INTRODUCTION

The text box (right) contains reviewers' scores for our prior submission. Responses to specific weaknesses by category are summarized below, with references to details in the application. No weaknesses were noted for INVESTIGATORS or ENVIRONMENT. Changes in the proposal are marked with a vertical line in the right margin.

REVIEWER	SIG.	INVEST.	INNOV.	APP.	ENV.
One	2	1	2	4	1
Two	2	1	2	5	2
Three	1	1	1	3	1

OVERALL IMPACT: Concerns related to lack of details on components of the approach and absence of a true control group contributed to a lower evaluation on this criterion. A description of how these issues have been addressed in the current submission is described below (see APROACH).

SIGNIFICANCE: Additional discussion of the relevance of this study to other populations has been added in this revision to address concerns about generalizability to other populations (see Research Strategy-Significance). Consideration of minor methodological concerns detailed in critiques for Approach are addressed below (see APPROACH) and in the revised application (see Research Strategy-Approach).

INNOVATION: Added discussion of the applicability of novel approaches, tools, and interventions to other populations to address concerns about generalizability is in this revision (see Research Strategy-Innovation).

APPROACH: Clarification and related justification is included in the revision to address concerns about the unstructured community approach and generalizability of study findings (see Research Strategy-Approach and Appendix-Menus of Community Strategies). We have reduced targeted cancer types to three with similar courses of treatment and long-term prognosis (breast, prostate, colorectal) to address concerns that about potential variability in study outcomes due to ability to adhere to a weight loss program because of clinical course (see Research Strategy-Approach-Target Audience and Location). Justification for the selected age-range based on the team's prior research and desire to maximize participant recruitment is added (see Research Strategy-Approach-Preliminary Studies and -Target Audience and Location). Additional justification for the broad definition of "family member" is no included (see Research Strategy-Approach-Methods). Planned analyses based on intervention intensity have been added (see Research Strategy-Approach-Methods). Clarification of the expansion of the existing community advisory board (CAB) to include additional cancer survivors and family members and CAB involvement (1 face-to-face meeting; 3 teleconferences per year) is added (see Research Strategy-Approach-Methods and Budget Justification). Additional discussion of the selection of study variables (see Research Strategy-Approach-Conceptual Framework) and further details regarding methods (including CHARP training) have been added as possible within the 12-page limit (see Research Strategy-Approach-Methods). Further, we have specifically identified individual, family, and environmental levels for intervention in this study (see Research Strategy-Innovation). Potential contamination and strategies to address this threat are discussed in greater detail in this revision (see Research Strategy-Approach-Study Design). We have also attempted to increase understanding and readability of the data analysis section (see Research Strategy-Approach-Data Analysis). Of significant note, we have revised our study design to include a 3rd non-treatment arm to address concerns related to the lack of a true control group in our previous 2-group design (see Specific Aims, Research Strategy-Approach-Study Design and Human Subjects). Efforts to address the prior weakness within the budgetary constraints resulted in the decision to focus the proposed study on counties within one state (Alabama). Resulting decreases in travel expenses between central project staff offices at UAB and field sites in Mississippi allowed for funds to be expended in the recruitment and retention of a cohort of African American cancer survivors and family members that we will observe longitudinally for natural patterns in weight status and related behavioral and clinical outcomes (see Budget and Justification, Research Strategy-Approach-Study Design and Methods). We believe the revised design greatly strengthens the rigor of the study and allows us to address concerns from our current community partners.

ADDITIONAL CRITERIA/CONSIDERATIONS: While the Scientific Review Officer's summary of the discussion of additional review criteria suggests all criteria were acceptable, at the suggestion of Reviewer 1 regarding protection of human subjects, we have added Karen Meneses, Ph.D., R.N., FAAN (Professor and Associate Dean for Research, UAB School of Nursing), a cancer survivor researcher not affiliated with this project to aid the investigative team in implementing the Data Safety and Monitoring Plan (see Research Strategy-Approach-Human Subjects and Letters of Support).

Obesity, believed in large part to be the result of positive energy balance, has been implicated in the development and recurrence of cancer, decreased cancer survival, as well as co-morbid conditions such as cardiovascular disease, type 2 diabetes, and hypertension.[1-3] As such, weight loss interventions targeting overweight and obese cancer survivors may have multiple benefits including decreased risk of cancer recurrence and cancer-related mortality, reduced risk of co-morbid conditions, and improved quality of life and increased survival rates.[4-6] Benefits for African American cancer survivors may be even greater given their higher cancer burden[2] and increased mortality from co-morbid conditions.[1-3] However, in the general population, African Americans are often less successful with weight loss than their white counterparts. Cited barriers include decreased motivation, lack of social support, and environmental challenges [e.g., limited availability of healthy affordable food and access to safe and convenient opportunities for physical activity (PA)]. Multilevel (individual, environment/policy) approaches have shown promise in achieving and sustaining weight loss;[1-3] however, to our knowledge, there are no published studies of multilevel weight-loss interventions for African-American cancer survivors. The proposed study leverages a 9-year academic-community partnership (UAB Deep South Network for Cancer Control) to reduce or eliminate cancer health disparities between African Americans and whites in the Deep South. Using a Community-Based Participatory Research (CBPR) approach, we are ultimately interested in testing the efficacy of a multi-level, evidence-based, and culturally tailored behavioral weight loss intervention among overweight or obese African American cancer survivors and their overweight or obese family members. Given the prominent role of family and community in the sociocultural context of many African Americans, a multi-component weight loss intervention that intervenes at the individual, family, and environmental levels may lead to increased weight loss and improvement in cancer-related outcomes.

Specific Aims

1. Adapt an evidence-based behavioral weight loss intervention for implementation with overweight or obese African American cancer survivors and their overweight or obese family members.

2. Select and implement community strategies supporting weight loss and weight loss maintenance.

3. Recruit overweight or obese cancer survivors (index participants) and overweight or obese family members (co-participants) for enrollment in a 24-month weight loss program or non-treatment comparison group.

4. Conduct a vanguard study of the effects on excess body weight and related behavioral and clinical outcomes among overweight or obese African-American cancer survivors (index participants) residing in communities assigned to one of three treatment arms: culturally-adapted behavioral weight loss intervention (Group 1), culturally-adapted behavioral weight loss intervention plus community strategies to support weight loss (Group 2), or non-treatment comparison group (Group 3).

   Primary Hypothesis 1: Index participants in Groups 1 and 2 will experience greater improvement in weight status at 6-mos (end of the intensive phase of the weight loss program) and 24-mos (end of the maintenance period of the weight loss program) compared with participants in Group 3.

   Primary Hypothesis 2: Index participants in Group 2 will experience greater improvement in weight status at 6-mos (end of the intensive phase of the weight loss program) and 24-mos (end of the maintenance period of the weight loss program) compared with participants in Group 1.

   Secondary Hypotheses:

   1. Index participants in Groups 1 and 2 will experience greater improvement in clinical outcomes (e.g., fasting insulin, blood pressure) and health related quality of life (HRQoL) by 6-mos compared with participants in Group 3. These differences will be sustained at 24-mos.
   2. Index participants in Groups 1 and 2 will experience greater improvement in overall healthy eating pattern (e.g., reduced energy intake, average daily % of energy from fat, diet quality, servings of fruit and vegetables) by 6-mos compared with participants in Group 3. These group differences will be sustained at 24-mos.
   3. Index participants in Groups 1 and 2 will experience greater improvement in adherence to PA recommendations by 6-mos compared with participants in Group 3. These group differences will be sustained at 24-mos.

A. SIGNIFICANCE

A.1 What groups experience higher rates of cancer incidence, morbidity, and mortality?

Three obesity-related cancers (breast, prostate, colorectal) represent over $^1/_3$ of cancer diagnoses and 112,520 deaths in 2009.[5] Despite notable progress in early detection and treatment, racial/ethnic minorities, socioeconomically disadvantaged, and rural residents experience greater cancer burden.[2] Deep South residents, of whom $^1/_3$ are African American,[8] are at even higher risk.[9-10] Cancer death rates in Alabama (AL) highlight the problem (Table 1). Geographic disparity is explained, in part, by greater poverty[11] and limited access to healthcare and health-promoting environments (e.g., food access; recreational facilities).[12-13]

Table 1. Annual Cancer Death Rates[a] by Race- U.S. vs. Study Sites (AL and MS)[7]

Cancer Site	U.S.		AL	
	W	*AA*	*W*	*AA*
Breast	23.4	32.4	22.6	32.3
Prostate	22.8	54.2	22.4	68.0
Colorectal	17.1	24.7	17.0	25.8

[a]per 100,000; W=White; AA=Black/African American

A.2 What groups experience higher rates of obesity?

Excess weight is a problem among all US residents, but African Americans are more likely to be overweight or obese (BMI≥25 kg/m^2) and over twice as likely to be severely obese (BMI≥40 kg/m^2) as other racial/ethnic groups.[14] Over 76% of African Americans are overweight or obese;[14] with rates highest in the South.[10] The rate of severe obesity for African Americans in AL is 40%, while rates are 27% for Caucasians and 29% for Hispanics.[10] Further, targeted study sites are among the most obese in the nation (rates ~44%).[10]

A.3 Why focus on weight loss for cancer control and prevention?

