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Exploring the Psychosocial Needs of Breast Cancer Survivors Among Young African American Women in Georgia: A Research Grant Proposal

BY

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Degree to be awarded: MPH

Executive MPH

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An abstract of

A Thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements of the degree of

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Abstract

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Young African-American (AA) women with breast cancer (under age 45) suffer poorer health outcomes than other survivor groups and may face distinct challenges in managing their diagnosis, treatment and aftercare. Research suggests that young AA survivors may have unmet psychosocial needs requiring culturally appropriate and age-specific clinical and therapeutic strategies as a result of these unique experiences. Previous work regarding quality of life issues in breast cancer survivorship has failed to distinguish psychosocial needs specific to young AA women. The proposed study seeks to identify psychosocial needs and areas of unmet need among young AA breast cancer survivors by exploring their perspectives on the issue, as well as those of the providers who care for and provide health services to them at each phase of the cancer continuum from detection to end-of-life. Using a mixed methods sequential exploratory approach, this study will explore common experiences, themes, and phenomena related to the psychological, emotional, and social aspects of breast cancer that affect young AA women through focus groups and a survey for survivors, as well as interviews with providers. The interviews will also assess the cultural competence and perceived self-efficacy of providers to effectively manage the psychosocial needs of this population. Information from this pilot study of Georgia women will be used to educate cancer care providers about the psychosocial health needs of young AA survivors as well as to inform the development of targeted interventions to address identified needs in order to improve the quality of care delivered to this high risk population.

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Chapter I: Introduction

Background

Breast cancer survivorship rates are at an all-time high due to advancements in early detection and treatment. However, the persistence of racial disparities in breast cancer survival for African-American (AA) women indicates the need for research to investigate areas of unmet need [1-3]. Studies show that young AA women in particular represent a high risk group among breast cancer survivors due to poorly understood biological factors that lead to more aggressive forms of the disease and later stage of disease at diagnosis, as well as factors such as diminished access to care, lack of sufficient support, and limited resources that are both culturally- and age-appropriate to meet psychosocial care needs for this population [4, 5]. Health care providers play a vital role in breast cancer survivorship, and the degree to which they are culturally competent to address the needs of medically underserved, minority survivors may have a significant impact on the quality of care received [6, 7].

Though a number of studies have examined breast cancer in AA women [2, 8, 9], and in young women [10, 11], few have explored the experience of breast cancer specifically in young AA women [3, 7]. While researchers have identified many of the psychosocial issues faced by breast cancer survivors in general [12, 13], and a number of those described by AA survivors of all ages [5, 6], limited information exists specifically detailing the psychosocial needs of young AA women with breast cancer [14-17].

The goal of the following research proposal is to develop a greater understanding of the psychosocial needs of young AA breast cancer survivors and the role of health care providers in addressing these needs by exploring the perspectives of a sub-population of each group in high burden areas for breast cancer within the greater metropolitan area of Atlanta, GA. Knowledge gained from this research will be used to improve the quality of care provided to young AA women with breast cancer and ultimately, their quality of life, as research shows a significant link between psychosocial factors and health outcomes [18-21]. While the study aims primarily to educate physicians and ancillary care providers who treat and provide health services to young AA patients with breast cancer, additional stakeholders include public health practitioners, researchers, policy makers, other health care professionals working in cancer prevention and control (particularly in areas of health disparities and minority health), medical specialty organizations (e.g., The Academy of Oncology Nurse Navigators and The American Medical Association), health educators, and breast cancer advocacy groups (e.g., Avon Foundation for Women and Sisters Network, Inc.). These individuals, organizations, and specialty groups will be key agents for disseminating the results of this research based on their professional expertise in cancer care, prevention, and control as well as their reputations, influence, and reach within the health care field. This chapter will provide an overview of disparities in breast cancer, describe the nature of psychosocial issues associated with breast cancer, and demonstrate the need for further study regarding the psychosocial aspect of breast cancer survivorship in young AA women.

Breast Cancer Disparities and African-American Women

Despite a recent decline in overall breast cancer mortality rates, AA women have the highest death rate and shortest survival among all racial and ethnic groups in the United States [3, 22]. Research shows that there are significant health disparities in the detection, diagnosis and treatment of this disease for AA women compared to women of other races that may greatly impact health outcomes for survivors [23, 24]. Examples of health inequity associated with breast cancer in AA women in the United States (U.S.) include the following:

- Breast cancer incidence rates have generally been higher in white women than AA women; however, between 2008 and 2012, incidence rates were significantly higher in black women compared with white women in 7 states, primarily in the South [25-27].
- AA women have higher mortality rates from breast cancer than white women—Death rates from breast cancer in 2012 were 42% higher in AA women than white women [25].
- The 5-year relative survival rate for breast cancer diagnosed in 2002-2008 was 78% among AA women compared to 90% among whites [7].
- Inequality in receipt of prompt, high-quality treatment has been demonstrated for AA women compared to whites. Disparities have been shown in receipt of a definitive primary therapy, adjuvant therapy, conservative surgery, and follow-up after potentially curative treatment [24].
- Compared to the general population, AA women have a higher incidence of early onset-breast cancer (prior to age 50), often with more aggressive tumors diagnosed at advanced stage of disease [3, 7].

In addition, socioeconomic factors such as poverty rates, likelihood of lacking medical insurance, and likelihood of relying on public insurance such as Medicaid (which are twice as high for AA's than whites) are key contributors to delays in breast cancer diagnosis and treatment, which result in higher mortality rates [9]. Health disparities concerning the physical characteristics of breast cancer in AA women are well documented, such as molecular subtype and tumor receptor expression in higher rates of triple-negative breast cancer among this population [20, 22, 23]. In particular, it has been noted that many of the aforementioned health inequities have been magnified among younger AA women, who tend to have more aggressive breast cancer subtypes, for reasons that are poorly understood [3, 7, 28]. The proposed research aims to delineate the health-related quality-of-life issues facing young AA women survivors of breast cancer in light of these disparities.

Psychosocial Effects of Breast Cancer

Women coping with breast cancer face a number of medical and psychosocial challenges that directly impact their quality of life and health outcomes. From the moment of self or clinical detection to diagnosis, treatment, and beyond, these women typically experience dramatic changes in almost every aspect of their lives. Issues related to family life, finances, relationships, self-esteem, and sexual identity often become more complex after a diagnosis of breast cancer and require a unique set of coping mechanisms for individuals during the transition from “patient” to “survivor” [1, 29, 30].

As such, medical management of breast cancer involves more than just clinical treatment of the disease. A thorough assessment of the psychosocial well-being of these patients is also required to ensure the best possible health outcomes. To provide the most effective care for breast cancer patients, health care providers must be adept at evaluating both the medical and psychosocial status of survivors under their care. This involves cultural competence in awareness of breast cancer disparities and the ability to address them in all aspects of the care continuum.

A Threat to Public Health (Problem Statement)

While researchers have begun to examine the impact of psychosocial issues on breast cancer survivorship [27, 29], there is limited information regarding the specific psychological, emotional and functional support needs of young AA breast cancer survivors [6, 10, 11]. Younger women have been shown to have different survivorship concerns after diagnosis than older women with breast cancer, such as infertility and premature menopause versus aging and lack of autonomy [10, 31]. Despite a greater risk for psychosocial adjustment problems, young women have breast cancer support needs that are often overlooked [11, 19]. These findings, coupled with indications of reduced health-related quality of life in AA women due to racial disparities in breast cancer [5, 15], suggest a need to identify potential areas of unmet psychosocial needs among young AA women in order to develop targeted interventions to improve health outcomes for this population.

A recent study on psychosocial and behavioral issues in cancer survivorship determined that to be effective, psychosocial interventions must be evidence-based, and "where possible" should be specifically designed to meet the needs of the individual cancer survivor [12]. Socioeconomic barriers to health care access coupled with unique survivorship experiences that are influenced by culture, age, and patient-provider relationships warrant further exploration to determine what specific needs of young AA breast cancer survivors remain unmet and how best to address those needs. The purpose of this thesis project is to write a research grant proposal to describe unmet psychosocial needs of young AA female breast cancer survivors in order to enhance cultural competence among providers and to improve health outcomes for this population.

Definition of Terms:

Breast Cancer Survivor-Women who have been diagnosed with and treated for breast cancer regardless of disease status (either with active disease or in remission).

Cultural Competence- The ability of providers and organizations to effectively deliver health care services that meet the social, cultural, and linguistic needs of patients.

Health Care Provider-Physicians, physician assistants, nurses, or other licensed medical professional who provides breast cancer screening, diagnostic, or treatment services.

Invasive Breast Cancer-Cancer that grows into or invades normal tissues within or beyond the breast.

Non-Invasive Breast Cancer-Cancer that stays within the milk ducts or lobules of the breast and do not invade surrounding tissue. (Also known as carcinoma in situ or "pre-cancer")

Psychosocial - Of or related to the interrelation of mental, emotional, social, spiritual, quality of life, and functional aspects of cancer.

Young Women-Women age 18 to 44.

Survivorship- The health and life of a person with cancer post treatment until the end of life. Survivorship covers the physical, psychosocial, and economic issues of cancer, beyond the diagnosis and treatment phases. It includes issues related to the ability to get health care and follow-up treatment, late effects of treatment, second cancers, and quality of life. Family members, friends, and caregivers are also considered part of the survivorship experience.

Chapter II: Literature Review

Introduction to the Review of Literature

Research has suggested that young AA women with breast cancer have a unique set of experiences compared to other survivor groups and, as a result, they may have specific unmet psychosocial needs that require comprehensive clinical and therapeutic strategies. Advances in early detection and treatment of breast cancer have increased survivorship and improved the quality of life for a countless number of individuals after diagnosis. However, for AA women, particularly those under the age of 45, morbidity and mortality rates due to breast cancer continue to be disproportionately high, subsequently leading to a detrimental impact on both health-related quality of life and survivorship [2, 3, 7].

The purpose of the following literature review is to provide a summary of the peer-reviewed, evidence-based literature surrounding the issue of psychosocial needs among young AA breast cancer survivors and to identify gaps in the literature that necessitate further research, including but not limited to the proposed study for this thesis. The burden of breast cancer in the United States is described followed by a discussion of the link between health disparities and health outcomes in young AA breast cancer survivors using the social-ecological model as a conceptual framework. The depiction of psychosocial needs of cancer survivors as identified in the literature is explored as well as issues related to the cultural competence of health care providers in addressing those needs among young AA women. Finally, gaps in the literature on this topic are highlighted and implications for the proposed study are described.

Overview of the Burden of Breast Cancer in the United States

Breast cancer is the most frequently diagnosed cancer in women worldwide, with one in eight women (12%) in the United States (U.S.) developing this disease over the course of her lifetime [49, 50]. Among U.S. women in 2016, approximately 246,660 new cases of invasive breast cancer will be diagnosed, another 61,000 women will develop non-invasive disease (or breast cancer in situ) and about 40,450 women are expected to die from the disease [49]. Breast cancer is the second leading cause of cancer death among all cancers diagnosed in females in the U.S. [27]. Due to advances in screening, diagnosis, and treatment, the 5-year survival rate for women living with breast cancer has increased over time from 74.8% for those diagnosed in 1975-1977 to 90.7% for those diagnosed in 2004-2011 [51]. Nonetheless, the effects of breast cancer and its treatments can impose drastic physical, psychological, and emotional changes to the lives of those diagnosed with the disease, as well as their loved ones.

In addition to the effect on individual survivors, breast cancer also represents a substantial portion of the growing burden of chronic disease in the U.S.; thereby contributing to rising health care costs. Though estimates vary widely regarding the cost of breast cancer treatment, a 2009 review of 29 different U.S. cost-of-illness studies for breast cancer showed an estimated range of lifetime per-patient cost of between $20,000 and $100,000 [51]. Evidence shows that treatment of breast cancer in early stages of the disease results in better survival outcomes than later stage treatment [52-54]. As such, costs of care increase by stage of breast cancer. The later cancer is detected and the more aggressive the disease at diagnosis, the higher the economic burden with regard to hospitalizations, clinic visits, therapeutic options, and physician billing. Studies have shown that young AA women are frequently diagnosed at later disease stages and with more aggressive breast cancer subtypes than other women, contributing to higher costs of health care for this population [55, 56].

Health Disparities in Breast Cancer

Braveman defines the term *health disparity* as a "particular type of difference in health (or in the determinants of health that could be shaped by policies) in which disadvantaged social groups systematically experience worse health or more health risks than do more advantaged social groups" [57]. For example, uninsured patient populations have been shown to have less access to recommended care, receive poorer quality of care, and experience worse health outcomes than patients with health care insurance [58]. Health disparities in breast cancer survivorship by race, age, and SES within the United States remain evident, imposing a significant impact on the physical, emotional, and psychosocial well-being of minorities and other marginalized populations [58-60].

Race

While breast cancer incidence rates are higher among white women, AA women experience disproportionately higher mortality rates from the disease [23]. Key factors contributing to this mortality disparity include differences in health care delivery, availability of culturally centered care, and treatment effectiveness among racial and ethnic minorities compared to whites in the U.S. AA breast cancer survivors have also reported having less information about self-care after diagnosis, being uninformed regarding disease sequelae, and a lack of emotional support [1]. The existence of racial disparities in breast cancer has been highlighted in multiple studies as a contributing factor to negative health outcomes for AA women [4, 9, 22]. However, few studies have specifically explored the reasons for risk disparity in breast cancer incidence and mortality among young AA women under the age of 45 [3, 23, 28, 62].

Age

Breast cancer is the most frequently diagnosed invasive cancer among young women of all races [28]. Research shows that the biology of breast cancer in young women (aged 18-44) is distinctly different than that of older women, however, the reasons for the biological variations are poorly understood [28]. Though overall incidence rates are higher among white women, the incidence of breast cancer has been shown to be higher among young AA women than among their white counterparts; and AA women younger than 45 tend to have more advanced stages of breast cancer at diagnosis with lower percentages of localized disease, larger tumors, and higher likelihood of lymph node involvement than white women [3]. They also tend to have greater susceptibility to Triple Negative Breast Cancer (TNBC), a subtype that has one of the poorest prognoses, highest risk of mortality, and highest recurrence rate among all breast cancer subtypes that disproportionately affects African Americans, young women, and carriers of the BRCA1 gene mutation [20].

While AA women of all ages experience lower breast cancer survival rates than white women, (79% and 92% respectively), young AA women have lower overall and stage-specific survival rates than those of either AA or white women 45 years of age and older at diagnosis [3, 53]. Key factors such as tumor subtype, genetic abnormalities, and hormonal risk factors (e.g. oral contraceptive use and age at menarche) fail to adequately explain the high breast cancer risk for this population compared to other women [3].

Socioeconomics and Access to Care

Studies have demonstrated a direct link between observed racial disparities in breast cancer health outcomes and factors such as socioeconomic status[SES], comorbidity, barriers to screening, and health care access [4, 63]. Low income, geographic location (e.g. rural vs. urban), lack of health insurance, and childcare needs are among the myriad of issues that contribute to breast cancer disparities in health outcomes. Health care system factors such as lack of care continuity, poor patient-physician communication, and administrative inefficiencies are often contributors to deficiencies in treatment and disease management among AA breast cancer survivors [22]. Additional factors include patient-specific barriers such as out-of-pocket financial hardship for health care services, time away from work, and lack of reliable transportation. Despite improvements in quality of care and medical advancements in breast cancer treatment overall, these factors present substantial barriers to the receipt of equitable care sufficient to meet the needs of AA breast cancer survivors.

Breast Cancer in Georgia

Based on age-adjusted data from 2009-2013, the incidence rate of breast cancer in the state of Georgia was 123.4 and the mortality rate was 22.9 compared to national rates of 123.3 and 21.5 respectively [64] ***(See Table 1 and Table 2)***. Among AA women under the age of 50 residing in Georgia, the incidence of breast cancer was 47.5 and the mortality rate was 7.7 compared to a national incidence of 45.7 and mortality rate of 7.8 [65]. According to the Georgia Department of Public Health, AA women in Georgia have higher breast cancer mortality rates than white women regardless of urban vs. rural geographic residence within the state, and a statistically significant gap was most apparent in the largest metropolitan areas and smaller urban communities [66].

Table 1. Breast Cancer Incidence Rates Among Women by Race and Age

	Whites*		**African-Americans***		**All**	
US and Georgia	**US**	**GA**	**US**	**GA**	**US**	**GA**
All	124.3	124.0	122.3	125.8	123.3	123.4
Age < 50	43.3	41.5	45.7	47.5	43.6	43.1
Age 50+	338.7	339.8	325.2	330.7	334.1	333.7

Source: State Cancer Profiles-Incidence Rates Table (2016). NIH-NCI [64]
**Age-Adjusted Incidence Rates per 100,000*

Table 2. Breast Cancer Mortality Rates Among Women by Race and Age

	Whites*		**African-Americans***		**All**	
US and Georgia	**US**	**GA**	**US**	**GA**	**US**	**GA**
All	21.0	20.9	29.6	28.9	21.5	22.9
Age < 50	4.2	4.0	7.8	7.7	4.6	5.1
Age 50+	65.0	65.3	86.6	84.6	65.9	69.6

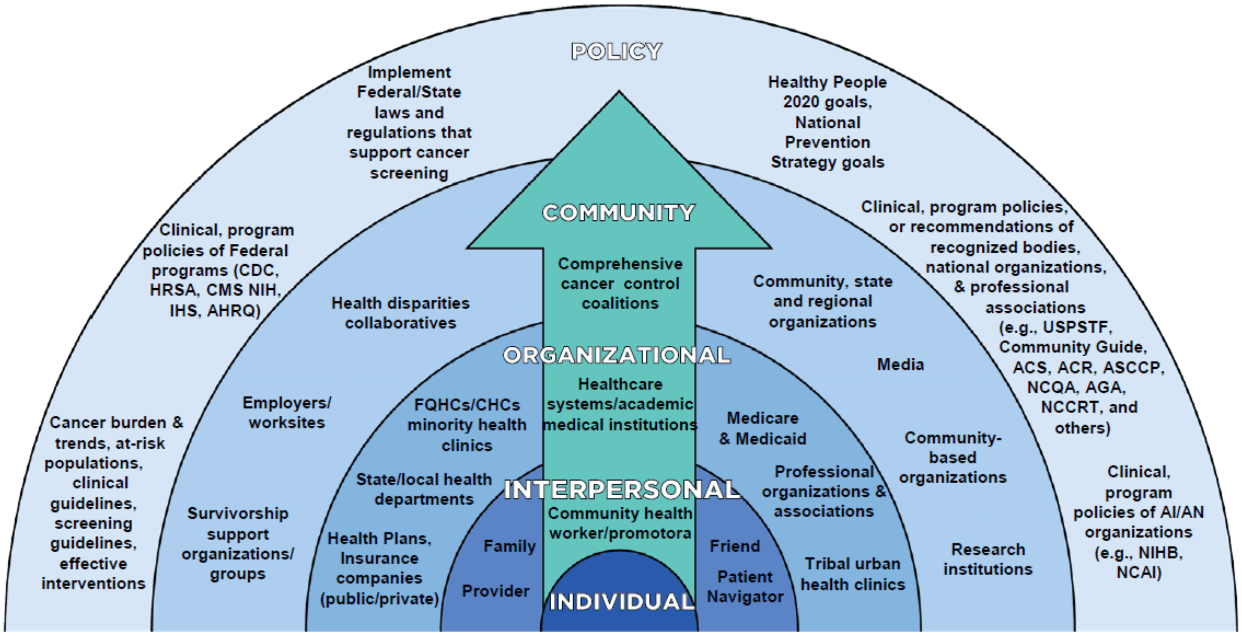
Source: State Cancer Profiles-Death Rates Table (2016). NIH-NCI [65]
**Age-Adjusted Death Rates per 100,000*

One study examining geographic and racial disparities in breast cancer-related outcomes in Georgia determined that AA women experienced worse outcomes than whites, even after controlling for area-level SES and geographic location [59]. Though evidence regarding an association between rural residency and breast cancer mortality was inconclusive, this study did show that women living in areas of low SES had more advanced disease at diagnosis, received less aggressive treatment, and had higher risk of all-cause mortality compared to women residing in high SES areas [59]. A study exploring racial disparities in Central Georgia pointed to higher rates of Medicaid versus private insurance as an indicator of both lower SES and education level for AA women experiencing worse breast cancer outcomes that may have been associated with poor access to mammography screening and later state disease at diagnosis [60]. The purpose of the 2015 Community Profile Report by Susan G. Komen® Greater Atlanta used to select research sites for the proposed study was to provide county level data about breast cancer in metro Atlanta that could be used to develop specific strategies to address these disparities in access to breast cancer care and health services [35].

