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

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**PART B. COLLECTIONS OF INFORMATION EMPLOYING  
STATISTICAL METHODS**

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## ***B1. Respondent Universe and Sampling Methods***

### Study Population and Setting

Participants for this study will be recruited through the California Cancer Registry (CCR), which is managed by the contractor, Public Health Institute (PHI). To facilitate this work, Macro International, Inc. (Macro), CDC's contractor for data collection for this study, established a subcontract with PHI.

Started in 1985, CCR is California's statewide population-based cancer surveillance system. CCR collects information about all cancers diagnosed in California (except basal and squamous cell carcinoma of the skin and carcinoma in situ of the cervix). CCR has collected detailed information on over 2.5 million cases of cancer, with over 140,000 new cases added annually. The CCR database includes information on demographics, cancer type, extent and stage of disease at diagnosis, treatment, and survival. CCR is a collaborative effort involving the California Department of Health Services, ten regional registries, hospitals, cancer researchers throughout the nation, and PHI.

CCR was chosen for this study due to its high quality data, research compatible policies, and the racial and ethnic diversity of the population that it covers.

### *Data Quality*

The North American Association of Central Cancer Registries (NAACCR) has certified that the data collected by CCR meets its gold certification criteria for 2003 and 2004 data (the years from which the sample of 5-year survivors will be drawn). This certification indicates that CCR has met the following criteria:

- Case ascertainment has achieved 95% or higher completeness
- Fewer than 3% of reported cancer cases rely upon a death certificate as the only source for identification
- Fewer than 0.1% duplicate case reports are on file
- All data variables used to create incidence statistics by cancer type, sex, race, age, and county are 100% error free
- Less than 2% of the case reports on file are missing meaningful information on age, sex, and county
- Less than 3% of the cases on file are missing meaningful information on race
- The file is submitted to NAACCR for evaluation within 23 months of the close of the diagnosis year under review.

### *Research Policies*

In order to keep track of registered cancer cases that have died, changed residences, or received treatment in another city or state, CCR conducts passive follow-up using the National Death Index, Department of Motor Vehicle records, Medicare and Medicaid data, Social Security data, as well as follow-up with major cancer centers around the country and other state registries. CCR policies also allow for physician permission for patient contact and direct contact for participant recruitment.

### *Population Diversity*

The state of California has an incidence of CRC that is comparable to the national average. Nationally, the incidence rate of cancer of the colon or rectum is 51.2 per 100,000, while the rate in California is 46.1 per 100,000 in 2003 (USCS, 2007).

Recruiting for the study through a state-based cancer registry offers the benefit of sampling from a population-based pool of CRC survivors, which yields results that are more generalizable to the general population than results obtained through a convenience sample. By working with the CCR and PHI to select our pool of potential participants, we aim to recruit a racially- and ethnically-diverse population-based sample of 5-year CRC survivors.

#### Participant Inclusion and Exclusion Criteria

Eligibility criteria will include being an adult (18 years or older) male or female diagnosed with a primary colon or rectal cancer of stage local or regional (SEER summary stages 1-5), in the state of California during the years 2003 or 2004 (i.e., approximately 5 years prior to the time of our data collection), and being able to respond to the survey in English. We are not including individuals who were diagnosed with distant-stage CRC because the 5-year survival rates for advanced-stage CRC are low (10.3%; Ries et al., 2006) and the likelihood of continued cancer treatment and severe health problems requiring extensive medical follow-up is high. Exclusion criteria will entail having been diagnosed with another cancer prior to the colorectal cancer diagnosis. While none of the following groups are explicitly targeted by the study, the pool of potential participants could include: pregnant women, HIV/AIDS-affected persons, mentally disabled persons, economically disadvantaged persons, and educationally disadvantaged persons.

#### *Justification for English-only surveys*

Due to the significant costs estimated for translating, testing, and replicating all of the proposed study materials into another language, our study team decided not to translate the data collection materials into non-English languages (i.e., Spanish) at this time. Based upon estimates of English language proficiency among Hispanic/Latino colorectal survivors in California (California Health Interview Survey, 2001; 2003), and an overall response rate of 60%, we estimate that a maximum of 52 of the 1600 total surveys disseminated for this study may not be returned from Hispanic/Latino participants because they lack English language proficiency. For these reasons, we have chosen to move forward with the English-only version of the survey at this time; however, we recognize that this is a study limitation. Depending upon the results of the current research, we may extend this line of research to include non-English-speaking cancer survivors in the future.