Weight status plays a major role in several cancers.[15] Obesity and overweight are risk factors for postmenopausal breast cancer, and are associated with reduced disease-free and overall survival. Further, excess weight is linked with risk of the most aggressive and fatal forms of prostate cancer and are poor prognostic factors at diagnosis. Observational and indirect evidence from clinical trials suggest that obesity, decreased PA, and poor diet may adversely affect disease-free and overall survival from a host of additional cancers including colorectal, cervical, and non-Hodgkin lymphoma.[16] Few weight loss programs have targeted cancer survivors and none have simultaneously intervened on the individual, family, and environment. Links between obesity and cancer risk also warrant intervention on other high-risk groups (overweight family members).

A.4 Why might culturally tailored interventions be required in African American populations?

Weight loss intervention for African Americans in the Deep South is logical; however, our community had initial concerns about community acceptance of a weight loss program for cancer control and prevention. Concerns mirror findings that only 51% of Americans realize obesity is a cancer risk factor[17] and African Americans are even less likely to see the link.[18] Partner concern was later mitigated by recent reports linking cancer with excess body fat.[15] Partners also cautioned about fear and stigma associated with cancer diagnosis among African Americans,[19-23] an issue that has been a focus of attention in our work to eliminate health disparities in the Deep South.[24] Activities in Year 1 of the proposed study include formative work to better assess cultural beliefs about links between obesity and cancer development and survivorship, fear and stigma, and other salient issues. Without increasing the perceived risk association between weight and cancer or establishing an environment where discussions about cancer are not stigmatizing, any potential intervention is likely to fail.

A.5. What are the evidence-based interventions for weight loss among African Americans?

There are few published evidence-based behavioral weight loss interventions for minority populations. A recent review[25] found only 24 controlled studies with minority sample sizes of at least 50% (or ≥25). Nine had only minority participants. Seven focused on modification of diet and PA, with only 4 delivered in community (vs. clinical) settings.[26-29] Variability in treatment length (2.75-58 mos) and intervention components (diet, PA, counseling and medication) were noted.[25] Weight-loss ranged from 0.4kg-8.6kg with a mean of 3.5kg. Racial/ethnic subgroup analysis was listed for only 1 study;[30] a clinically-based study with modest (2.35kg) weight loss in African Americans.[25] More promising outcomes are noted in randomized trials published since 2005. The Diabetes Prevention Program (DPP),[31-33] Look AHEAD (Action for Health in Diabetes),[34-36] Weight Loss Maintenance (WLM),[37] and Supporting Healthy Activity and eating Right Everyday (SHARE)[38] trials achieved clinically significant weight loss in African Americans (Table 2). DPP, Look AHEAD, and WLM were modified to target African Americans and SHARE was culturally-specific to African Americans. SHARE also included a treatment arm where participants enrolled with 1-2 family members or friends (family stratum) as a cultural adaptation strategy given the role of family and support networks for African Americans.[39-41] Each trial included behavioral modification of diet and PA and an initial intensive intervention (weekly for ~6 mos) followed by less frequent (e.g., monthly) contact for an extended period (up to 4 yrs). Sessions were delivered by trained experts in nutrition, counseling/psychology, and exercise science. WLM was selected for our study based on its primary outcome of long-term weight loss maintenance, high sample of African American participants, and reduced participant burden (i.e., phone-based maintenance phase). We believe; however, adaptation to the

unique social and cultural experiences of African Americans in the Deep South[42] and cancer survivors and family members is needed. We will add relevant content pertinent to cancer survivorship and use SHARE's family stratum enrollment given the relevance of family/friend support for African Americans and cancer survivors[43] and evidence supporting the need to study and intervene on family and caregivers of survivors.[44-45]

Table 2 Comparison of body weight change among participants of randomized trials with diverse samples

Study	Sample	Intervention	Weight Loss % Δkg (%SD) *AA Participants*
DPP (Lifestyle Intervention Arm) [31-33]	962 adults age ≥25 years with BMI ≥24 21% African American	Intensive Lifestyle Intervention consisted of a 16-session diet (caloric restriction) and PA behavior (150 min/wk) modification core curriculum delivered by case managers in individual sessions over 6-mos followed by individual (usually monthly) and group sessions (~3/yr) reinforcing behavior changes.	6-mo: -5.8 ± 5.8 12-mo: -5.8 ± 5.8 18-mo: -5.6 ± 6.1 24-mo: -4.6 ± 6.2 30-mo: -3.6 ± 5.0
LookAHEAD (Intensive Lifestyle)[34-36]	2570 adults age 45-74 with BMI ≥25 15.5% African American	Modeled after the DPP, the initial 6-mo program combines caloric restriction and increased PA (175 min/week) in 3 group and 1 individual session/month led by registered dieticians, behavioral psychologists, and exercise specialists. Group sessions every other month and monthly individual sessions augmented with phone, mail and email contact for month 7 and up (through 4 yrs).	12-mo: 6.9 ± 5.4
WLM (Intensive Weight Loss Program - Phase I)[37, 46]	1685 adults age ≥25 with BMI 25-45 kg/m^2 44% African American	Intensive Weight Loss (Phase 1): 20 weekly group sessions led by nutrition and behavioral counselors focused on calorie reduction (~500 kcal less/day) and increased moderate-intensity PA (180 min/wk); Maintenance Interventions (Phase II): The next 30-mos is similar to Phase 1 but with a 45 min/week increase in PA. Participants assigned to (1) combined monthly telephone and personal contact or (2) internet-based program (continuously available).	6-mo: -4.8 ± 5.2
SHARE[38] (Family Stratum-High Support)	130 index participants; 153 partners 100% African American	Adapted from DPP and LookAHEAD, the initial 6-mo program included weekly 90-min group sessions led by African American counselors with graduate training in nutrition, exercise science and/or weight counseling. Sessions focused on caloric restriction and gradual increase in PA to 180 min/wk. After the initial 6 mos, groups met bimonthly for 6 mos, then monthly for an overall intervention duration of 2 years. In the *family high-support* arm, index participants and partners participated in all sessions together, and were counseled on how to provide social support to one another, and were given homework assignments to collaborate with one another between intervention sessions.	Index Participants 6-mo: -5.2 ± 4.0 12-mo: -5.6 ± 5.1 18-mo: -4.6 ± 6.8 24-mo: -3.1 ± 6.1 Partners 6-mo: -4.3 ± 4.6 12-mo: -4.0 ± 5.8 18-mo: -3.8 ± 6.4 24-mo: -2.2 ± 6.7

A.6 What is the potential benefit of intervening with the built environment?

Behavioral change interventions alone may be insufficient for sustained weight loss if the environmental context is unsupportive.[47] Cumulative evidence points to environmental factors (food access; PA resources) for weight management.[48-50] Environments in which African Americans and rural residents live may promote obesity[51-53] and barriers to weight control[47,52,54] due to limited number of supermarkets[12,55] and poor access to safe places to engage in PA.[13,56] Larger food stores are more likely to stock healthy foods[55,57] at lower cost.[58-60] Similarly, light traffic, sidewalks, and safety from crime characterize neighborhoods with increased PA.[61] There is limited published work on food and activity environments in rural areas despite higher prevalence of obesity.[62-65] Community-level interventions have been successful in improving dietary intake,[66-68] increasing PA,[69-70] and reducing or preventing obesity.[71-72] Interventions like the menu of strategies[67] included in the proposed study are both cost-effective and efficacious in reducing disease incidence.[73] However, these interventions have focused almost exclusively on urban and non-minority communities. Understanding of the combined impact of individual and environmental factors for weight management among rural residents is warranted.[58,74-76]

A.7 Summary of study significance for advancing the field of cancer and energetics

The proposed study targets the most vulnerable populations for cancer and obesity – African Americans residing in the Deep South. Extremely high rates of obesity, limited awareness of links between obesity and cancer, and fear and stigma likely contribute to disparities in cancer mortality. Weight loss can lower risk of recurrence and improve quality of life among cancer survivors, and lower cancer risk for family members. Evidence-based weight loss programs exist; however, for maximum reach, they must be responsive to the unique social, cultural, and environmental contexts of the populations targeted. The success of the proposed study would aid the understanding of multi-level approaches to obesity control among African-American cancer survivors and family members. While we have targeted African American residents of the rural Deep South for this study, it is very likely that findings gleaned here can be applied to groups beyond this group. WLM has been effective in achieving and maintaining weight-loss in racially- and geographically- diverse populations[37,46] and community strategies have been implemented and evaluated in communities throughout the country.[67]

B. INNOVATION

The proposed intervention for survivors of obesity-related cancers and family members is innovative and challenges prevailing clinical practice paradigms. The proposed study is a first of its kind. Building on a 9-yr community-academic partnership, we will test a multi-level intervention to promote weight loss among over-

weight African American cancer survivors in rural communities in the Deep South. Interventions at the individual (WLM for cancer survivor), familial (WLM for family member), and environment (community strategies) levels are included. We employ CBPR and have included community members in every aspect of the proposed research (including proposal development). We will modify the WLM program using social and cultural adaptations to increase relevance to African-American cancer survivors and family members residing in rural communities. Adaptation occurs at multiple levels including culture-specific program content (tailored for race/ethnicity and rural residence) and dual enrollment of cancer survivors and family members. We model our intervention after SHAPE and Demark-Wahnefried's Daughters And MothErS (DAMES) Against Breast Cancer. Further adaptation of the program challenges the prevailing paradigm that clinically significant weight change only occurs in clinic-based settings and/or delivered by content experts. Prior work[28, 77-78] suggests trained community leaders are capable of delivering behavioral interventions; however, they are rarely used. For evidence-based programs to reach those in greatest need, they must be accessible beyond clinic settings and communities with large numbers of experts (both less common in rural areas). Further adaptation to allow trained community health leaders to deliver program content will occur. This study is also novel in that it will test the impact of adding a community-level intervention to a weight loss regimen. Few studies have tested this approach, and none have focused on rural communities in the Deep South. We will provide community-members a menu of potential options to choose from and will provide direct funding and technical assistance to implement these strategies. We expect findings from this study will easily generalize to other sites in our academic-community network and the Deep South region. In addition, we see tremendous potential to greatly inform the work of others across the country. We are utilizing evidence-based interventions with demonstrated efficacy in diverse populations/locations and will tailor to the unique needs of the targeted group using established research methods.[111] Further, novel approaches, tools, methodologies, interventions, and lessons learned will be widely shared to diverse audiences (see Approach-Methods-Aim 4).

