Supporting Statement: Part A

Evaluation of the Young Sisters Initiative: A Guide to A Better You! Program

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Evaluation of the Young Sisters Initiative: A Guide to a Better You! Program

A. Justification

A1. Circumstances Making the Collection of Information Necessary

It has been well documented that younger women tend to experience more difficult adaptation and quality of life following breast cancer diagnosis. When compared with older women, younger women display poorer emotional functioning and undergo more disruptions from the disease and its treatment due to child-rearing activities and work-home responsibilities (Rosen, Rodriquez-Wallberg, & Rosenzweig, 2009; Thewes, Butow, & Girgis, 2004; Baucom, Porter, Kirby, Gremore, & Keefe, 2006; Knobf, 2006; Camp-Sorrell, 2009; Phillips et al., 2008; Peled, Carmil, Siboni- Samocha, & Shoham-Vardi, 2008; Bloom et al., 2004; Avis, Crawford, & Manuel, 2005).

Among young premenopausal women with breast cancer, counseling about premature menopause and fertility changes is often overlooked in decision making and preparation for treatment. A further concern is time sensitivity; decisions about fertility preservation must usually be made quickly between diagnosis and treatment initiation (Rosen et al., 2009; Quinn, Vadaparampil, & Gwede, 2007). Women often face life-saving decisions, and do not or cannot consider fertility implications. However, many decisions are irreversible once treatment begins.

There appear to be differences in the biology of breast cancers that occur in Caucasian and African American women. Some studies have found that breast cancers in African American women are more often high grade, lack hormone receptors, and have more mutations in the gene (Rose & Royak-Schaler, 2001; Jones et al., 2004; Chlebowski et al., 2005). African American women also appear more likely to have basal-like/triple negative breast cancer (estrogen receptor-negative, progesterone receptor-negative, and HER2/neunegative), a subtype of breast cancer with a poor prognosis. Other factors are suggested in the observations of aggressive tumors in African American women. A homeobox gene, BP1, has been identified that is seen more often in African American women's breast tumors than in Caucasian women's tumors. This gene is associated with estrogen receptor-negative tumors and aggressive tumors.

In 2010 the Centers for Disease Control and Prevention (CDC) launched the Breast Cancer in Young Women (BCYW) project to raise awareness about these issues among YBCS and provide YBCS psychosocial and reproductive health support. The BCYW project is a 3-year project to identify, strengthen, and promote real-world, evidence-based interventions that support young breast cancer survivors (YBCS). The Education and Awareness Requires Learning Young Act, Sec. 10413 of the Patient Protection and Affordable Care Act (H.R. 3590), defines YBCS as women who had a diagnosis of breast cancer before the age of 45 years. A key component of the BCYW program is to test, design, implement and evaluate the Young Sisters Initiative: A Guide to a Better You (YSI) program. The YSI program is a web-based intervention targeting the African American YBCS audience to provide them psychosocial and reproductive health information and support for their needs as cancer survivors.

Through the BCYW the CDC will conduct a process evaluation of the first YSI program at www.sniyoungsisters.com (note that the website is under construction). To do this, CDC will conduct a baseline demographic screener, analyze Website analytics, and conduct a post YSI program website use survey. The demographic screener will collect program users' demographic data and will be used to assess whether the YSI is reaching its intended audience. The post YSI program website use survey (post-use survey) will collect data about respondents' perceptions of the YSI site structure, content (per section), site resources, and usefulness of YSI program content. Participation in the baseline demographic screener and post-use survey is voluntary; however the screener must be completed to access the online program.

CDC is authorized to collect information for the process evaluation by the Public Health Service Act (**Attachment 1**). OMB approval is requested for one year.

Privacy Impact Assessment

Overview of the Data Collection System

CDC will collaborate with a partner organization, Sisters Network Inc. (SNI), and an evaluation contractor, ICF International (ICF), to recruit respondents for the YSI program evaluation and collect the information needed to conduct a process evaluation. SNI will have primary responsibility for recruiting women to visit the YSI program website and participate in the YSI process evaluation. ICF will have primary responsibility for data collection, management and analysis.