Study participants for the proposed research will be recruited from four counties within the greater metropolitan Atlanta area that have the highest burden of breast cancer among young AA women and the highest overall burden of breast cancer in Georgia as reflected by incidence, mortality, and late-stage diagnosis rates—Fulton County, DeKalb County, Henry County and Clayton County [64, 67, 68].

Theoretical Framework

The social-ecological model provides a conceptual framework through which the link between breast cancer disparities in health outcomes and quality of life among young AA women can be understood. The premise of this model lies in the depiction of multiple "environmental levels" (e.g., individual, family, relational, community/peers, institutional, and societal/cultural) that collectively influence individual behavior, beliefs, attitudes, and experiences [68] **(See Figure 1)**. Adapted from Urie Bronfenbrenner's classic model of an ecological approach to health promotion, the social-ecological theory asserts that each level influences the next, (with the outermost level exerting an influence on all levels beneath it), such that attempts to modify any one level can have a downstream effect on the other levels [69]. When applied to the issue of breast cancer disparities, this model demonstrates the potential for improving health outcomes for young AA women living with breast cancer by addressing their unmet psychosocial needs. For example, what is known about the breast cancer experiences of AA women through research to date indicates the existence of a complex interplay between the individual, interpersonal, community, and institutional levels that is influenced by racial disparity, as well as other health inequities, and has a significant effect on quality of life for these women [2]. By increasing understanding of upstream determinants of health for the target population of young AA women, (such as psychosocial well-being), the knowledge gained can be used to develop appropriate interventions to address them.



*Some groups may fit within multiple levels of this model.

The Social-Ecological Model [70]

Psychosocial Needs of Women with Breast Cancer

Women living with breast cancer face tremendous obstacles at each stage along the continuum of survivorship. In addition to what may be lifelong physical symptoms of the disease and comorbidities, breast cancer survivors often must cope with a myriad of psychosocial issues such as financial burden, fear of recurrence, depression, body image disruption, and sexual dysfunction [12, 71]. A recent systematic review of multiple longitudinal studies showed a distinct relationship between psychological adjustment after a breast cancer diagnosis and psychosocial factors such as perceived social support, coping strategies, and body image variables [18]. Psychosocial factors have been shown to be predictive of future depression, anxiety, psychological distress, and ultimately, quality of life for breast cancer survivors [18]. In addition, the social isolation many women experience after breast cancer diagnosis has been linked to an elevated risk of mortality, often due to lack of access to care via informal caregiving from friends and family [72].

Psychosocial Needs Specific to Young AA Women with Breast Cancer

Though the psychosocial impact of breast cancer in general has been studied, there remains limited information on the experiences of women from diverse ethnic and socioeconomic backgrounds or high risk populations such as young AA women [73]. Along with bearing the unequal burden of late-stage diagnoses and often, more aggressive disease, young AA breast cancer survivors have reported poorer physical and social well-being that may be demonstrative of factors related to greater need for information, emotional care, and assistance with navigation of the health care system [20, 74-76]. In a study exploring the psychosocial concerns of 33 AA breast cancer survivors under the age of 45, Lewis et. al. concluded that many psychosocial issues were common among both white and AA survivors diagnosed before age 50, however, concerns regarding several issues such as relationship problems and lack of information about fertility and sexual dysfunction after treatment were more prevalent and severe among young AA women [81]. The investigators for this study went on to assert that the impact of breast cancer on psychosocial issues among young AA survivors may be exacerbated by the often aggressive nature of disease among this population and persistent stigmatization of cancer in the AA community [81]. According to a study examining the experience of women with triple negative breast cancer, young women with breast cancer have been reported to experience poorer psychological outcomes, greater fears of recurrence, more concerns about body image and overall worse quality of life compared to older women [20]. In concert, these factors are likely to contribute to greater psychosocial distress for young AA breast cancer survivors regardless of disease subtype [3, 5, 6].

Though not specific to young women, studies that have examined quality of life after breast cancer diagnosis for AA women have suggested that racial disparities in survivorship may be reflected in a unique set of psychosocial issues and care needs for this population [15, 78]. For example, many AA women have reported a lack of information about breast cancer survivorship, including specific information about their disease (e.g. triple negative breast cancer traits), what to expect after treatment (e.g. short and long-term physical sequelae), and guidelines for follow up [1, 30]. This information gap has been attributed to uncertainty, anxiety, and "decisional regret" for women following medical recommendations for treatment options such as bilateral mastectomy and chemotherapy [20]. In addition, breast cancer survivors face elevated health risks compared to the general population, such as cancer recurrence and second primary cancers [78]. The most commonly used tools for reducing risk are medical interventions requiring specific patient education such as chemotherapy, radiation, endocrine treatment, and increased surveillance through mammography. Lack of information regarding these mechanisms for treatment and prevention of cancer may be life-threatening for survivors and may contribute to decreased breast cancer survival rates among young AA women [20, 27].

Women also expressed a desire for culturally appropriate resources for AA breast cancer survivors such as complexion-matched prosthetics, appropriately colored wigs, and peer support groups with other AA women [15, 56, 79]. Emotional distress due to fear and stigmatization within the AA community has been described as another determinant of psychosocial well-being for breast cancer survivors [1]. What has been characterized as a "culture of silence" among AA regarding breast cancer has deterred many women from seeking care and support from friends and family because of fears of perceived weakness for those typically viewed as matriarchal figures, as well as fears of being shunned by intimate partners due to sexual dysfunction or changed physical appearance [10, 15, 77]. Ultimately, barriers to accessing information about breast cancer, including prognosis, follow-up guidance, and resource availability, may negatively impact several aspects of quality of life for young AA survivors such as emotional and social well-being, interpersonal relationships, and ability to cope with cancer diagnosis and treatment. Further research examining the specific psychosocial needs of young AA breast cancer survivors may suggest additional areas for intervention.

Cultural Competence of Health Care Providers

Studies show that patient expectations regarding their interaction with health providers during treatment and follow-up for breast cancer go beyond medical care and information sharing, as women have often reported a desire for more time to discuss emotional needs with their providers [29]. Lack of cultural competence among providers, historical issues of medical mistrust ,and individual health beliefs are key factors in provider-patient relationships that may contribute to unmet support needs for survivors [29]. Though the Institute of Medicine has outlined a set of recommendations for cancer survivorship planning that include addressing the psychosocial needs of cancer survivors, population-based estimates indicate that efforts in this area have been insufficient, particularly with minorities [1, 80]. Some providers have been shown to provide minority women with less survivorship information than their counterparts, with variation noted by age, race, and income [1]. Studies show that there is less rapport building between patients and physicians in primary care settings and oncology appointments tend to be shorter with AA patients than whites [15]. Educating breast cancer patients about survivorship and resource availability while demonstrating compassion and sensitivity are vital components to quality of care. Little guidance is available for providers or survivors to bridge the gap that impedes progress in this area, even for those working to overcome communication barriers and access to care issues to help their patients achieve an improved quality of life after breast cancer.

Summary and Implications for the Proposed Research

As long-term survival rates for women with breast cancer have continued to rise, so too have the number of challenges faced by the medical community in effectively managing the sequelae of this chronic disease in high risk populations such as young AA women. In particular, addressing the unmet psychosocial needs of this underserved group may have significant implications for improving survivorship among young AA women with breast cancer. Efforts to identify and mitigate these issues may reduce racial disparities in health outcomes, particularly emotional, psychosocial, and social well-being (mental health) as well as quality of life and breast cancer survivorship, by increasing the number of interventions that are tailored to meet the specific sociocultural needs of this population and by educating the medical community on effective strategies to manage challenges in breast cancer survivorship for young AA women.

During a national forum on breast cancer among AA women held in 2000 in Washington, D.C., a number of researchers and health care leaders established a set of recommendations for future research. Among them were [3]:

- Conducting more focus groups, case-control studies and population studies
- Studying young AA women with breast cancer and including more AA female breast cancer survivors in research
- Educating young women and healthcare providers about breast cancer, including risk factors and treatment options.
- Engaging AA organizations (e.g. National Coalition of Black Women, Black Nurses' Association, National Medical Association, and historically AA

sororities) to address issues related to breast cancer while providing leadership for AA women survivors

- Providing support groups specifically tailored to the needs of the AA community.

While many of these efforts have been initiated such as community engagement among AA organizations in promoting breast cancer awareness and focus group studies exploring the experience of breast cancer in AA women, there are still significant challenges and gaps in relevant information regarding breast cancer survivorship and support needs in AA women in general, even more so for young AA Women [20, 53, 81]. A number of studies have examined some aspect of this issue (e.g. racial disparities in breast cancer, psychosocial needs of women with TNBC, breast cancer in young AA women, etc.), however, few studies have specifically explored the psychosocial needs of young AA women with breast cancer [14, 76, 82]. The proposed research activities, including focus groups with young AA survivors and a survey to assess psychosocial needs among young women with breast cancer in Georgia, are in alignment with these recommendations and aim to elicit information to fill knowledge gaps surrounding areas of unmet psychosocial need among young AA breast cancer survivors.

The literature on cancer survivorship has demonstrated a link between psychosocial needs and health outcomes in breast cancer survivors [12, 20, 21], and the importance of identifying the unmet psychosocial needs of young AA women is underscored by disproportionally lower survival rates than those of other women with breast cancer [3]. Research aimed at describing the psychosocial needs of this population will enhance the practice of patient-centered care by granting greater insight and more specific guidance to health care providers to assist them in the management of breast cancer in high risk populations. The proposed study will not only add to the sparse body of literature on the subject of breast cancer in AA women, but it will help to inform the development of culturally (and age-) appropriate interventions to better address the specific needs of young AA women living with breast cancer. Having a health care community that is better equipped to attend to the needs of patients at highest risk for breast cancer-related morbidity and mortality will likely lead to improvements in health outcomes, such as enhanced quality of life, for those most vulnerable to this disease.

Chapter III: Methodology

Description of Grant Announcement

The research proposal for this thesis project was developed in response to the American Cancer Society's Research Scholar Grant funding announcement, specifically, the Special Initiative: Priority Focus on Health Equity Research in the Cancer Control and Prevention Research Grants Program. The American Cancer Society (ACS) is a national, community-based voluntary health organization working to eliminate cancer as a major health problem through research, education, advocacy, and service [83]. The ACS funds Research Scholar Grants (RSG) to support investigator-initiated projects, (primarily those of early career researchers) across the cancer research continuum [84]. Eligible candidates include independent investigators in the first six years of an independent research career or faculty appointment. Awardees may receive funding for up to four years and for up to $165,000 per year (direct costs), plus 20% allowable indirect costs. Exceptions include the following: (1) RSG applicants to the Cancer Control and Prevention Research Program may be at any career stage as long as the focus of their project is either: a) health policy/health services research or b) achieving cancer health equity; 2) RSG applicants to the Cancer Control and Prevention Research Program (limited to psychosocial and behavioral studies or health policy and health services research) that are population based and focused on achieving health equity may be up to 5 years with a maximum budget of $400,000 per year (direct costs), plus 20% allowable indirect costs.

Proposal Review Criteria: The following is a summary of the review criteria listed in the ACS Research Scholars Grant application along with a brief description of how the proposal detailed in chapter V is responsive to the criteria.

Part I-Candidate/Investigator: *Provide an overall evaluation of the candidate's academic, clinical, or scientific qualifications as well as their potential to succeed as an independent investigator and commitment to a career in cancer-related research.*

The submitted proposal contains a detailed description of my qualifications as the principal investigator for this study, including my education and professional experience, as well as aspirations to further my career in cancer-related research as a medical officer in the CDC's Division of Cancer Prevention and Control.

Part II-Research Plan

Significance: *Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice improve? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?*

This proposal centers around the psychosocial care needs among young AA women with breast cancer, a topic for which limited information is available, from the perspective of survivors and the providers who care for them and provide additional cancer-related health services. By achieving the aims of this project, we will reduce the gap in knowledge regarding breast cancer survivorship in AA women while identifying areas of unmet psychosocial need among young AA breast cancer survivors and providing a more comprehensive picture of the psychosocial issues faced by this population. This information can then be used to develop a set of guidelines for providers to implement when caring for young AA breast cancer survivors that are tailored to the cultural and age-specific needs of this population, thereby increasing the quality of care delivered.

Cancer Relevance: *How is this research relevant or how will it impact persons at risk for, or living with, cancer and their family members and/or caregivers?*

By increasing knowledge about the psychosocial care needs of young AA women with breast cancer that can be used to improve the quality of care provided to this population, our study will to contribute to improvements in quality of life and health outcomes for these women.

Innovation/Improvement: *What is the potential that the proposed study will challenge and seek to shift current research understanding or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Does the research propose meaningful improvements or address critical gaps?*

This study has great potential to fill a knowledge gap in AA breast cancer survivorship related to the psychosocial needs of young AA women. By exploring a diverse array of patient and provider perspectives of the problem, including ancillary care providers and AA breast cancer survivors under the age of 40, who's voices are often excluded from discourse on breast cancer survivorship, a more comprehensive strategy can be developed to improve the health status of this population.

Investigator/ Research Team: *Does the PI and research team have the training and experience needed to carry out the proposed research?*

An expert, multidisciplinary team of researchers has been assembled for this project to ensure the highest standards of scientific integrity and research principles are upheld in pursuit of knew knowledge. Collectively, the team has extensive knowledge of and expertise in the fields of public health, clinical medicine, research methodology (qualitative and quantitative), health disparities, cancer prevention and research, and behavioral health.

Approach: *Are study design, methods for implementation, data collection and analysis appropriate for answering the research question.*

This research proposal was developed by the principle investigator with the guidance of an advisory committee of highly experienced researchers, public health educators and field experts to ensure that (1) the study design and methodology are appropriately aligned with the research questions, (2) the recruitment plan is well developed, (3) the sample size is adequate, and (4) the research timeline is realistic and future plans are articulated.

Environment: *Will the scientific environment and institutional support contribute to the probability of success? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?*

The research team will be supported by Emory University Rollins School of Public Health (RSPH) in Atlanta Georgia. A world-renowned research institution and academic center, RSPH will provide our team with state-of-the-art technology and research facilities to conduct this study. We will collaborate with several community partners for this project, including Emory University Hospital, Grady Memorial Hospital, DeKalb Medical Center, Piedmont Henry Hospital, and Southern Regional Hospital. These are premier health centers in the greater metropolitan Atlanta area with unparalleled access to our target demographic and where additional research activities, such as focus groups and recruitment of subjects, will take place.

Part III-Budget-Not Applicable for Thesis Proposal

Part IV-Compliance Statements

Human Subjects: *If the project involves research on humans, are the plans for protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed?*

Our investigators and collaborative partners subscribe to the basic ethical principles underlying the conduct of research involving human subjects. All planned research activities will be evaluated by the Emory University Institutional Review Board (IRB), which is authorized to review, approve, disapprove, or require changes in research activities involving human subjects as deemed appropriate.

Plans for the protection of human subjects from research risks include:

-Submission of a detailed protocol with complete information regarding experimental design to the Emory University IRB.

-Assembly of a qualified research team with sufficient subject matter and research methodology expertise to complete the study.

-Requirements for projected sample size to be sufficient to yield useful results.

Inclusion of Women, Minorities, and Children: *When the proposed project involves human subjects, evaluate the adequacy of the proposed plans for inclusion or exclusion of minorities, male and female genders, as well as children.*

This study aims to explore a cancer-related phenomenon among young AA women in order to inform the development of tailored interventions to improve the health status of this group. Therefore, the inclusion of women and minorities is imperative to the research aims of the study. The minimum age of eligibility for study participants is 18 years, therefore no children will be included in the proposed research.

Additional Criteria- Priority Focus on Health Equity Research in the Cancer Control and Prevention Research Grants Program: *For health equity applications in Cancer Control and Prevention, reviewers will assess the potential impact of the proposed study, if the specific aims are accomplished, in advancing the field pertaining to an aspect of the cancer continuum and the target areas of focus aimed to contribute to achieving health equity. For example, how will this research: (1) substantially improve equity in access to cancer prevention, early detection, diagnosis, and/or treatment services; (2) accelerate efforts to reduce cancer burden or costs, improve quality of care, delivery or care or quality of life; or (3) impact public policy to advance health equity relevant to cancer?*

Young AA women with breast cancer typically have poorer health outcomes than other survivors for a number of reasons that are poorly understood. Identifying key psychosocial concerns and areas of unmet need among young AA breast cancer survivors is vital to improving quality of life for this population, as cancer-related psychosocial distress has been shown to contribute to negative health outcomes for these women [1, 3, 10]. The quality of life of breast cancer survivors is often negatively impacted by the quality of care received [30], so by engaging health care providers in this study, we aim to address issues of cultural competence and self-efficacy in providing comprehensive care to young AA survivors among those who diagnose, treat and provide cancer-related health services to this high risk population. Research suggests that providers are willing to implement psychosocial care models into their practices but lack the knowledge and confidence to provide evidence-based survivorship care [30, 53, 85]. Results from this study will be used to develop provider guidelines for best practices in the delivery of psychosocial care to young AA breast cancers survivors in an attempt to increase access to quality care and improve the quality of life for this population.

Additional Funding Agencies for Breast Cancer Research

National Cancer Institute (NCI): The NCI is a member of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services (HHS). It is the federal government's principle cancer research and training agency. This organization coordinates the National Cancer Program, which conducts and facilitates research, training, health education and other programs related to cancer prevention, treatment and care. NCI receives its funds from congress, most of which are used to fund grants and contracts to universities, medical schools, cancer centers, research laboratories and private firms in the U.S. and internationally [86].

Susan G. Komen® Foundation: The Susan G. Komen® Foundation is the world's largest nonprofit source of funding for breast cancer prevention and research. Founded by the sister of a woman dying from breast cancer, the organization's humble beginnings sparked a global movement of awareness and efforts to fight this disease. Using a multifaceted approach to tacking breast cancer that includes research, community health, global outreach and public policy initiatives, this organization has had a tremendous impact on the decreasing the breast cancer epidemic worldwide. To date, Susan G. Komen® has funded more than $889 million to researchers in 49 states and 20 countries [87].

