Supporting Justification for OMB Clearance Package

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN AMERICAN WOMEN
PHASE II

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A. JUSTIFICATION

A1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

One of the objectives of Healthy People 2010 is to increase the proportion of women aged 40 years and older who have received a mammogram within the preceding 2 years (U.S. Department of Health and Human Services, 2000). In August 1990, Congress enacted the Breast and Cervical Cancer Mortality Prevention Act, thereby authorizing CDC to establish a national public health infrastructure to increase breast and cervical cancer screening among low-income women who are uninsured (Attachment A). In 1991, CDC established the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), a comprehensive women's health initiative implemented through cooperative agreements with qualifying health agencies. The NBCCEDP seeks to increase breast and cervical cancer screening among uninsured, low-income women. Participating programs provide breast and cervical cancer screening; diagnostic testing; surveillance and follow-up; case management; public education and outreach; professional education and training; quality assurance of screening tests; coalition and partnership development; and program evaluation.

The NBCCEDP has had success in delivering mammography and Papanicolaou (Pap) screening tests to participants; however, nationally, the program is estimated to reach only approximately 18% of eligible women aged 40 to 64 years with mammograms (Tangka et al., 2005). As a result, a priority of the NBCCEDP is to identify effective strategies to increase enrollment among program-eligible women who have never received breast or cervical cancer screening. There is a need to improve outreach to this population of at-risk women for whom services exist and are accessible, but who are not participating for reasons not yet identified in previous studies.

Why NBCCEDP-eligible women do not participate in screening is not well understood. CDC's strategic priorities include addressing why women do not participate, as well as the disparity in screening detection rates among African American women. The results of the proposed data collection will inform the design, planning, and implementation of future CDC efforts to reach never or rarely screened women, particularly African American women, to increase their participation in the NBCCEDP.

The Centers for Disease Control and Prevention (CDC), Division of Cancer Prevention and Control, is requesting Office of Management and Budget (OMB) approval for the second phase of an ongoing research study to test communication concepts and radio messages with low-income, African American women aged 40 to 64 years in Macon and Savannah, Georgia.

In phase I of this study, CDC obtained approval (OMB number 0920-0652) to investigate, through a series of eight focus groups, the reasons why low-income, African American women aged 40 to 64 years and eligible for participation in the NBCCEDP in Macon and Savannah, Georgia do or do not participate in the program and the viable sources, messages, and channels through which to reach this population with promotional screening messages to motivate them to obtain annual mammograms.

Phase I of the study produced the following findings:

- Across groups, participants (especially NBCCEDP enrollees) believed that African American women in general were at increased risk of developing breast cancer due to family history of cancer, poor diet, and lack of health insurance.
- Participants were generally unaware of national guidelines for getting a mammogram. They offered varied thoughts about when a woman should obtain a mammogram, including the following: if she detects a lump in her breast; when she turns 40; at 18 years of age; when she becomes sexually active; every 3 to 6 months; and twice a year.
- NBCCEDP enrollees who had recently received a mammogram through their local breast and cervical cancer program (BCCP) were more likely than non-enrollees to exhibit awareness of local screening services; however, overall, participants did not know the name of their local BCCP.
- Across groups, many participants voiced concerns about mammograms, including exposure to radiation during screening, discomfort, pain, and embarrassment.
- Non-enrollees (of the NBCCEDP) were extremely skeptical about the quality of low- or no-cost mammograms and were ambivalent about technician qualifications; correct interpretation of results; technicians' treatment of them because they are African American, poor, and uninsured; and follow-up care if diagnosed with breast cancer.
- Participants preferred to receive health information via print media in the mail, at doctor's offices, and from the health department; however, they were also receptive to receiving health information via the radio. Across groups, they stated that they wanted factual, serious health messages about breast cancer and mammography disseminated to them via print media, radio, and television.
- Participants commonly identified the health department, hospitals, churches, breast cancer survivors, doctors, and health care professionals as trusted organizations and individuals to provide health information to African American women.
- Participants reported that serious messages showing concern, sympathy, and reassurance; messages providing statistics about breast cancer risk among African American women specifically; and messages stating how early detection can save lives would be the most effective in motivating African American women to get screened for breast cancer.

The purpose of phase II of this study is to (1) test audience response to concepts that arose in the phase I formative research related to breast cancer and screening and (2) test audience response to radio health messages about breast cancer and screening. Specifically, the objective of concept testing is to determine whether the ideas, words (e.g., strength, live long), images (e.g., African American women, reflections of self), or concepts (e.g., shared experiences) developed on the basis of phase I formative research findings are clear and understandable to the target audiences; are personally relevant to the target audiences; have sensitive or controversial elements; capture the audience's attention; match the audience's preferences for wording and format; and confirm that selected settings and activities are appropriate. The objective of message testing is to explore participants' thoughts about radio messages identified and developed on the basis of phase I formative research findings. Participants will be asked questions about message comprehension, source credibility, approval of the voices, and message ability to reinforce and/or motivate desired behaviors (e.g., breast cancer screening/mammography).

The information collection for this approval was sought and approved in accordance with CDC's mission to conduct, support, and promote efforts to prevent cancer and to increase early detection of cancer, authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment B).

A2. Purpose and Use of the Information Collected

The results of this study will inform the development of health communication to women eligible for services through local programs in Georgia. The specific planned use of the information gained from this study will help improve NBCCEDP outreach to eligible African American women and, consequently, work to address health disparities related to mammography and breast cancer in this population.

