sensitive Questions

The proposed data collection includes sensitive information related to the respondent's personal cancer history. In addition, questions concerning education level may be viewed as sensitive by a portion of respondents. We will also be asking participants about their race and ethnicity. Race and ethnicity, cancer history, and education level are important factors in this research study and will be collected to use as covariates in the multivariate analysis.

Additionally, some participants may feel uneasy or uncomfortable answering some of the questions about their experiences with cancer and their thoughts about being diagnosed with cancer recurrence. To minimize psychological distress, participants will be informed that they may skip over any questions that they do not want to answer and that they may stop participating at any time. Participants will be given the telephone numbers of the study coordinator at Macro International and the Associate Director for Science at CDC to answer questions pertaining to the study or their rights as a research volunteer. We will also have available for respondents telephone numbers and information for publicly available support services if requested (e.g., American Cancer Society support line, and CancerCare telephone number and website address).

A12. Estimates of Annualized Burden Hours and Costs

Burden

The initial recruitment contact for each eligible patient will be with the patient’s physician of record. Each physician associated with one or more eligible patients will receive a customized List of Potential Study Participants (**Attachment D**) prepared by PHI study staff. The physician will be asked to provide permission for PHI study staff to send the eligible participant information to Macro so that they can contact eligible patients for recruitment purposes. The physician will also identify any patients who should not be contacted about participating in the study. If every physician of record provides medical care to just one patient in the survey sample, approximately 1,950 physicians will be asked to review a customized List of Potential Study Participants. This may over-estimate the number of physician respondents, since some physicians are likely to provide medical care for multiple patients who are eligible for the study. The estimated burden for reviewing the List of Potential Study Participants form is 13 minutes. To minimize burden, physicians are only asked to notify study staff of patients who should not be recruited for the study.

Eligible patients will be asked to complete the Survey of Health Behaviors (**Attachment E**). The survey, which should take an average of 40 minutes, will be completed by a total of approximately 1,000 respondents. Of those that participate, ninety percent (900) are expected to complete the paper version of the survey that they received in the mail. Ten percent of respondents (100) are expected to complete the survey via CATI. A brief additional script (**Attachment F**) is associated with the CATI.

Table A.12-1 provides a summary of estimated annualized burden hours.

Table A12-1: Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Physicians	List of Potential Study Participants	1,950	1	13/60	423
CRC Survivors	Script for CATI Follow-up	100	1	3/60	5
	Survey of Health Behaviors	1,000	1	40/60	667
Total					1,095

Respondent Cost

Table A12-2 presents the calculations for cost of burden hours. Average hourly wages for general practitioners were used to calculate the cost of burden for physicians giving consent. Average hourly wages for all occupations were used to calculate the cost of burden for cancer survivor participants. Hourly wage information is from the U.S. Department of Labor, Bureau of Labor Statistics web site (<http://www.bls.gov/home.htm>) and is specific to all workers in the state of California (http://www.bls.gov/oes/current/oes_ca.htm#b00-0000). The total estimated cost to respondents is approximately \$42,567.

Table A12-2: Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. of responses per respondent	Total Burden Hours	Hourly Wage Rate (mean)	Total Respondent Cost
Physicians	List of Potential	1,950	1	423	\$66.89	\$28,294

	Study Participants					
CRC Survivors	Script for CATI Follow-up	100	1	5	\$21.24	\$106
	Survey of Health Behaviors	1,000	1	667	\$21.24	\$14,167
Total						\$42,567

A13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

Respondents will incur no capital or maintenance costs to complete this data collection.

A14. Annualized Cost to the Government

Two types of government costs will be incurred: (1) government personnel, and (2) contracted data collection.

Government Personnel

Role	Base Salary, % Effort	Cost
Technical Monitor	\$88,549 @ 30%	\$26,565
Epidemiologist	\$44, 988 @ 50%	\$22,494
Medical Officer	\$123,658 @ 5%	\$6,183
Medical Officer	\$123,658 @ 5%	\$6,183
Statistician	\$88,549 @ 2%	\$1,771
Total, Government Personnel		\$63,196

The Technical Monitor is responsible for overseeing the project, maintaining contact between study collaborators, and generally maintaining responsibility for the study’s daily operations. The Epidemiologist is responsible for assisting with the project’s operations and development, and maintaining contact between the study collaborators. The Medical Officers are responsible for providing expertise on matters involving clinical care of cancer survivors, assisting with development of the study protocol, and analyzing study data. The Statistician is responsible for contributing expertise on statistical methods and research analysis.

