

**Study Title:**  
**Social Ecological Based Smoking Cessation Intervention in Public Housing  
Neighborhoods**

**# R01HL090951**

**Date: 8/09/2018**

## Study Protocol

**Design.** A matched-pair cluster-randomized design will be used. We will form 7 matched pairs of 14 public housing neighborhoods, based on neighborhood size within geographic location, and randomly assign one neighborhood in each pair to either a bundled, multi-level smoking cessation intervention (TX) or control condition (C) (7 per condition). Eight (8) public housing neighborhoods in Augusta, GA and 6 in Charleston, SC that range in size from 100 units to 272 units will be used. The trial will be conducted in 7 overlapping waves of recruitment and intervention delivery over 4 years as shown in Table 1. Staggering the participants allows ease of operational feasibility as shown in Table 1.

**Table 1: Timeline for Implementation of Community Trial (N=406)**

Wave	Condition	Neighborhood Data Collection	Recruitment/ Individual data collection	Treatment Intervention	6 month data collection	12 month data collection
1	TX NBH #1-Aug (n=29)	Mo 9	Mo 10	Mo 11-16	Mo 17	Mo 23
	TX NBH #2-Chs (n=29)	Mo 9	Mo 10	Mo 11-16	Mo 17	Mo 23
2	C NBH #1-Aug (n=29)	Mo 12	Mo 13	-----	Mo 20	Mo 26*
	C NBH #2-Chs (n=29)	Mo 12	Mo 13	-----	Mo 20	Mo 26*
3	TX NBH #3-Aug (n=29)	Mo 15	Mo 16	Mo 17-22	Mo 23	Mo 29
	TX NBH #4-Chs (n=29)	Mo 15	Mo 16	Mo 17-22	Mo 23	Mo 29
4	C NBH #3-Aug (n=29)	Mo 18	Mo 19	-----	Mo 26	Mo 32*
	C NBH #4-Chs (n=29)	Mo 18	Mo 19	-----	Mo 26	Mo 32*
5	TX NBH #5-Aug (n=29)	Mo 21	Mo 22	Mo 23-28	Mo 29	Mo 35
	TX NBH #6-Chs (n=29)	Mo 21	Mo 22	Mo 23-28	Mo 29	Mo 35
6	C NBH #5-Aug (n=29)	Mo 24	Mo 25	-----	Mo 32	Mo 38*
	C NBH #6-Chs (n=29)	Mo 24	Mo 25	-----	Mo 32	Mo 38*
7	TX NBH #7-Aug (n=29)	Mo 27	Mo 28	Mo 29-34	Mo 35	Mo 41
	C NBH #7-Aug (n=29)	Mo 30	Mo 31	-----	Mo 38	Mo 44*

TX = Treatment C = Control NBH= Neighborhood Aug= Augusta Chs = Charleston Mo = Month

\*Following the final data collection at 12 months in the C neighborhoods, a delayed intervention will be offered to C participants.

The intervention components for each condition are listed below:

<b>Multi-level Smoking Cessation Intervention (TX):</b>	<b>Control Condition (C):</b>
<ul style="list-style-type: none"> <li>• 1:1 contact by CHW weekly for 12 weeks, every other week for 4 weeks, every 4 weeks for 8 weeks (24 weeks total)</li> <li>• Weekly peer group behavioral counseling sessions by cessation specialist for 6 weeks</li> <li>• Neighborhood level strategies (countermarketing and policy implementation) by neighborhood advisory board over 24 weeks</li> <li>• 8-week supply of nicotine patches</li> <li>• Study specific written cessation materials (<i>Sister to Sister Handbook</i>)</li> </ul>	<ul style="list-style-type: none"> <li>• Written cessation materials (<i>Pathways to Freedom</i>) at enrollment/baseline data collection</li> <li>• Mailed written materials               <ul style="list-style-type: none"> <li>- Week 6: <i>State Sponsored, Toll-Free Quit- Line</i></li> <li>- Week 12: <i>You Can Quit Smoking (AHRQ)*</i></li> <li>- Week 18: <i>When Smokers Quit (ACS)**</i></li> </ul> </li> </ul>

\*Agency for Research on Healthcare Research and Quality

\*\*American Cancer Society

**Subjects.** A total of 406 participants will be recruited from 14 public housing neighborhoods (29 women from each neighborhood) in the *Augusta, GA and Charleston, SC areas*. With consultation of our community advisory board and housing authority partners, we have chosen not to exclude non-AA women.