Avon Foundation: The Avon Foundation for Women aims to improve the lives of women globally through its core initiatives in breast cancer and domestic violence. The organization's mission is to accelerate progress, accountability and discovery in these areas while reducing the social stigma that works against prevention efforts. The Avon Foundation carries out its breast cancer work through the Avon Breast Cancer Crusade, LLC. using 4 key strategies: (1) funding the most promising work, (2) convening grantees, partners, and other thought leaders in collaborative efforts, (3) initiating innovative projects to accelerate progress and (4) educating the public to drive/modify behavior and to achieve mission goals. The Avon Foundation provides funding through its breast cancer research grants, breast health outreach grants, and breast cancer safety net grants to nonprofits, research institutions and organizations that have traditionally cared for the medically underserved [88].

Centers for Disease Control and Prevention (CDC): The CDC is one of the major operating components of HHS. It operates 24/7 to ensure the health security of the U.S. by implementing programs and activities to save lives and to protect people from health threats. The CDC works in collaboration with public, nonprofit and private partners to combat the breast cancer epidemic through research, surveillance, and community programs. The CDC currently funds 6 National Comprehensive Cancer Control Program grantees in their research utilizing evidence-based approaches to increase the length and quality of life of breast cancer survivors.

The American Cancer Society was selected as the potential funding agency for this project based on alignment of the proposed project goals with the ACS Research Scholar Grant funding mechanism aims, including (1) supporting research for beginning investigators or health equity researchers at any stage in their career and (2) emphasis on reducing health disparities in breast cancer [90].

Description of Grant Review Process Methodology

Five external grant reviewers were selected based on their knowledge and expertise in the areas of breast cancer research, research methodology, health disparities, minority health issues and grant writing. Reviewers were given 2 weeks to complete their review of the proposal. Each reviewer was contacted individually and all communication regarding proposal review was conducted electronically. A reviewer template developed by Emory University Rollins School of Public Health faculty was provided along with the proposal and a copy of the funding announcement. The template asked the reviewer to assess the following: (1) Responsiveness to the call for proposals, (2) Degree to which the proposal was "well thought out and theoretically sound," (3) Degree to which the PI made a compelling case for the proposed research and (4) Innovation of the proposal. Reviewers were also encouraged to make edits directly to the document in Microsoft Word via track changes and to add additional comments as they deemed appropriate to provide greater context and more in-depth understanding of the proposal review. Responses to the proposal were sent via email by reviewers and were not shared among the group. Each reviewer sent an edited copy of the proposal in Microsoft Word with track changes and additional comments provided, as well as a PDF version of the completed reviewer template.

Reviewer comments and principle investigator (PI) responses were detailed in Chapter IV of the thesis and Chapter V includes the final proposal with revisions based on reviewer feedback.

Description of the Grant Proposal Reviewers

Ashani Johnson-Turbes, PhD

Dr. Ashani Johnson-Turbes is a Senior Technical Specialist at Inner City Fund, International (ICF). She also serves as the Health Communication Evaluation Expert in ICF's Public Health Line of Business. Dr. Johnson-Turbes has over 18 years of experience in research and evaluation, including the development of mixed-method and qualitative evaluation designs and instruments to assess knowledge, awareness, behavioral intentions and behaviors, particularly for marginalized populations. She manages and provides conceptual and technical expertise on mixed-method, qualitative and quantitative proposals and studies. She has led formative, process, and outcome evaluation of multiple public health interventions, and consumer-directed campaigns, including development and evaluation of CDC's award-winning, mass media campaign (*African American Women and Mass Media* campaign) to promote mammography among African American women. She also served as the Project Director to strengthen and evaluate interventions to promote the psychosocial and reproductive health of young breast cancer survivors (YBCS). She has presented at the *Biennial Cancer Survivorship Research Conference* sponsored by ACS, NCI, CDC, and LIVESTRONG, and published her work in peer-reviewed journals. Dr. Johnson-Turbes was selected as a grant reviewer based on her experience in developing research designs/protocols, designing data collection instruments, and conducting both quantitative and qualitative research.

Jacqueline Miller, MD, FACS

Dr. Jacqueline Miller is a Captain with the U.S. Public Health Service, a board-certified general surgeon, and a Fellow of the American College of Surgeons. She earned her undergraduate degree from Spelman College in Atlanta, GA, and her medical degree from Washington University School of Medicine in St. Louis, MO. She completed an internship and residency in General Surgery at the University of Mississippi Medical Center in Jackson, MS. Following her training, Dr. Miller worked as a General Surgeon in private practice for 8 years in Atlanta, GA with a special interest in breast cancer. In 2002, she joined the Centers for Disease Control and Prevention as an Epidemic Intelligence Service Officer in the Division of Adult and Community Health. Currently, she is the Medical Director for CDC’s National Breast and Cervical Cancer Early Detection Program in the Division of Cancer Prevention and Control, where she serves as CDC’s subject matter expert for breast cancer. Dr. Miller continues to provide clinical care to patients at the Atlanta VA Medical Center and is an Assistant Clinical Professor at Emory University School of Medicine. Dr. Miller was selected to participate as a grant reviewer based on her expertise in providing breast cancer detection, diagnosis and treatment services to AA women in the Atlanta metropolitan area.

Alicia L. Best, PhD, MPH, CHES, CPH

Dr. Alicia Best is an Assistant Professor in the Department of Community and Family Health in the College of Public Health at the University of South Florida. She is a socio-behavioral researcher and certified health education specialist (CHES) with academic training and experience in cancer-related health disparities, health education and promotion, and health communications. Dr. Best earned an MPH in Health Education and Health Promotion from Morehouse School of Medicine, as well as a PhD in Health Promotion, Education, and Behavior and a Certificate of Graduate Study in Health Communications from the University of South

Carolina's Arnold School of Public Health. She also received postdoctoral training in behavioral research with a focus on cancer disparities at the American Cancer Society. Dr. Best conducts original research focused on identifying, understanding, and contextualizing social and cultural factors influencing disparities across the cancer continuum, and the use of communication strategies to better reach marginalized groups. Her previous work has focused on mechanisms through which spiritualty impacts the effectiveness of breast cancer screening messages among AA women, as well as the role of spirituality on quality of life among of AA cancer survivors. Her current research is focused on the psychosocial impact of HPV-associated cancers, and further exploring the role of religion in coping with these cancers. This work is funded by the American Cancer Society, Moffitt Cancer Center, and USF's Women's Health Collaborative. In addition to her research, Dr. Best teaches graduate-level courses in health disparities, social marketing, and socio-behavioral science. She also developed and supervises a large undergraduate course on health disparities and social determinants of health. Dr. Best was selected as a grant proposal reviewer based on her expertise in cancer-related health disparities involving psychosocial issues and her research experience with AA women.

Anna Holbrook, MD

Dr. Anna Holbrook is a board certified radiologist specializing in breast imaging at the Winship Cancer Institute of Emory University in Atlanta, GA. She is an Assistant Professor in the Breast Imaging Division of the Department of Radiology and Imaging Science at Emory University School of Medicine, where she also serves as an Assistant Program Director of the Diagnostic Radiology Residency Program. Dr. Holbrook received her MD from Vanderbilt University School of Medicine. She completed residency training in Diagnostic Radiology at the Mayo Clinic and the University of Chicago, and a fellowship in Breast Imaging at Duke University.

She is Co-Chair of the Service Excellence Committee and is a graduate of the Emory Healthcare Quality Academy. She is involved in teaching at both the local and national level and has worked on multiple research projects involving the imaging of breast cancer. Dr. Holbrook was selected to participate in this grant proposal review based on her experience as a grant reviewer for Susan G. Komen of Greater Atlanta as well as her clinical expertise in breast cancer health service delivery and her extensive research experience.

Barbara Crane, MN, APRN

Ms. Barbara Crane has been practicing nursing in the Atlanta metropolitan area for almost 45 years. She received her Diploma in nursing from the Crawford W. Long School of Nursing, a Bachelor's degree majoring in nursing from Georgia State University's School of Allied Health Sciences and a Master's degree from Emory University Nell Hodgson Woodruff School of Nursing which included a clinical specialty in Nurse Midwifery. Following 30 years of practicing obstetrics, Ms. Crane retired from midwifery to begin another career in Public Health. As the Women's Health (WH) Coordinator for the Clayton Health District for almost 9 years, she was responsible for overseeing all clinical services related to WH services, including the Breast and Cervical Cancer Program. She transferred to the State Office as a Nurse Consultant for the Breast and Cervical Cancer Program before assuming the leadership role as a Deputy Director of the Chronic Disease Prevention Section over Prevention, Screening and Treatment three years later. Prior to assuming this leadership role, Ms. Crane had been assigned as the Nurse Consultant to the CDC cooperative agreement, "Enhancing Breast Cancer Genomics through Education, Surveillance and Policy. For her work related to the Breast Cancer Genomic Project, Ms. Crane was awarded the "Dorothy Barfield Nursing Section" award in 2015. Ms. Crane was selected as a reviewer for the proposed study based on her clinical expertise in the diagnosis and treatment of breast cancer among low-income and minority populations in the Atlanta metropolitan area, as well as her knowledge of barriers and facilitators of providing breast cancer-related services for vulnerable populations.

Chapter IV External Reviewer Comments

The following is a detailed description of the comments provided by reviewers and the responses generated by reviewer feedback. The research proposal outlined in Chapter V has been revised based on these comments where indicated.

Reviewer 1-Ashani Johnson-Turbes, PhD

External Reviewer Template

1. **Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.** "*Agree*"

2. **How could the submission have been more responsive to the call for proposals?** "*The proposal is responsive to the call for proposals, particularly the call for proposals related to the special initiative 'PRIORITY FOCUS ON HEALTH EQUITY RESEARCH IN THE CANCER CONTROL AND PREVENTION RESEARCH GRANTS PROGRAM.' As noted in my edits/comments in the proposal, the response could offer more detail regarding breast cancer health disparities among young women in Georgia-Specifically why Georgia versus other locations in the US. The proposal explains why the specific locations in Georgia are selected—'…counties identified as having the highest breast cancer incidence or mortality rates among African American women under the age of 50 within the state' however it is unclear why the researcher selected Georgia versus other states in the US with high incidence and/or mortality for young women with BC.*"

Response: I have added the following language to clarify this point in the Specific Aims section of the proposal on page #79: "Compared to the national average, Georgia has higher age-adjusted rates of incidence, mortality and late-stage diagnosis despite higher rates of mammography screening [9-11]. Four Metro-Atlanta counties within the state were selected as research sites for this study due to relatively large populations of AA residents and the high burden of breast cancer in these areas, as indicated by mortality, incidence and late-stage diagnosis rates, [11]." (Please note, references for the citations in this text can be found in section J of the grant proposal beginning on page #93.

3. **Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.** "*Agree*"

4. **What improvements could be made to the theory and structure of the proposal?** *"The theoretical justification for (e.g., review of literature to illustrate gap in literature and discussion of the social-ecological theory) as well as the overall structure of the proposal is well done. As noted in comments, it should be made clear at the start what is meant by racial disparities in BC 'survivorship.' Further, the researcher should indicate how her proposed methods and approach to analysis tie back to the social-ecological theory described at the outset of the proposal. How will that theory guide the research and/or analysis of the data obtained to answer research questions? Other recommended improvements to theory and structure are noted in edits and comments in the body of the proposal.*

Response: Racial disparities in breast cancer survivorship is further defined in the Specific Aims section on page #79 as "racial health disparities in breast cancer screening, diagnosis and treatment leading to worse health outcomes among young AA women." The link between the proposed research approach and the social-ecological model was described beginning on page #81 with the addition of the following language: "The proposed research strategy of exploring a diverse array of perspectives on psychosocial need among survivors and providers at multiple environmental levels (e.g., individual, interpersonal, and community within focus groups and organizational in provider interviews) builds upon the principles of the social-ecological model by gathering evidence to direct the development of interventions to be employed at the policy and organizational levels that will ultimately improve health outcomes at the individual level."

5. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.** *"Strongly Agree"*

6. **What would have improved the argument that the proposed activities are necessary?** *"See comment under Q2. Also, the researcher can improve her case for the mixed-method research design by describing the design and proposed analysis plans more thoroughly. Recommendations related to this are included in edits/comments in the body of the proposal document.*

Response: This has been addressed in Chapter V beginning on page #79 with the inclusion of revised descriptions of the focus groups, interviews, and surveys, a more detailed explanation of the sequential mixed-methods exploratory design, sampling frames and stratification descriptions, and additional revisions based on the recommended edits or comments that were provided by the reviewer.

7. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the**

proposed activities with the resources and time allocated. *"Neither Agree nor Disagree"*

8. **What changes would improve the perceived feasibility of the proposed activities?** *"The main improvements regarding feasibility are related to the proposed methodological approach. First the researcher should better define the planned, mixed-method research design. For example, state that this is a sequential exploratory design earlier in the proposal, and offer justification for why this is selected research design. Second, specific research questions need to be articulated in the proposal. Third, the feasibility for proposed research activities should more thoroughly describe plans for analysis of quantitative and especially qualitative data, as well as recommended for "mixing" the methods to answer overarching research questions.*

Response: These points have been addressed in the revised plan. The study design is described a "mixed methods sequential exploratory approach" on page #79 in the Specific Aims section and further described beginning on page #84 in the Research Design section, including additional language as recommended to clarify plans for data collection and analysis. A description of the "mixing" of data can be found in the Triangulation section on page #90. The research questions and specific aims for each question have been added and can be found on page #83.

9. **Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.** *"Strongly Agree"*

10. **What additional comments and suggestions do you have for the PI?** *"This is critically needed research that fills an important gap in literature and interventions."*

Comment 1- In the first paragraph of the Specific Aims section, you refer to the term "health outcomes," stating that they are intricately tied to the psychosocial needs of breast cancer survivors. Please give examples to clarify which health outcomes you are referring to.

Response: *I have updated this section on page #79 to include clinical depression and anxiety as health outcomes that are "intricately tied" to the psychosocial needs of breast cancer patients. See response to Comment 4 for additional commentary on the term "health outcomes"*

Comment 2- You state that the proposed research aims to "offer evidence-based information to providers" who care for young AA breast cancer survivors. Evidence-based information on what? Consider "…offer evidence-based information on AA women's psychosocial and reproductive health needs…"

Response: *This statement has been revised as follows on page #79: "Using Georgia as a pilot study, the proposed research will offer valuable information regarding AA women's* *psychosocial health needs to providers who care for these patients and inform the development and/or strengthening of interventions and strategies designed to effectively address identified psychosocial needs that are both age and culturally appropriate." While reproductive health issues are a major factor of concern for young AA women as documented by the literature, I think the emphasis of this study will be more related to informational, psychological and emotional needs related to reproductive health than to the actual reproductive issues themselves (e.g. infertility, premature menopause, etc.), which would fall under physical needs, in my opinion.*

Comment 3- When you refer to the aim of the proposed research to "inform the development of interventions and strategies designed to effectively address" the psychosocial needs of young AA survivors through your study, I would say "to inform the development and/or strengthening of interventions and strategies."

Response: *Agreed. There are existing strategies and interventions that may address psychosocial need that may simply need to be improved upon or otherwise tailored to meet the specific needs of the target population. This has been updated on page #79 in the second paragraph of the Specific Aims section.*

Comment 4- What health outcomes are you referring to when you state that "both short and long-term health outcomes may be improved" by your research that will influence/reduce disparities in survivorship?

Response: *While the literature clearly indicates a link between the psychosocial needs of breast cancer survivors and health outcomes [10, 18, 19], particularly among AA women [5, 6, 20, 21], the term "health outcomes" is not specifically defined other than in association with symptoms of anxiety and depression in a few articles [6, 18, 20]. Others terms used were "physical functioning outcomes" [21] and "psychosocial adjustment problems" [19]. Even an article titled "Disparities in Breast Cancer Treatment and Outcomes…" used the term "health outcomes" multiple times without indicating what is meant by the term. One article discussing measurement of health care outcomes in general (not sited elsewhere in this proposal) defines health care outcomes as "measures of the end result of what happens to patients as a consequence of their encounter(s) with the healthcare system (Krousel-Wood, M., 1999— "Practical Considerations in the Measurement of Outcomes in Healthcare)," which could be indicative of the the fact that the term essentially refers to a change in health status from baseline as the result of some modifying factor such as disease (e.g. breast cancer), intervention or some other interaction with an external agent.*

That said, your point is well taken regarding the ambiguity of this term and I have revised my proposal to specify the health outcomes I believe my research will address, including psychological, emotional, and physical well-being as well as quality of life. This has been addressed on page #79 by adding the following language to further clarify that our research aims to improve psychosocial well-being among young AA breast cancer survivors: "By increasing the knowledge and capacity of the health care community to better meet young AA, breast cancer survivors' psychosocial needs, both short and long-term health outcomes associated with psychosocial well-being may be improved, thereby reducing racial health disparities in breast cancer survivorship." The following statement was also added to page #83 in the Statement of Cancer Relevance section, "Better quality of care may improve quality of life and other health outcomes such as psychological, emotional, and physical well-being for young AA women with breast cancer."

Comment 5- In paragraph 2 of the Specific Aims section, you state that you are using a qualitative approach, but under Aim 1 you say you are conducting a survey. If you are fielding a survey also this sounds like mixed method study. You should say this at outset and state what type of mixed-method design you are proposing – There are many."

Response: *Thank you for noting this error. I meant to say "Using a mixed-methods approach…" but I mistakenly missed that edit from a previous draft. This has been updated on page #79 to indicate my use of a mixed methods sequential exploratory approach.*

Comment 6- You don't need to say "qualitative interviews" when describing your methods. Interviews are qualitative method. But you should say if these are structured or unstructured interviews. In depth interviews I presume?

Response: *Agreed. I have updated the Specific Aims section on page #79 to say "...semi-structured, in-depth interviews…" under Aim 2.*

Comment 7- What types of physicians are you recruiting for this study? What are 'ancillary' providers? Please provide examples. I think early on you should also tell the reader why you have selected Georgia."

Response: *I have included a sampling frame for provider recruitment detailing the types of physicians, and other provider groups that will be represented in the study in Section G-Research Design, under Phase 1b-Provider Interviews on page #88. Ancillary care providers are non-physician members of the cancer care team who provide both medical and non-medical health services to patients.*

Table 1. Sampling Plan for Provider Interviews

Breast Cancer Health Service Providers	**Physicians**	**Nurses**	**Patient Navigators**	**Ancillary Care Providers**
# Recruited Per County (Total 40-60)	2-3	2-3	2-3	4-6
Counties of Practice **Fulton** **DeKalb** **Henry** **Clayton**	-Primary Care -Med. Oncologists -Breast Surgeons -OBGYNs	-RNs -NPs -Family Practice -OBGYN	Cancer Care Patient Navigator	-Social Workers -Genetic Counselors -Radiation Therapists

I have also included a brief description of my reason for selecting Georgia in the Specific Aims section on page #79 by adding the following language: "Compared to the national average, Georgia has higher age-adjusted rates of incidence, mortality and late-stage diagnosis despite higher rates of mammography screening [9-11]. Four metro-Atlanta counties within the state were selected as research sites for this study due to relatively large populations of AA residents and the high burden of breast cancer in these areas, as indicated by mortality, incidence and late-stage diagnosis rates, [11]. Using Georgia as a pilot study, the proposed research will offer valuable information regarding AA women's psychosocial health needs to providers who care for these patients and inform the development and/or strengthening of interventions and strategies designed to effectively address identified psychosocial needs that are both age and culturally appropriate."

Comment 8- Make clear at the outset what is meant by racial disparities in BC "survivorship". One may think you mean race/ethnic disparities in mortality (death rates), but I believe your definition goes beyond this to include disparities all of the things that a young survivor (person diagnosed with cancer <45) experiences from time of diagnosis until the end of life, such as treatment, aftercare, reproductive health support, mental health, etc. The reader needs to understand this from the start.