C. APPROACH

C1. Preliminary Studies

Study investigators are transdisciplinary (public health, nutrition science, medicine, nursing, exercise science) and highly skilled in CBPR, cancer prevention, cancer survivorship, weight loss interventions, recruitment and retention of African American research participants, multilevel assessments, and qualitative and quantitative analysis. Below is a brief discussion (see biosketches for more detailed descriptions).

Interventions for Cancer Prevention and Control

Monica Baskin, PhD, a behavioral scientist, was an investigator for the NCI-funded Deep South Network for Cancer Control (DSN).[24] For > 9 years, the DSN has engaged in CBPR to eliminate cancer disparities between whites and blacks in AL and MS. The DSN includes Community Health Advisors as Research Partners (CHARPs), lay health advisors trained in cancer education, clinical trials, participant recruitment and retention, and group facilitation.[79] Over 1300 CHARPs have been trained to date with 420 currently active. Dr. Baskin worked with DSN staff and CHARPs to implement NCI's Body and Soul program[80] in 20 churches and a community walking program with 1865 participants.[81] **Wendy Demark-Wahnefried, PhD, RD,** a nutrition scientist, has extensive experience and success conducting large NIH-funded trials to promote improved diets, PA and weight loss among cancer survivors and other high risk groups [e.g., Project LEAD (n=182), FRESH START (n=543), RENEW (n=641)[82-84]]. These programs were implemented with cancer survivors with broad age ranges. For example, the FRESH START sample was age 28-85. Protocols from RENEW[84] (tailored home-based diet and exercise intervention for breast and prostate cancer survivors) and DAMES (home-based weight loss trial of overweight breast cancer survivors and overweight daughters) will aid adaptation of WLM materials. Dr. Demark-Wahnefried, founded the North Carolina Cancer Control Plan which led to several community projects in racially diverse populations,[85] and was the Duke PI on the collaborative North Carolina Black Churches United for Better Health study, a multilevel dietary intervention for rural African American adults.[86]

Dr. Baskin (Research Project Leader) and **Drs. Ard and Demark-Wahnefried** (Co-Investigators) are part of NCI's CNP Center for Deep South Network for Cancer Control. The research project for this U54 grant involves testing the efficacy of community-level interventions in support of weight loss in overweight African American women living in the rural Deep South. Like the proposed project, the recently-awarded study includes randomizing sites to a modified WLM intervention alone or with community-level strategies. Several differences in the proposed study highlight how the 2 studies are substantially different in content and scope. First, the target populations differ. The R01 study specifically targets cancer survivors (men and women) and focuses on tertiary rather than primary prevention (focus of U54). Second, the R01 includes an additional level of intervention (interpersonal) by enrolling cancer survivor-family member pairs. Third, the individual level intervention will be modified to address lifestyle change for cancer survivorship, incorporating prior work from

RENEW and DAMES. Fourth, targeted sites for the R01 are not part of the U54 research project. Finally, the proposed study addresses an important limitation of the U54 study by including a non-treatment control group.

Other Interventions for Weight Management

Jamy Ard, MD, a physician-scientist, has contributed to multiple multi-site diet/weight loss trials with significant African-American samples. He was a co-investigator on the PREMIER trial (Durham center), an 18-mo, multicomponent lifestyle intervention for blood pressure reduction.[88] Overweight/obese participants in active treatment (n=694) received 33 intervention sessions and recommendations to self-monitor diet and PA. Participants lost an average of 5.3 ± 5.6kg at 6 mos and 4.0 ± 6.7kg (4.96% of body weight) by 18 mos. Those who lost 3.5% and maintained their weight loss (n=195) kept a higher number of food records/wk (2.1 ± 2.1), reported more exercise days/wk (1.9 ± 1.9), and attended more intervention sessions.[89] **Dr. Ard** also collaborated with the WLM trial. On average, phase I participants (44% black; 67% female) attended 72% of the 20 group sessions, reported 117 mins of moderate-intensity PA/wk, kept 3.7 daily food records/wk, and consumed 2.9 F&V servings/day. Weight was measured for 92% of Phase I participants with weight change of -5.8kg $\pm$ 5.2kg (67% lost $\geq$ 4kg). All race-sex subgroups experienced clinically significant weight loss. Dr. Ard's weight management expertise and familiarity with WLM protocols will significantly contribute to the proposed study.

Gary Hunter, PhD, an exercise physiologist, has >30 yrs experience conducting clinical trials involving exercise training and testing (much of it in older adults for whom prostate and breast cancer are prevalent). Trials have included long-term weight loss interventions with significant African American samples[90-92] and measurement of free living energy expenditure.[93] Hunter et al., have found that following weight loss, African American women are less physically active[92] and more likely to overestimate PA[94] than their white counterparts. In addition, perception of exercise difficulty is predictive of weight gain.[95] The proposed study will emphasize continued participation in enjoyable PA that may be perceived as less challenging (e.g., brisk walking, aerobic dance) during weight maintenance and will enhance self-reported PA with the use of accelerometers in a subsample. **Dr. Baskin** served as co-PI on an NHLBI-funded trial to develop and test a culturally appropriate obesity prevention program for overweight African American adolescents and caregivers.[87] A total of 147 overweight (BMI $\geq$ 80th percentile) participated in the 6-mo behavioral intervention to reduce BMI by diet modification and increased PA. Interactive group sessions (weekly 90-mins) augmented with motivational interviewing phone calls made up the treatment arm. Girls in the treatment arm attending $\geq$ 75% of sessions showed favorable changes in BMI, weight, waist circumference, lipids, glucose, and insulin at 6-mo follow up. The adiposity effects were sustained among these "high attenders" at 1-year follow-up.[87] Dr. Baskin's training and experience in group-based weight management and motivational interviewing will be utilized in the proposed study.

Cultural Adaptation of Interventions Promoting Weight Loss

A prior study by **Dr. Ard** demonstrated the feasibility and effectiveness of modifying a traditional weight loss intervention to be "culturally appropriate" for African-American participants.[96] Modifications included decreased cost, use of foods that were culturally-familiar to the participants, addressing attitudes about exercise, and inclusion of family members in weight loss efforts. Participants enrolled in the adapted- vs. traditional intervention showed BMI decreases from 37.8 kg/m^2 to 35.3 kg/m^2 ($p<0.01$) with the control group showing no appreciable change over 8-weeks. Work by **Drs. Ard** and **Baskin** further underscore the need for cultural consideration in weight loss interventions. In a study of racial influences and weight related beliefs,[97] structured focus groups were conducted with black (n=30) and white (n=30) women. Participants generated responses to the question, "How does being a black (white) woman affect your weight?" Black women generated 48 unique ideas, including unhealthy food preparation, poor food selection habits, lack of exercise, stress, increased risk of chronic diseases and associated medical costs. White women produced 32 responses, including distorted expectations of perfect body type, success linked to thinness and beauty, social pressures, media, and men's preferences. Additional data on cultural tailoring will be gleaned from **Dr. Baskin's** current NCMHD-funded study in which 360 African American women in the Deep South are being followed for 2 years to evaluate associations between social and cultural influences and dietary intake. Knowledge and techniques from each of the aforementioned studies will be used to tailor WLM protocols and materials for our target population.