#### Sample Size Estimates

The California Cancer Registry reports 15,432 and 14,878 cases of colon or rectal cancer diagnosed in the years 2003 and 2004, respectively. Based on incidence data from SEER (SEER, 2007), we can estimate that 39% or 11,821 of those 30,310 cases were diagnosed while the cancer was confined to the primary site (localized stage) and 36% or 10,912 cases were diagnosed after the cancer had spread to regional lymph nodes or directly

beyond the primary site (regional stage). The 5-year relative survival rate is 89.8% for localized CRC and 67.7% for regional CRC (SEER, 2007) which means that we can expect roughly 10,615 of the survivors diagnosed with localized CRC and 7,387 diagnosed with regional CRC during 2003 and 2004 to be alive in 2009. Of those 18,002 combined cases, we will impose our exclusion criteria (i.e., over 18 years, no diagnoses prior to the CRC diagnosis) and draw a random sample of 1,950 CRC survivors for recruitment into our study. Using response rate information found in the literature, we expect to receive physician permission to contact patients for 95% of the selected cases (Blanchard et al., 2004; Smith et al., 2007), and, thus, will send pre-notification letters to approximately 1,852 CRC survivors. Upon receiving this letter, we estimate that 10% (185) will contact the registry to request that they not be contacted for recruitment into any research studies. Thus, we expect to send approximately 1,667 survey packets to the remaining potentially eligible participants. Based upon the range of participant response rates reported in the literature from studies using cancer registries (e.g., Blanchard, et al., 2004; Demark-Wahnefried, et al., 2000; Ramsey et al., 2000; Trentham-Dietz, et al., 2003), we estimate a final participant response rate of approximately 60% resulting in a final sample size of approximately 1,000.

#### Precision of Study Estimates and Power

We propose to use structural equation modeling (SEM) to examine relationships among the variables specified in our conceptual model. SEM is a general technique that allows one to specify, estimate, and evaluate models of relationships among variables (Kline, 1998). The objective is to develop a parsimonious model that provides an explanation of observed relationships among variables that is interpretable and that fits the observed data adequately.

There is no minimum sample size required in SEM; however, models based on an  $N < 100$  are not recommended. A minimum of 10 cases for every parameter estimated in the model has been suggested and between 10 and 20 cases per parameter is considered desirable (Bentler & Chou, 1987; Kline, 1998). For our analyses, we estimate that the maximum number of parameters to be estimated within a single SEM will be 45. Therefore, we will need complete survey data from 450 to 900 participants. It is common in research involving self-administered questionnaires for participants to return incomplete questionnaires with missing data; therefore, the estimated final sample size of 1,000 detailed above includes a 10% over-recruitment buffer to account for surveys that are returned with missing or incomplete data (e.g., 100 surveys returned with incomplete data, 900 surveys returned with complete data).

## ***B2. Procedures for the Collection of Information***

### Study Design

In order to investigate the correlates of prevention and screening behavior in 5-year survivors of CRC, we propose to conduct a cross-sectional survey of adult men and women who were diagnosed with colon or rectal cancer approximately 5 years before the time of data collection. The survey will be self-administered and will include questions intended to assess each of the study variables of interest. Additional information on the

research questions and the design of the information collection instrument is included in **Attachment C**, Technical Supplement.

After OMB approval has been granted, PHI staff will conduct a review of CCR data to identify and select all potentially eligible participants from the 2003 and 2004 record years. PHI will de-identify this list and share it with Macro so that Macro staff may select from it a random sample of 1,950 potentially eligible participants. Macro will send this de-identified random sample back to PHI, so that PHI can re-identify participants and follow its standard procedures for gaining physician permission to contact cancer survivors for research participation (see **Attachment D2**, for the physician permission letter). PHI will then mail an advance letter (**Attachment E1**) and informational brochure (**Attachment E2**) about the CCR to potentially-eligible participants who received physician permission. The advance letter will inform the eligible participants of the study and offer them a way to decline participation in the current study and/or all future research studies. Three weeks after the advance letters have been sent, PHI will provide Macro with names and contact information for all potential participants (excluding any individuals who have requested to be removed from participation). Macro will then send questionnaire packets to all potential participants. Questionnaire packets will include a cover letter (**Attachment E3**), a consent form that includes the California-mandated "Participant's Bill of Rights for Non-Medical Research" form (**Attachment E4**), a Survey of Health Behaviors (**Attachment E**), a \$10 cash incentive, an ink pen/highlighter for participants to use and keep, and a pre-addressed, postage-paid envelope for returning the survey. Participation will entail completing the self-administered survey and returning it by mail in the provided envelope. We estimate that completing the survey will take approximately 30 to 45 minutes, with an average response time of 40 minutes.