Response: *Agreed. I have included this description in the summary section of the specific aims on page #79 with the following language: "…By achieving these aims, this study will advance efforts to reduce racial disparities in breast cancer survivorship, defined as differential experiences in daily living for survivors (e.g., treatment, aftercare, reproductive health support,* *mental health, etc.) from the time of diagnosis to the end of life, by providing evidence to inform the development and/or strengthening of policies and interventions to improve the quality of care for young AA women with breast cancer."*

Comment 9- Sometimes you spell out African American and other times it says AA. You just need to be consistent.

Response: *Thank you for catching this error.* ☺ *I received this feedback for a previous draft and neglected to update the entire document. This correction has been made on each page of the proposal.*

Comment 10- An additional citation to support your statement that AA women under the age of 45 may face distinct challenges can be found in the article Johnson-Turbes, et. al, 2015—"Young breast cancer survivors (YBCSs, defined as women diagnosed prior to their 45th birthday) may experience increased difficulty managing their diagnosis, treatment, and aftercare."

Response: *Thank you, this citation has been included in the Background and Significance section in paragraph 1 on page #80 to support the following statement, "A diagnosis of breast cancer can be devastating for any woman, however, young survivors may face distinct challenges managing their diagnosis, treatment and aftercare."*

Comment 11- When referring to "the existence of racial disparities" highlighted in the literature, do you mean racial disparities in general or racial disparities in health? I would think health and if so that should be stated here and the definition in parentheses should be about that – "differences in health and health care between population groups." There are many definitions. I like this one: *"A health disparity is a particular type of difference in health (or in the determinants of health that could be shaped by policies) in which disadvantaged social groups systematically experience worse health or more health risks than do more advantaged social groups."—Braveman, 2006*

Response: *I am referring here to racial disparities in health and I have revised the language here to include the definition by Braveman as you suggested in the Background and Significance section under "Health Outcomes for Young AA Breast Cancer Survivors" on page #80 using the following language: "Defined as "type(s) of difference in health (or in the determinants of health that could be shaped by policies) in which disadvantaged social groups systematically experience worse health or more health risks than do more advantages social groups [35],* *health disparities have been highlighted in multiple studies as a contributing factor to negative health outcomes for AA women…" Thank you for this reference!*

Comment 12- Do you have a citation for the image of the social-ecological model?

Response: *I have replaced the previous model for which I had no citation with a different (and I believe better) model from the CDC with the citation included on page #82.*

Comment 13- Please provide a citation for the statement, "Differences in the ability to receive quality patient care or have access to vital health resources for breast cancer survivors in this population due to race, age, financial status or similar characteristics (health disparities) have a major impact on the long-term health status of young women."

Response: *I have included two citations for this statement about the impact of health disparities on health outcomes for young AA women from Swanson et al., 2003- and Jones et al., 2015 on page #82 under the Statement of Cancer Relevance section.*

Comment 14- You mention that there is "limited information" known about the psychosocial needs of young AA breast cancer survivors. Actually, there are a few studies that do provide this information. Dr. Leslie Schover has done work on this topic. CDC's work with Dr. Schover, Sister's Network and ICF was specifically to identify and address AA YBCS psychosocial needs. See literature on SPIRIT and on the Young Sister's Initiative."

Response: *Thank you. I have added references for "Effect of Age and Race on Quality of Life in Young Breast Cancer Survivors" and "Psychosocial Concerns of Young African American Breast Cancer Survivors" to my discussion of previous research about the psychosocial needs of young AA breast cancer survivors and their impact on quality of life to support the following statement under the Statement of Cancer Relevance section on page #82: "Limited information is known about the psychological, emotional, social and functional needs of young AA women with breast cancer, however, previous research has shown that these factors are important determinants of quality of life after diagnosis and treatment of breast cancer." I also believe that my study will contribute to the literature on this subject by providing perspectives from a significantly larger population of young AA breast cancer survivors than any of the previous studies described, including a greater number of survivors in the 18-30 age group and women of lower SES based on recruitment methods and study location in large urban metropolitan area.*

Comment 15- You mention the fact that there is limited information about the psychosocial needs of young AA breast cancer survivors. Your study addresses an issue where I think there is a real dearth of information (perhaps more-so than the psychosocial needs of young AA women)-On providers' attitudes and role!

Response: *Agreed, I believe the provider perspectives on this issue add a novel approach to my study. I have not yet seen a similar study with providers in the literature. I included "unique and multiple perspectives" in the Innovation section of the study proposal on page #83, highlighting this fact with the statement, "…the 'provider' prospective is expanded to include non-physician groups such as patient navigators and social workers, who are vital members of the cancer care team due to their extensive interaction with breast cancer patients and ability to offer valuable information regarding the psychological, emotional, social, and functional needs of breast cancer survivors that go beyond basic medical care."*

Comment 16- Is your study examining women in rural and urban communities? If yes, please indicate this in your proposal.

Response: *My study locations are generally considered urban and suburban as they are all in the greater Atlanta metropolitan area, though Henry county is actually considered a mixed urban and rural county. I have included a table in Appendix B on page #97, Priority/High Burden County Characteristics, to describe my target communities.*

Comment 17- Why did you choose Georgia for this study?

Response: *I have included additional language on page #79 describing the burden of breast cancer in GA, ("Compared to the national average, Georgia has higher age-adjusted rates of incidence, mortality, and late-stage diagnosis despite higher rates of mammography screening [9-11]. Four Metro-Atlanta counties within the state were selected as research sites for this study due to relatively large populations of AA residents and the high burden of breast cancer in these areas, as indicated by mortality, incidence and late-stage diagnosis rates, [11]. Using Georgia as a pilot study, the proposed research will offer valuable information regarding AA women's psychosocial health needs to providers who care for these patients and inform the development and/or strengthening of interventions and strategies designed to effectively address identified psychosocial needs that are both age and culturally appropriate."). Page #80 also includes a section called Breast Cancer Among AA Women in Georgia highlighting statewide trends in disease for the target population. Appendix A: Female Breast Cancer Incidence, Death, and Late-Stage Rates on page #96 shows a county-level breakdown of breast cancer statistics comparing state and national rates. In addition, several premier health centers and cancer* *research institutions are located in Georgia and would be advancing their work by joining this study (see our collaborative partners on page #85).*

Comment 18- When discussing the survey in your methods section, you need to say what this is gathering that may be different from or how it is a complement to survivor interviews.

Response: *In my description of the mixed methods, sequential exploratory design in the overview of the Research Design section beginning on page #84, I describe how the qualitative result from phase 1 of this study will be used to design a quantitative data collection instrument that will be used to assess a larger sample of the target population and to corroborate qualitative research findings to provide a more complete picture of the issue being addressed. Further discussion of the survey can be found on page #88 under Phase II-Survivor Survey ("Qualitative data from focus groups and interviews in phase 1 will be used to develop an online survey to further explore the psychosocial needs of young AA women with breast cancer among all Georgia survivors who meet the eligibility criteria for the study and agree to complete the survey. Surveys are useful for describing characteristics of a large population and provide a standardized method of data collection with results that are more precisely measured than either focus group or interview data. Online surveys allow for greater reach at a low cost to the researcher. This survey will also allow for the assessment of variables identified through qualitative methods with a larger sample and corroboration of any emerging themes that developed.")*

Comment 19- I would move the entire section describing your research approach from the Innovation section to the Research Design section and lead with something like: "*This study will use a mixed-method, sequential exploratory design starting with a qualitative research phase to explore participant views followed by a quantitative phase to explore…*" And then go on to explain your data sources."

Response: *I removed the mixed methods description from the Innovation discussion and moved it to the Research Design section in the Overview beginning on page #84.*

Comment 20-You need to say more about how you are going to triangulate data for your study. Also…What type of analysis will you use for the qualitative data? Thematic? Narrative? Notes based? Transcript based? Using an emic and/or etic perspective? Inductive and/or deductive coding? Using QDA software? Multiple coders?

Response: *Using your questions and additional reviewer feedback as a guide, I attempted to incorporate more detailed descriptions of my data collection and analysis plan. By describing the steps of the mixed methods sequential exploratory design, I was able to flesh out some of these areas in my proposal. For example, on page #85 I used the following language to describe the process for analyzing qualitative data from focus groups, "We will apply an integrated deductive (structural) and inductive thematic analysis approach [58] to the focus group transcripts, beginning with the conceptual framework of the social-ecological model…and a deductive organizing framework for conceptual codes that identify key domains [determined from previous research]… inductive thematic analysis [51] to the focus group transcripts as follows: (1) The transcripts will be read repeatedly, (2) statements concerning psychosocial issues and areas of unmet need will be extracted, (3) initial coding will be performed by multiple coders who will look for emerging themes, (4) using NVivo11 qualitative analysis software, emerging themes will be revised in relation to both extracted statements and the complete data set and a thematic map will be developed, (5) we will further "define and refine" themes and subthemes, and (6) we will write-up a report of our findings."*

Comment 21- Are you adapting the psychosocial distress questionnaire for breast cancer (PDQ-BC) only for development of the survey? Not interviews? Just need this to be clearer.

Response: *Yes, I am only adapting this questionnaire for development of the survey and I have clarified that in the proposal on page #88 under Phase II-Survivor Survey. ("The online survey will be adapted from the Psychosocial Distress Questionnaire-Breast Cancer (PDQ-BC). …Dr. Laurie Gaydos, a research team member with expertise in mixed methods research design (qualitative and quantitative), will lead the research team in adapting the PDQ-BC to incorporate measures of cultural experiences in cancer care and areas of unmet need with the addition of approximately 10 questions to be added to the online survey.")*

Comment 22- I suggest stating at the start of the Research Design section what the design of the study will be and why. Also state what are the overarching study questions (linked to specific aims).

Response: *Good idea! I have revised my description of the research approach to include the mixed methods approach and rationale beginning on page #84 in paragraph 1of the Research Design section. It now reads, "We will use a mixed method, sequential exploratory design [12, 13]beginning with a qualitative research phase consisting of 16 focus groups with 8-10 young AA breast cancer survivors per group and 40-60 provider interviews to explore perspectives of young AA breast cancer survivors and health care providers who treat this population to identify psychosocial needs of young AA women with breast cancer and to assess provider awareness of,* *cultural competence and perceived self-efficacy in addressing identified needs of young AA survivors in their care. We will use data from phase one to inform the development of an online survey that will be administered to explore psychosocial issues among a larger population of survivors in order to develop a more complete understanding of the psychosocial needs of this population." I have also included the following research questions linked to the specific aims just before the Research Design section on the same page:*

<u>Research Questions:</u>

Primary Research Question-*What are the psychosocial needs of young African-American women with breast cancer as perceived by survivors within this population and health care providers who treat them?*

Secondary Research Questions

Aim 1: To identify the psychosocial needs of young AA women with breast cancer by assessing survivor perspectives.

- *To what extent are the psychosocial needs of young AA female breast cancer survivors being addressed by the health care community?*
- *At which system level(s) of the social-ecological model are psychosocial needs of young AA breast cancer survivors greatest (e.g., individual, interpersonal, organizational, community, and policy)?*
- *How do factors such as socioeconomic status, demographics, stage at diagnosis, geographic location and survivorship status affect perceptions of unmet psychosocial needs among AA female breast cancer survivors?*

Aim 2: To explore provider practices and policies regarding the psychosocial needs of young AA women with breast cancer and barriers to management of these needs.

- *To what extent are health care providers aware of the perceived areas of unmet needs of young AA female breast cancer survivors? Which provider groups are most knowledgeable of the psychosocial needs and areas of unmet need among young AA women? Of those with knowledge of these areas of unmet need, to what extent do they feel competent to address them?*
- *Are there additional considerations regarding unmet psychosocial needs of AA breast cancer survivors that need to be addressed?*

Comment 23- You could do this study in any state. Why GA? Does GA have really high BC morbidity and/or mortality among young Black women? Why 4 locations?

Response: *Yes, Georgia does have breast high mortality rates. See my response to comment 17. Ultimately, Georgia will be used as a pilot study to explore psychosocial issues among young AA breast cancer survivors that may be adapted to other locations. Having 4 locations with different community profiles based on SES, geography, etc. will facilitate recruitment of a sufficient sample size for this study (young survivors, particularly the 18-29 group, may be difficult to recruit in large numbers in other settings.).*

Comment 24- "But why qualitative methods? Why focus groups with survivors and not interviews? Why interviews with providers and not focus groups OR just using the survey.

I like the mixed method approach, but what is justification for why this design and methods? To best answer study questions?”

Response: *Yes, these methods as described in my revisions will more completely address the research questions (see my response to comment 22). The purpose of the focus groups is to identify common themes among young AA women regarding psychosocial concerns which may be facilitated by a guided group discussion where survivors can share their experiences. Individuals may be more comfortable expressing themselves in the focus group setting because they have the ability there to hear and react to similar experiences with their peers. The number and types of providers I am looking to recruit would be difficult to convene for focus groups. Physicians, in general, typically prefer interviews, are more difficult to schedule time with, and are most useful for the purpose of this study for the expression of their professional rather than personal opinions. Additionally, one of the goals with providers is to determine whether differences in perceptions of psychosocial need exist by provider type and specialty to the individual interviews would be the best mechanism for collecting that information.*

Comment 25- How will you use focus group and in depth interview data to guide the survey?

Response: *Integrated deductive and inductive thematic analysis will allow for the development of emerging themes in focus group and interview data to be used to develop a more comprehensive assessment of psychosocial need that can be used to collect information from a larger sample of survivors. Specifically, as stated on page #89, information gathered from focus groups and interview data, such as identified needs associated with race, culture or age as well as those related to provider-patient communication dynamics, will be used to develop additional questions beyond those currently included in the PDQ-BC to address a broader scope of psychosocial issues among young AA breast cancer survivors.*

Comment 26- Your statement, “Participants may feel more comfortable discussing their cancer experiences in an informal group setting than individual interviews and more information may be generated from increased interaction among the group” represents a good defense of why you have chosen focus groups. Do you have a citation for this? See also literature by R. Kreuger. Consider that while FGs may allow for in depth exploration of a sensitive subject, might women not want to share sensitive information in a group of people?”

Response: *Thank you, I have added the citation referencing the following article to this statement on page #86 under Phase 1a: Gill, et al., 2008-Methods of data collection in qualitative research: interviews and focus groups. The article states that "Pre-existing groups may be easier to recruit, have shared experiences and enjoy a comfort and familiarity which facilitates discussion or the ability to challenge each other comfortably. In health settings, pre-existing groups can overcome issues relating to disclosure of potentially stigmatizing status which people may find uncomfortable in stranger groups…" though the author does acknowledge that there may be situations when disclosure of such information may be more comfortable in stranger groups. That said, adherence to evidence based guidelines for conducting focus groups (e.g. homogeneity) should facilitate a comfortable environment for rich discussion of psychosocial issues among our target population. Please see also my response to Comment 24. I will read more about Krueger's work in this area—thank you for the reference.*

Comment 27- I have a few additional questions regarding the methods proposed in your study.

Focus Groups (FG's)

- **Will they be in-person, by telephone or digital FGs? And why?**
- **How will you sample and stratify for FGs?**

Interviews (IDI's)

- **Will they be in person, by phone or digital? Why?**
- **Sampling method for these? Stratification?**

Surveys

- **Will the surveys be paper, mail, RDD, online or intercept surveys? Why?**
- **Sampling method? Random? Non-random? Power analysis done to identify sample needed?"**

Response: *All great questions and I have included responses to most of them in my revisions including sampling frames and stratifications (see Research Design section beginning on page #84). I am not yet well versed enough in research methodology to determine the sample size though power analysis on my own, however, I understand that there is an algorithm for determining sufficient sample size and that factors such as statistical significance and representativeness are dependent on a sound approach.*

Comment 28- Explain sampling and stratification for the 16 focus groups.

Response: *The sampling frame and discussion of stratification for focus group participants has been added to the proposal on page #86. It includes AA female residents from each of the 4 high* *burden counties between the ages of 18 and 44 with a primary breast cancer (BC) diagnosis (Stage I-IV) at least 1 year prior to recruitment, either currently in or post-treatment and able to read and understand English. See table below for further clarification.*

Sampling Plan for Focus Group Participants				
Young Breast Cancer (BC) Survivors	**Fulton County**	**DeKalb County**	**Henry County**	**Clayton County**
# Recruited (128-160 Total)	16-20	16-20	16-20	16-20
Age 18-29	-AA -Female -At least 1 year post primary BC diagnosis (Stage I-IV) -In or Post Tx -Resident of Fulton County	-AA -Female -At least 1 year post primary BC diagnosis (Stage I-IV) - In or Post Tx -Resident of DeKalb County	-AA -Female -At least 1 year post primary BC diagnosis (Stage I-IV) - In or Post Tx -Resident of Henry County	-AA -Female -At least 1 year post primary BC diagnosis (Stage I-IV) - In or Post Tx -Resident of Clayton County
Age 30-44	-AA -Female -At least 1 year post primary BC diagnosis (Stage I-IV) - In or Post Tx -Resident of Fulton County	-AA -Female -At least 1 year post primary BC diagnosis (Stage I-IV) - In or Post Tx -Resident of DeKalb County	-AA -Female -At least 1 year post primary BC diagnosis (Stage I-IV) - In or Post Tx -Resident of Henry County	-AA -Female -At least 1 year post primary BC diagnosis (Stage I-IV) - In or Post Tx -Resident of Clayton County

Comment 29- Will there be audio recording at these locations? Video? Opportunity for observation?

Response: *All of the focus groups and interviews will be digitally recorded (audio) and transcribed. We will not use video recording. All members of our research team will be present for focus groups and at least 2 for interviews, however there will be no additional observers. This information has been clarified on page #'s 86 and 88.*

Comment 30- A stratification/segmentation table would be helpful to see in the description of your recruitment strategy. You should also provide information on what kind of sampling you are doing and why you are sampling a certain way. Purposive sampling of

course but stratified, purposive sample (seems like it), critical case sampling, homogeneous sampling (I think so a little bit), etc. Discuss your sampling approach and why.

Response: *Purposive homogenous sampling will be used based on the fact that we are looking to study a particular phenomenon within a specific population (psychosocial need among young AA breast cancer survivors) and need to identify who are knowledgeable and/or experienced in relation to the issue being studied who are able and willing to communicate their experiences/knowledge. This information has been updated on page #89.*

Comment 31- How are you recruiting for focus groups? In person on the ground recruiting? Using existing lists of people? Using radio ads? Recruitment ads in newspapers? What types of papers?

Response: *Most of the recruitment described in this study will either be in person recruiting at meetings, support groups, doctor's offices, etc. or derived from patient records and cancer registry lists. This has been specified on page #86.*

Comment 32- Your incentive for focus group participants of $25 is rather low. $75 or more is more common these days. Especially for 90 minutes!

I have increased all of the financial incentives to more appropriate levels. See page #'s 86, 87, and 89.

Comment 33- I don't understand what you meant by this statement in your description of focus group data analysis, "Based on qualitative research methods and grounded theory, the focus group discussion will follow a sequential approach of open-ended questions followed by non-specific prompts and follow-up probes to the open-ended replies." Based on what qualitative research methods will the FG discussion follow a sequential approach? I don't think you need to say based on qualitative research methods. You can just say that the moderator will use a semi-structured, FG moderator guide including open ended questions and probes to elicit information on… Also I don't understand what it means to say "based on grounded theory the discussion will follow a sequential approach". Grounded theory is an analytic method and to my knowledge is analysis for theory building. Grounded theory is very time consuming and I'm not sure applicable to what you are doing. Are you theory building? If so that needs to come earlier. Seems that thematic analysis is more appropriate, but consider analytic methods to think of what's best for your aims and research questions.