<b>Inclusion Criteria:</b>	<b>Exclusion Criteria:</b>
<ul style="list-style-type: none"> <li>• Females age 18 years or older</li> <li>• Current daily smoker</li> <li>• Resides in the respective neighborhood</li> <li>• Thinking about quitting in next 6 months</li> <li>• Willingness to follow through with protocol requirements</li> <li>• Able to provide names and phone numbers of 3 contacts</li> <li>• Able to speak English</li> </ul>	<ul style="list-style-type: none"> <li>• Acute serious medical illness</li> <li>• Pregnancy or breast feeding</li> <li>• Acute psychiatric disorder</li> <li>• Myocardial infarction in past month, unstable angina or serious arrhythmias</li> <li>• Plan to move in next 12 months</li> </ul>

**Neighborhood and Subject Recruitment.** We have received permission from the respective housing authorities to conduct the interventions in the 14 eligible neighborhoods. Our team has worked with public housing neighborhoods and residents for the past 8 years. *The respective universities (Medical University of South Carolina and Medical College of Georgia) both have long-standing relationships with the housing authorities and residents.* The PI, Co-I, and/or project managers will meet with neighborhood leaders (i.e., tenant association) prior to data collection to explain the overall purpose of the study. *Following, ethnic minority graduate students will complete the neighborhood level data collection. During this neighborhood data collection process and interaction, the graduate students will elicit assistance from neighborhood liaisons to distribute flyers (dates and times of neighborhood information sessions, inclusion/exclusion criteria, and toll-free lines for further information) and “word of mouth” to recruit individual participants for the study.* They will also place flyers in the community center, mailbox center, housing authority office, and other key sites in the neighborhoods.

The study information sessions will be held in the neighborhood activity center and include a neighborhood bingo game, cookout, or preferred activity of that neighborhood (as identified by the tenant association) based on our pilot work. During these sessions, the PI or Co-I and project manager will provide a brief overview of the study. Women who are interested will be screened for eligibility and consented by the PI or Co-PI, enrolled, and baseline data collected.

Based on our preliminary studies, we expect to schedule two introductory/baseline data collection sessions in each neighborhood to enroll 29 eligible participants. *We are anticipating one month to complete the neighborhood data collection and one month to enroll eligible individual participants in each neighborhood.*

**Subject Retention.** Several previously used strategies will be continued to maintain high retention rates. These include: 1) using indigenous CHWs with expertise in navigating the social environment; 2) providing telephone messages where participants can leave voice mail; 3) scheduling evening and weekend group meetings and data collection schedules; 4) scheduling all meetings and data collection in the neighborhood (i.e., community center); 5) use of incentives (i.e., door prizes such as candles, lotions, kitchen supplies) for all group counseling meetings; 6) graduated remuneration at the end of each data collection (\$25 gift card at baseline; \$50 gift card at 6 months; \$100 gift card at 12 months); 7) collecting three contact names, addresses, and phone numbers from participants with specific emphasis on obtaining older contacts (i.e., mothers, aunts, grandmothers) since these contacts are less mobile; 8) sending periodic postcards to participants as well as birthday and holiday cards; and, 9) providing stress balls, t-shirts, and other gifts with study logo and phone number.

## **Setting.**

*This study will be conducted in two similar metropolitan settings: Augusta, GA and Charleston, SC. The Augusta metropolitan area has a population of 193,316, with 46% African Americans. The median income in Augusta is \$32,972 and an estimated 20% of the population lives below the poverty level. The Charleston metropolitan area has a population of 217,070, with 38% African Americans. The median income in Charleston is \$35,295, and 19.7% of the population lives below the poverty level. Both communities have Housing Authorities that were established in the 1930's and sponsor traditional public housing programs.*

*There are a total of 14 traditional public housing neighborhoods in the Augusta metropolitan community. Eight of these 14 have at least 100 adult women residents, are family residential neighborhoods (vs. high rise senior complexes), and have not been previously used in our pilot studies. There are a total of 12 public traditional public housing neighborhoods in the Charleston metropolitan community. Six of these 12 have at least 100 adult women residents, are family residential neighborhoods, and have not been previously used in our pilot studies. In total, we have permission to use all 8 eligible in Augusta and 6 eligible in Charleston for a total of 14 neighborhoods for this study. We will pair-match the neighborhoods based on location and size. (See Section D3a). An estimated 40% of adult women in each neighborhood are current smokers based on our pilot data [19,52]. Approximately 98% of the women are AA. Table 4 displays demographic information for each neighborhood and estimated number of female smokers.*

