

**Insurance Coverage, Employment Status, and Copayments/Deductibles Faced by Young  
Women Diagnosed with Breast Cancer**

**Supporting Statement – Section B**

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## 1LIST OF ATTACHMENTS

**Attachment 1a** – Education and Awareness Requires Learning Young (EARLY) Act of 2009

**Attachment 1b** – Section 301 of the Public Health Service Act

**Attachment 2** – 60-Day FRN

**Attachment 3** – Mail-in Survey Instrument English

**Attachment 3s** – Mail-in Survey Instrument Spanish

**Attachment 4** – Web-based Survey Instrument English

**Attachment 4s** – Web-based Survey Instrument Spanish

**Attachment 4-scr** – Intro/screening for Web-based Survey English

**Attachment 4s-scr** – Intro/screening for Web-based Survey Spanish

**Attachment 5** – Cover Letter/ Passive Consent English

**Attachment 5s** – Cover Letter/ Passive Consent Spanish

**Attachment 6** – Reminder/ Thank You Postcard English

**Attachment 6s** – Reminder/ Thank You Postcard Spanish

**Attachment 7** – Reminder Letter English

**Attachment 7s** – Reminder Letter Spanish

**Attachment 8** – Recruitment Flier/ Invitation English

**Attachment 8s** – Recruitment Flier/ Invitation Spanish

**Attachment 9** – RTI Code of Conduct

**Attachment 10** – RTI IRB Approval Letter

**Attachment 11** – Letter of Support, NCI

## **Section B – Data Collection Procedures**

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

Our study targets two groups of young breast cancer survivors, which we refer to as Sample 1 and Sample 2, respectively.

#### **Sample 1**

The respondent universe for Sample 1 consists of all female breast cancer survivors who were diagnosed between the ages of 18 and 39 for the first time with ductal carcinoma in situ (DCIS) or invasive breast cancer between January 1, 2103 and December 31, 2014 or at least one year prior to contact. The respondent universe includes respondents in one of four state cancer registries that are alive, have agreed to allow the cancer registry to contact them, and whose eligibility has been confirmed by the registry. We plan to enter into agreements with the California, Georgia, Florida and North Carolina state cancer registries. Final selection of state cancer registries will be based on availability of the sample and approval from the states. Based on preliminary data directly from the state cancer registries, the universe could comprise a total of 3,863<sup>1</sup> female, breast cancer survivors.

Table 1 illustrates our expected sample size by whites, blacks and Hispanics. Our sample for recruitment will be comprised of a random sample of 36% of eligible whites in each sampling pool along with 100% of eligible blacks and Hispanics. We plan to contact a total of 2,000 registry patients for the survey. With an expected response rate of 60% across the entire sample, this design will yield around 1,200 completed surveys across white, black and Hispanic cancer survivors sampled.

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<sup>1</sup> Based on 2013-2014 incidence data from four state registries—California, Florida, Georgia, and North Carolina.

**Table 1: Projected Sample Size by State and Race/Ethnicity**

<b>State</b>	<b>Incidence (n) 2013–2014<sup>a</sup></b>	<b>White</b>	<b>Black</b>	<b>Hispanic</b>
California (CRGC cases only) <sup>b</sup>	1,171	319	75	207
Florida	1,380	373	149	190
Georgia	610	154	167	13
North Carolina	702	195	145	12
<b>Total<sup>c</sup></b>	<b>3,863</b>	<b>1,041</b>	<b>536</b>	<b>422</b>

<sup>a</sup> Total number of female breast cancer survivors ages 18-39 years at diagnosis. The survey will be administered starting in October 2016, so the registries should have more than 90% of the cases diagnosed in 2014 and 100% of the new cases reported in 2013.