Response-*This was my initial attempt to develop an analytic approach based on my interpretation of the literature and methods designs of other studies that seemed similar. Upon further reading, your feedback and additional guidance, I have re-written this section to describe thematic analysis beginning on page #87. I will continue to explore research methodology to learn how to design and conduct both quantitative and qualitative public health research.*

Comment 34- I have the same comments for the provider interview section as for the focus group section about describing and justifying your sampling and stratification approach. Why 16-24 interviews? How are you stratifying providers and why? A stratification/segmentation table would help the reader. Why telephone interviews?

Response: *The provider recruitment sampling frame (see below) includes physicians, nurses, patient navigators, and ancillary care professionals (e.g., social workers, genetic counselors, and radiation therapists) who practice and provide health services for breast cancer patients in one of the 4 high burden counties. Note the number has increased since we decided to stratify by provider type and specialty for each location. Telephone use will facilitate the number of interviews we are attempting to conduct based on scheduling (e.g. More providers can be interviewed in one day by phone than if we conduct them all in person.) Also, providers are busy and may be more amenable to a phone call than an in-person meeting that takes them away from their work. This information has been revised on page #87. See table below for further clarification.*

Table 1. Sampling Plan for Provider Interviews

Breast Cancer Health Service Providers	**Physicians**	**Nurses**	**Patient Navigators**	**Ancillary Care Providers**
# Recruited Per County (Total 40-60)	2-3	2-3	2-3	4-6
Counties of Practice **Fulton** **DeKalb** **Henry** **Clayton**	-Primary Care -Med. Oncologists -Breast Surgeons -OBGYNs	-RNs -NPs -Family Practice -OBGYN	Cancer Care Patient Navigator	-Social Workers -Genetic Counselors -Radiation Therapists

Comment 35- Again, you have listed a very low incentive as compensation for provider interviews.

Response- *Agreed, this has been increased to $150. See page #87.*

Comment 36- I have the same questions/comments as previously stated about your use of grounded theory as described in the provider interview data analysis section. Grounded theory is labor intensive and requires continued sifting through data. It is also an inductive approach, however your identification of domains seems more deductive, whereby you have codes (domains) in mind based on previous research, a framework, or your own experience.

Response- *In my revisions, I refer to the use of an inductive thematic analysis (see page #87) because we are not only looking at emerging patterns in the data, but the questions we are asking about psychosocial issues may evolve as we learn more from the focus groups and interviews through coding and theme development (Braun & Clarke, 2006). (e.g,. The survey may ask completely different types of questions than what we begin the focus groups with if we discover that young AA survivors' primary psychosocial concerns are different than our domains would suggest. However, I would argue that my proposed methodology uses an integrated approach[91] because the use of domains in the development of focus group and interview questions based on previous research represents a deductive approach as well. This language has also been revised on page #'s 87 and 88.*

Comment 37- Is the PDQ-BC questionnaire you are adapting for your survey considered to be a validated tool? Also if the interviews are exploring this, what more does the survey data offer?"

Response-*Yes, the PDQ-BC is a validated tool for assessing psychosocial distress, however it does not currently contain measures to assess culturally or age-specific needs (e.g. it may not address coping mechanisms employed by young AA women) nor does is assess patient-provider relationships. We propose to adapt the survey to include such measures as described on page #89. (See also response to Comment 38 below.)*

Comment 38- I suggest talking about how you will use findings from the qualitative findings to inform adapting the survey. That is part of using the exploratory sequential design. Include some text about how you will do this. Also…Will you pilot test the adapted survey before fielding? It sounds like there will be much adaptation of a tool that uses validated questions and items, so pilot testing is in order. Are you re-validating after adaptation? When and how?

Response-*I have included discussion about phase 2 adaptation of the survey from phase 1 data analysis on page #89. ("The PDQ-BC is an evidenced based data collection tool that was developed from widely accepted, valid questionnaires and has been shown to be an easy-to-use, psychometrically sound, and acceptable survey instrument [14, 53]. Dr. Laurie Gaydos, a research team member with expertise in mixed methods research design (qualitative and quantitative), will lead the research team in adapting the PDQ-BC to incorporate measures of cultural experiences in cancer care and areas of unmet need as well as patient-provider communication dynamics with the addition of approximately 10 questions to be added to the online survey. The additional questions will be validated by expert review with qualified research faculty at Rollins School of Public Health prior to administration of the survey to research participants.") I have added the following language to the Research Design Overview section to reflect our plans to pilot test all 3 of our data collection methods (focus group guide, provider interview guide and survey questions): "Each data collection tool will be pilot tested with a subset of the sample population prior to implementation of research activities to ensure that questions … are clearly stated or written (including response options for the survey) and can be completed in a reasonable length of time as well as to assess the feasibility of our data collection methods and allow for corrections as needed."*

Comment 39- You need to talk about the survey sampling frame and expected sample. Sounds like the sampling frame are all YBCS served by providers or in support groups in partner hospitals in 4 areas in GA. Please describe the sampling plan? Random? Non Random? What are benefits and challenges with sampling plan? Did you conduct power analysis to determine sample needed to make inferences/generalize to larger pop of AA YBCS in GA (in US)?

Response-*We propose a non-random purposive homogenous sampling plan (see page #89) since we have specific qualities that we are looking for in the sample of women who will complete this survey. We want to use the information we gain from this study to develop medical guidelines for providers as well as interventions to improve quality of life for young AA women, so we want to make sure that our survey respondents can, and are willing to provide information regarding their psychosocial needs [45]. Non probability sampling is less costly and easier to conduct than probability sampling but it lends itself more to bias and is often difficult to achieve generalizable results.*

Comment 40- A few words about facilitators and barriers to conducting a phone survey would be good to include in your description of the survey methodology if you are using that format. What is expected response rate?

Response-*The study will use an online survey as described on page #88, which is easier to administer to large populations (easier to collect and analyze large data sets, cheaper, and wider reach) however, it may be more difficult to reach certain populations of interest.*

Comment 41- A t-test is not a descriptive statistic, however, you describe it as such in your quantitative data analysis plan. Also…I think that a t-test does not identify associations between data, as you indicated in your description, but rather assesses two groups (the means) are *statistically* different from each other."

Response-*Thank you. I have rephrased this section as follows on page #89: "Using quantitative research methods [57], analysis of survey results will be conducted using SPSS statistical software. Response frequencies and percentages will be calculated for each question to facilitate prioritization of topic areas and variables reported by survivors to aid in the determination of the greatest areas of psychosocial need and areas of unmet need among young AA women with breast cancer… Descriptive statistics will be run to detect emerging patterns from the data and findings will be summarized in a final report."*

Comment 42- Why did you specify logistic regression in your discussion of the survey analysis methodology? Was it because the dependent variable is categorical? If yes, probably good to say so."

Response- *Yes, I did include logistic regression because the variable is ordinal (categorical), however, I have since removed that sentence from the description of data analysis (See response to comment 41).*

Comment 43- I would add section on "mixing" data as that is part of your analysis.

Response- *Agreed. I have added the following language under the Triangulation of Data section on page #90: "Qualitative and quantitative data collected and analyzed during phase 1 and phase 2 will be triangulated to provide the greatest insight on the unmet psychosocial needs of survivors by "mixing" the data during data collection and interpretation of results [12, 13]. We will first connect qualitative data to quantitative data for this study in the development of the data collection instrument that will be informed by focus group and interview results. The second instance of merging will occur when we compare and contrast codes, variables and themes that emerge from both qualitative and quantitative data sets and present them all of the data in one summary report with visual displays that will be disseminated to stakeholders upon completion of the study. Collectively, these research methods will increase the breadth of understanding gained regarding the psychosocial needs of the target population while offsetting limitations of each individual method (e.g. interviewer bias, focus group sample size, inflexible survey design, etc.)."*

Reviewer 2-Jacqueline Miller, MD, FACS

External Reviewer Template

1. **Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.** *"Strongly Agree"*

2. **How could the submission have been more responsive to the call for proposals?** "*Include social determinants of health when assessing needs to AA women with breast cancer in order to address disparities on health outcomes. The current survey description sounds more on the individual level and less on the actual woman's environment."*

Response: Social determinants of health including access to health care services, availability of resources, SES, race, and culture are addressed throughout the study in the focus groups, interviews and the survey component. As discussed on page #88, the PDQ-BC questionnaire will be modified based on information gathered from survivor and provider perspectives regarding psychosocial needs of young AA breast cancer survivors to include additional measures related to these social determinants such as the impact of race, age, and culture on the type of cancer care received.

3. **Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.** *"Agree"*

4. **What improvements could be made to the theory and structure of the proposal?** **"***The definition of "survivorship" needs to be clear in the proposal. It is not quite clear if survivorship begins at the time of diagnosis or after treatment. Because needs start at time of diagnosis, most look at survivorship starting at that time."*

Response: A "Definition of Terms" section has been added to the proposal on page #92 that includes the following definition of survivorship: "The health and life of a person with cancer post treatment until the end of life. Survivorship covers the physical, psychosocial, and economic issues of cancer, beyond the diagnosis and treatment phases. It includes issues related to the ability to get health care and follow-up treatment, late effects of treatment, second cancers, and quality of life. Family members, friends, and caregivers are also considered part of the survivorship experience."

5. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.** *"Strongly Agree"*

6. **What would have improved the argument that the proposed activities are necessary?** *"None"*

7. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated.** *"Agree"*

8. **What changes would improve the perceived feasibility of the proposed activities?** **"***Proposal should include data on number of women of the specific age groups involved in the support groups and at the participating facilities to be sure they will be able to identify enough women for the younger age group of 18-29."*

Response: Agreed. This information would be obtained prior to study implementation from our community partner organizations including support group organizers and program administrators in Sisters by Choice, Inc. and Shades of Pink Foundation as well as tumor registrars within each of the partner hospital agencies.

9. **Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.** *"Agree"*

10. **What additional comments and suggestions do you have for the PI?** *"This is a very important topic that has been discussed in the literature, but few studies have actually looked at the cause going beyond the biological factors. This level of research removes the theories and assumptions, leading to exact causes of disparities and barriers which can be used in clinical practice to improve outcomes among young AA women with breast cancer"*

Comment 1- In the Specific Aims section of the proposal, you state that "this research aims to offer evidence-based information to providers who care for" young AA breast cancer survivors… This isn't what you would call "evidence-based" information. You will be finding exact problems and concerns That providers need to address, but not necessarily identifying the exact (correct) solutions to the problems. Evidence-based suggests you know what will work."

Response: *Agreed. Based on your feedback and that of another reviewer, this sentence has been corrected on page #79 to say, "Using Georgia as a pilot study, the proposed research will offer valuable information regarding AA women's psychosocial health needs to providers who care* *for these patients and inform the development and/or strengthening of interventions and strategies designed to effectively address identified psychosocial needs that are both age and culturally appropriate."*

Comment 2- In the Background and Significance section, you refer to "risk disparity in breast cancer incidence and mortality among young AA" women. It's not a risk, it's the actual disparity. Suggest removing the word "risk".

Response: *Agreed. The term "risk" has been removed from this sentence on page #80.*

Comment 3- Have you looked at any data is those areas to know that you will be able to recruit the number of women you are proposing for this age group?

Response: *Yes, I have looked at U.S. Census Data, American Cancer Society Data and a 2015 community profile report by Susan G. Komen® Greater Atlanta highlighting the percentage of AA residents and percentage of AA female residents in the target communities for my study. Though I did not locate prevalence data, I did find incidence rates for AA women under 50 for these communities (See Priority Georgia Region Characteristics table in Appendix B on page #97.) If I were to actually implement this study, I would attempt to get statistics about the actual number of AA women under age 45 diagnosed with breast cancer living in each target community and across the state through cancer registry data and other sources.*

Comment 4- How are you defining the criteria of "significant AA patient population and/or demonstrated experience providing services to AA clients…" as described in your eligibility criteria for providers to participate in the study? It needs to be a little clearer to exactly what you are looking for….a certain number of AA patients, a certain percentage of AA patients, etc. Will it be AA population treated within a certain time frame?

Response: *I have actually removed these criteria now that I have data from the Komen Community Profile because the counties selected have high populations of AA's so I am assuming the the distribution of patients among providers in these urban communities will have enough AA patients to participate in my study. (See Priority Georgia Region Characteristics table in Appendix B on page #97.)*

Reviewer 3-Alicia L. Best, PhD, MPH, CHES, CPH

External Reviewer Template

1. **Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.** *“Neither Agree nor Disagree”*

2. **How could the submission have been more responsive to the call for proposals?** “*The scope of this project is not at the level of this mechanism.”*

3. **Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.** *“Disagree”*

4. **What improvements could be made to the theory and structure of the proposal?** **“***SEM is ok, but not sufficient. There are several other theories that would provide more rich insight into this unique, complex issue.”*

5. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.** *“Disagree”*

6. **What would have improved the argument that the proposed activities are necessary?** *“See Document”*

7. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated.** *“Agree”*

8. **What changes would improve the perceived feasibility of the proposed activities?** **“***Strong Research Team.”*

9. Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area. *“Agree”*

10. **What additional comments and suggestions do you have for the PI?** *“Great idea but the proposal needs work. See specifics in document.”*

Comment 1- Starting out, the purpose of your research is unclear. You mention disproportionate BC mortality, the link between psychosocial needs and health outcomes,

reproductive changes in younger BC survivors, and racial disparities in breast cancer (which is vague). This is the reader's introduction to your study; thus it should be clear and targeted. The specific aims page should stand alone and provide a brief but clear snapshot of your study. Why start with describing disparities in mortality if your study does not address this? You are focused on improving the QoL among survivors; so I would suggest starting with that and why it is important.

Response: *Thank you for your thorough feedback! I have revised this section on page #79 to draw what I believe is a clearer picture of the purpose of this study, including the link between the psychosocial needs of young AA breast cancer survivors, racial disparities in breast cancer screening, diagnosis, screening, and ultimately, health outcomes related to quality of life and survivorship for this population. The "treatment-associated reproductive changes" were listed as an example of an area associated with psychosocial needs that may be specific to young women with breast cancer. I agree that improvement in quality of life is more closely linked to the aims of my study than reductions in mortality rates and have attempted to indicate that fact where appropriate throughout the proposal.*

Comment 2- In the first paragraph of the specific aims when you say, "Other research has point to significant racial health disparities in breast cancer leading to worse health outcomes among young AA women," are you referring to racial disparities in treatment leading to differential outcomes? Be clear.

Response: *Here, I am referring to racial health disparities in breast cancer screening, diagnosis, and treatment to help make the case that young AA breast cancer survivors have disproportionately poorer health outcomes and that further study is needed to address breast cancer-related issues in this population.*

Comment 3- The significance of your research goal to identify psychosocial needs among young AA breast cancer survivors was not well established in the first paragraph of the proposal.

Response: *Agreed. I added a sentence on page #79 detailing the goal of the proposed research to the end of the 1st paragraph to establish this early in the proposal using the following language, "The goal of the proposed research is to identify the psychosocial needs of young AA women with breast cancer among high risk counties in Georgia." The next paragraph goes into further detail about the research study goals.*

Comment 4- My first reaction is that this sounds like a small exploratory study (no current pilot data). The scope does not warrant the ACS Research Scholar mechanism – this mechanism is equivalent to an NIH R01. Perhaps an R03 or R21 would be more appropriate?

Response: *Thank you for this information, as I am admittedly new to the grant writing process. This proposal was developed as a thesis project and the Research Scholar Grant funding announcement is outdated. However, the purpose of selecting this application was to demonstrate my abilities in creating a research proposal that would be responsive to a funding announcement in my general topic area. Should I decide to submit a version of this proposal for future funding, I will be sure to identify the most appropriate funding mechanism to submit my application to.*

Comment 5- In reference to your Specific Aims, it sounds like you are assessing more than psychosocial needs – you mentioned availability of resources and physician relationship as well.

Response: *My goal for this study is to gain a deeper understanding of the psychosocial needs of young AA breast cancer survivors and the role of health care providers in addressing these needs by exploring the perspectives of both the survivors and providers who diagnose, treat and provide health services for them. My assessment of the literature indicates that resource availability and patient-provider relationships are factors that both determine and reflect psychosocial need so they are vital aspects of this study. For example, lack of information regarding treatment effects of breast cancer (including infertility and sexual dysfunction) may be a function of poor patient-provider communication.*

Comment 6- Your Specific Aims should be direct products of your proposed study. They should map on to your methods. After reading the proposal, Aim 3 "to develop a set of guidelines for health care providers to inform clinical management of psychosocial care needs for young AA women with breast cancer" was never mentioned again, and no methods related to it. Thus, this is more of an implication and plan for future research than an aim of this study.

Response: *Agreed. I have modified my specific aims on page #79 such that the goal of developing guidelines is now listed as a future use of the results of this study rather than a research activity that will be completed during the funding period using the following language, "**Summary:** The results of this research will be used to develop a set of guidelines for health care providers to inform clinical management of psychosocial care needs for young AA women with breast cancer. By achieving these aims, this study will advance efforts to reduce racial* *disparities in breast cancer survivorship, defined as differential experiences in daily living for survivors (e.g., treatment, aftercare, reproductive health support, mental health, etc.) from the time of diagnosis to the end of life, by providing evidence to inform the development and/or strengthening of policies and interventions to improve the quality of care for young AA women with breast cancer."*

Comment 7- The first few sentences of the Background and Significance section are really good and should have been in the very first paragraph of the proposal. Small thing, but check the application's reference format requirement. It seems strange to have them in alphabetical order AND number format. It is usually one or the other."

Response: *Thank you.* ☺ *The revisions I have made to earlier sections based on reviewer feedback have resulted in this information being stated in the first paragraph as well. (Slightly different wording but the concept is the same.) I have also re-aligned the subheadings for this section on page #80 to better emphasize my key points. Hopefully this further clarifies what I am trying to convey about my study goals.*

Comment 8- It is not good to have a whole paragraph describing negative health outcomes with no mention of how this relates to your work. This paragraph is all about increased mortality among this population, but your study doesn't address any of these items mentioned. Basically, it's like setting up a problem with no proposed resolution. It's okay to mention these things broadly as relevant to your topic; but it should lead somewhere relating to your work."

Response: *Point well taken. As stated in my response to comment 7, I have realigned my subheadings and paragraphs for the Background and Significance section to ensure that key concepts are tied together well. For the section in question on page #80, I have reframed that paragraph under the subheading "Health Outcomes for Young AA Breast Cancer Survivors" to describe higher burden of disease among young AA women with breast cancer (e.g., poorer health outcomes and greater need for emotional care after treatment).*

Comment 9- On page #80, you state, "The diagnosis of breast cancer, the physically demanding (often life-threatening) treatment regimens that follow and additional symptoms of illness, fatigue and pain produce tremendous amounts of stress for those suffering from this disease [1,4]. These factors may lead to emotional distress and mental health problems for cancer patients, often triggering a cascade of social problems, such as

the inability to work, reduced income, and relational dysfunction [14,19]. Often magnified by psychological and social stressors that were present prior to the onset of cancer, such as low income, lack of health insurance, and weak or absent social supports, these effects stem from and contribute to one another in a manner that affects both recovery and quality of life for AA breast cancer survivors [4, 54] The existence of racial disparities, (differences in access to or availability of resources for racial minorities), has been highlighted in multiple studies as a contributing factor to negative health outcomes for AA women [6,38,49]. However, few have specifically explored the reasons for risk disparity in breast cancer incidence and mortality among young AA women under the age of 45 [3,23,47,48]."