*The 14 neighborhoods (8 in Augusta and 6 in Charleston) are not contiguous and are all located in separate school zones, which limit the risk of contamination across neighborhoods. Each neighborhood has its own tenant association and residential manager. Further, most women do not own cars, do not actively participate in organized community social groups (i.e., church groups) and are isolated to the neighborhood, except for public transportation. The residents typically do not move to other neighborhoods (average length of residency is 6-8 years), with many living in the same neighborhood their entire lifetime. These neighborhoods provide ideal settings for multi-level interventions randomized by clusters due to the circumscribed geographical space, isolation of residents, and density of the population.*

**Table 4: Study Sites**

<i>Pair</i>	<i>Name</i>	<i># Households</i>	<i>Adult Women &gt; 18 yrs</i>	<i>Estimated # of women smokers (40%)</i>	<i>Name</i>	<i># Households</i>	<i>Adult Women &gt; 18 yrs</i>	<i>Estimated # of women smokers (40%)</i>
<b>Augusta Public Housing Neighborhoods</b>								
#1	<i>Hahn Village</i>	100	102	41	<i>Barton Homes</i>	143	152	61
#2	<i>Allen Homes</i>	146	135	54	<i>Jennings Place</i>	148	165	66
#3	<i>Cherry Tree</i>	219	230	92	<i>Oak Pointe</i>	246	190	76
#4	<i>Dogwood Terrace</i>	266	305	122	<i>Gilbert Manor</i>	272	285	114
<b>Charleston Public Housing Neighborhoods</b>								
#5	<i>Wraggborough</i>	178	185	74	<i>Horizon Village</i>	200	210	84
#6	<i>Meeting St. Manor</i>	201	210	84	<i>Cooper River</i>	216	235	94
#7	<i>Robert Mills</i>	257	270	108	<i>Gasden Green</i>	264	280	112

**Bundled, Multi-level Treatment Intervention (Sister to Sister) Overview.** The *Sister to Sister* intervention has been developed using CBPR methods and incorporates the preferred socio-cultural dimensions of the targeted population as described in our recent publication in *Ethnicity & Disease*. The intervention was named by the women in the feasibility study, which

reflects a sisterhood of women helping other women. This social-ecological intervention *bundles* multi-level strategies (i.e., individual, interpersonal, neighborhood) in addition to nicotine replacement therapy and study specific written materials.

**Individual Level Strategies.** The individual level strategies will be led by CHWs (i.e., AA women who are from the community, former smokers, and credible leaders). The 1:1 CHW interventions will be initiated in the **TX** neighborhoods within the first week of the 24-week intervention period. There will be 2 CHWs assigned to the **TX** neighborhood, with *14-15 participants* assigned to each CHW (i.e., *total of 29 participants*). The CHWs will make proactive personal contact (e.g., face-to-face, or phone) with participants using semi-structured guides to assist women in quitting smoking by assisting to build their confidence in quitting (self-efficacy) and the use of spiritual resources as a coping strategy. These semi-structured guides will incorporate the use of the CHWs own language and cultural style, and the opportunity to share testimonials and personal experiences. The CHWs will encourage the participant to set a quit date within the first 2 weeks of the intervention. To enhance smoking cessation self-efficacy, the CHWs encourage the participants' success with comments such as: "I know you can quit smoking....if I can quit smoking, so can you." The CHWs will provide recommendations to avoid trigger situations and motivational strategies to encourage positive smoking behaviors. To enhance spiritual well-being, the CHWs will offer prayer and share favorite biblical scriptures, poems, and inspirational meditations. The CHW will encourage participants to maintain their personal diaries as directed in the group sessions (described below). Based on our experiences and feedback from our pilot studies, the protocols for proactive CHW contacts include weekly contacts for 12 weeks, every other week for 4 weeks, and every 4 weeks for 8 weeks (24 weeks total). *This schedule is preferred to allow time for the CHW and participant to facilitate successful closure of the structured relationship.* Each CHW contact with participants will be face-to-face or by telephone and will last approximately 10–15 minutes. Reactive contacts (i.e., from participants) can occur at any time, with participants being able to reach our research staff through the toll-free lines. All CHWs will be paid.