SNI will recruit potential YSI program respondents from lists of women who are members of SNI affiliate/chapter organizations. SNI will distribute an email announcement about the YSI program to potential YSI program users and additional partner organizations who work with members of the target audience (**Attachment 3A).** The announcement will include a link to the SNI website, by which users can access the YSI program landing page (**Attachment 3B**). When users visit the YSI landing page, interested individuals will first complete the ***demographic screener*** (**Attachment 4A**). See **Attachment 4B** for the full version demographic screener with skip patterns included. Users will then register to access the site by selecting a username, password, security question, and answer. For evaluation purposes, users are required to both complete the demographic screener and register for the YSI web site in order to access the YSI program. Respondents who are members of the primary intended audience for the YSI program will also be asked to complete the ***post-use survey*** (**Attachment 5**). See **Attachment 5B** for full version of the post-use survey with skip patterns included. The post-use survey will be sent to program users (the intervention group), 2-4 weeks after YSI registration (measured by completion of the demographic screener).

Neither CDC nor ICF will collect personal information in identifiable form (PII). As a means of limiting non-response, SNI will send reminders to all potential respondents during the implementation of the YSI program website (**Attachment 3C**). We estimate that the YSI program website and process evaluation will be in data collection for approximately 4-6 months.

Information from respondents will be collected on a weekly basis for 4-6 months and for 2 months post-program implementation.

Items of Information to be Collected

The demographic screener includes questions on respondents' demographics, stage, and type of breast cancer. Data collected from the demographic screener confirms that we are collecting data from the target audience. However, because we do not collect any PII to track respondents in the demographic screener, we must repeat some of the demographic screener questions in the post-use survey in order to verify that we are collecting information regarding the target audience's use of the YSI program. The recollection of this information is necessary because data collected during the initial screening cannot be linked to data collected in the post use survey (as a safeguard for respondent privacy). Our team decided not to collect PII in order to facilitate users being more candid in their responses to evaluation questions and to inhibit participant nonresponse. Our approach allows us to gather necessary data and remains most protective of audience privacy.

The post-use survey includes questions on users' appreciation of the YSI program materials, usage barriers, and users' perceptions of the YSI program site structure, content (per session), resources, usefulness of content, and effectiveness of information provided. To minimize burden to respondents, the survey will be programmed with skip patterns to route the respondent only to the most relevant questions. The post-use survey also requests demographic information from respondents.

Note that while the YSI program will be accessible for all interested individuals (i.e., individuals who are not members of the target audience will be able to access the YSI program), only users belonging to the target audience will be contacted to participate in the post-use survey and included in the process evaluation.

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

The demographic screener will be housed on the YSI program website at www.sniyoungsurvivors.org and the post-use online survey will be conducted using Survey Monkey. Neither the demographic screener nor the post-use survey has any content targeting children less than 13 years of age. The screening process will exclude anyone under 18 years of age. The demographic screener and Survey Monkey system has the capability of collecting computer "cookies," however this function will be de-selected for this data collection. The Survey Monkey privacy policy is posted on the website.

A2. Purpose and Use of Information Collection

The data collection will allow CDC to assess and determine necessary changes in the YSI structure and content for program improvement. Without this data, CDC will not be able to identify or aggregate information related to the efforts of YSI program and potential changes necessary to improve the program content, structure and implementation.

The data collected will be analyzed and compiled into a report to be published by CDC. One of the primary purposes of program monitoring and evaluation activities is to improve programs by sharing and using lessons learned. Therefore, CDC will disseminate the summary report to

partner organizations involved in the development and implementation of the YSI program so that all organizations associated with the YSI can learn about the YSI and the steps needed to replicate the evaluation and the YSI success with African American YBCS.

Privacy Impact Assessment Information

The information being collected will aid in determining and documenting YSI program reach, users' perception of the program, and strategies to improve the program. The information will be compiled into a report and shared with CDC, partner organizations (organizations including SNI involved in recruitment and data collection) to aid them in identifying future activities that they can replicate based on information provided in the report that will be developed.

The proposed data collection will have little or no effect on the respondent's privacy. Respondents are YSI program website users and no IIF is being collected. The demographic screener and Survey Monkey system has the technical capability of collecting cookies; however, cookies will be turned off for this data collection.

A3. Use of Improved Information Technology and Burden Reduction

All data collected (100%) for this project will be gathered using electronic surveys available on the internet. By using an electronic format for the evaluation instrument, this will reduce the burden of respondents having to use a paper format and then mail their responses back to CDC.

A4. Efforts to Identify Duplication and Use of Similar Information

The information proposed to be collected is unique in that it relates solely to YSI program outcomes. This is the first time that these YSI program specific outcomes will be evaluated. There are no existing projects to our knowledge that will collect data from YSI program website users in regards to their use of the YSI program.