The information is really good and most relevant to your work – I would mention at least some of this earlier. It sounds like the crux of your research centers on the notion of intersectionality – young AA breast cancer survivors have unique supportive care needs that are compounded by the burden of disease and treatment, SES (e.g. lack of insurance, low income, etc.), racism, social norms (may be the head of family, etc.), and the challenges of younger age (e.g. reproductive decisions, etc.). This should be clearly stated rather than having the reader piece it together.

Response: *Thank you. I have included a comment about intersectionality in this section on page #80 , "The intersectionality of the burden of breast cancer (disease and treatment), with race, gender, younger age (reproductive decisions, age-specific supportive care needs), SES (low income, lack of insurance), and social norms (stigma, household roles) underscores the importance of this research as it relates to health disparities because each of these factors collectively create a disadvantaged health state for young AA breast cancer survivors" and added 2 references to support my argument: "Class, Race and Ethnicity and Information Avoidance Among Cancer Survivors" (McCloud et al., 2013) and "Race by Gender Group Differences in the Protective Effects of Socioeconomic Factors Against Sustained Health Problems Across Five Domains" (Assari et al., 2016). I also rephrased several sections to more fully describe the connection between factors such as race, gender and SES and psychosocial health for young AA breast cancer survivors.*

Comment 10- In the Conceptual Framework section you refer to the "social-ecological theory." This is a model rather than theory. Have you considered other frameworks? SEM is ok, but Intersectionality seems like a good fit too. Maybe even a combination?"

Response: *I have changed my wording to describe the social ecological model as such on page #81, rather than a theory, and I added language to clarify my description of the conceptual framework for this study. While I agree that intersectionality is a key concept in the research design and background for this proposal, I also respectfully contend that the social-ecological approach is a sound theoretical framework for this study because it conveys the idea that* *applying an intervention strategy (e.g., medical guidelines and training in best practices) to the providers who care for young AA breast cancer patients will have a downstream effect on the patients themselves via improved quality of life.*

Comment 11- You begin your Statement of Cancer Relevance section with a discussion of of increased breast cancer mortality risk for young AA women "due to many factors." Are any of the factors that increase mortality (e.g. genetic mutations, highly aggressive tumors, etc.) related to their psychosocial needs? In other words, what is the impact your research would have on this problem? If not much, then I would not mention this here.

Response: *Good point! This sentence has been removed. I have tried to revise my proposal, based on your feedback, to emphasize my research aim to improve quality of life for patients rather that making the stretch to reduction of mortality rates (a downstream potential outcome, but one that would require a strong evidence base to prove association for).*

Comment 12- Given the scope of your work, it may be a stretch to say addressing these psychosocial factors could increase survival rates. I think it's sufficient to say addressing these factors could improve QoL among survivors. You talk a lot throughout your proposal about disparities in mortality; but as a reviewer, I would say your study will have very little impact on breast cancer mortality among AA women in general."

Response: *Agreed. See response to comment 11.*

Comment 13- You use the term "cultural competency" a few times but never defined what you mean by it, or why it is important to your work.

Response: *You are correct and I did not realize I had made that oversight. I have since gone back and added Section C: Cultural Competence of Cancer Care Providers on page #81 to give a bit more context to what is meant by this term. The first sentence of this section defines the term with the following language: "Cultural competence has been defined as 'the ability of providers and organizations to effectively deliver health care services that meet the social, cultural, and linguistic needs of patients...' followed by a description of the relevance of this term to patient-provider interactions and psychosocial needs of young AA breast cancer survivors. I have also replaced the term "cultural competency" with cultural competence" to align with the literature.*

Comment 14- You mention "triangulation" of data in your description of the study in the Innovation section but it is not clear in the analysis section how you will triangulate. Your proposed analyses seem disjointed; particularly, the rationale for the quantitative analysis plan is unclear.

Response: *I have updated my analysis section to better describe my mixed methods research design, including triangulation of data, which can be found on page #90.*

Comment 16- Reviewers may want to see more detailed recruitment information for these focus groups. Is there registry data available for recruitment sites showing the eligible participant pool? How many navigators? Are they being hired on the study or providing letters of support detailing their participation?

Response: *My revised proposal references hospital records and the Georgia Comprehensive Cancer Registry as tools for recruitment with the assistance of patient navigators and tumor registrars from our community partner health system agencies on page #'s 86 and 89. I stated that there will be 4 navigators from partner hospitals in our 4 target counties, and these agencies will provide letters of support for study participation.*

Comment 17- What is the sample size for your patient survey?

Response: *My goal is to survey at least 1000 women, however, the official sample size will be based on the total number of eligible women identified through Georgia cancer registry data.*

Comment 18- Your qualitative analysis description sounds more like a quantitative analysis rather than exploratory qualitative.

Response: *I have revised my proposal to reflect a mixed methods sequential exploratory approach beginning on page #84.*

Comment 19- The description of the survey instrument would go in the Measures rather than Analysis section.

Response: *Thank you, I removed the comment about the Likert-type scale for the survey from the analysis section and describe the survey in greater detail on page #88.*

Comment 20- Your data analysis description is very under-developed and does not seem to align well with your aims. What outcomes are you attempting to assess with regression? Also, up until this point, you have not discussed any rationale for testing associations between survey constructs. Your aims suggest an exploratory study to assess unmet needs from survivor and provider perspectives, and use the survey to further assess the prevalence/magnitude of those needs. This explanation of your analysis plan does not appear to reflect triangulation of your data or support your aims. Also, your 3rd aim related to developing guidelines is never mentioned again.

Response: *I have attempted to provide a more in-depth and accurate description of my mixed methods research approach beginning on page #84, which I believe will address many of these areas. Admittedly, I have yet to conduct this kind of research so I am learning as I go with regard to describing the study. I have removed the 3rd aim and converted it into a summary statement of future plans for the results of this study on page #79, because I felt that the development of guidelines is beyond the scope of this particular research project. However, this research is intended to contribute to the development of medical guidelines for providers by establishing psychosocial needs and areas of unmet need for young AA breast cancer survivors.*

Comment 21- Overall, I think you address a very important topic and you have assembled an extremely qualified research team. I do not think this project is ready for submission for the proposed grant mechanism.

Response: *Agreed., ☺ I have quite a bit of work to do before I am ready to submit a grant proposal for funding, but this has been an excellent opportunity to learn about the research grant writing process. I will continue to study and perhaps partner with a mentor on a few studies to gain more experience in this area. Thank you so much for your feedback and guidance!*

Reviewer 4-Anna Holbrook, MD

External Reviewer Template

1. **Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.** *"Strongly Agree"*

2. **How could the submission have been more responsive to the call for proposals?** *"It could not be improved in this area in my opinion."*

3. **Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.** *"Strongly Agree"*

4. **What improvements could be made to the theory and structure of the proposal?** *"Some paragraphs should be split into smaller ones."*

5. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.** *"Strongly Agree"*

6. **What would have improved the argument that the proposed activities are necessary?** *"Nothing in my opinion."*

7. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated.** *"Strongly Agree"*

8. **What changes would improve the perceived feasibility of the proposed activities?** *"Explain how the number of women in the survivor group was determined. Explain how many survivors will be surveyed."*

Response: *The sampling frame and discussion of stratification for focus group participants has been added to the proposal on page #86. It includes AA female residents from each of the 4 high burden counties between the ages of 18 and 44 with a primary breast cancer (BC) diagnosis (Stage I-IV) at least 1 year prior to recruitment, either currently in or post-treatment and able to read and understand English. The sample size for focus groups will be 8-10 individuals per group for 4 separate group sessions at each of the 4 study locations (total=16 focus groups). Stratification by age group (2 groups each of women aged 18-29 and 30-44 per site) and cancer stage (2 groups each of early stage disease, stages I-II and late stage disease, stages III-IV) was done in order to identify potential differences in psychosocial needs among young AA women that may be age-and/or stage-specific. See table on page #51 for further clarification.*

9. **Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.** *"Strongly Agree"*

10. **What additional comments and suggestions do you have for the PI?** *Use either 'AA' or 'African American', but do not switch back and forth."*

Comment 1- I notice you switch back and forth between using the full term "African American" and "AA". You may want to just use "AA" for consistency.

Response: *Thank you for catching this error.* ☺ *I received this feedback for a previous draft and neglected to update the entire document. This has been corrected throughout the proposal.*

Comment 2- It may read better to start a new paragraph within the Innovation section at each of the italicized headings.

Response: *This would be my preference as well, however, I had to be careful about conserving space given the page limits of the grant application. I was, however, able to reformat this section as you recommended.*

Comment 3- I'm confused by the tense of this sentence, "Informed by data from survivor focus groups and provider interviews, a survey to assess psychosocial needs among the target population was included as a quantitative method of studying the variables identified through qualitative methods with a larger sample and corroborating any emerging themes that developed." Was the survey already developed? If not, say "will be included". If I'm all mixed up and you are referring to a survey created from data from OTHER groups and provider interviews, specify that, because it now to me reads as you are referring to the groups you plan on interviewing/surveying."

Response: *No, the survey will be developed during phase II of the study based on focus group and interview data results. I revised the survey discussion to reflect future tense on page #84.*

Comment 4- Can we split up the paragraph describing the research team? Start each name as a new paragraph.

Response: *Again, formatting was done for the proposal based on space limitations specified by the grant (12 pages), however, I have re-formatted this section for better clarity on page #85.*

Comment 5- How did you pick this number? Statistics? If you have a good reason, you may want to include it here, so the reviewers understand why this number, and not more or fewer.

Response: *The sampling frame for recruitment of focus groups has now been included in the proposal, which breaks down the number of survivors recruited by priority region, the number of focus groups (16 total with 4 at each location) and the number of survivors per focus group (8-10). The groups will be stratified by age and stage of disease at diagnosis to identify potential differences in psychosocial needs among young AA women that may be age-and or-stage specific. For each age grouping, 18-29 and 30-40, there will be an early stage focus group (Stage1-II at diagnosis) and a late stage focus group (Stage III-IV).*

Comment 6- How many people are you planning to survey?

Response: *My goal is to survey at least 1000 women, however, the official sample size will be based on the total number of eligible women identified through Georgia cancer registry data.*

Reviewer 5-Barbara Crane, MN, APRN

<u>External Reviewer Template</u>

1. **Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.** *"Strongly Agree"*

2. **How could the submission have been more responsive to the call for proposals?** *"In-depth psychosocial evaluation in this proposal. When completed, will give ↑ knowledge of social needs of survivor."*

3. **Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.** *"Strongly Agree"*

4. **What improvements could be made to the theory and structure of the proposal? "***No Recommendation"*

5. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.** *"Strongly Agree"*

6. **What would have improved the argument that the proposed activities are necessary?** *"Poss. some personal examples from young AA BR CA survivors."*

7. **Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated.** *"Agree"*

8. **What changes would improve the perceived feasibility of the proposed activities? "***Excellent Team. Concern with clinician interviews-may be too long."*

Response: The proposal has been revised to indicate that 30-45 minutes will be allotted for each interview on page #87 rather than saying the interview will be conducted for 30-45 minutes. I wanted to make sure that there was an adequate amount of time for each interview. In addition, several studies in the literature have reported provider interviews of 30 minutes or more.

9. **Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.** *"Strongly Agree"*

10. **What additional comments and suggestions do you have for the PI?** *"Excellent proposal -Look forward to results."*

Comment 1- Recently, the American Cancer Society, which was the basis for the new screening recommendations suggested that the majority of BC diagnosis is to women 45-50. They also noted a decrease in incidence in women 55 and older. Still higher than the younger group, but lower than 45-50.

Response: *I was unable to find this updated statistic however I did add a citation from the American Cancer Society Facts & Figures 2015-2016 report indicating that women age 50 had the highest incidence of breast cancer on page #80. Unfortunately, the breakdown for age groups was done in 10 year increments (e.g. ages 40-49) so I wasn't able to tease out the information for the 45 and under age group. I believe the point made is still accurate regarding the incidence of breast cancer among older vs. younger women.*

Comment 2- Should there be a space after each comma in your citations?

Response: *Yes, thank you. This has been corrected throughout the proposal.*

Comment 3- Do you want to continue with AA instead of spelling it out so as to be more uniform?

Response: *Thank you for catching this error. ☺ I received this feedback for a previous draft and neglected to update the entire document. This has been corrected throughout the proposal.*

Comment 4- Would it be better to stick with one – either African American or AA

Response: *See response to Comment 3.*

Comment 5- The time/length of these interviews may discourage participation for busy clinicians. Can this interview be accomplished in less time?

Response: *Yes. The proposal has been updated to say "Approximately 30-45 minutes will be allotted for each interview." They may absolutely be conducted in less time, however, I want to give a bit of extra time for set up, scheduling delays or other miscellaneous factors. See response to question #8 above.*

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Chapter V: Research Proposal

Research Plan and Environment (Sections A-J)

A. SPECIFIC AIMS

In the United States, African-American (AA) women under the age of 45 are at a disproportionately higher risk of mortality from breast cancer and suffer poorer health outcomes related to this disease than other women for reasons that are poorly understood [1-3]. Psychosocial needs of breast cancer survivors are intricately tied to health outcomes, (e.g., clinical depression and anxiety), as indicated by the well-established link between breast cancer survivorship and quality of life issues such as emotional well-being, social support, and financial stability [4]. Research has demonstrated that younger women with breast cancer experience distinct psychosocial concerns, particularly related to treatment-associated reproductive changes [5]. Other research has pointed to significant racial health disparities in breast cancer screening, diagnosis, and treatment leading to worse health outcomes among young AA women [6, 7]. However, very little direct study about the experiences of young AA women with breast cancer focuses on survivorship issues related to quality of life [6, 8]. Furthermore, there is a dearth of research that has specifically examined the psychosocial issues of AA women under the age of 45 living with breast cancer. The goal of the proposed research is to identify the psychosocial needs of young AA women with breast cancer among high risk counties in Georgia.

Compared to the national average, Georgia has higher age-adjusted rates of incidence, mortality, and late-stage diagnosis despite higher rates of mammography screening [9-11]. Four Metro-Atlanta counties within the state were selected as research sites for this study due to relatively large populations of AA residents and the high burden of breast cancer in these areas, as indicated by mortality, incidence and late-stage diagnosis rates, [11]. Using Georgia as a pilot study, the proposed research will offer valuable information regarding AA women's psychosocial health needs to providers who care for these patients and inform the development and/or strengthening of interventions and strategies designed to effectively address identified psychosocial needs that are both age and culturally appropriate. By increasing the knowledge and capacity of the health care community to better meet young AA, breast cancer survivors' psychosocial needs, both short and long-term health outcomes associated with psychosocial well-being may be improved, thereby reducing racial health disparities in breast cancer survivorship. Using a mixed methods sequential exploratory approach [12, 13], the proposed research will explore common experiences, themes, and phenomena related to the psychological, emotional, and social aspects of breast cancer that affect young AA women.

Aim 1: To identify the psychosocial needs of young AA women with breast cancer by assessing survivor perspectives. We will meet this aim by collecting primary data through two research methods; (1) focus groups with young AA breast cancer survivors living in one of 4 high priority counties in Georgia and (2) patient surveys with a larger sample of young AA breast cancer survivors in GA to assess their perspectives regarding cancer-related psychosocial issues such as availability of resources, emotional well-being, and physician relationships [14].

Aim 2: To explore provider practices and policies regarding the psychosocial needs of young AA women with breast cancer and barriers to management of these needs. We will conduct semi-structured, in depth interviews with physician and ancillary health care providers in Georgia to understand the extent to which providers are knowledgeable of and feel equipped to care for the psychosocial needs of young AA women with breast cancer.

Summary: The results of this research will be used by health policy makers to develop guidelines for health care providers to inform clinical management of psychosocial care needs for young AA women with breast cancer. By achieving these aims, this study will advance efforts to reduce racial disparities in breast cancer survivorship, defined as differential experiences in daily living for survivors (e.g., treatment, aftercare, reproductive health support, mental health, etc.) from the time of diagnosis to the end of life, by providing evidence to inform the development and/or strengthening of policies and interventions to improve the quality of care for young AA women with breast cancer.

B. Background and Significance. ***Overview of Breast Cancer in Young Women-***Though the majority of breast cancers are found in women age 50 and older, approximately 11% of all new cases in the United States each year are found in women under the age of 45 [15, 16]. Among younger women (under age 45), the incidence of breast cancer is higher for AA's than whites [17]. A diagnosis of breast cancer can be devastating for any woman, however, young survivors may face distinct challenges managing their diagnosis, treatment, and aftercare [18]. Research has suggested that young AA women with breast cancer have a unique set of experiences compared to other survivor groups and, as a result, they may have specific unmet psychosocial needs that require comprehensive clinical and therapeutic strategies [19, 20]. Advances in early detection and treatment of breast cancer have increased survivorship and improved the quality of life for a countless number of individuals after diagnosis [21]. However, for AA women, particularly those under the age of 45, morbidity and mortality rates due to breast cancer continue to be disproportionately high, subsequently leading to a detrimental impact on both health related quality of life and survivorship [3, 22].