**Interpersonal (Peer Group) Strategies.** Behavioral, peer group counseling sessions will be conducted by a certified smoking cessation counselor, who has a minimum of masters degree in health professions and experience with group counseling. The group sessions will be initiated in the **TX** neighborhoods within the first week of the 24-week intervention period. The behavioral group sessions will be offered weekly for 6 weeks and are based on recommendations from PHS *Treating Tobacco Dependence Guideline*, with adaptations based on the community's input during our formative work. The adaptations reflect this population's socio-cultural preferences including group meetings with food, ethnically appropriate graphics and content, emphasis on stress reduction, spiritual themes and prayers, and opportunities for storytelling.

Each participant will be encouraged to set a quit date within the first two weeks of the intervention period. A major aspect of the group sessions is to enhance positive social support systems, both intra-treatment-and extra-treatment social support among peers, as recommended by the PHS *Treating Tobacco Dependence Guideline*. To promote social support, the group leader will facilitate the delivery of emotional support (i.e., empathetic listening, displaying trust and concern) among peers in the group and assist them to identify other positive support systems in the family and/or neighborhood. The major content of the group sessions include:

Week 1: Making the Decision to Quit Smoking includes introductions and establishing group norms and rules; introductory discussions on addiction, self assessment of tobacco addiction, readiness to quit, pros and cons of quitting smoking, self evaluation, opportunities for sharing experiences (storytelling), inspirational and spiritual tools, goals and action plan, journal

assignment, and group prayer. Participants are encouraged to set a quit date within the first 2 weeks of the intervention period.

Week 2: Understanding the Risks of Smoking and Benefits of Quitting includes health risks of smoking, reasons to quit, benefits of quitting, establishing a quit date, opportunities for sharing experiences (storytelling), inspirational and spiritual tools, goals and action plan, and journal assignment.

Week 3: Tools for Quitting Smoking includes review of progress, behavioral and coping strategies, medications to assist with quitting smoking, opportunities for sharing experiences (storytelling), inspirational and spiritual tools, goals and action plan, journal assignment, and group prayer.

Week 4: Staying Quit includes review of progress, relapse prevention, opportunities for sharing experiences (storytelling), inspirational and spiritual tools, goals and action plan, journal assignment, and prayer.

Week 5: Staying a Nonsmoker includes a review of progress, long-term relapse prevention strategies, opportunities for sharing experiences (storytelling), inspirational and spiritual tools, goals and action plan, journal assignment, and prayer.

Week 6: Overcoming Other Hurdles includes a review of progress, weight management, nutrition, physical activity, opportunities of sharing experiences (storytelling), inspirational and spiritual tools, goals and action plan, journal assignment, and prayer.

To promote individual and group interaction, each group will be limited to 8-12 participants. We will offer three groups in each **TX** neighborhood to accommodate the 29 enrolled women. Each participant will have a choice of attending an afternoon or evening session (based on our formative work) and will be given the schedule at study enrollment. CHWs will deliver a reminder (phone call, postcard, visit) 24 hours prior to each scheduled session. Each group session will last approximately one hour. Socio-culturally preferred food and door prizes (i.e., candles, lotions) will be available at each meeting.

**Neighborhood Level Strategies.** Neighborhood level strategies will be led by a 5-member neighborhood advisory board. Within each **TX** neighborhood, the project directors and PI/Co-I will work with neighborhood and housing authority leaders to identify, screen, and recruit adult residents for the appropriate composition of the board (both informal and formal resident leaders, smokers and nonsmokers, men and women, and representative of varying ages) as we have done in our pilot studies. Board members must be a resident of the neighborhood, be influential and credible among peers, and have interest in collective neighborhood efforts. We will hold the first neighborhood advisory board meeting in the **TX** neighborhoods within the first two weeks of the 24-week intervention period. At the first meeting, the research staff will make a brief presentation on the unique health risks of smoking for AAs, an overview of our study protocols, and the objectives of the advisory board. They will be told that 29 women in the neighborhood have enrolled in a cessation study, but the identification of enrolled participants will not be shared. The project directors, PI or Co-I, and CHWs will attend each neighborhood advisory board meeting.