A5. Impact on Small Businesses or Other Entities

Respondents will be individuals, not businesses. The proposed information collection will have no impact on business entities.

A6. Consequences of Collecting the Information Less Frequently

This is a one-time process evaluation of the YSI program, web-based intervention. The YSI program will be implemented using the Internet and evaluated over a 4-6 month period. Website users will be asked to complete the demographic screener and post-use survey each once during the implementation time period. Collecting the evaluation data this way allows CDC to determine the status of each expected outcome related to program reach, usage facilitators and barriers, appreciation and perceptions. Without this information collection, CDC will have limited ability to improve the usability of the YSI program website and YSI program materials for the primary intended audience. There are no legal obstacles to reducing the burden.

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

There are no special circumstances relating to the guidelines of 5 CFR 1320.5 and the project fully complies.

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

A.8a. The 60-Day Federal Register Notice was published on June 6, 2012, Vol. 77, pages 33460-33462 (see **Attachment 2A**). One public comment was received; CDC provided a courtesy reply (see **Attachment 2B**).

A.8b. The demographic screener and post-use survey were designed with input from members of the BCYW project team at CDC, and CDC's partner organization, SNI. There were no additional efforts to consult outside the agency.

A9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any incentive, payment or gifts as a result of participation in this information collection.

A10. Assurance of Confidentiality Provided to Respondents

A11. Privacy Act Determination

The Privacy Act does not apply. The survey will not ask for respondents' names and response data can not be identified, stored, or retrieved by respondent name or other unique personal identifier. Although demographic information and personal information will be collected, the response data will not be identifiable.

B. Safeguards

The CDC project officer will safeguard the responses and will not release any information. All data collected will be compiled into a report that does not contain any personal identifiers. Although the online data collection system provides the option of obtaining respondents' e-mail addresses, this option will not be selected. The data collection systems collect and use IP addresses for system administration and record-keeping purposes, but IP addresses will not be provided to CDC. Survey responses cannot be linked or traced to any unique respondent identifiers. Additional information about Survey Monkey is available at http://www.surveymonkey.com.

C. Consent

CDC has determined that this project is considered public health practice rather than research involving human subjects. IRB approval is not required and there is no formal consent

document. However, the introductory section of the pre demographic screener (**Attachment 4A**) provides respondents with the advisements typically provided in a consent process.

D. Voluntary

All respondents are informed through the instructions to complete the demographic screener and post-use survey that their responses are voluntary.

A11. Justification for Sensitive Questions

The majority of questions asked on the demographic screener and post-use survey will not be of a highly sensitive nature, but some questions may be viewed as somewhat sensitive by some respondents; these include questions about breast cancer diagnosis, type and treatment. These questions are necessary because the research investigates YSI program users use and perceptions of a program providing psychosocial and reproductive health information about breast cancer, and seeks input about the program structure, content and effectiveness.

A12. Estimate of Annualized Burden Hours and Costs

The principal information collection instruments are the demographic screener (**Attachment 4A**) and the post-use survey (**Attachment 5A**). Potential YSI program respondents will receive an email announcement (**Attachment 3A**) and reminder (**Attachment 3C**) from SNI to use the YSI program. The estimated burden per response for the screener is 5 minutes. The estimated burden per response for the post-use survey is 20 minutes. For all information collection, the total estimated burden to respondents is 150 hours, as summarized in Table A12-1 below.

Table A.12-1. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
YSI Program Users (Demographic screener)	YSI Program Demographic Screener	500	1	5/60	42
YSI Program Users (Post-Use Survey)	YSI Program Post-Use Survey	300	1	20/60	100
	Total				142

Participants' response to YSI program process evaluation questions will be completely voluntary, and there are no costs to respondents other than their time.

B. Table A12-2 presents the calculations for cost of annualized burden hours. The wages of persons completing the survey is unknown and may significantly vary depending on respondent employment status, and type of employment. Given this we use a minimum wage amount to calculate costs to respondents. The US minimum hourly wage rate information is from the U.S. Department of Labor (http://www.dol.gov/whd/minimumwage.htm). The federal minimum wage is $7.25 per hour effective July 24, 2009. The total annualized respondent cost of burden hours is estimated at $ 1,027.

Table A.12-2. Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Burden (in hours)
YSI Web Site Users (Demographic screener)	YSI Program Demographic screener	500	1	5/60	$7.25	$302
YSI Program Web Site Users (Post-Use Survey)	YSI Program Post-Use Survey	300	1	20/60	$7.25	$725
	Total					$1,027

A13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents.