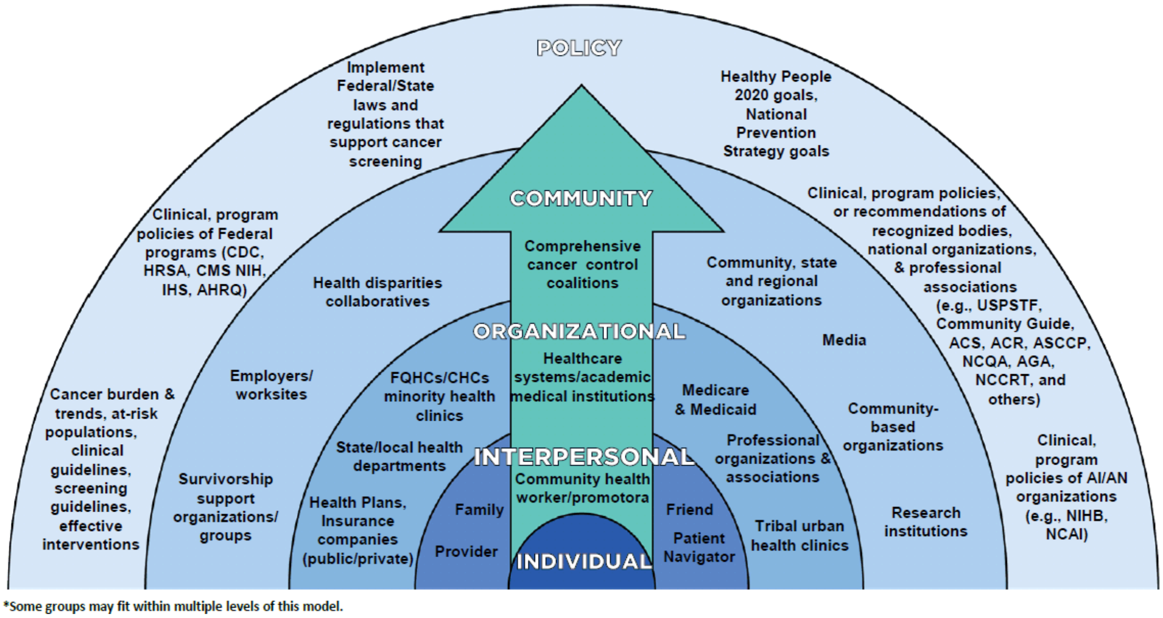
Breast Cancer Among AA Women in Georgia. Consistent with national statistics, the incidence of breast cancer in Georgia is higher among white women than AA women, however, AA women in Georgia have higher breast cancer mortality rates than white women [9,10]. This holds true regardless of geographic location within the state, with the widest disparities between AA women and whites existing in the large metropolitan areas and smaller urban counties [23]. Though Georgia women over the age of 60 have the highest overall breast cancer incidence rates and white women typically have the highest incidence rates among all women, AA women in Georgia have higher incidence rates than white women at younger ages [23]. These trends are highlighted in a recent report by the Susan G. Komen® Foundation profiling Georgia communities with a high breast cancer burden in the greater Atlanta metropolitan area [11]. Among the highest burden regions for breast cancer incidence, mortality and late-stage diagnosis rates were Fulton, DeKalb, Henry, and Clayton counties, target communities disproportionately comprised of medically underserved communities and poverty areas where research activities for this study will occur. *See* ***Figure 1.*** *Female Breast Cancer Incidence, Death and Late-Stage Rates and Trends in Appendix A.*

Health Outcomes for Young AA Breast Cancer Survivors-AA women with breast cancer have been shown to suffer from worse health outcomes and lower survival rates than any other population [2, 24]. Compared to white women, AA women are more frequently diagnosed at later disease stages, have more aggressive tumor subtypes, and experience lower breast cancer survival rates [25, 26]. Young AA women, in particular, are more likely to develop triple-negative breast cancer (TNBC), which has one of the poorest prognoses, highest risk of mortality and highest recurrence rate among all breast cancer subtypes [2, 8]. Compared to other groups, AA breast cancer survivors have reported greater malaise, poorer physical functioning and more frequent inability to work, as well as a greater need for emotional care and anticipatory guidance after treatment [8, 27]. The diagnosis of breast cancer, the physically demanding (often life-threatening) treatment regimens that follow and additional symptoms of illness, fatigue and pain produce tremendous amounts of stress for those suffering from this disease [28, 29]. These factors may lead to emotional distress and mental health problems for cancer patients, often triggering a cascade of social problems, such as the inability to work, reduced income, and relational dysfunction [30, 31]. Often magnified by psychological and social stressors that were present prior to the onset of cancer, such as low income, lack of health insurance, and weak or absent social supports, these effects stem from and contribute to one another in a manner that affects both recovery and quality of life for AA breast cancer survivors [29, 32]. The intersectionality of the burden of breast cancer (disease and treatment), with race, gender, younger age (reproductive decisions, age-specific supportive care needs), SES (low income, lack of insurance), and social norms (stigma, household roles) underscores the importance of this research as it relates to health disparities because each of these factors collectively create a disadvantaged health state for young AA breast cancer survivors [33, 34]. Defined as "type(s) of difference in health (or in the determinants of health that could be shaped by policies) in which disadvantaged social groups systematically experience worse health or more health risks than do more advantaged social groups [35], health disparities have been highlighted in multiple studies as a contributing factor to negative health outcomes for AA women [3, 36, 37]. However, few have specifically explored the reasons for these disparities in health among young AA women under the age of 45 [1, 2, 6, 38].

Link Between Psychosocial Issues and Breast Cancer Survivorship-Along with bearing the unequal burden of late-stage diagnoses and often, more aggressive disease, young AA breast cancer survivors have reported poorer psychological outcomes, greater fears of recurrence, more concerns about body image and overall worse quality of life compared to older women and women of other racial groups [2, 8] In concert, these factors may be demonstrative of greater needs for information, emotional care, and culturally appropriate cancer resources, which may contribute to higher morbidity and mortality rates for young AA women with breast cancer [8, 38, 39]. Identifying and addressing psychosocial needs of patient populations is vital to breast cancer survivorship because research shows that they are predictive of later health outcomes, such as depression, anxiety, and health-related quality of life [5, 28, 30]. Health care providers, including physicians and ancillary care professionals (e.g. nurses, therapists, social workers, etc.) play a significant role in addressing the psychosocial care needs of young AA women with breast cancer. These patients rely on their providers for information and guidance regarding the physical, psychological, and functional implications of breast cancer diagnosis and the consequences of treatment, as well as referrals to various support services to assist them in daily management of their disease [8, 20, 22, 61]. Strategies to address these issues should emphasize cultural competence among providers in addition to the need for more substantial guidance in the medical management of this survivor population. Ultimately, the psychosocial needs of young AA women with breast cancer are vast and require comprehensive, evidence-based strategies to address them that are tailored to the specific needs of the individual survivor [5, 28, 40].

C. Cultural Competence of Cancer Care Providers- Cultural competence has been defined as "the ability of providers and organizations to effectively deliver health care services that meet the social, cultural, and linguistic needs of patients" [41]. The concept of cultural competence has been widely adopted by the U.S. health care system as a means to help improve health outcomes and quality of care while contributing to the elimination of racial and ethnic health disparities [42]. This study will assess cultural competence among cancer care providers for young AA breast cancer survivors through in-depth provider interviews as well as exploring the perspective of survivors regarding the quality of care received through focus groups and a survey questionnaire in order to (1) determine the degree to which providers are aware of the psychosocial issues that maybe unique to this population and (2) to inform the development and/or enhancement of public health interventions to meet culturally specific psychosocial care needs for these women.

D. Conceptual Framework and Determinants of Health. The development of this research project was informed by the social-ecological model, a depiction of multiple "environmental levels" (e.g., individual, family, relational, community/peers, institutional, and societal/cultural) that collectively influence individual behavior, beliefs, attitudes and experiences [43]. Adapted from Urie Bronfenbrenner's classic model of an ecological approach to health promotion, this model demonstrates multiple levels of influence that interact in such a way that to modify any one level can have downstream effects on the other levels [44]. Race, gender, age, barriers to treatment service access, and quality of care are each contributing factors to psychosocial health for young AA women with breast cancer, which is an upstream determinant of health for survivors [45, 46]. By gaining a deeper understanding of areas of unmet cancer-related psychosocial need among young AA women, we can facilitate the development of targeted interventions, such as provider assessment tools and best practices, to address identified needs that are age-specific and culturally appropriate. The proposed research strategy of exploring a diverse array of perspectives on psychosocial need among survivors and providers at multiple environmental levels (e.g., individual, interpersonal, and community within focus groups and organizational in provider interviews) builds upon the principles of the social-ecological model by gathering evidence to direct the development of interventions to be employed at the policy and organizational levels that will ultimately improve health outcomes at the individual level. Effective strategies to improve the quality of care delivered to young AA breast cancer survivors will ultimately lead to improvement in quality of life for this high risk population. The image below depicts the bidirectional influence of factors at each level of health care service from the interpersonal provider-patient relationship to national health policy implementation of clinical guidelines. It also outlines the primary stakeholders who will use, influence, or be affected by the results of the proposed study including, young AA breast cancer survivors, providers, health care systems, and policy makers. Our research is designed to highlight key interactions between these levels, (e.g. patient navigator connections with cancer patients and survivorship support organizations' link to both survivors and health care systems/providers), in order to reveal intervention targets for health promotion among young AA breast cancer survivors.



The Social Ecological Model. Source: CDC-Colorectal Cancer Control Program, Div. of Cancer Prevention and Control (2015).

E. Statement of Cancer Relevance. Differences in the ability to receive quality patient care or have access to vital health resources for breast cancer survivors in this population due to race, age, financial status or similar characteristics (health disparities) have a major impact on the long-term health status of young AA women [2, 24]. Limited information is known about the psychological, emotional, social and functional needs of young AA women with breast cancer, however, previous research has shown that these factors are important determinants of quality of life after diagnosis and treatment of breast cancer [47, 48]. The proposed research study will contribute to the limited body of literature on AA breast cancer survivorship by defining the experiences and psychosocial needs of a population at high risk for breast cancer mortality [22]. By identifying the psychosocial needs of young AA women with breast cancer and exploring health care provider practices and policies to address identified needs (as well as barriers to this process), valuable insights can be gained regarding strategies to improve the quality of health care delivery to this population. Better quality of care may improve quality of life and other health outcomes such as psychological, emotional, and physical well-being for young AA women with breast cancer. In addition, efforts to improve patient-physician relationships and increase cultural competence among health care providers may improve quality of care delivery for all cancer patients.

F. Innovation.

Target Population: AA women younger than 45 have lower breast cancer survival rates and poorer health outcomes after diagnosis than other women for reasons that are poorly understood [3]. Limited information is available about the survivorship experiences of this population [2]. ***Psychosocial Issues in High Risk Minority Cancer Population:*** Though psychosocial issues in breast cancer survivorship have been explored in the literature [21, 29, 30], few studies have gone beyond biological factors to examine survivorship issues related to psychosocial well-being for young AA women with breast cancer. This study aims to fill the knowledge gap regarding the psychosocial needs of this high risk population to inform the development of targeted interventions, such as clinical guidelines for providers, that will help to increase quality of life for these women and to reduce racial disparities in breast cancer survivorship. ***Unique and Multiple Perspectives:*** The diverse array of perspectives explored in this study to assess psychosocial needs of young AA breast cancer survivors includes young AA women under 40 whose voices are rarely heard surrounding breast cancer issues because current guidelines target screening and prevention efforts to women age 40 and above. In addition, the "provider" perspective is expanded to include non-physician groups such as patient navigators and social workers, who are vital members of the cancer care team due to their extensive interaction with breast cancer patients and ability to offer valuable information regarding the psychological, emotional, social and functional needs of breast cancer survivors that go beyond basic medical care.

Research Questions:

Primary Research Question-*What are the psychosocial needs of young African-American women with breast cancer as perceived by survivors within this population and health care providers who treat them?*

Secondary Research Questions

Aim 1: To identify the psychosocial needs of young AA women with breast cancer by assessing survivor perspectives.

- *To what extent are the psychosocial needs of young AA female breast cancer survivors being addressed by the health care community?*
- *At which system level(s) of the social-ecological model are psychosocial needs of young AA breast cancer survivors greatest (e.g., individual, interpersonal, organizational, community, and policy)?*
- *How do factors such as socioeconomic status, demographics, stage at diagnosis, geographic location and survivorship status affect perceptions of unmet psychosocial needs among AA female breast cancer survivors?*

Aim 2: To explore provider practices and policies regarding the psychosocial needs of young AA women with breast cancer and barriers to management of these needs.

- *To what extent are health care providers aware of the perceived areas of unmet needs of young AA female breast cancer survivors? Which provider groups are most knowledgeable of the psychosocial needs and areas of unmet need among young AA women? Of those with knowledge of these areas of unmet need, to what extent do they feel competent to address them?*

- *Are there additional considerations regarding unmet psychosocial needs of AA breast cancer survivors that need to be addressed?*

G. Research Design

Overview: We will use a mixed method, sequential exploratory design [12, 13]beginning with a qualitative research phase consisting of 16 focus groups with 8-10 young AA breast cancer survivors per group followed by 40-60 provider interviews to explore perspectives of young AA breast cancer survivors and health care providers who treat this population to identify psychosocial needs of young AA women with breast cancer and to assess provider awareness of, cultural competence and perceived self-efficacy in addressing identified needs of young AA survivors in their care. We will use data from phase one to inform the development of an online survey that will be administered to explore psychosocial issues among a larger population of survivors in order to develop a more complete understanding of the psychosocial needs of this population. Each data collection tool will be pilot tested with a subset of the sample population prior to implementation of research activities to ensure that questions from focus group guides, provider interview guides, and the online survey are clearly stated or written, (including response options for the survey), and can be completed in a reasonable length of time, as well as to assess the feasibility of our data collection methods and allow for corrections as needed.

A total of 4 high burden counties in Georgia as designated by proportion of AA residents and breast cancer incidence, mortality and late-stage disease rates, have been identified as priority areas for this study. We will collect both qualitative and quantitative data around the unmet needs of young AA, female breast cancer survivors via focus groups, administration of a survey for survivors, and interviews with providers who care for, or provide health services to this demographic. Recruitment of study participants, particularly for focus groups and provider interviews, will be facilitated by well-established partnerships with local breast cancer survivor groups, health systems, and providers in throughout the state of Georgia. Survivor focus groups and provider interviews will be triangulated with survey results to examine the development of emerging themes among perspectives of each group regarding the psychosocial needs and areas of unmet need among young AA women with breast cancer [12, 13]. Qualitative methods were selected to answer questions regarding the experiences, beliefs and attitudes of young AA breast cancer survivors and health care providers about the psychosocial needs of the target population. Quantitative methods were used to further explore the psychosocial needs of young AA women with breast cancer and to describe the attributes of survivors in this group among a larger sample of the population.

Setting: Study activities will take place in 4 Georgia counties identified as high burden areas for breast cancer based in incidence, mortality and late-stage diagnosis rates within the state and affiliated with major health centers or cancer treatment programs in the area. Sixteen survivor focus groups will be held in meeting rooms at partner locations in each of the 4 priority locations including: Emory University Hospital Midtown in Fulton County, DeKalb Medical Center in DeKalb County, Southern Regional Health Center in Clayton County and Piedmont Henry Hospital in Henry County. Provider interviews will be conducted by telephone or in person. ***Figure 2 in Appendix B*** shows a comparison of the 4 priority regions for this study.

Research Team: Our research team includes a diverse array of knowledge and expertise in multiple scientific disciplines including public health, clinical medicine, research methodology (quantitative and qualitative), disparities research, cancer prevention and research, and behavioral sciences.

Minda D. Reed, MD, MPH (Candidate)-*Principle Investigator*: Dr. Reed is a medical doctor in training for a career as a preventive medicine physician with a concentration in women's health. She is a fellow on the Health Systems Team within the Health and Trauma Systems Branch at the CDC in Atlanta, GA. She is also a student in the executive MPH program at Emory University, Rollins School of Public Health (RSPH) in the prevention science track. Dr. Reed will begin a preventive medicine residency at Emory University School of Medicine upon completion of her fellowship and plans to further her research career in health disparities as a medical officer in the Division of Cancer Prevention and Control at the CDC. Dr. Reed will have lead responsibility for all aspects of study development and implementation. She will assist with development of the provider interview guide for and conduct provider interviews.

Ingrid J. Hall, PhD, MPH-Dr. Hall is an epidemiologist in the Division of Cancer Prevention and Control's Epidemiology and Applied Research Branch at the CDC in Atlanta, GA. She will assist with development of data collection instruments as well as moderation of survivor focus groups.

Laurie Gaydos, PhD-Dr. Gaydos is an associate professor at Emory University, (RSPH) in the Department of Health Policy and Management. Her research interests include health policy and sexual health/behavior. Dr. Gaydos will assist with development of data collection instruments and quantitative/qualitative data analysis.

Sarah C. Blake, PhD, MA-Dr. Blake is an assistant research professor in the Department of Health Policy and Management at Emory University, (RSPH). She is a member of the Cancer Prevention and Control Research Program at Winship Cancer Institute. Dr. Blake will assist with implementation of study design and qualitative data analysis.

Ruby Johnson, WHNP-BC, CCRC-*Research Coordinator*. Mrs. Johnson is a women's health nurse practitioner in the Doris Shaheen Breast Health Center at Piedmont Atlanta Hospital with over 15 years of experience as a nurse navigator. She is a certified research coordinator who has worked on several breast cancer study teams in the Atlanta metropolitan area. She will be responsible for all administrative aspects of the the study as well as recruitment and adherence to study protocol.

Tiffany Stroud, MSW, MPH (Candidate)-*Research Assistant.* Ms. Stroud has experience as a health care social worker and case manager at Atlanta Medical Center. She is currently completing her Masters of Public Health at Emory University, Rollins school of Public Health. Ms. Stroud will moderate and digitally record all focus groups for the study. She will also assist with qualitative data analysis.

Collaborative Partners include 5 leading Georgia health centers: ***DeKalb Medical Center*** in Decatur, GA (DeKalb), ***Emory University Hospital***-Midtown in Atlanta, GA (Fulton), ***Grady Memorial Hospital*** in Atlanta, GA (Fulton)**,** Southern ***Regional Medical Center*** in Riverdale, GA (Clayton), and **Piedmont Henry** in McDonough, GA (Henry) as well as 2 well-established AA breast cancer support groups headquartered in the Atlanta metropolitan area: **Sisters by Choice** and **Shades of Pink Foundation** which have provided letters of support for this project. A core group of community partners representing each institution will assist the research team with implementation of research activities including recruitment of study participants among patient populations in each center and provision of meeting spaces for focus groups and interviews.

Phase 1a-Survivor Focus Groups**:** With the assistance of our community partners, we will recruit 128-160 young AA women with breast cancer, ages 18-44, for a total of 16 survivor focus groups (8-10 women each) with 4 groups scheduled at each of the 4 priority locations to examine the beliefs, attitudes and experiences of this population regarding psychosocial needs and potential areas of unmet need. The use of focus groups allows for in-depth exploration of sensitive subject matter due to the ability of the moderator to ask probing questions, address new issues as they arise and ask participants to elaborate on specific topics. Participants may feel more comfortable discussing their cancer experiences in an informal group setting than individual interviews and more information may be generated from increased interaction among the group [50]. The sampling frame for focus group participants includes AA female residents from each of the 4 high burden counties between the ages of 18 and 44 with a primary breast cancer diagnosis (Stage I-IV) at least 1 year prior to recruitment, either currently in or post-treatment and able to read and understand English. Two groups at each county location will be comprised of AA women ages 18-29 and two groups will include AA women ages 30-44, with each group further stratified by early (I-II) or late (III-IV) stage at diagnosis in order to identify needs that may be unique with respect to age, disease status and other variables such as education level, employment, and treatment status. We will recruit AA women in both age groups (18-29 and 30-44) to to participate in 4 focus groups per study location (8-10 women per focus group) using state cancer registry data to identify eligible participants. Women with breast cancer diagnoses of stages I-IV (invasive disease) were chosen to ensure that study participants in each age group would have experience in coping with effects of breast cancer treatment as well as substantial interactions with cancer care providers during detection, treatment and aftercare that could be assessed for the purposes of this study. Focus group participants will be recruited by 4 patient navigators via direct outreach to, and referral of, patients being seen by providers at breast centers in each of the health system partner sites. We will solicit the help of our partners in Sisters by Choice, Inc. and Fifty Shades of Pink Foundation to identify and heavily recruit women in the younger age group of 18-29, who may be more difficult to isolate from health centers alone, based on their access to a wider age range of AA survivors though their statewide support group networks. Eligible participants will be approached by patient navigators during routine medical appointments with the permission of the referring provider to provide information about the study and request patient participation. Patients interested in participating will be consented and enrolled for the study in the office and those interested but unwilling or unable to provide consent initially will receive a follow-up call from a member of the research staff within 24 hours to provide additional information and obtain informed consent. If the 1st phone attempt after the office encounter is unsuccessful, a 2nd phone call will occur 1 week later to determine patient willingness to participate. If research staff are unable to reach interested patients by phone after 1 week, an email will be sent briefly describing the study and asking for participation. No additional attempts will be made to contact patients after the follow-up email is sent. Patient navigators have traditionally been employed to help eliminate health disparities in cancer outcomes among underserved populations and are well-suited for recruitment efforts of young AA women with breast cancer due to their knowledge of survivor profiles within the priority region health care centers and their work in facilitating services to improve health outcomes for vulnerable populations [49]. Sisters by Choice and Shades of Pink Foundation will also assist with recruitment of focus group participants by sending emails, posting flyers and soliciting volunteers during support group meetings and other functions. Approximately 90 minutes will be allotted for each focus group session. Upon completion of written informed consent, focus group participants will be asked to complete a brief demographic and cancer history questionnaire prior to each focus group session. Refreshments and a $75 incentive will be provided to all focus group participants for their study involvement. All 16 focus groups will have an AA female moderator (Ms. Stroud) and co-facilitators (Drs. Reed, Hall, Gaydos and/or Blake) trained in qualitative research methods using a semi-structured interview guide adapted from previous studies exploring the unmet needs of young women with breast cancer and survivorship in AA women [27, 67, 32] Research team members will be available during all focus group sessions to address any questions that may arise. The focus group discussion will follow a sequential approach of open-ended questions followed by non-specific prompts and follow-up probes to the open-ended replies [50]. Focus groups will be digitally recorded for transcription and handwritten notes will be taken by a member of the research team during each session. We will apply an integrated deductive (structural) and inductive thematic analytic approach [58] to the focus group transcripts, beginning with the conceptual framework of the social-ecological model as previously described, (e.g., key interactions between providers, patients, community, and health systems and multiple environmental levels that influence cancer care and survivorship) and a deductive organizing framework for conceptual codes that identify key domains (and essential dimensions of these domains) determined from previous research regarding psychosocial needs of cancer patients with special emphasis on young AA women (*see Appendix C).* Inductive thematic analysis [51] will then be applied as follows: **(1)** The transcripts will be read repeatedly, (2) statements concerning psychosocial issues and areas of unmet need will be extracted, (3) initial coding will be performed by multiple coders who will look for emerging themes, (4) using NVivo11 qualitative analysis software, emerging themes will be revised in relation to both extracted statements and the complete data set and a thematic map will be developed, (5) we will further "define and refine" themes and subthemes, and (6) we will write-up a report of our findings. ***Figure 3 in Appendix C*** includes a list of domains to be included in the moderator guide, as well as examples of the types of questions that will be asked during the focus groups.