The data collection is being conducted under a contract with Macro International, which has a subcontract with the Public Health Institute. The study execution portion of this contract is for a total of \$423,388. The collection (including data collection, data management, data analysis and dissemination of results) will last two years, making the annualized cost of the data collection \$211,694. Macro is responsible for assisting CDC in the development of all study materials, cognitive testing of the survey, assisting CDC in the selection of a state cancer registry and establishing a subcontract with the state cancer registry, recruiting participants to the study, collecting study data, storing study data, and providing CDC with a complete, de-identified data file upon the completion of the study.

Therefore, total annualized cost to the federal government for this data collection is \$274,890 (\$64,196 + \$211,694).

A15. Explanation for Program Changes or Adjustments

This is a new, one-time data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule

Table A16-1 presents the estimated timeline for this study. A 1-year clearance is requested.

Table A16-1: Project Time Schedule

Study Activity	Estimated Date of Completion
Study Logistics	1-3 months after OMB approval
Recruitment and data collection	4-12 months after OMB approval
Analysis, interpretation, and reporting	13-24 months after OMB approval

Analysis Plan

We plan to conduct a series of analyses employing multivariate techniques to address the research questions outlined in section A2—Purpose and Use of the Information Collection. Initially, we will employ descriptive statistics to summarize the characteristics of the sample and examine the distributions of individual variables. For scales that were drawn from the literature and are being used as they were originally designed (e.g., SF-12, perceived severity, PSQ-18), scale scores will be calculated as described by the instruments’ developers. Descriptive statistics on the scale scores will be compared to those reported in the literature. Similarly, we will calculate reliability coefficients and compare to those reported in the literature. Analyses planned for addressing the study’s primary objectives and research questions are described below.

1. The first analysis will examine and describe the receipt of guidance from medical care providers regarding follow-up medical visits, cancer screening, and prevention behaviors after cancer. We will use descriptive statistics to report the proportions of survivors who received guidance on each of the various screening and prevention practices, describe the channels through which survivors received guidance (e.g., verbal, written instructions, or reminders) and will stratify across key subgroups (e.g., demographic characteristics, cancer/treatment history, and current health status) to describe characteristics associated with receiving more or less guidance for prevention after cancer. These analyses will be conducted using cross tabulation with statistical tests of association, for example Chi square for categorical variables and analysis of variance and independent samples t-tests for continuous variables. In the event that the data do not satisfy assumptions regarding normality, appropriate transformations will be used to adjust the data prior to the analyses. Potential predictors identified from the bivariate analysis will be included in multivariate analyses. Because receipt of guidance can be constructed as a dichotomous variable, we will use logistic regression modeling techniques. Table A16-2 gives an example of how the results of such analyses will be presented.

Table A16-2: Odds Ratios and 95% Confidence Intervals for Receipt of Guidance Regarding Medical Follow-Up (n=###)

	Receipt of Guidance	
	Crude OR (95% CI)	Adjusted OR (95% CI)
Age		
Race/Ethnicity		
Marital Status		
Insurance		
Education		
Cancer Stage		
I		
II		
III		
Treatment(s)		
Chemotherapy		
Radiation therapy		
Both		
Comorbidities		

2. The second analysis will describe the prevalence and characterize the predictors of prevention behavior. We hypothesize that compliance with recommended prevention behaviors will be associated with awareness of recommendations, perceiving oneself at risk of recurrence, perceiving support from physicians, friends and family, and satisfaction with previous cancer care. We will use descriptive statistics to examine and describe the prevention and screening practices of the sample and will stratify across key subgroups (e.g., gender, age, stage at diagnosis). These analyses will be conducted using statistical tests of association, for example Chi square for categorical variables and analysis of variance and independent samples t-tests for continuous variables. Potential predictors identified from the bivariate analysis will be included in multivariate analyses. We will use logistic regression modeling techniques. Table A16-3 gives an example of how the results of such analyses will be presented.