Environments Supportive of Weight Management

Jennifer Robinson, PhD, RN a clinician-scientist, is skilled in identifying community resources and studying social determinants of health, particularly in rural areas.[102] She leads a study to (1) identify the environmental determinants of walking in older African Americans, (2) modify an existing environmental survey instrument, and (3) pilot the use of global positioning system (GPS) to validate environmental determinants.[103] Focus group and photovoice methodology are used to identify salient factors of neighborhood environments influencing walking among African American adults. She also led a study that retrospectively geocoded participants in the Jackson Heart Study[102] to facilitate future spatial epidemiology studies. While geocoding participant data is

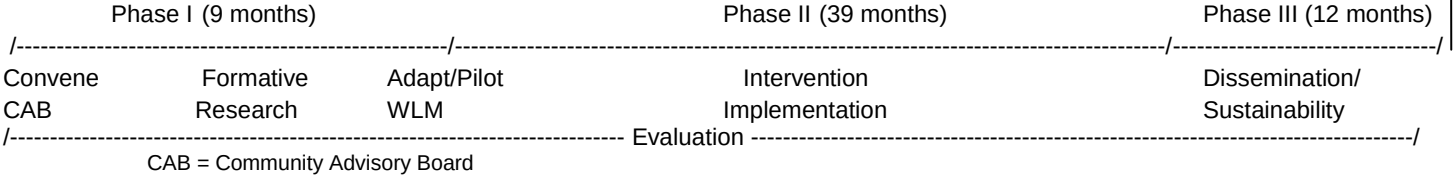
cost-prohibitive in the proposed study, we will utilize protocols from her prior work to enable future investigation of links between the built environment and health behaviors in our study population. **Dr. Baskin** led a project with DSN CHARPs to measure the nutrition and PA environments in a rural county. CHARPs were trained on the Nutrition Environment Measures-Stores (NEMS-S) scale[98] by Dr. Baskin (a certified NEMS trainer). Food license data and ground-truthing (where community members verified stores on the list, making additions and deletions as needed) identified 31 stores (70% convenience). Twenty-seven (87%) were assessed in opposing seasons to capture variability. Limited availability of healthier items was found (avg 7.65 out of 30).[99] Findings likely relate to the limited number of grocery stores and supermarkets. Similarly, CHARPs and DSN staff were trained on the Rural Active Living Assessment (RALA) tool[100] by Dr. Baskin (trained by instrument developers). A total of 24 street segments were selected[100] and assessed by CHARPs and DSN staff completed the town-wide and program and policy assessment tools. The county had limited safety features, no policies requiring pedestrian walkways, and limited access to free or low-cost recreational facilities. We will incorporate training and assessment tools from this work into the proposed study. In another study, **Dr. Baskin** in partnership with a local non-profit faith-based organization, completed a study concerning perceived environmental influences on childhood obesity[101]. Caregivers of African American 3-11 year olds (n=30) photographed aspects of the environment they believed influences childhood obesity. Community partners, trained by Dr. Baskin, conducted participant interviews, and assisted in the data analysis and dissemination of findings.[101] A similar methodology (photovoice) will be used in the proposed study to capture community assets supportive of weight loss.

C.2. Overview of Proposed Strategy

Reducing excess weight is beneficial in to cancer prevention and survivorship; however, achieving and maintaining weight loss is complicated by individual, socio-contextual and environmental factors. Multilevel community-based interventions have been successful in achieving weight loss among select groups;[71-72] however, to date, there are no published studies of multilevel weight loss interventions for groups at greatest risk for obesity (e.g., African Americans residing in rural communities in the Deep South) or cancer survivors. Our study will evaluate the efficacy of a multi-level and culturally relevant intervention on weight loss among overweight African American cancer survivors residing in the rural Deep South. The proposed three-group clustered design will enroll 450 overweight African Americans (225 cancer survivors and their 225 family members) $\geq$ 19 years residing in 9 rural communities in AL. Communities will be assigned to receive either an evidence-based and culturally-adapted weight loss intervention (Group 1), an evidence-based and culturally-adapted weight loss intervention plus community strategies to support weight loss (Group 2), or a non-treatment longitudinal comparison group (Group 3). We hypothesize that participants in Groups 1 and 2 will experience greater improvement in metabolic (e.g., weight, fasting lipids) and behavioral (e.g., diet, physical activity) outcomes relative to participants in Group 3. Further, we expect that participants in Group 2 will experience greater improvements in metabolic and behavioral outcomes than Group 1. The proposed study design and methods extend previous CBPR by study investigators by undertaking a controlled comparison of evidence-based interventions designed to reduce risk of cancer reoccurrence (cancer survivors) or cancer diagnosis (family members) among African Americans living in rural communities in the Deep South by facilitating weight loss.

C.3. Timeline

The figure below is a summary timeline by study phase (see Appendix for more detailed version)



C.4 Study Design

The proposed study constitutes a three-group clustered design[104] to answer the research question: ***Do evidence-based community strategies supporting weight loss in addition to an evidence-based weight loss program result in greater weight loss among overweight cancer survivors residing in rural communities in the Deep South?*** When randomization of individuals to treatment or control groups is impossible, impractical or unethical, the use of group randomized design is a viable alternative. For this study, a key element of the approach to weight loss is the influence of the community environment. Thus, randomization of communities (clusters) retains the methodological strength of randomization, while capitalizing on the influence of the organizing unit. Cluster randomization reduces risk of cross-contamination in communities that are socially connected and/or are naturally clustered (e.g., geographic proximity) such as the proposed sites. In addition to the clustered design, we will stratify sites (Groups 1 & 2) based on geographic proximity (e.g., adjacent

counties) prior to randomization to increase to further minimize potential contamination between study arms. To address the critique of our prior submission related to the absence of a non-treatment control condition, we have added a non-treatment arm (Group 3). To accommodate this change, we now only include DSN sites with no competing weight-loss programs from AL (n=6). This allowed us to reduce costs for interstate travel to DSN counties in Mississippi and offset increased costs of recruitment and retention of a longitudinal cohort for comparison. Due to the limited number of DSN counties in AL and lack of support from AL DSN sites to be assigned to a non-treatment comparison group, we will expand the DSN into three new counties demographically-matched to the current sites (see Letters of Support and Appendix-Map of Targeted Communities). The new counties would make up Group 3. Participants are not sampled independently but within communities and families with a cancer survivor. Randomization of participants in clusters (communities) and nests (families) as opposed to each person individually has important consequences for sample size estimation, interpretation and analysis. Observations of individuals in the same cluster tend to be correlated (non-independent), therefore the effective sample size is less than the actual number of individual participants suggests. We have taken this into account in evaluating the proposed sample and statistical power described below.

C.5 Conceptual Framework

Our study extends a 9-year academic-community partnership to better understand community needs and design programs with maximal appeal to the targeted group.[105] The proposed research closely adheres to the nine principles of CBPR[106] (see Appendix for detailed description) and may offer the greatest promise for addressing cancer disparities.[107] Community partners were directly involved in identifying the problem and shaping the study design. They will likewise participate in implementation, evaluation and dissemination of findings. Our study is predicated on the premise that behavioral weight loss interventions are viable and beneficial to reducing cancer risk and improving cancer prognosis. Grounded in a Social Ecological Model (SEM),[108] we believe health behaviors promoting weight loss (and thus lower risk of initial and recurring cancer) are influenced by interactive relationships between the individual and his/her environment (social and physical). Behavioral choices supporting energy balance have multiple levels of influence including individual factors (e.g., demographics, health history, self-efficacy), interpersonal factors (e.g., social support, social/cultural norms about eating and exercise, and neighborhood perceptions) and community factors (e.g., availability of healthy affordable foods, access to safe and convenient PA resources). Controlling for individual and intrapersonal factors, health indicators such as weight status are increasingly attributable to community-level factors. As such, greater weight loss is more likely to occur in the context of communities supportive of energy balance. Evidence-based community strategies[67] to be implemented in this study are generally guided by a SEM with particular focus on upstream approaches (e.g., environmental/policy) to obesity prevention. The evidence-based WLM is guided by multiple behavioral theories including Social Cognitive Theory, behavioral self-management techniques, and motivational enhancement techniques.[37] The intervention is guided by the premise that excessive weight is a function of high caloric intake and limited PA.[109] It is presumed that increased PA, reduced intake of energy-dense foods, and improves dietary quality (i.e., increased consumption of F&Vs, low-fat dairy, and fiber; and decreased consumption of saturated and total fat and refined carbohydrates) will contribute to sustainable weight loss. To test the efficacy of the proposed interventions, we will collect data on variables across the SEM. Variables selected are based on multiple prior studies demonstrating a consistent positive relationship between specific theoretical constructs of individual behavior change (i.e., self-efficacy, social support) to successful weight loss among African Americans in weight loss interventions.[126-127] Additional interpersonal variables (e.g., social and cultural norms, perceived neighborhood environment) have been postulated as influencing weight status; however, there has been limited empirical investigation of these constructs. They are included here to test the potential impact of these variables on weight loss intervention success.

C.6 Target Audience and Location

Overweight African American survivors of obesity-related cancers with similar course of treatment and long-term prognosis (breast, prostate, colorectal) and their overweight family members residing in 9 rural DSN counties in AL are targeted. The targeted region (AL Black Belt) has historically lacked access to adequate health and social services[24] and has an average annual per capita income of $12,691.[110] Counties were selected based on demographic similarity and desire to maximize access to African American cancer survivors. Selected counties have a median of 25 new African American adult cases of obesity-related cancers per year,[7] year (potential of 125 survivors within 5 years of diagnosis). To maximize recruitment, we will enroll cancer survivors age 19 (age of majority in AL) and up; though from our prior work,[83] we suspect the lowest end of the age range to be about 30 years. Further, we expect to accrue 20%, well within the accrual seen in our prior work.[83] We recognize residents of existing DSN counties are unique in that they have potentially benefited from 9+ yrs of cancer outreach and education. As such, findings may have limited generalizability. However, the ad-

vantage of working within the DSN relates to the established community trust, mutually-beneficial academic-community partnership, and our ability to offer a requested intervention. Given historical challenges engaging this population in cancer research and noted stigma about the topic, a convenience sample may be more ideal to establish feasibility, acceptability and potential outcomes prior to broader investigation. Further, the DSN includes 22 counties in AL and MS and thus generalizability within the DSN is a substantial part of this region.

C.7 Methods

Aim 1. Adapt the WLM intervention for African American cancer survivors and family members

1.1 Expand DSN into Three New Counties. To facilitate recruitment of a non-treatment control group to be observed longitudinally for natural patterns of metabolic and behavioral outcomes, we will expand the existing DSN network into three new counties demographically matched to the six current DSN sites. We will work with partners in each county (see Letters of Support) to identify applicants for a part-time county coordinator (CC) and 10-15 CHARPs and promote and disseminate information regarding the DSN in their communities. CCs and CHARPs will participate in a 10-week training on the community health advisor model[79] conducted by Ms. Claudia Hardy, who has led training efforts for over 1300 DSN CHARPs and staff. Training will focus on basic cancer education, group facilitation, and community leadership skills. This training is to bring new CHARPs in line with the skills and training of existing CHARPs. Project-specific training of CHARPs is described below.