Phase 1b-Provider Interviews: A total of 40-60 telephone interviews will be conducted with health care professionals who provide breast cancer screening, diagnostic or treatment services to women, in any of the 4 target study locations to assess provider knowledge, and self-efficacy in management of psychosocial needs of young AA women with breast cancer. In-person interviews may be requested by providers if preferred and will take place at one of the community partner health centers. Approximately 30-45 minutes will be allotted for each interview. The provider recruitment sampling frame includes physicians, nurses, patient navigators, and ancillary care professionals (e.g., social workers, genetic counselors, and radiation therapists) who practice and provide health services for breast cancer patients in one of the 4 high burden counties. Physicians and ancillary care providers are key members of cancer treatment teams and their perspectives on psychosocial needs may vary based on factors such as the type of care or services provided, amount of time spent with patients (frequency of visits and duration of encounters), and level of knowledge of patient medical history. Providers will again be recruited with the assistance of our community partners who will initially contact eligible providers within hospital organizations in the high priority counties through multiple channels including direct outreach during local tumor board conferences, meetings and associations of specialty groups such as the Georgia State Medical Association and the Georgia Nurses Association. "Snowball sampling" using sequential recommendations from the key informants initially referred will be used to recruit additional providers [52]. This process will also be facilitated by well-established relationships among members of the research team at Rollins School of Public Health and the Centers for Disease Control and Prevention with Georgia providers in each of the 4 study locations. Eligibility criteria for providers will include (1) current, unrestricted, valid licensure, registration or certification as applicable based on discipline in fields of specialization, (2) residence or professional practice in one of the 4 priority counties, and (3) ability to speak and understand English. The study coordinator will contact selected providers by email to invite them to participate in the study. Those interested in participating will complete an informed consent form and a brief demographic questionnaire contained in the invitation email. If no response is received from the initial email, a 2nd email will be sent out 1 week later. A 3rd email will be sent if no other responses are received within 2 weeks of email #2. No additional attempts will be made to contact providers after the 3rd email is sent. Each participating provider will receive $150 as compensation for participation in the study. Interviews will be led by Dr. Blake, with the assistance of Dr. Reed, both team members with substantial qualitative research methodology expertise. Using a similar approach to the focus group protocol, and a semi-structured interview guide with open-ended questions and probes designed to elicit information pertaining to our conceptual framework as well as unanticipated information that may be useful for providing additional context to interview responses. Providers will be asked to describe their knowledge of the psychosocial needs of young AA women with breast cancer, including current policies and best practices to address those needs, and barriers to medical management of this population. Additional research staff will take notes and oversee audio recording of the interviews, which will be transcribed verbatim. Interview data will be analyzed using the same integrated deductive and inductive thematic stepwise plan used in the analysis of focus group data with the exception of step 2 including extraction of statements about the patient-provider relationship and the role of providers in addressing psychosocial needs among young AA breast cancer survivors. Key informant interviews provide an opportunity to gain insights from individuals with specialized knowledge of the subject matter (i.e. breast cancer, racial disparities, health policy, etc.) and also allow for more in-depth probing of topics during discussion. Obtaining qualitative information about the psychosocial needs of young AA women with breast cancer from multiple providers with a diverse set of backgrounds and professional experiences with the study population will provide a more comprehensive view of the public health problem to be addressed and the role of providers in caring for these women.

Figure 4 in Appendix D includes a list of domains to be included in the interview guide, as well as sample questions for providers.

Table 1. Sampling Plan for Provider Interviews

Breast Cancer Health Service Providers	**Physicians**	**Nurses**	**Patient Navigators**	**Ancillary Care Providers**
# Recruited Per County (Total 40-60)	2-3	2-3	2-3	4-6
Counties of Practice **Fulton** **DeKalb** **Henry** **Clayton**	-Primary Care -Med. Oncologists -Breast Surgeons -OBGYNs	-RNs -NPs -Family Practice -OBGYN	Cancer Care Patient Navigator	-Social Workers -Genetic Counselors -Radiation Therapists

<u>Phase II-Survivor Survey:</u> Qualitative data from focus groups and interviews in phase 1 will be used to develop an online survey to further explore the psychosocial needs of young AA women with breast cancer among all Georgia survivors who meet the eligibility criteria for the study and agree to complete the survey. Surveys are useful for describing characteristics of a large population and provide a standardized method of data collection with results that are more precisely measured than either focus group or interview data. Online surveys allow for greater reach at a low cost to the researcher. This survey will also allow for the assessment of variables identified through qualitative methods with a larger sample and corroboration of any emerging themes that developed. The online survey will be adapted from the Psychosocial Distress Questionnaire-Breast Cancer (PDQ-BC). The PDQ-BC consists of 9 subscales assessed by 35 questions designed to measure psychological risk factors (e.g. trait anxiety and lack of social support), and a wide range of psychosocial issues (e.g. anxiety, depression, body image, social problems, physical problems, and financial problems) [14]. Response options for each question range from 1 (not at all) to 4 (very much) and higher scores correlate to higher levels of psychosocial distress [53]. In addition to the 35 psychosocial response questions, the PDQ-BC includes a set of questions that assess sociodemographic factors such as marital status, age, and clinical factors (e.g. type of surgery, type of adjuvant treatment and pre-treatment psychiatric morbidity). The PDQ-BC is an evidenced based data collection tool that was developed from widely accepted, valid questionnaires and has been shown to be an easy-to-use, psychometrically sound, and acceptable survey instrument [14, 53]. Dr. Laurie Gaydos, a research team member with expertise in mixed methods research design (qualitative and quantitative), will lead the research team in adapting the PDQ-BC to incorporate measures of cultural experiences in cancer care and areas of unmet need as well as patient-provider communication dynamics with the addition of approximately 10 questions to be added to the online survey. The additional questions will be validated by expert review with qualified research faculty at Rollins School of Public Health prior to administration of the survey to research participants. Survey respondents will be recruited via purposive homogenous sampling [54] by our research coordinator and tumor registrars within our community partner health system organizations from a list of eligible participants identified from the GCCR patient profiles. Survey eligibility criteria include: AA female residents of Georgia between the ages of 18-44 with a primary breast cancer diagnosis (Stage I-IV) at least 1 year prior to recruitment, either currently in or post-treatment with the ability to read and understand English. Though the research team plans to recruit at least 1000 women to complete the survey with an estimated response rate of 20% based on standard participation rates for patient-based studies [55], the actual sample size and response rate for the survey will be determined by the number of women who meet study criteria identified from the Georgia Comprehensive Cancer Registry (GCCR) [56] by our research coordinator and tumor registrars within our community partner hospitals. A series of 3 emails, (each containing a form for informed consent and a brief demographic questionnaire), will be sent to all eligible women in the sampling frame requesting them to complete the survey online, which should take less than 20 minutes to complete. If a response is received from the 1st email, no additional recruitment emails will be sent. Otherwise, a 2nd follow up email will be sent within 1 week of email #1 and a 3rd email will be sent within 2 weeks of email #2 if no responses are received by that time. No additional attempts will be made to contact survivors after email #3. Respondents will receive a $25 incentive for their participation in the study. Using quantitative research methods [57], analysis of survey results will be conducted using SPSS statistical software. Response frequencies and percentages will be calculated for each question to facilitate prioritization of topic areas and variables reported by survivors to aid in the determination of the greatest areas of psychosocial need and areas of unmet need among young AA women with breast cancer. Survey responses will be compared to qualitative results from phase 1 data to detect areas of overlap among survivors or between survivors and providers (high priority issues or highest degree of psychosocial need) as well as areas of patient/provider divergence (potential areas of unmet need and/or targets for intervention) or disparity among survivor responses (lesser degree psychosocial need, variation by other factors beyond race or age, etc.). Descriptive statistics will be run to detect emerging patterns from the data and findings will be summarized in a final report.

Table 2. Survivor Survey Inclusion and Exclusion Criteria

Demographic	**Inclusion**	**Exclusion**
Ethnicity	African American	All Others
Age	18-44	Under 18 and over 44
Location	Georgia Resident	Residency outside of Georgia
Cancer Status	-Primary breast cancer diagnosis (Stage I-IV) at least 1 year prior to recruitment -Currently in or post-treatment	-Breast cancer in situ/Stage 0 -Cancer diagnosis less than 1 year prior to recruitment -Pre-treatment status
Language	Able to read and speak English	Unable to read or speak English

***Triangulation of Data*:** Qualitative and quantitative data collected and analyzed during phase 1 and phase 2 will be triangulated to provide the greatest insight on the unmet psychosocial needs of survivors by "mixing" the data during data collection and interpretation of results [12, 13]. We will first connect qualitative data to quantitative data for this study in the development of the data collection instrument that will be informed by focus group and interview results. The second instance of merging will occur when we compare and contrast codes, variables and themes that emerge from both qualitative and quantitative data sets and present them all of the data in one summary report with visual displays that will be disseminated to stakeholders upon completion of the study. Collectively, these research methods will increase the breadth of understanding gained regarding the psychosocial needs of the target population while offsetting limitations of each individual method (e.g. interviewer bias, focus group sample size, inflexible survey design, etc.).

Figure 5 outlines the project timeline for the proposed study.

Figure 5 Project Timeline

Months	1		3			6			9			12			15			18			21			24
Dev. Study Tools/IRB	■	■	■																					
Recruitment				■	■	■	■	■	■	■	■	■	■	■	■									
Focus Groups							■	■	■	■														
Focus Group Data Analysis										■	■	■	■											
Provider Interviews											■	■	■	■										
Provider Interview Data Analysis														■	■	■	■							
Survey Data Collection																		■	■	■	■			
Final Reporting																						■	■	■

H. Environment. The Rollins School of Public Health on the campus of Emory University in Atlanta, GA is a premier multidisciplinary research institution with state-of-the-art technology and recently expanded research facilities to include 60,000 square feet of new laboratory space that can accommodate a wide range of research project sizes. Rollins shares facilities and resources with other centers within the Emory Woodruff Health Sciences System, a consortium of academic and service institutions that includes: Rollins School of Public Health, Emory University School of Medicine, Nell Hodgson Woodruff School of Nursing, Winship Cancer Institute, Yerkes National Primate Research Center, and Emory Healthcare. In addition to extensive laboratory space, Rollins provides access to approximately 30 lecture and seminar rooms, 10 mid-to-large conference rooms, advanced information technology services and computer labs, and the Emory University Library System.

I. Ethical Considerations

For each phase of this study, our research team will ensure that human subjects' procedures are carefully followed so that all study participants are aware and understand that their involvement in this research is voluntary and that their confidentiality will be protected. An application for review will be submitted to the Emory University Institutional Review Board prior to study initiation.

Summary: The proposed study design and research plan provide a unique, yet reproducible and sound method of gathering evidence to support the development of targeted interventions to reduce racial health disparities in breast cancer survivorship among high risk populations.

Definition of Terms:
Breast Cancer Survivor-Women who have been diagnosed with and treated for breast cancer regardless of disease status (either with active disease or in remission).
Cultural Competence- The ability of providers and organizations to effectively deliver health care services that meet the social, cultural, and linguistic needs of patients.
Health Care Provider-Physicians, physician assistants, nurses or other licensed medical professional who provides breast cancer screening, diagnostic or treatment services.
Invasive Breast Cancer-Cancer that grows into or invades normal tissues within or beyond the breast.
Non-Invasive Breast Cancer-Cancers that stay within the milk ducts or lobules of the breast and do not invade surrounding tissue. (Also known as carcinoma in situ or "pre-cancer")
Psychosocial - Of or related to the interrelation of mental, emotional, social, spiritual, quality of life and functional aspects of cancer.
Young Women-Women age 18 to 44.
Survivorship- The health and life of a person with cancer post treatment until the end of life. Survivorship covers the physical, psychosocial, and economic issues of cancer, beyond the diagnosis and treatment phases. It includes issues related to the ability to get health care and follow-up treatment, late effects of treatment, second cancers, and quality of life. Family members, friends, and caregivers are also considered part of the survivorship experience.

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Appendix A

Female Breast Cancer Incidence, Death, and Late-Stage Rates

Figure 1. Female Breast Cancer Incidence, Death and Late-Stage Rates and Trends

		Incidence Rates & Trends			Death Rates & Trends			Late-stage Rates & Trends		
Population Group	**Female Population (An. Avg.)**	**# of New Cases (An. Avg.)**	**Age-adjusted Rate/ 100,000**	**Trend (An.% Change)**	**# of Deaths (An. Avg.)**	**Age-adjusted Rate/ 100,000**	**Trend (An.% Change)**	**# of New Cases (An. Avg.)**	**Age-adjusted Rate/ 100,000**	**Trend (An.% Change)**
US	154,540,194	182,234	122.1	-0.2%	40,736	22.6	-1.9%	64,590	43.8	-1.2%
Georgia	4,838,820	5,997	121.5	-0.3%	1,146	23.4	-1.4%	2,253	45.5	-0.4%
Fulton County	453,948	590	135.1	-0.7%	124	29.2	-1.1%	218	49.6	-0.5%
DeKalb County	357,137	465	135.0	0.4%	87	26.1	-1.2%	183	51.8	0.2%
Henry County	100,4440	109	118.2	1.0%	22	25.1	-0.9%	43	45.6	5.1%
Clayton County	135,658	135	117.0	-2.6%	28	26.9	0.9%	57	46.1	3.0%

Adapted Susan G. Komen Greater Atlanta 2015 Community Profile Report. Data are for years 2006-2010. Rates are in cases or deaths per 100,000. Age-adjusted rates are adjusted to the 2000 US standard population. Source of Incidence and late-stage data: North American Assoc. of Central Cancer Registries (NAACCR)-Cancer in North America (CINA) Deluxe Analytic File. Source of death rate data: CDC-National Center for Health Statistics (NCHS) death data in SEER*Stat. Source of death trend data: National Cancer Institute (NCI)/CDC State Cancer Profiles.

Appendix B

Priority/High Burden County Characteristics

Figure 2-Priority Georgia Region Characteristics					Georgia	U.S.
County	Fulton	Dekalb	Clayton	Henry		
Breast cancer incidence rate, AA women <50, age-adjusted, per 100,000 persons, 2009-2013	47.7	48.5	47.9	58.9	47.5	45.7
Breast cancer mortality rate, AA women <50, age-adjusted, per 100,000 persons, 2009-2013	10.6	7.6	6.4	11.1	7.7	7.8
Total Population estimates, 7/1/15	1,010,562	734,871	273,955	217,739	10,214,860	321,418,820
Total Population Census, 4/1/10	920,581	691,893	259,424	203,922	9,687,653	308,758,538
% Black or AA alone, 7/1/15	44.3%	54.7%	68.7%	41.8%	31.7%	13.3%
% White alone 7/1/15	40.3%	29.7%	13.1%	47.3%	53.9%	61.6%
High school graduate or higher, % of persons age 25 years+, 2010-2014	90.7%	88.4%	81.8%	89.6%	85.0%	86.3%
Bachelor's degree or higher, % of persons age 25 years+, 2010-2014	48.6%	40.3%	18.1%	26.2%	28.3%	29.3%
Median household income (in 2014 dollars), 2010-2014	$56,642	$50,779	$40,314	$60,269	$49,342	$53,482
Persons in Poverty, %	17.4%	20.4%	22.9%	13.7%	17.0%	13.5%

Adapted from NIH-National Cancer Institute State Cancer Profiles: GA Incidence and Mortality Tables, 2010-2014 and U.S. Census Bureau Quick Facts: Georgia Cities Table

Appendix C

Survivor Focus Group Sample Guide

Figure 3 Survivor Focus Group Guide Example

Domain	**Sample Questions**
Diagnosis Experience & Reaction to Diagnosis	*How did you find out that you had breast cancer? How old were you when you were diagnosed?*
Relationships	*What was your spouse/significant other's reaction to your breast cancer diagnosis? How did this influence your treatment decision?*
Impact on Life	*How did breast cancer affect your personal life? How did breast cancer affect your work life? How did breast cancer affect your finances?*
Post-Treatment Concerns	*How do you cope since you have stopped cancer treatment? What physical complaints do you have now that treatment has ended?*
Survivorship	*What does it mean to you to be called a survivor? What concerns do you have as you enter survivorship?*
Support	*Tell me about your support system. What, if any, additional support would have been most helpful?*
Cultural Experiences and Resources	*Given your experiences following diagnosis and treatment for breast cancer, what would you like to see offered to other young AA women coping with this disease?*
Unmet Needs	*What is the worst part about being a breast cancer survivor? How do your health care providers (doctors, nurses, therapists, etc) make this better? How do they make it worse?*

Appendix D

Provider Interview Sample Guide

Figure 4 Provider Interview Guide Example

Domain	Sample Questions
Communication/Provider Sensitivity	*To what extent are patients/clients encouraged to share experiences or ask questions about breast cancer during your professional encounters? Describe your approach to communicating with patients/clients regarding sensitive topics.*
Assessment of care needs	*To what extent are you able to assess non-medical care needs of breast cancer patients in your practice encounters (e.g. psychological, emotional, social, etc.)?*
Availability of Patient Resources	*To what extent are you able to provide your patients/clients with support in coping with psychosocial issues related to breast cancer? To what extent are available support resources tailored to young AA women?*
Training	*Have you received any training in cultural competency? If so, please describe your experience and any lessons learned. How has this training influenced your interaction with patients/clients?*
Awareness of Health Disparities	*How would you characterize the ability of your AA patients/clients to access affordable, quality breast cancer care and support? What barriers/facilitators to care access exist for your AA patients?*