The objectives of the neighborhood advisory board are to implement tobacco-related policy and counter-marketing strategies that will foster the success of the women attempting to quit smoking and any other resident who wishes to quit smoking. A set of “core” events and activities for each neighborhood will include a neighborhood “kick-off event,” at least two neighborhood anti-smoking events, and at least one policy change. Neighborhood advisory boards will receive a program implementation manual that describes how to implement the program and suggested potential events and activities. Examples of neighborhood counter-marketing activities include: having a Smoke-Out Day, messages from community leaders, community food events with testimonials from former smokers, distribution of pamphlets on passive smoke exposure and risks to children, and message boards at the entrance to the community. Examples of policy activities include

setting guidelines about smoking at the community center, prohibiting smoking during children/family events, and allowing “public service credit” for women enrolled in study. In addition, neighborhoods will be encouraged to promote the project through strategies such as announcements on display boards and newsletters. Board members will receive training, project manuals, and technical assistance as needed.

Timelines and strategies will be developed during the first month, with implementation of planned events activities during the 24-week time frame. The research team will negotiate with the board to have a minimum of monthly meetings during the 24-week intervention period to adequately plan activities, assess progress, and establish feedback mechanisms. Each neighborhood advisory board will be provided a \$750 budget for the intervention period, and each advisory board member will receive a \$100 honorarium.

**Nicotine Replacement Therapy.** In accordance with the PHS *Treating Tobacco Dependence Guideline*, an 8-week supply of transdermal nicotine patches will be offered to each participant at no cost. The patches will be administered and monitored weekly following the group sessions by the certified smoking cessation counselor. Participants will initiate the nicotine patch on their established quit date (usually set within 2 weeks of the intervention period). Participants who smoke 10 or more cigarettes per day will receive the 21 mg patch for 2-4 weeks, 14 mg patch for 2 -4 weeks, and the 7 mg patch for 2 weeks. Individuals who smoke less than 10 cigarettes per day will receive the 14 mg patch for 2-4 weeks and the 7 mg patch for 2-4 weeks. In addition to the receptiveness of using the nicotine patch in our pilot studies, research findings have repeatedly demonstrated effective smoking cessation outcomes with the use of over-the-counter (OTC) nicotine patch and behavioral interventions with low-income, inner-city AAs [65,72,109]. *The use of an OTC product in clinical studies may allow sustainability of translating the intervention in a “real world” setting in this population.*

**Study Specific Written Cessation Materials.** Written cessation materials (*Sister* handbook) will be given to each participant at enrollment. This 96-page, 8 1/2 x 11 inch handbook is designed to accompany each group session (described above). The materials are organized into the 6 thematic group sessions. The materials contain information on principles of addiction, pros and cons of quitting smoking, health risks of smoking, benefits of quitting, behavioral and coping strategies, stress reduction, pharmacotherapeutics for cessation, relapse prevention, weight management, nutrition, and physical activity. There are prompts and space available to record personal diaries and goal setting, and selected inspirational scripture and poems throughout the handbook. This handbook has been developed by our initial neighborhood advisory board and CHW staff, with multiple revisions during the preliminary and pilot work based on focus group and process evaluation measures. A CHW developed the chosen logo for the locally developed handbook which reflects a figure of two AA women supporting each other with the preferred ethnic body image and style of the neighborhood women. Based on recommendations from the literature [110,111] and from the study partners, the *Sister* handbook has been developed at a 3<sup>rd</sup> – 4<sup>th</sup> grade reading level. The handbook contains colorful ethnic graphics and photos of “ordinary women;” uses easy-to-read, monosyllabic words printed in large font; contains graphics and photos that provide meaning to the text; uses a simplistic and concise formatting design with simple page layouts and adequate white space; and is printed on glossy paper and bound in a 3-ring binder. (A copy of the handbook is provided in the Appendix). The handbook is distributed to participants at the first group session. Our preliminary studies show that women bring the handbook to each group session, and report using the handbook for up to one year post cessation [19].