1.2 Identify and Convene Community Advisory Board (CAB). We will utilize a CAB made up community representatives (including cancer survivors and family members) to help guide our work. CAB members will provide advice, counsel, and guidance to the investigative team and lead community forums where local asset and needs assessment findings are presented. We anticipate six CAB members with general familiarity with 1 or more of the proposed study sites. CAB members will be drawn from the current membership of the DSN CAB (n=10) based on the aforementioned characteristics and availability of time. The CAB will offer input throughout the project. There will be a one-day face-to-face meeting in Years 1 and 5 (to aid in formative research and dissemination planning, respectively) in addition to quarterly teleconferences in all years.

*1.3 Adapt Weight Loss Maintenance (WLM) intervention. W*e will review WLM protocols (available at: http://www.kpchr.org/WLMPublic/public/default.aspx) and modify with respect to cancer-specific content and cultural relevance. Content concerning familial (genetic) links to cancer; association between obesity and cancer prevention and survivorship; relevance of nutrition and PA to cancer risk, prognosis and quality of life; relevance of familial support in weight loss will be added based. Resnicow's[111] framework will be used to address unique social and cultural factors influencing energy balance in this group. Investigators, community health educators (CHEs), and select CHARPs will review program materials and help in modification. We expect additional content will extend Phase I by 1 mo and thus we propose a 6-mo Phase I intervention. We will also reduce Phase II to conform to a total 24-mo intervention to minimize participant burden and respond to financial and time constraints imposed by the overall project budget and timeline. Despite the truncated follow-up, we are confident that a 2-yr follow-up is sufficient to demonstrate longer-term weight maintenance.

1.4 Pilot test adapted WLM. The adapted WLM will be piloted with a convenience sample of 10 overweight African American cancer survivors and overweight family members in a community similar to study sites. Sessions will be led by CHEs experienced in lifestyle interventions for weight management and/or cancer prevention and control. The pilot will be delivered similarly to the full implementation, though abbreviated. Participant feedback surveys, a focus group at the end of the pilot, process notes from CHEs will be used to determine what (if any) additional changes may be necessary. This pilot methodology will continue until no substantive additional changes are recommended. We will document all modification from the original program.

1.5 Finalize study protocols. Investigators and CHEs will finalize study protocols (e.g., recruitment and retention procedures, intervention materials, data collection methods) and document modifications.

1.6 Train program staff on study protocols. CHEs and County Coordinators (CCs) will attend a 2-day assessment training at UAB (led by Drs. Baskin, Ard, Demark-Wahnefried, and Hunter, Project Director, and Data Manager). Training will include study overview, human subject protection, recruitment and retention strategies, data collection, and data management and entry. Longer training for Group 1 & 2 CCs on the WLM protocols will be led by CHEs and conducted in multiple sessions over a 4-mo period prior to participant recruitment. Ongoing supervision by the CHE and refresher trainings (as needed) will occur. All CHARPs will receive assessment training held in their community and led by CCs and CHEs. CHARP training will focus on human subject protection, recruitment and retention strategies, and data submission. Written protocols will be reviewed using didactic and experiential methodologies (role plays, mock assessments). Additional training on the WLM protocols will be conducted in multiple sessions over 4 mos prior to starting the intervention. Similarly, CCs and CHEs will lead these trainings that include direct instruction on group facilitation and motivational counseling and mock group sessions. Ongoing supervision by CC and refresher trainings will also occur.

Aim 2. Select and implement community strategies supporting weight loss

2.1 Randomize communities (Groups 1 & 2). The 6 existing DSN counties will be matched on demographic characteristics and entered into a database in blocks prior to randomization. Communication with leaders in the proposed communities indicate their agreement to randomization (see Letters of Support). Formal Memorandums of Understanding (MOUs) with local government, businesses, and/or other participating partners will be secured for communities assigned to Group 2. The MOU will specify deliverables with timeline, technical assistance, and schedule of distribution of funds for implementation and evaluation of strategies.

2.2 Conduct community level asset mapping/needs assessment. Data will be collected to establish community assets and needs with respect to: availability of affordable healthy food, presence of safe communities that support PA, and other assets supporting weight loss.

- Availability of Affordable Healthy Food: A list of licensed food stores will be obtained from each local health department. Addresses will be geocoded and mapped using ArcGIS software and CHARPs will verify the list by "ground truthing,"[112] a method by which the presence of stores is verified and omitted stores identified by canvassing the community. CHARPs will measure availability and pricing of healthy and unhealthy foods on a 50% sample using the NEMS-S,[98] a valid and reliable tool used by CHARPs in our prior work.
- Access to Safe, Convenient, and Aesthetically Pleasing PA Resources: A list of public parks and recreation facilities will be obtained from local governments. Addresses will be geocoded and mapped using ArcGIS and verified by "ground truthing."[112] CHARPs will be trained on the Rural Active Living Assessment (RALA) tools,[100] which allow community members to capture information on the physical environment features and amenities, town characteristics, and programs and policies that may influence levels of PA among rural residents. The RALA tools are valid and reliable[100] and have been used by CHARPs in our prior work.
- Other Assets (Group 2 only): We recognize that communities may have additional assets that support healthy eating and PA. As such, we will use Photovoice, a participatory method in which community members record their communities' assets through photography and later tell the stories to accompany their photos[113], to capture additional assets. In each community, 20 local residents will be provided disposable cameras and instructed to take pictures over a 1-wk period that reflect aspects of their community that support healthy eating and regular PA. Developed photos will be presented in a focus group format in which participants will explain the photographs and help analyze the data by identifying the most salient photographs depicting community assets and assigning appropriate captions for each photo. Photos and related narratives will be presented with community assessment data in a local forum to aid in the selection of strategies to be implemented.
- *Select community strategies for communities (Group 2 only).* CAB members will present needs/assets assessment data in a community forum to facilitate selection of strategies from a menu of options to increase availability of affordable healthy food and beverages and access to safe and convenient opportunities for PA. A range of programs and policies identified from published research[67] were reviewed and narrowed down by investigators and community members who helped with this proposal (See Appendix for details on selected strategies). Selection was based on perceived relevance, strength of the evidence, ease of implementation and sustainability, and needed resources (financial, personnel). While offering multiple options may slightly diminish generalizability of findings, selection from a limited menu (5 healthy eating; 3 PA) maximizes the potential impact of the intervention by allowing local sites to select relevant strategies based on asset/needs mapping. A prioritized list of strategies from the menu will be developed at the conclusion of each community meeting. This list will be presented to local stakeholders for final selection of one strategy in each category based on ability to secure resources and commitments needed for implementation. A full proposal with implementation and evaluation plans, technical assistance needs, and budget will be submitted to study investigators for review and approval prior to releasing up to $7,500 per community to support the implementation of the two strategies.

2.3 Implement community strategies (Group 2 only). Communities will implement selected interventions according to the approved implementation plan and timeline. CHEs will work with community leaders to monitor progress and provided TA as needed. For logistical reasons, community-level interventions will be staggered by 8 mos (see detailed timeline in Appendix) and are designed to start 6 mos before the weight loss intervention to ensure community strategies are in place prior to the individual-level intervention.

Aim 3. Recruit overweight cancer survivors and family members

3.1 Recruit potentially-eligible overweight African American cancer survivors and their overweight family members. CHARPs in all arms will identify and recruit potentially-eligible survivors of obesity-related cancers via existing DSN databases, informal networks, and word-of-mouth (asking potential participants to share study contact information with other survivors they know). CHARPs will screen for self-reported diagnosis of obesity-related cancer (i.e., breast, colorectal, prostate) in the past 5 years, weight, and interest. Participants will provide a list (rank-ordered) of at least 2 potentially-eligible family member co-participants. "Family member" is

defined broadly to include biological relatives, romantic partners, household members, and others providing a major source of social support as suggested when working with African American populations.[114] Further, prior weight loss research[38] suggests similar beneficial impact of persons enrolling with either a family member or friend. Thus, allowing for a broadly defined family member co-participant increases the potential for successful recruitment of needed subjects. Potential index participants will verify family member interest prior to CHARP contact. The highest ranked family member completing screening will be forwarded for enrollment verification. CHARPs will recruit 30 index participants per site (allowing up to 20% loss after eligibility verification). We expect to meet recruitment goals using DSN contacts and connectors; however, we will augment this strategy with a recruitment letter from the DSN to potentially eligible participants from the AL cancer registry (see Letters of Support). The personal connection between CHARPs and potential members is ideal given previously noted concerns about cancer stigma. A letter that links the participant to DSN, a trusted brand in the region, is the next best alternative. The Project Director will track participant recruitment daily during the recruitment phase and communicate progress relative to recruitment goals during weekly project meetings. Based on this tracking, investigative staff will determine as necessary when to implement recruitment via cancer registry list. Only those communities demonstrating recruitment challenges will use this additional method.