To respondents who do not return a completed survey after the initial mailing, Macro will send a reminder post card (see **Attachment E5**), followed by a duplicate survey packet with a slightly modified cover letter (see **Attachment E6**) and excluding the \$10 in cash. If Macro does not receive indication that any of the materials sent in the mail have been received by the respondent (i.e., the respondent does not refuse participation nor return a completed survey), Macro will make follow-up telephone calls to invite participation via computer-assisted telephone interviewing (CATI; see **Attachment F** for the CATI script).

We have proposed a mixed-mode data collection method (i.e., self-administered paper survey plus 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 response rates that are higher 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-person or telephone interviews (Dillman et al., 2001).

### Conduct of Survey

PHI staff will conduct a review of CCR data to identify and select potentially eligible participants who are not known to be deceased based on the registry's standard procedures for follow-up of registered cases. PHI will share a de-identified list of potentially eligible participants with Macro, and Macro staff will draw a random sample of 1,950 CRC survivors. Macro will send this de-identified random sample back to PHI, so that PHI can re-identify participants and then follow its standard procedures for gaining permission from physicians to contact patients. Specifically, PHI will send letters to the physicians of record for the selected eligible participants, 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. Physicians will be asked to respond within 3 weeks of the date on the letter if they believe their patient(s) should not be invited to participate. They will also be notified that non-response to the letter within 3 weeks will imply their permission to contact their patient(s). After the 3 weeks have passed, PHI will mail a brochure about the CCR and an advance letter to potentially eligible participants who have received physician permission. The enclosed advance letter will explain the purpose of the study, the process by which the respondent's information was acquired (i.e., the CCR and PHI), and will invite the respondent to participate in the study by completing the questionnaire scheduled to arrive subsequently by mail. The letter will also offer respondents an opportunity to decline participation before receiving the questionnaire packet if they do not wish to receive any further correspondence. Individuals will be asked to contact PHI (via a toll-free number provided in the advance letter) within 3 weeks of the date on the letter if they have been contacted in error or would like to ensure they will not be contacted further. After the 3 weeks have passed, PHI will provide Macro with names and contact information for all potential participants (excluding any individuals who have requested to be removed from participation).

After receiving the list of eligible participants from PHI, Macro will send the questionnaire packet to all eligible participants who have not declined participation. The questionnaire packet will include the following: (1) a brief cover letter; (2) a consent form; (3) the study questionnaire; (4) \$10 in cash; (5) an ink pen/highlighter; and (6) a postage-paid return envelope. The survey should take approximately 40 minutes to complete. Participants will be instructed to return their completed surveys via mail to Macro. If participants complete and return their questionnaire to Macro, they will not be contacted further, unless they request to receive a mailed summary of the study findings after data collection concludes. Macro will send a brief summary of the findings to any such interested participants.

To those respondents who do not return a completed survey or participation refusal within 2 weeks, Macro will send a reminder post card. If respondents still do not respond within 2 weeks, Macro will send a duplicate survey packet. If, after two weeks of sending the duplicate packet, Macro still does not receive any indication that the mailed materials were received by the respondent (i.e., the respondent does not refuse participation nor return a completed survey), Macro will make follow-up telephone calls to invite participation via CATI. Individuals reached by phone will be greeted by trained interviewers administering a standard introductory script, and interviewers will reference

the prior mailings to ensure that respondents' correct addresses are in the database. If the interviewers learn that questionnaire packets were sent to an incorrect address, a correct address will be obtained and a packet, which will include a consent form, \$10 in cash, and a pen/highlighter, will be sent to the new address. Individuals reached by phone will be invited to participate through the telephone interview option or the paper survey option. CATI participants will be read the IRB-approved consent information, followed by the survey questions. If necessary, up to 10 attempts will be made to contact individuals via telephone from whom mailed surveys are not received.