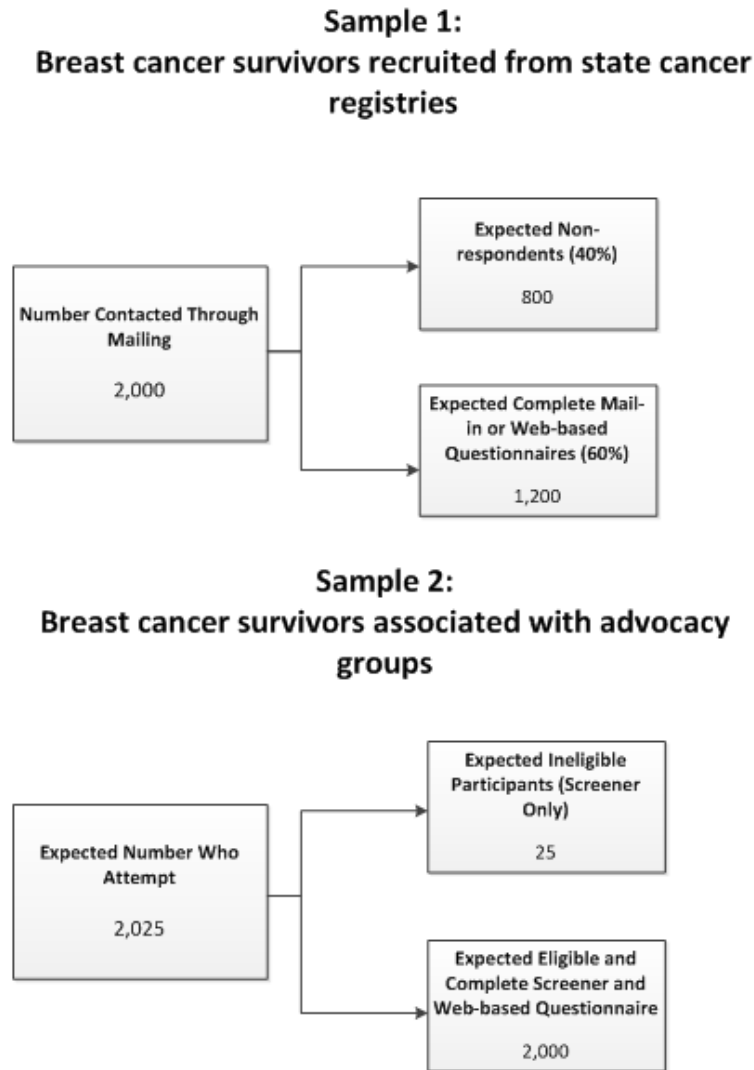
<sup>b</sup> The Los Angeles area has an ongoing study following Hispanic breast cancer survivors, so RTI is targeting cases reported to the Cancer Registry of Greater California (CRGC), which represents about 50% of the state's total cancer cases.

<sup>c</sup> The proportions reported are derived by summing all cases across the four registries.

## **Sample 2**

The universe for Sample 2 is members of two advocacy groups: Living Beyond Breast Cancer and the Young Survival Coalition. The combined membership of these groups is estimated to be more than 2,000 young women. The Sample 2 respondents will be a convenience sample of women who complete surveys in response to communications from the advocacy groups. Eligible participants will be female breast cancer survivors diagnosed with DCIS or invasive breast cancer for the first time between the ages of 18 and 49, and who do not live in one of the Sample 1 states (California, Florida, Georgia, and North Carolina). These criteria will be confirmed through an eligibility screener on the Web-based version of the survey instrument, only used for Sample 2 respondents. We expect there to be completed survey responses from 2,000 eligible participants and partial responses from 25 respondents due to ineligibility. Figure 1 illustrates our expected sample sizes for both samples.

**Figure 1: Sample 1 and Sample 2 Expected Responses**



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

We will use one survey instrument with minor modifications to collect data from Sample 1 and Sample 2. The survey instrument for the proposed study includes sections on: (1) insurance status; (2) financial burden and out-of-pocket medical costs following diagnosis with breast cancer; (3) employment status; (4) access to cancer treatment and overall treatment compliance; (5) perceived quality and coordination of breast cancer treatments received; (6) quality of life following breast cancer diagnosis; (7) cancer and medical history; and (8) respondent demographic characteristics (Attachments 3 and 3s).

## **2.1 Data Collection Procedures**

### **Sample 1**

Sample 1 data will be collected using either a mail-in or web-based questionnaire. While respondents can respond via a paper survey or online (**Attachments 4 and 4s**), we emphasize in our survey cover letter that respondents can only respond once (**Attachment 5**).

RTI is seeking cancer registry data from cancer registries that do not have an active physician notification requirement. Depending on cancer registry preferences, either RTI or the cancer registry will be responsible for directly mailing the physician passive notifications (if required) and survey materials to participants. If the registry prefers to do the mailings, RTI will select the survey sample using de-identified data and will not perform any direct patient contact. The survey cover letter and passive consent form will be sent to our sample that includes the website address where respondents can complete the survey electronically. A few weeks after the initial mailing, we will send a reminder postcard to individuals who have not responded, to thank them for their willingness to participate in this survey (**Attachment 6**). Approximately 6 weeks after the initial mailing, we will mail a reminder letter and second survey to individuals who have not responded to the survey (**Attachment 7**).

### **Sample 2**

Data will be collected online using a web-based instrument that will be made accessible to members of our two collaborating advocacy groups—Living Beyond Breast Cancer and Young Survival Coalition. The online recruitment flyers for the online survey will emphasize that individuals can only respond to the survey once. Also, we plan to use a survey data collection program that will restrict the number of responses individuals can make from the same computer Internet Protocol address to one.

In both samples, respondents will have a period of 75 days to complete the instrument. We estimate the time burden to on average 22 minutes for Sample 1, 24 minutes for Sample 2 including eligibility questions, and 2 minutes for ineligible and incomplete Sample 2 respondents.

## **2.2 Estimation Procedure**

### **Nonresponse Bias and Nonresponse Bias and Survey Weights**

In Sample 1, all whites have the same probability of selection and all blacks and Hispanics will be selected with certainty. To evaluate nonresponse bias, we will use a logistic regression model to examine the impact of cancer patient characteristics on the probability that the survey was completed. Explanatory variables in this model will include cancer type and stage, insurance status at time of diagnosis, and demographic characteristics. The results of this analysis will indicate which subgroups

are over- or underrepresented in the survey data. We will compute survey weights generated by SAS PROC SURVEYSELECT for nonresponse. The sample survey data analysis procedures in SAS (SAS Institute 2012) will be used to generate weighted sample estimates of means or proportions for the domains of interest, and to conduct statistical tests of differences among these estimates.