3.2 *Verification of participant eligibility and study enrollment*. CCs will meet with recruited co-participant pairs to confirm interest, verify eligibility, and obtain informed consent. Index participants are eligible if they: (1) self-identify as African American; (2) are ≥age 19; (3) have a verified history of breast, colorectal, or prostate cancer within 5 years, and have no current evidence of disease; (4) have a measured BMI between 25-45 kg/m^2 (consistent with the original WLM trial); (5) reside in a study site; (6) enroll an overweight family member as co-participant; (7) report being currently sedentary (<150 mins/wk of moderate to vigorous PA); and (8) are willing to participate for the entire 24-mo duration. Eligibility is the same for co-participants except for cancer diagnosis. Index or family member participants will be ineligible if they: (1) are pregnant or are planning to become pregnant during the study period, (2) have a known major medical or psychological condition known to influence weight loss [e.g., medicated or poorly controlled diabetes (HbA1c ≥ 8%), uncontrolled hypertension (BP≥160 mm Hg systolic or BP≥100 mm Hg diastolic), cardiovascular event in the past 12 mos, history of gastric bypass or bariatric surgery], (3) history of psychiatric hospitalization in past 2 yrs, (4) history of substance abuse or eating disorder, or (5) any other condition by which a medical professional has suggested diet modification, PA, and/or weight loss would be contraindicated. Cancer diagnoses will be verified against state registry data; while such a process may not work in a more transient population, residents within the Deep South tend to be stable ("born there and die there"). In the rare event that diagnosis has been rendered elsewhere, we will ask participants the location of diagnosis and will obtain relevant validation (path reports, MD's diagnostic note, ICD-9 code, etc.) with appropriate participant release of information documentation. We expect to enroll 25 Index participants with their 25 family members in 9 proposed study sites (i.e., 450 total participants).

Aim 4. Evaluate Program Efficacy

4.1 Non-treatment Control Group. CHARPs in Group 3 will participate in cancer awareness training delivered across 6 months (parallel to the Phase I WLM). This training will allow CHARPs to maintain a working knowledge for cancer awareness and further build capacity in the newly-formed DSN sites. Study participants will receive periodic contact between assessments (described further below).

4.2 Implement Adapted WLM intervention. The WLM intervention will be delivered across Groups 1 & 2. Weekly group sessions (Phase I) will be co-facilitated by the CC and CHARPs with training and/or professional experience in nutrition, behavioral counseling, education and/or health. Two group sessions per community will be delivered based on participant availability (e.g., weekday, weekend, mid-day, evening) to limit meetings to ≤25 participant; however, participants will be asked to stick with the day/time initially enrolled to maximize group cohesion. Phase II will be implemented by local CHARPs. CHARPs (10 per community) will be assigned to 5 participants each. CHARPs will maintain regular personal contact (monthly by phone plus 2 face-to-face visits each year) and encourage continued healthy behaviors and maintenance of personalized weight maintenance goals. Phone calls (~15 mins) will include personal guidance and support based techniques from motivational interviewing (MI)[115]. Face-to-face contact (~45 mins) will include the same focus but will occur with other participants in small groups. CHARPs will provide assistance with transportation as needed.

4.3 Conduct process evaluation of WLM. A checklist including site name, facilitators, lesson name/number, and participant attendance will be completed each session. Open ended items will ask the facilitators to report on what worked/didn't work in the lesson. Program sessions will be audio taped for supervision and assessment of treatment integrity. A random sample of 20% of tapes will be reviewed by the CHE for protocol adherence. CHEs will provide specific feedback to CCs and CHARPs regarding facilitation skills and group dynamics, and offer assistance as needed. Similarly, a checklist for monthly motivational calls (Phase II) will be com-

pleted by CHARPs for each call. This checklist will record full, partial, and non-completion of each call, major topics discussed, and barriers to continued healthy behaviors expressed by participants. CCs will review checklists to verify implementation and provide feedback to the CHARPs and assistance in helping the participant stay on track. Questionnaires assessing participant overall evaluation of each session and the overall program will be developed. We will track: recruitment, retention, session attendance, completion of counseling calls, session evaluations and overall program satisfaction. We will use descriptive statistics to analyze quantitative data (e.g., attendance, completion of calls) and content analysis for qualitative data (e.g., responses to open-ended questions). Results from the process evaluation will greatly inform the investigative team about progress on completion rates, program acceptability, and facilitators and barriers to successful implementation.

4.4 Implement participant retention efforts. Participant retention is a top priority. Multiple points of contact (e.g., phone numbers, addresses, alternate contacts) will be collected at enrollment. For WLM Phase I participants, CHARPs will keep regular contact (phone, mail) to remind them of assessments and weekly meetings. During Phase II, CHARPs will connect with participants with their monthly phone calls during which multiple contact information will be verified. Phase II participants will also receive periodic mail correspondence (e.g., assessment date reminders, holiday greetings and birthday cards). Alternate contacts will be contacted when participants can not be reached directly for over 2 mos. CHARPs will maintain regular contact with participants between assessments and as needed, make home visits to try and reach participants. Retention of Group 3 participants includes periodic contact between assessments including phone calls, letters, holiday cards, etc.

4.5 Conduct Outcome Evaluation Assessments. Multiple assessments will be completed by trained research staff, CCs and CHARPs (Table 3 on next page). Group assessments (~2 hours) will be conducted at a local facility (e.g., church, community recreational facility) in early morning to allow for fasting blood draw.

4.6 Participant Compensation. Participants will receive $40 for each full assessment battery (0, 6, 12, 24 mos). Non-monetary incentives (e.g., t-shirts, water bottles) will be distributed at select WLM sessions (Groups 1 & 2) and for the 18-mo weight check (All) as this requires limited time/effort on the part of the participants.

4.7 *Data Quality.* Data submission from local sites to the UAB research office will be ongoing throughout the project. Data recorded on scannable forms will be scanned into the study database. A standard data cleaning protocol including visual verification of paper measures, data entry verification, and system edits to flag out-of-range values, will be used and protocols to correct inconsistent or erroneous data will be implemented. Periodic reports (local and interim findings) will be generated throughout the study to facilitate trial monitoring, evaluation of participant safety, and feedback to community partners. A final cleaned dataset will be certified by the data manager prior to making data available for final analysis and dissemination.

4.8 *Sample Size and Statistical Power.* *Sample Size and Statistical Power.* Table 4.0 illustrates the relationship between statistical power and the intraclass correlation coefficient assuming fixed effect size, number of clusters, and observations per cluster. To illustrate, the table shows that assuming an alpha of .05 and an intraclass correlation coefficient of .005, then 9 communities assigned to three study arms (3 per arm), with 25 observations per community will provide 88% power to detect a standard deviation among treatment means of .25 units assuming the outcome standard deviation is 1 unit. To place in the context of a weight loss study, the table shows that assuming an alpha of .05 and an intraclass correlation coefficient of .005, then 9 communities assigned to three arms (3 per arm), with 25 observations per community will provide 88% power to detect differences among treatment means of 0 kg weight change in the control arm, 1.1 kg weight change in the weight loss intervention treatment arm, and 2.2 kg weight change in the weight loss and community interventions arm assuming the standard deviation of 24-month weight change in this population is 3.5 kg.

Table 4.0 Power as a function of Effect Size and Intra-Class Correlation for a fixed sample size of 9 communities with 25 index cases per community

Effect Size	Intra Class Correlation Coefficient			
	.005	.010	.015	.02
0.250	0.88	0.84	0.80	0.77
0.275	0.95	0.92	0.90	0.87
0.300	0.97	0.96	0.94	.0.92

4.9 Statistical Analysis. Descriptive statistics, specifically measures of central tendency (sample mean, sample median) and measures of variability (variance, inter-quartile range), will be calculated for all continuous demographic characteristics and outcomes. For categorical characteristics (e.g. education, marital status), sample proportions and standard deviations will be calculated. To test Primary Hypotheses 1 and 2, mixed linear models will be employed to account for the non-independence of observations nested with communities while testing for intervention effects. Two specific mixed linear models will be developed to measure the intervention effect at 6 months for multiple outcomes (weight, fasting insulin, blood pressure, lipids, glucose, dietary intake, and psychosocial variables). First, the crude intervention effect will be estimated without controlling for covariates. Second, the crude intervention effect will be estimated controlling for covariates (e.g., age, education, regional stratum, baseline measurements, number of intervention sessions attended). Interaction effects between intervention arms and covariates will be examined. Similar models will be created for 24-mo