### ***B3. Methods to Maximize Response Rates and Deal with Non-response***

This study was designed following the principles of the Tailored Design Method of Dillman and colleagues (2007). The Tailored Design Method (TDM), an update of the Total Design Method Dillman proposed in the 1970's, covers several aspects of survey research, modeled and tested to improve response rates. In writing survey questions, we were careful to ensure that questions were worded clearly and at a low literacy level. There was a concerted effort placed on making sure that vague quantifiers were avoided, that appropriate scales were used for answer categories, that scale items were equally balanced, that time referents were used to avoid telescoping, and that questions were not double-barreled.

We have placed much focus on constructing a questionnaire that is easy to follow and will appear interesting and important to the respondent. Dillman holds that surveys are written in both textual and graphical languages and that careful attention must go into both to increase the likelihood that a person will respond to the survey. Survey sections were ordered taking into account several order effects (e.g. norm of evenhandedness, anchoring, summary effects, and addition or subtraction effects) and ease of response.

In designing the survey, we intended to create a navigational path that would be easy for the respondent to follow, especially when dealing with skip patterns. Instructions were placed in appropriate locations and item-in-a-series questions were kept on the same page to avoid flipping back and forth between pages. Careful attention was paid to the legibility of the survey. Font type, size, style, color and shading were used to make the survey easier to read, especially for an older population. Shading was used to emphasize questions and answer categories, and font color was used to distinguish between questions and answer options. We strove to maintain simplicity, regularity, and symmetry in order to make the task of responding easier. The survey design was thoroughly checked for consistency in use of visual guides. A front and back cover were designed that were visually interesting and included the study title, yet, kept the respondents' cancer history private to potential onlookers. It was also decided that the survey should be printed as a booklet to help respondents avoid skipping over pages, as recommended by Dillman (2007).

As described in section B.2, there will be multiple contacts with potential respondents. At each of the contacts, attention has been paid to maximizing response rates. The first contact will occur through a pre-notification letter. Research reports that the use of a pre-

notification letter consistently results in an increase in response rates (Dillman, 2007). This letter will include a brochure that describes the CCR.

The second contact is the study packet, which includes a cover letter (**Attachment E3**), consent forms (**Attachment E4**), the study survey (**Attachment E**), the \$10 incentive, the ink pen/highlighter, and a return, postage-paid envelope. The effectiveness of including financial and material incentives in boosting response rates has been well documented (Dillman, 2007). The ink pen also potentially makes it easier for participants to complete the survey (i.e., cutting out the need to go searching for a pen or pencil). Special attention will be paid to the ordering and packaging of the survey packet so that all elements are easily identified and instructions are clear.

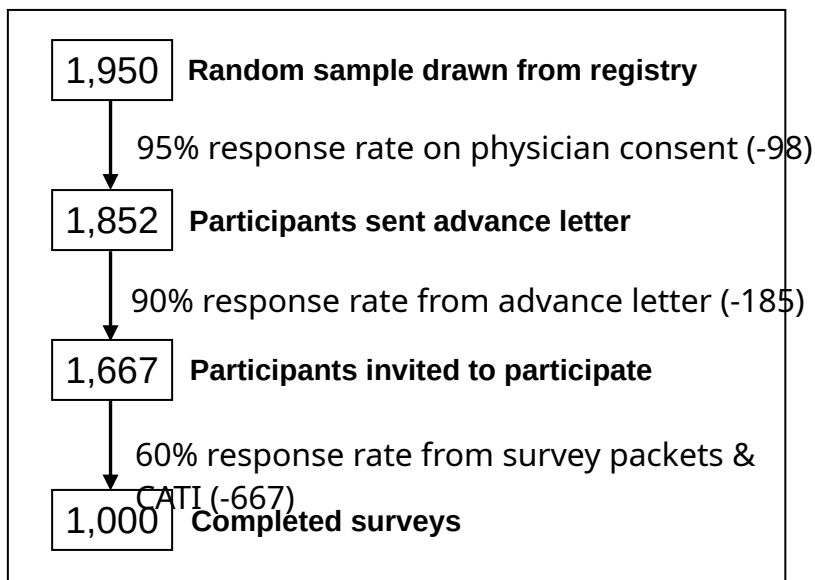
The third contact is a postcard (**Attachment E5**), which provides contact information for Macro in case the respondent needs another study packet or wishes to discontinue receipt of recruitment materials.