Table A16-3: Odds Ratios and 95% Confidence Intervals for Compliance with Recommended Cancer Screening Practices (n=###)

	Crude OR (95% CI)	Adjusted OR (95% CI)
Age		
Race/Ethnicity		
Marital Status		
Insurance		
Education		
Cancer Stage		

I
II
III
Comorbidities
Recommendation awareness
Satisfaction with care
Perceived risk
Self-efficacy
Perceived support
Physician recommendation

3. The third set of analyses will be conducted using structural equation modeling (SEM). SEM is a technique that allows specification, estimation, and evaluation of theoretically-based models of relationships among variables (Kline, 1998). The objective is to develop a parsimonious model that provides a theoretically-based explanation of observed relationships among variables. SEM also provides the opportunity to test models that contain mediating and moderating relationships among variables and allows one to compare the fit of data in a proposed model against alternate models. We will construct several empirically-based models of prevention behavior to be compared against one another. For example, we will compare models that include *perceived severity of health threat*, which has been found to be an unreliable predictor of health behavior but which may hold special significance among cancer survivors, with models that exclude this construct. We will also compare models that treat all of our psychosocial constructs as having a distinct and direct influence on prevention behavior with other empirically-based models that specify indirect, or mediated, effects through other constructs.

Attachment C, Technical Supplement, includes a graphic of two competing conceptual models that show hypothesized relationships for predicting follow-up cancer screening behavior. The attachment also includes a summary of concepts and variables in relation to questions on the survey instrument.

Publication Plan

Results of the study will be disseminated through presentations at the CDC, national scientific meetings, and publications in peer reviewed journals. We anticipate the development of several scientific articles based on the research questions guiding the study. All abstracts, poster presentations, and manuscripts will undergo CDC clearance review prior to submission to conferences or journals.

Study participants will be offered an invitation to receive a brief summary of study findings via mail after data collection is complete. In addition, respondents will be directed to the

survivorship page of the CDC's Division of Cancer Prevention and Control's website, which will provide links to published articles as they become available.

A17. Reason(s) Display of OMB Expiration Date Is Inappropriate

Exemption to display of OMB expiration date is not being requested.

A18. Exemptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

- ACS (2006). American Cancer Society's complete guide to colorectal cancer.
- ACS & NCCN (2005). Colon and Rectal Cancer. Treatment Guidelines for Patients.
- AGA (1997). American Gastroenterology Association issues guidelines for colorectal cancer screening. Retrieved August 22, 2006 from www.findarticles.com/p/articles/mi_m3225/is_n8_v55/ai_19555282/pg_3
- Ahmed, F., Goodman, M. T., Kosary, C., Ruiz, B., Wu, X. C., Chen, V. W., & Correa, C. N. (2006). Excess risk of subsequent primary cancers among colorectal carcinoma survivors, 1975-2001. *Cancer, 107*, 1162-1171
- ACS & NCI (2002). Facing Forward Series: Life After Cancer Treatment (Vol. Publication No. 02-2424).
- AICR (2006). Cancer Survivors: Nutrition Guidelines for Cancer Survivors after Treatment. Retrieved September 25, 2006, from www.aicr.org/site/PageServer?pagename=cs_guidelines
- ASCO (2005). ASCO: Patient Guide. Retrieved September 15, 2006 from http://www.plwc.org/plwc/external_files/Colorectal_Cancer_Patient_Guide.pdf
- Bentler, P.M. & Chou, C. P. (1987). Practical issues in structural modeling. *Sociological Methods & Research, 16*, 78-117.
- Bines J & Gradishar WJ. (1997) Primary care issues for the breast cancer survivor. *Compr Ther* 23:605-611.
- Blanchard, C. M., Stein, K. D., Baker, F., Dent, M. F., Denniston, M. M., Courneya, K. S., et al. (2004). Association between current behavior and health related quality of life in breast, colorectal, and prostate cancer survivors. *Psychology and Health, 19*, 1-13.
- Brown BW, Brauner C, Minnotte MC. (1993) Noncancer deaths in white adult cancer patients. *J Natl Cancer Inst. 85:979-997*
- Brown JK, Byers T, Doyle C, et al. (2003) Nutrition and physical activity during and after cancer treatment: An American Cancer Society guide for informed choices. *CA Cancer J Clin* 53: 268-291
- Demark-Wahnefried, W., Aziz, N. M., Rowland, J. H., & Pinto, B. M. (2005). Riding the crest of the teachable moment: promoting long-term health after the diagnosis of cancer. *Journal of Clinical Oncology, 23*. 5814-5830.