Table 3 Study Measures and Data Collection Schedule

Measure	Description and Procedure	Assessment Timeline (mos)				
		0	6	12	18	24
COMMUNITY						
Nutrition Environment	50% of local stores will be assessed for availability of affordable healthy food by CHARPs using the NEMS-S,[98]	X		X		X
PA Environment	Physical and political environments related to safe and convenient PA will be assessed by CHARPs and CCs using the RALA[100]	X		X		X
Nutrition and PA Community Strategies[1]	Strategy-specific outcome measurements assessing community-level change over time will be conducted using recommendations from the CDC guide.[69] Data will be collected by trained CHARPs with assistance as needed by CHEs.	X		X		X
INTERPERSONAL						
Social and Cultural Norms about Eating	Adapted from prior research,[116-117] 5 questions assess group identification (e.g., Being an African American living in the South is an important part of who I am) and 3 items assess perceived group norms (e.g., What percent of African Americans living in the South do you think will eat healthily in the next 2 wks?). Group identification index yielded α=.57 and the perceived group norms α=.89.[116]	X	X			X
Perceived Neighborhood Environment	Neighborhood Environment Walkability Scale (NEWS[55]) subscales [pedestrian safety (8 items; α=.77); safety from crime (6 items; α=.80), and neighborhood surroundings (6 items; α=.79)] will be used.	X	X			X
Social Support for Eating Habits and Exercise	The Social Support and Eating Habits Survey (10 items) and the Social Support and Exercise Survey (13 items)[37] will measure be used. These instruments have been widely used in diverse samples and have strong psychometric properties (α=.70).	X	X			X
INDIVIDUAL						
Demographics and Health History [2]	A survey will be developed for use in this study to capture demographic information such as age, marital status, education, and employment. In addition, a healthy history questionnaire will be used to capture history of disease.	X	X	X		X
Self-efficacy for Eating & Exercise Behaviors	The tool includes 20 items assessing self-efficacy for healthy eating (i.e., eating low-fat and recommended portions of foods) and 12 items assessing exercise self-efficacy (e.g., ability to exercise ≥5times per week despite barriers). This tool has been used with African American adult populations and has shown good psychometric properties (e.g., α=.85 to .93).[118]	X	X	X		X
OUTCOMES						
Weight	Participants wearing light clothing and no shoes will be weighed to the nearest 0.1kg using calibrated professional digital scales.	X	X	X	X	X
Waist circumference	Waist circumference will be measured to the nearest 0.5 cm using a constant-tension spring-loaded tape device on bare skin at the end of a normal expiration at the natural indentation between the 10th rib and the iliac crest.	X	X	X	X	X
Height	Height to the nearest 0.1 cm will be measured without shoes using a portable and calibrated stadiometer.	X				
Fasting Blood	UAB staff trained in phlebotomy will collect fasting blood samples by venipuncture. Samples will be appropriately prepared for storage on-site and transported to UAB for analysis by for insulin, lipid profile and glucose. Lab results will be provided to participants as a community service and participants whose results are outside of the normal range will be referred to their personal physician or local health department for follow-up.	X		X		X
Blood pressure	Participant blood pressure (BP) will be measured by trained staff using a calibrated automatic sphygmomanometer. Arm circumference will be measured to determine the proper size arm cuff. Participants will sit and rest in a quiet location without talking for 5 mins before measurement. BP will be measured twice according standard NHLBI protocols[119] and the average of 2 measurements will be recorded. Subjects with baseline BP above 179 systolic or 109 diastolic will be placed "on hold" until they are evaluated by their physician and provided clearance, as per the American College of Sports Medicine (ACSM) guidelines.[120]	X	X	X		X
Dietary Intake	NCI's Automated Self-administered 24-hour Dietary Recall (ASA24) [3] includes multi-level food probes to accurately assess food types and amounts, an animated character guide, and audio cues to enhance use by persons with low-literacy. CCs will access the free on-line tool using netbook computers[4] to collect data participant homes or a convenient public location (e.g., library). CCs will visit participants on nonconsecutive days (1 weekday, 1 weekend) ± 2 wks of group assessment. Participant data files will be used to compute nutrient and food group estimates (i.e., avg energy consumed per day, % energy from fat, and servings of F&Vs).	X	X	X		X
Physical Activity	The Godin Leisure-Time Exercise Questionnaire (GLTEQ)[121] is reliable, valid, compares favorably with other self-report measures and objective activity monitors[122] and has been used with cancer patients and healthy controls. While accelerometry is preferred, associated costs prohibit use with all participants; however, we will assess concurrent validity of the GLTEQ with accelerometery on a 25% subsample (selected as the nth person among all participants agreeing to wear the monitor) who will wear the GT3X-plus Actigraph accelerometer 7 consecutive days. The monitor is compact and lightweight and can be worn at the waist or wrist. It will be programmed to assess a global index of PA (i.e., time spent at or above moderate to vigorous PA per day).	X	X	X		X
Health Related Quality of Life (HRQoL)	The 36-item HRQoL[123] assesses social functioning, emotional-well being, in addition to physical health. The HRQOL has established psychometric properties[123] and has has been validated in healthy and ill, and rural African American populations.[124-125]	X	X	X		X

[1]Group 2 only (See Appendix K for more details); [2]Abbreviated after baseline; [3]Available at http://riskfactor.cancer.gov/tools/instruments/asa24/); [4]Study sites are within the Verizon 3G coverage area

outcomes. Hierarchical linear models will be used to model outcomes longitudinally. Careful examination of distributional assumptions will be conducted using normal probability plots. If, for any models, distributional assumptions are violated, permutation testing will be used. Separate analyses for index and co-participants will be conducted. Finally, mixed linear models will be constructed to test secondary outcomes of fasting insulin, blood pressure, quality of life, and energy intake according to the analysis strategy presented above. For adherence and other non-normally distributed outcomes, generalized linear mixed models will be employed.

*4.10 Disseminate findings to community advisory board and communities. F*indings will be shared with study communities via multiple sources including: a written 1-page summary to study participants and presentations by local CCs and CHARPs at community meetings. Additional methods will be explored with our CAB.

4.11 Disseminate findings to scientific community. Study findings will be disseminated to the scientific community using a variety of methods (professional scientific meetings/conferences, peer-reviewed manuscripts, interim and final reports to NIH). Community members will be actively participate in the development of scientific dissemination products as co-authors as suggested by a CBPR approach.

4.12 Pursue resources to sustain programs. We will work with our CAB and community partners to identify additional resources to sustain successful interventions including appeals to local government and business leaders. In addition, we anticipate that this research will lead to the development of other research applications to various NIH institutes with interests in obesity (e.g., NCI, NIDDK, NHLBI, NCMHD, NINR) and funding agencies with specific focus on cancer prevention and control (e.g., American Cancer Society, Komen Foundation).

C.8. Strengths/Limitations of the Study Design

Like all projects, this study has some limitations, which we have diligently tried to minimize in our research design. First, as with all longitudinal trials, are challenges of participant recruitment and retention. Our team has extensive experience recruiting and retaining African American participants and cancer survivors in long-term behavioral research. We expect to meet recruitment goals and obtain a high retention rate given careful attention to frequent contact, incentives, and previous success. Second, we acknowledge the potential for contamination from adjacent communities. We have taken this into account in the study design (e.g., stratified cluster design) and selection of study sites. Finally, we are cognizant that our study participants may not be representative of African American cancer survivors and family members in other Deep South counties due to the long-standing involvement of the DSN in study sites. We will appropriately acknowledge this limitation in disseminating study findings and work toward future studies examining the efficacy of these interventions in communities with and without a long-standing academic-community partnership.

In contrast, the project has several strengths that outweigh its weaknesses. First, the target populations addressed in this study have the greatest burden of cancer and obesity. Obesity-related cancer death rates for African Americans in AL underscore the unacceptable disparities. Second, the proposed study focuses on multi-level interventions that move the field of cancer survivorship, as well as obesity-research, from the individual to the community by integrating scientists, clinicians, health professionals and community members in the process. Third, this study leverages a 9-year successful academic-community partnership that has led to the active engagement of community residents in behavioral and biomedical research as well as increased cultural competence of faculty. This partnership affords high community trust essential for our team to better understand the sensitive issues that may contribute to disparities in cancer outcomes, as well as, aid in targeted participant recruitment and retention. Community support for the expansion of our network into 3 additional counties further underscores the potential to leverage this model for conducting biobehavioral research. Fourth, the selected interventions for this study are evidence based and culturally appropriate for African American populations. Cultural tailoring to rural residence and cancer survivorship and prevention is planned to better take into account the individual's social and cultural context in achieving and maintaining weight loss. Fifth, this study is innovative in its use of community peers to help with intervention delivery and the exploration of multiple levels of influence on weight loss (e.g., individual, interpersonal, and environment). Successful strategies employed in this study can likely be replicated in similar communities throughout the US. Sixth, the proposed study design is rigorous (including a non-treatment control group), yet consistent with our ethical obligations to communities we have partnered with for years to eliminate cancer disparities. Seventh, study measures selected have high accuracy ratings to help answer our research question, but also providing timely and relevant data to study participants with minimized participant burden. Finally, this study is greatly strengthened by its adherence to each of the principles of CBPR. The target community has been an active part of the writing of this proposal and will play substantial roles in the data collection, analysis, interpretation, and dissemination of study findings to various audiences (e.g., general public, policy makers, and researchers).

SUMMARY STATEMENT

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(Privileged Communication)

Release Date: **10/11/2011**

Application Number: **1 R01 CA160313-01A1**

Principal Investigator

BASKIN, MONICA L PHD

Applicant Organization: UNIVERSITY OF ALABAMA AT BIRMINGHAM

Review Group: **CLHP**
Community-Level Health Promotion Study Section

Meeting Date: **09/26/2011**
Council: **JAN 2012**
Requested Start: **04/01/2012**

RFA/PA: **PA10-067**
PCC: **O1CD**

Dual IC(s): **NR**

Project Title: **Promoting Weight-loss in African American Cancer Survivors in the Deep South**

SRG Action: **Impact/Priority Score: 11 Percentile: 5**
Human Subjects: **30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **1A-Both genders, scientifically acceptable**
Minority: **1A-Minorities and non-minorities, scientifically acceptable**
Children: **1A-Both Children and Adults, scientifically acceptable**
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1		
2		
3		
4		
5		
TOTAL		

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R01CA160313-01A1 BASKIN, MONICA

RESUME AND SUMMARY OF DISCUSSION: This highly significant application will implement and evaluate a weight loss intervention for African American cancer survivors living in the rural Deep South. If successful, this research could likely inform efforts to reduce health disparities associated with obesity-related cancers. The investigators are a strong team and a good match for the project with a stellar publication record. This submission addresses the majority of concerns raised during the previous review. During the discussion the panel noted several strengths of the application, including: the strong theoretical and conceptual frameworks; the rigorous research design; the highly innovative component that includes home-based delivery and the strong CBPR component. The panel expressed concerns regarding how family members will be retained during the study. Nevertheless, the proposed research was seen as potentially very important with a high probability of success. Overall the strengths of the application outweigh the minor weaknesses of the application and reviewers concurred that the impact of this research on the field would likely be high.