The fourth contact is a duplicate survey packet. This packet will be sent to individuals who have not responded to the original packet or the reminder postcard. It will contain a modified cover letter (**Attachment E6**), consent forms, the study survey, and a return, postage-paid envelope. This fourth contact is intended to emphasize the importance of their personal participation in the study and offer them another opportunity to participate if the original materials have been displaced.

For those eligible participants who do not respond to any of the four mailings, Macro will conduct follow-up by telephone and offer the opportunity to participate via computer-assisted telephone interview (CATI; **Attachment F**). Dillman endorses the use of telephone follow-up because it not only increases coverage and reduces non-response, but it also gives the interviewer the opportunity to reassure those who do not understand the nature of the study or to address any of the participant's unanswered questions. In the event that participants choose not to respond to the survey with the telephone interviewer, the reason for refusal will be recorded (e.g. language difficulties, disinterest, etc.). Up to 10 attempts will be made to contact individuals via telephone, if contact is unsuccessful the first time.

Studies with similar methodology to the proposed study have seen response rates averaging at approximately 60%. Expected response rates and sample size can be found in Figure B3-1 for all phases of the study and they are also discussed in Section B1, under Sample Size Estimates.

Figure B.3-1. Expected response rates and sample sizes.



In order to determine whether those who responded to the study survey are different from those who did not respond (e.g. non-response error), we plan to compare responders and non-responders using data provided by the CCR (such as stage at diagnosis, age at diagnosis, current age, gender, etc.). This will help us determine whether there are any significant differences between the two groups. In addition, the use of the CATI follow-up will also provide us with information about why individuals may have refused study participation.

#### ***B4. Tests of Procedures or Methods to Be Undertaken***

The study survey was tested for clarity of wording and appropriate response categories through cognitive interviewing methods. Nine individuals, all colorectal cancer survivors, varying by levels of education, race, age, and socioeconomic status participated in cognitive interviews to ensure that a diverse range of respondents can complete the measures. Cognitive interviews are semi-structured interviews that allow researchers to determine respondents' perceptions of the meanings of questions and response choices, the best sequencing of questions, the appropriateness of response categories, the best question and response wording, and any items that may cause difficulty for respondents. Based on feedback received in the cognitive interviews, we revised the survey to improve clarity and ease of responding.

#### ***B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data***

All questionnaires, study design, and statistical methods were developed and reviewed extensively by the study team in the Division of Cancer Prevention and Control (DCPC) at the Centers for Disease Control and Prevention (CDC) (Table B5-1), Macro International, and the Public Health Institute (PHI). Staff from DCPC/CDC will participate in the analysis of data and development of scientific manuscripts. Individuals who will continue to be involved in the project during the time of data collection are listed in the tables below.

Table B5-1. Individuals to be involved in Data Analysis & Statistical Procedures

<b>Division of Cancer Prevention and Control, Centers for Disease Control and Prevention</b>					
<b>Name</b>	<b>Degree</b>	<b>Position</b>	<b>Address</b>	<b>Phone</b>	<b>E-mail</b>
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Loria A. Pollack	M.D., M.P.H.	Medical Officer	4770 Buford Hwy, MS K-55 Atlanta, GA 30341	770-488-3181	lpollack@cdc.gov
Zahava Berkowitz	M.P.H.	Statistician	4770 Buford Hwy, MS K-55 Atlanta, GA 30341	770-488-4881	zberkowitz@cdc.gov
Juan Rodriguez	M.P.H.	Epidemiologist	4770 Buford Hwy, MS K-55 Atlanta, GA 30341	770-488-3086	Jrodriguez2@cdc.gov

Table B5-2. Individuals to be involved in Data Collection Efforts

<b>Macro International Inc.</b>					
<b>Name</b>	<b>Degree</b>	<b>Position</b>	<b>Address</b>	<b>Phone</b>	<b>E-mail</b>
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