Demark-Wahnefried, W., Peterson, B., McBride, C., Lipkus, I., & Clipp, E. (2000). Current health behaviors and readiness to pursue life-style changes among men and women diagnosed with early stage prostate and breast carcinomas. *Cancer*, *88*, 674-684.

Desch, C. E., Benson, A. B. 3rd, Somerfield, M. R., Flynn, P. J., Krause, C., Loprinzi, C. L., Minsky, B. D., Pfister, D. G., Virgo, K. S., Petrelli, N. J., American Society of Clinical Oncology (2005). Colorectal cancer surveillance: 2005 update of an American Society of Clinical Oncology practice guideline. *Journal of Clinical Oncology*, *23*, 8512-8519.

Dillman, D.A., Phelps, G., Tortora, R., Swift, K., Kohrell, J., & Berck, J. (2001). Response rate and measurement differences in mixed mode surveys using mail, telephone, interactive voice response and the Internet. Retrieved April 7, 2008, from http://www.sesrc.wsu.edu/dillman/papers/Mixed%20Mode%20ppr%20_with%20Gallup%20POQ.pdf

Dillman, D.A. (2007). *Mail and Internet Surveys: The Tailored Design Method* (2nd ed.). New Jersey: John Wiley & Sons, Inc.

Elston-Lafata J., Simpkins J., Schultz L., Chase G.A., Johnson C.C., Yood M.U., Lamerato L., Nathanson D., Cooper G. (2005). Routine Surveillance Care After Cancer Treatment with Curative Intent. *Medical Care*, *28*, 592-599.

Ganz, P.A. (2001). Late effects of cancer and its treatment. *Seminars in Oncology Nursing*, *17*, 241-248.

Humpel, N., Magee, C., & Jones, S. C. (2007). The impact of a cancer diagnosis on the health behaviors of cancer survivors and their family and friends. *Supportive Care in Cancer*, *15*, 621-630.

Kline, R. B. (1998). *Principles and Practice of Structural Equation Modeling*. D. A. Kenny (Ed.). The Guilford Press: New York, NY.

Li FP, Stovall E. (1998) Long-term survivors of cancer. *Cancer Epidemiol Biomarkers Prev* *7*(4):262-270.

Mahon, S. M., Williams, M. T., & Spies, M. A. (2000). Screening for second cancers and osteoporosis in long-term survivors. *Cancer Practice*, *8*, 282-290.

Maunsell, E., Drolet, M., Brisson, J., Robert, J., & Deschenes, L. (2002). Dietary change after breast cancer: extent, predictors, and relation with psychological distress. *Journal of Clinical Oncology*, *20*, 1017-1025.

Meyerhardt, J. A., Heseltine, D., Niedzwiecki, D., Hollis, D., Saltz, L. B., et al. (2006). Impact of physical activity on cancer recurrence and survival in patients with stage III colon cancer: findings from CALGB 89803. *Journal of Clinical Oncology*, *24*, 3535-3541.

NCCN (2006). Practice Guidelines in Oncology – v. 1. 2002, COL-3/REC-2. Available at: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp#site. Accessed May 1, 2007.

Patterson, R. E., Neuhouser, M. L., Hedderson, M. M., Schwartz, S. M., Standish, L. J., & Bowen, D. J. (2003). Changes in diet, physical activity, and supplement use among adults diagnosed with cancer. *Journal of the American Dietetic Association*, *103*, 323-328.