For Sample 2, we will not be able to weight the responses because they will be drawn from a convenience sample.

### **Power Analysis**

For Sample 1, estimating a 60% response rate, we expect to obtain completed surveys from 600 white, 322 black, and 253 Hispanic survivors (Malin, Diamant et al. 2010, Arora, Reeve et al. 2011, Jagsi, Pottow et al. 2014).

On the basis of previous surveys completed by recruitment from the advocacy groups, we anticipate that at least 2,000 women will complete the Web-based survey from Sample 2. We aim to have at least 500 respondents who were previously diagnosed during three age ranges (18-39; 40-44; and, 45-49) to assess group differences. At  $\alpha = 0.05$ , the power to detect a 10% difference between groups is 0.89.

### **B3. Methods to Maximize Response Rates and Deal with Nonresponse**

**Sample 1.** Two reminder letters (see **Attachments 6 & 7**) will be utilized to maximize response rates. We also are using a multiple-mode approach whereby sampled individuals have the option of completing the survey either by mail or via the web. This data collection protocol follows Dillman's tailored design method for maximizing survey response rates (Dillman et al., 2014). In addition, we are offering a \$10 monetary incentive (i.e., gift card) to participants who complete and return the survey. Finally, we will provide a toll-free number that can be used by survey participants to contact survey staff from 9am to 5pm Eastern Standard Time to address specific questions or obtain clarifications.

**Sample 2.** We will send virtual recruitment flyers out via multiple channels including through social media channels (via Facebook, email listservs, email groups) and the advocacy groups' websites.

### **B4. Test of Procedures or Methods to be Undertaken**



The questionnaire was pilot tested with nine English-speaking, and nine Spanish-speaking young, female breast cancer survivors living in the Raleigh/Durham area. The pilot tests assessed the survey quality and usability and were used as a tool to estimate time burden associated with completing the questionnaire. Feedback from pilot testing was incorporated into the final version of the questionnaires. The estimates of time burden presented in Part A of the Supporting Statement were generated from pilot testing results.

### **Continuity of Insurance Coverage.**

We will produce descriptive statistics of the proportion that experience the following: become uninsured, have gaps in enrollment, or have any other discontinuity (based on all the above discontinuity categories). In addition, we will report the proportion continuously enrolled for 6 months and 1 year (we will consider presenting other time frames on the basis of data distribution). We will use survival analysis to perform multivariate assessments to study factors that affect the continuity of enrollment. The dependent variable will be specified as the total number of months continuously enrolled before disenrollment. Independent variables will include demographics, stage at diagnosis, cancer site, comorbidities (using Charlson index categories) and year of diagnosis. We will assess whether the Cox proportion hazard model or parametric hazard model will be the most appropriate approach to assess odds of disenrollment (Chien et al., 2010; Collett, 2003; Ramsey et al., 2008).

### **Access-to-Care Barriers and Quality of Care Experienced by Cancer Patients.**

RTI will generate descriptive statistics on access to care and quality of care variables, including the mean score, standard deviation, and range. In addition, we will also assess differences by continuity of enrollment, socioeconomic status, and race using multivariate models. These models will include independent variables from both the survey and linked databases such as the state registry databases as well as possibly the Spatial Impact Factor Database (SFID). Information available for survey respondents will include detailed elements to describe socioeconomic status (i.e., income, education, and occupation).

### **Employment Status and Changes after Cancer Diagnosis.**

Work status at the time of diagnosis will be classified as full-time, part-time, or not employed. Changes in employment status will be reported to assess changes from before to after cancer diagnosis. We will also assess whether employment status is affected by the type of treatment received and will perform significance testing to assess whether differences in rate of employment

(based on those who were working before diagnosis) are present 1 or 2 years after diagnosis.

**Out-of-Pocket Costs.**

RTI will summarize the average and range of out-of-pocket costs reported by the survey respondents. We will stratify costs by type, including copayments, deductibles, and self-pay treatments (e.g., interventions not covered by insurance or those who have no health insurance).

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

Florence Tangka, Ph.D., of the Division of Cancer Prevention and Control, is the Principal Investigator and Technical Monitor for the study, and has overall responsibility for overseeing the design, conduct, and analysis of the study. She will approve and receive all contract deliverables. Telephone: 770-488-1183.

The survey instrument, sampling and data collection procedures, and analysis plan were designed in collaboration with researchers at Research Triangle Institute (RTI) International. RTI will conduct data collection and will perform data analysis, in consultation with the CDC investigators. Sujha Subramanian, Ph.D. [781-434-1749] has overall technical and financial responsibility for the study at RTI and led the RTI effort to design this protocol. Dr. Subramanian will direct the overall data collection and analysis effort.

Other personnel involved in design of the protocol and data collection instruments are:

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