A14. Annualized Cost to the Federal Government

Government personnel – Governmental costs for this project include personnel costs for federal staff involved in the planning and designing the YSI program, data collection instruments and OMB materials, collecting and analyzing the data, and reporting, which includes approximately 5 percent of three GS-13 behavioral scientists' time assuming a $100,000 annual salary for scientists. The total estimated annualized cost to the Federal Government is $15,000.

Contracted data collection –The project design and data collection is being conducted under a contract with CDC's data collection contractor, ICF Macro. The current contract is for a total of $906,120 and includes costs for planning, conducting, and analyzing the focus groups. Approximately ½ of the contract ($453,060) is devoted to the YSI program development and evaluation.

Table A.14-1. Estimated Annualized Cost to the Federal Government	
Labor:	
5% Behavioral Scientist's time for project, planning, management, OMB review, analysis of findings, and report writing	$5,000
5% Behavioral Scientist's time for project, planning, management, OMB review, analysis of findings, and report writing	$5,000
5% Behavioral Scientist's time for project, planning, management, OMB review, analysis of findings, and report writing	$5,000
Contractor	$453,060
Total estimated cost	$468,060

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

A.16-1 Survey Time Schedule	
Activity	**Time Schedule**
Distribute Invitation	1 month after OMB approval
Collect demographic screener data (immediately upon launching the YSI program website)	1 month OMB approval
Collect post-use survey data (2-4 weeks after YSI users registration and use of the YSI program website)	1-6 months after OMB approval and during the 4-6 months of execution and implementation
Complete data analyses	6-8 months after OMB approval
Report on survey results	8-9 months after OMB approval

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

An exemption to displaying the OMB expiration date is not being requested.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable. No certification exemption is being sought.

References

Avis, N. E., Crawford, S., & Manuel, J. (2005). Quality of life among younger women with breast cancer. Journal of Clinical Oncology, 23(15), 3322—3330.

Baucom, D., Porter, L., Kirby, J., Gremore, T., & Keefe, F. (2006). Psychosocial issues confronting young women with breast cancer. International Journal of Breast Disease, 23, 103–113.

Bloom, J. R., Stewart, S. L., Chang, S., & Banks, P. J. (2004). Then and now: Quality of life of young breast cancer survivors. Psychooncology, 13, 147–160.

Chlebowski, R. T., Chen, Z., Anderson, G. L., Rohan, T., Aragaki, A., Lane, D., et al. (2005). Ethnicity and breast cancer: Factors influencing differences in incidence and outcome. Journal of the National Cancer Institute, 97(6), 439–448.

Jones, B. A., Kasl, S. V., Howe, C. L., Lachman, M., Dubrovoz, R., Curren, M. M., et al. (2004). African-American/White differences in breast carcinoma: p53 alteration and other tumor characteristics. Cancer, 101, 1293–1301.

Knobf, T. (2006). The influence of endocrine effects of adjuvant therapy on quality of life outcomes in younger breast cancer survivors, Oncologist, 11, 96–110.

Peled, R., Carmil, D., Siboni-Samocha, O., & Shoham-Vardi, I. (2008). Breast cancer, psychological distress and life events among young women. BMC Cancer, 8(1), 245.

Phillips, K.-A., Osborne, R. H., Giles, G. G., Dite, G. S., Apicella, C., Hopper, J. L., et al. (2008). Psychosocial Factors and Survival of Young Women With Breast Cancer: A population-based prospective cohort study. Journal of Clinical Oncology, 26(28), 4666–4671

Quinn, G., Vadaparampil, S., & Gwede, C. (2007). Discussion of fertility preservation with newly diagnosed patients: Oncologist reviews. Journal of Cancer Survivorship, 1, 146–155.

Rose, D. P., & Royak-Schaler, R. (2001). Tumor biology and prognosis in black breast cancer patients: a review. Cancer Detection and Prevention, 25, 16–31

Rosen, A., Rodriguez-Wallberg, K. A., & Rosenzweig, L. (2009). Psychosocial distress in young cancer survivors. Seminars in Oncology Nursing, 25(4), 268–277.

Thewes, B., Butow, P., & Girgis, S. (2004). The psychosocial needs of breast cancer survivors: A qualitative study of the shared and unique needs of younger versus older survivors. Psycho-Oncology, 13(3), 177–189.