Pinto, B.M., Eakin, E., & Maruyama, N.C. (2000). Health behavior changes after a cancer diagnosis: what do we know and where do we go from here? *Annals of Behavioral Medicine*, *22*, 38-52.

Ramsey, S. D., Andersen, M. R., Etzioni, R., Moinpour, C., Peacock, S., Potosky, A., et al. (2000). Quality of life in survivors of colorectal carcinoma. *Cancer*, *88*, 1294-303.

Rex, D. K., Kahi, C. J., Levin, B., Smith, R. A., Bond, J. H., Brooks, D., et al. American Cancer Society; US Multi-Society Task Force on Colorectal Cancer. (2006). Guidelines for colonoscopy surveillance after cancer resection: a consensus update by the American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology*, *130*, 1865-1871.

Ries, L.A.G., Melbert, D., Krapcho, M., Mariotto, A., Miller, B.A., Feuer, E.J., Clegg, L., Horner, M.J., Howlader, N., Eisner, M.P., Reichman, M., Edwards, B.K. (eds). (2006). *SEER Cancer Statistics Review, 1975-2004*, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2004/.

Rowland, J., Mariotto, A., Aziz, N., Tesauro, G., Feuer, Blackman, D., et al. (2004). Cancer Survivorship-United States, 1971-2001. *Morbidity and Mortality Weekly Report*, *53*, 526-529.

Rulyak, S. J., Mandelson, M. T., Brentnall, T. A., Rutter, C. M., & Wagner, E. H. (2004). Clinical and sociodemographic factors associated with colon surveillance among patients with a history of colorectal cancer. *Gastrointestinal Endoscopy*, *59*, 239-247.

Satia, J. A., Campbell, M. K., Galanko, J. A., James, A., Carr, C., & Sandler, R. S. (2004). Longitudinal changes in health behaviors and health status in colon cancer survivors. *Cancer Epidemiology Biomarkers and Prevention*, *13*, 1022-1031.

Smith, T., Stein, K.D., Mehta, C.C., Kaw, C. Kepner, J.L., et al. (2007). The rationale, design, and implementation of the American Cancer Society's studies of cancer survivors. *Cancer*, *109*, 1-12.

Surveillance, Epidemiology, and End Results (SEER) Program (2007). SEER*Stat Database: Incidence - SEER 17 Regs Limited-Use, Nov 2006 Sub (1973-2004 varying), National Cancer Institute, DCCPS, Surveillance Research Program, Cancer Statistics Branch, released April 2007, based on the November 2006 submission. (www.seer.cancer.gov)

Tichansky, D. S., Cagir, B., Borrazzo, E., Topham, A., Palazzo, J., Weaver, E. J., et al. (2002). Risk of Second Cancers in Patients with Colorectal Carcinoids. *Dis Colon Rectum*, *45*, 91-97.

Trask P.C., Rabin C., Rogers M.L., Whiteley J, Nash J., Frierson G., Pinto B. (2005). Cancer screening practices among cancer survivors. *American Journal of Preventive Medicine*, 28, 351-356.

Trentham-Dietz, A., Remington, P. L., Moinpour, C. M., Hampton, J. M., Sapp, A. L., & Newcomb, P. A. (2003). Health-related quality of life in female long-term colorectal cancer survivors. *Oncologist*, 8, 342-349.

U.S. Cancer Statistics Working Group. (2007). *United States Cancer Statistics: 1999–2004 Incidence and Mortality Web-based Report*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Available at: www.cdc.gov/uscs.

USPSTF (2002). Screening for colorectal cancer: Recommendations and rationale. *Annals of Internal Medicine*, 137, 129-131.

Weiderpass E, Gridley G, Persson I, Nyren O, Exbom A, Adami NO. (1997) Risk of endometrial cancer in patients with diabetes mellitus. *Int J Cancer* 71(3):360-363.

Winawer, S., Fletcher, R., Rex, D., Bond, J., Burt, R., Ferrucci, J., et al. (2003). Colorectal cancer screening and surveillance: Clinical guidelines and rationale. Update based on new evidence. *Gastroenterology*, 124, 544-560.