DESCRIPTION (provided by applicant): Three obesity-related cancers (breast, prostate, colorectal) account for over 1/3 of cancer diagnoses annually and caused 112,520 deaths in 2009. Despite notable progress in early detection and treatment in recent years, African Americans living in the Deep South experience greater cancer burden. Obesity-related cancer death rates for African Americans in Alabama (AL) exceed national and state rates for their white counterparts, as well as national rates among African Americans. Overweight and obesity, which characterizes 76% of African Americans in the US, are implicated in multiple cancers. While reducing excess weight is beneficial in both cancer prevention and survivorship, achieving and maintaining weight loss is complicated by individual, socio-contextual and environmental factors. In the general population, African Americans are often less successful with weight loss than their white counterparts. Cited barriers include lack of social support and environmental challenges (e.g., limited availability of healthy affordable food and access to safe and convenient opportunities for physical activity). Multilevel (individual, interpersonal, environment/policy) approaches have shown promise in achieving and sustaining weight loss; however, to our knowledge, there are no published studies of multilevel weight-loss interventions for African American cancer survivors. The proposed three-group cluster design will enroll 450 overweight African Americans (225 cancer survivors and their 225 family members) residing in 9 rural communities in AL. Communities will be randomly assigned to receive either an evidence-based and culturally-adapted weight loss intervention (Group 1), an evidence-based and culturally-adapted weight loss intervention plus community strategies to support weight loss (Group 2), or no intervention (Group 3). The study seeks to answer the research question: Do evidence-based community strategies supporting weight loss in addition to an evidence-based weight loss program result in greater weight loss among overweight cancer survivors (and their family members) residing in rural communities in the Deep South? Unique elements of the study include its community-based participatory research (CBPR) approach; focus on social and environmental barriers to weight loss success, use of community health advisors to deliver program content, and long-term involvement of targeted counties in a successful academic-community partnership seeking to eliminate cancer disparities.

PUBLIC HEALTH RELEVANCE: African Americans living in the rural Deep South experience a greater burden of obesity-related cancers than their white counterparts or African Americans living in other geographic regions. This study will evaluate multilevel weight loss interventions for African American cancer survivors living in the rural Deep South. Findings from this study may decrease risk for cancer recurrence and cancer-related mortality, improve quality of life, and perhaps ultimately increase survival rates for this vulnerable population.

CRITIQUE 1:

Significance: 1
Investigator(s): 2
Innovation: 2
Approach: 1
Environment: 1

Overall Impact:

This strong and innovative proposal builds on work of other researchers demonstrating efficacy of weight-loss strategies in a variety of populations. However, this work has not yet been applied to cancer survivors in African American populations who already experience higher rates of obesity and cancer incidence. The Deep South communities in Alabama, the site of the proposed study, are more likely to be tightly woven communities where social support is imperative to making sustained behavior change. The addition of a community-level condition may enhance individual level weight loss of both cancer survivor and family members. This community-level condition is an important element to test, particularly for populations experiencing health disparities. These communities often face isolation and poor resources that limit the population's exposure to healthy foods and environments that are safe for physical activity. The utilization of a CBPR methodology, if it leads to successful outcomes, will be an important contribution to the literature. This is not because of the specific strategies that will result from the engagement with the community, but because the ways in which the community is engaged will provide examples of how a community can be mobilized to address its own problems. The generalizability of the study will be the ways in which the community is engaged, not in the specific strategies that are chosen to ameliorate the problem.

1. Significance:

Strengths

- The focus on the obese cancer survivors in African American populations in the South
- The application of efficacious weight loss and exercise strategies to a population which has not often (if ever) participated in such studies makes the study generalizable to other populations with significant health disparities

Weaknesses

- None noted

2. Investigator(s):

Strengths

- All of the investigators are experienced, well published, and experts in their respective fields. Many have worked together with the PI.

Weaknesses

- None noted.

3. Innovation:

Strengths

- The examination of the benefits of a community level component to address environmental factors is very innovative and likely to enhance generalizability for communities experiencing health disparities. These communities are often more reliant on local resources; they are often isolated and travel is impaired due to recent economic conditions.

Weaknesses

- None noted

4. Approach:

Strengths

- The investigators responded to all of the methodological concerns outlined in the summary statement, in particular the addition of a true control group.
- Additional involvement of the CAB and the enhancement of the CAB with cancer survivors and family members is particularly important for the CBPR approach.

Weaknesses

- None noted.

5. Environment:

Strengths

- Excellent resources are available for the study

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M2A - Only Minority, Acceptable

C3A - No Children Included, Acceptable

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- The investigators have responded to the comments from the previous review in a very detailed and thoughtful manner.

Budget and Period of Support:

Recommended budget modifications or possible overlap identified:

- The applicant should identify ways in which the effort of co-investigators can be increased. As proposed in the application, the effort is unlikely to be sufficient for the activities described. While it is acknowledged that budget caps limit financial support for these investigators, this reviewer is concerned about the mismatch between the described scope of work and the low effort allocation, particularly in years 2, 3 and 4. We recommend that the institute to which this project is assigned consider this concern. It may be appropriate for some investigators to be dropped from the study to ensure that participating investigators can devote adequate attention to the project. Alternatively, the institution could be asked to provide some support for these investigators to participate in the project through other sources.
- It is unlikely that the co-investigators will be able to undertake their stated responsibilities with such little effort (particularly in years 2-4) devoted to the project, unless the University has agreed to contribute other resources to their participation. The amount of effort proposed in years 2-4 would barely support their participation in one one-hour meeting each week, and the minimally increased effort in Years 1 and 5 begs the question about the realistic commitment of these investigators. As an example, Dr. Ard's responsibilities are: "finalize study protocols, train research staff, help lead data analyses from formative research, participate in data safety monitoring, and assist in the interpretation and dissemination of study findings."
- ● It is not clear why the CAB members will not be compensated for their travel to CAB meetings during the 2, 3, 4 years. This will potentially limit their participation in those years.

CRITIQUE 2:

Significance: 1
Investigator(s): 1
Innovation: 2
Approach: 2
Environment: 1

Overall Impact:

The study has strong potential for long-term impact using a community-centered intervention strategy at multiple levels within this population of cancer survivors and families. Overall, the study has many strengths in terms of conceptual framework, proposed use of CBPR, drawing on sustained community partnerships, and an experienced research team. Excellent response to previous concerns of reviewers, well-written, well argued strategies, and very worthwhile outcomes potentially for this proposed research.

1. Significance:

Strengths

- Strong rationale for the burden of cancer and associated obesity in this population, and for piecing together evidence for the high potential of the proposed interventions to be tested

Weaknesses

- None noted.

2. Investigator(s):

Strengths

- Great balance of expertise in CBPR, nutrition, exercise science, intervention research

Weaknesses

- None noted.

3. Innovation:

Strengths

- The combination of context, cultural adaptation, environmental conditions, and community support provide some level of innovation, definitely worth exploring

Weaknesses

None noted.

4. Approach:

Strengths

- None noted.

Weaknesses

- Seems odd to pose a research question in abstract, only asking if the design that includes culturally adapted intervention with community-based support results in greater weight loss (than what?) when the two control groups are uniquely designed to test specific aspects of the previously developed program. Hypotheses would be in order to specify more fine-tuned expectations. The specific aims and analysis sections are clearer about these aspects of the study, well described. Not sure if there is sufficient support for power to achieve signif differences between groups, but having the capacity to examine both interventions in comparison to control will provide important information.

5. Environment:

Strengths

- Excellent

Weaknesses

None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M2A - Only Minority, Acceptable

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Revision:

- Very responsive

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3:

Significance: 2
Investigator(s): 1
Innovation: 1
Approach: 2
Environment: 1

Overall Impact

A tertiary prevention trial is described, in which overweight cancer survivors will be assigned (by community membership) to one of three groups: a weight-loss intervention administered by community health advisor research partners (CHARPs); the weight-loss intervention plus a community/environmental intervention component; and a no-intervention control group. The investigative team is quite strong and has an extensive history of collaborating with the community, thus providing a strong foundation for the proposed CBPR approach. The simultaneous targeting of individual, intra-personal, and environmental influences on physical activity and nutrition is innovative. The environment is well suited to the proposed activities. It is not clear how the program will harness the potential intra-personal influences of including family members. Simply enrolling them simultaneously in the program may not be sufficient.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Adequate protections are planned.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M2A - Only Minority, Acceptable

C3A - No Children Included, Acceptable

- The project will target African-American adult cancer survivors.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- The concerns of the prior review have mostly been addressed. There is some lingering concern about the generalizability of the findings, given that the intervention will be tailored to the specific target population, but this is an inevitable limitation to CBPR.

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-10-080 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html.
The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The

criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

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CENTER FOR SCIENTIFIC REVIEW
CLHP
September 26, 2011 - September 27, 2011

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.