**Summary of Protocol for Treatment Condition.** *In each TX neighborhood, the 24-week intervention will occur after the neighborhood data collection and recruitment/enrollment of*

eligible participants. *During the recruitment period*, we will recruit and enroll 29 eligible women who smoke and collect the baseline data. *During the 24-week intervention period*, we will concurrently deliver strategies at the individual, peer groups, and the neighborhood level for the 29 women participants who have enrolled. In the first week of the intervention period, the CHWs will begin their 1:1 contacts with the 29 enrolled women, and the cessation counselor will initiate the peer group counseling sessions. Within the first two weeks of the intervention period, the neighborhood advisory board will meet to develop a timeline and strategies to promote neighborhood level smoking policies and counter-marketing campaigns. The CHWs will interact (face-to-face or phone) with the 29 enrolled participants weekly for 12 weeks, every other week for 4 weeks, and every 4 weeks for 8 weeks to enhance smoking cessation self-efficacy and spiritual well-being. The smoking cessation counselor will lead peer group meetings for the 29 enrolled participants as a means for social support (8-12 participants per group) weekly for 6 weeks, and administer the nicotine patch and the Sister to Sister handbook. The 5-member neighborhood advisory board will identify and implement neighborhood level strategies (policies and counter-marketing campaigns) over this 24-week period to enhance participants' cessation success.

**Control Condition.** Participants in the control condition will receive *Pathways to Freedom: Winning the Fight Against Tobacco* at baseline. It is a 36-page self-help manual designed for AAs and written at the 6<sup>th</sup>-8<sup>th</sup> grade reading level [111]. The manual includes characteristics of smoking among AAs, health risks of smoking, how to quit smoking, coping strategies, and how to stay quit. Control participants will receive additional materials in the mail at week 6 (*State-Sponsored Toll-Free Tobacco Quit Line* pamphlet), week 12 [PHS Guideline patient pamphlet (*You Can Quit Smoking*)], and week 18 [ACS pamphlet (*When Smokers Quit*)].

At the request of our CAB, the control participants will be offered a delayed intervention at the end of the study (i.e., the 12 month data collection has been completed). This intervention will include a 1-hour face-to-face counseling session with the cessation specialist, personal contact by a CHW every other week for 8 weeks, and an 8-week supply of nicotine patches. The cessation specialist will meet with the participant to discuss readiness to quit smoking, risks and benefits of quitting, strategies for cessation, and the use of the nicotine patch. If the participant sets a quit date, an 8-week supply of nicotine patches will be offered to the participant. The CHW will have 4 personal follow-ups with the participant over an 8-week period to assess progress, share personal testimonials, and reward positive achievements. *The treatment teams will have no contact with the control participants until after all 12-month data collection has been completed.*

### **Data Collection Procedures.**

**D2d1. Neighborhood level:** *To assess neighborhood level moderators, baseline neighborhood-level data will be collected by ethnic minority graduate students at each site. This neighborhood data will be collected from a 20% random sampling among female heads-of-households in each neighborhood. For example, in a neighborhood with 240 households, n=48 households will be sampled. There are a total of 2,856 households in these 14 neighborhoods, and the total sample size (20%) for this neighborhood data will consist of 571 female heads-of-households. A diagram of the layout of each housing neighborhood will be used to randomly assign the households for the respective neighborhood. A uniform random number will be generated using SAS 9.1.3 and assigned to each household. Households will then be sorted in ascending order by their corresponding random number. Randomization procedures will be done by the project statistician. Adult female heads-of-households will be approached (up to 3 visits) by the graduate students for participation in order of randomization until the number of households (i.e., 48) in each neighborhood has been surveyed. After providing an information sheet and obtaining verbal*



*assent, the graduate student will read aloud the surveys (36-items; 3 instruments) as described in D2c3 and mark their responses on the data collection tool. Data collection will take place at the respective household. Each woman completing the survey will receive a \$10 gift card, with choice of selection from local merchants (i.e., Wal-Mart, local grocery store).*

*Individual level: Data collection procedures for eligible, consented participants will occur after the neighborhood level data have been completed. Neighborhood residents will be invited to attend an informational session at the respective community center in the housing complex. Immediately following this session, eligible participants will be screened, consented, enrolled, and baseline data will be collected. Data collection for individuals enrolled in the study will be conducted by trained research assistants and will take place in the neighborhood community center. The data collectors are independent from both the intervention and interventionists.*

*The data collector (i.e., research assistant) will read aloud the instruments for each participant and mark their responses on the data collection tool. The entire data collection will take approximately 45 minutes for each participant at each time point. Ten days prior to scheduled 6- and 12-month data collection, a post-card will be mailed to each participant. Twenty-four to 48 hours prior to the 6- and 12-month data collection, the staff will make personal or phone contact with participants as a reminder. Separate toll-free phones lines will be established for participants at each site. Individual participants will receive a \$25 gift card at baseline; \$50 gift card at 6 months; and \$100 gift card at 12 months.*