To develop effective interventions, the project must consider the audience, message, medium, and source of the message. The purpose of this ongoing research project is to use focus groups to test communication concepts and radio messages targeting African American women who are between the ages of 40 and 64 years and eligible for participation in their local BCCP. Although the findings from focus groups are neither quantitative nor generalizable to the population as a whole, the information gained from the focus groups will assist the NBCCEDP in determining more effective avenues for reaching the target population in Georgia with tailored interventions aimed at increasing participation rates among these women. The NBCCEDP received $4 million for fiscal year 2006 to provide screening services to eligible women across the country.

There is an expected phase III of this project, which will use the findings from phases I and II to develop, implement, and evaluate a radio campaign aimed at promoting breast cancer screening in the target population.

A3. Use of Improved Information Technology and Burden Reduction

The proposed project does not involve automated, electronic, mechanical, or other advanced technologies in the collection of information other than the use of audiotape to retain an accurate record of the focus group discussions. Focus group data will be collected in hotel conference rooms in Macon and Savannah, Georgia. Participants' use of information technology is not applicable, as the Pre-Discussion Information Sheet (PDIS) (Attachment D) will be administered via a pencil-and-paper format and focus group discussions will be conducted in person.

Because of the nature of this study and the population with which it is conducted, it is not feasible to employ information technology in the form of electronic respondent reporting. A recent systematic review of the evidence on literacy and health outcomes found that people who live in the South or Northeast, are female, are from certain racial or ethnic groups, are elderly, or have completed fewer years of education have higher prevalence of low literacy (Berkman et al., 2004). Because many of the respondents in this study are likely to have low literacy and, as a result, may have difficulty using complicated information technology in reporting, efforts have been made to design a written study protocol and instruments that are brief, easy to use, and understandable. In addition, the study investigators have carefully considered the content, appropriateness, and phrasing of questions in both the PDIS and the focus group discussion.

Only the minimum information necessary for the purposes of this project will be collected. Standard focus group methodology recommends conducting multiple focus groups with any one type of participant (Krueger & Casey, 2000). This is done to ensure that comparisons can be

made among groups of the same type of participant and that saturation (the point when the range of all ideas is heard and no new information is collected) is reached. Despite this suggestion, the project will include only one focus group with each audience segment, to reduce burden by collecting the minimum information necessary for the study as was previously approved for the first phase of study (OMB number 0920-0652).

A4. Efforts to Identify Duplication and Use of Similar Information

The literature review on the utility of mass media outlets in communicating public health messages showed that radio and television can play a role in health promotion in the African American community. Studies indicated that airing health messages on radio stations serving the African American population can be an effective way to reach a broad African American audience with information about important health issues (Johnson & Birk, 1993). Other studies indicate that visual aids and media outlets may be even more effective than print materials in sharing health information, given health literacy issues among this particular population (O'Malley, Kerner, & Johnson, 1999; Davis et al., 1998).

However, these studies are limited, and there is a dearth of literature on how effective using radio stations that target African Americans can be in broadcasting health information to this population and, more importantly, in motivating them to seek breast cancer screening. The initial study gathered information on preferred sources and channels of health promotion messages targeted specifically to African American women, in two locations in Georgia, with a sample size large enough to identify common themes and yield reasonable estimates.

This study (phase II) proposes to test concepts and messages with information identified as important to the target audience in the phase I formative research. Specifically, this study will test communication concepts and radio health messages developed to increase mammography screening among low-income, African American women aged 40 to 64 years in selected Georgia cities. The goal of this study is to determine the cultural appropriateness of the message, determine its effectiveness in promoting screening among these women, and confirm that selected settings and activities are appropriate.

A5. Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be impacted by this data collection.

A6. Consequences of Collecting the Information Less Frequently

This is a one-time study. Reducing the respondent burden below the estimated levels (i.e., reducing the number of focus groups or number of participants per group) would diminish the utility of the study. Although it is methodologically desirable to have at least two focus groups per audience segment (Krueger & Casey, 2000), the study has already reduced the number of focus groups to one per segment to minimize burden (see Table B2). Collecting the information less frequently would detract from the purpose of the study. There are no legal obstacles to reducing the burden further.

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

This project fully complies with all guidelines of 5 CFR 1320.5.

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

A8a. 60-Day Federal Register Notice

A 60-day notice for public comments on the proposed data collection activities required by 5 CFR 1320.8(d) was published in the Federal Register on February 16, 2006, volume 71, number 32, pages 8306–8307. One comment was received and a response was given. A copy of the notice is included in Attachment I.

A8b. Efforts to Consult With Persons Outside the Agency

The evaluation plan and instruments were developed and/or revised on the basis of discussions with Kimberly Redding, M.D., M.P.H., medical director, State of Georgia Department of Human Resources, Division of Public Health (GA DHR). Discussions with Dr. Redding in December 2005 through January 2006 helped clarify and focus the goals and objectives for phase II of this study and ensure that the data collected would inform health communication and outreach to African American women eligible to participate in their local (i.e., Georgia) NBCCEDP. The GA DHR was a partner in the first phase of study where focus groups were held with women who had been screened through the state screening program. The following information was requested about consultation with representatives outside of the agency to obtain their views on this research and data collection.

Consultation Year(s)	2005, 2006
Contact information for those consulted	Dr. Kimberly Redding Division of Public Health Georgia Department of Human Resources Two Peachtree Street NW Atlanta, GA 30303-3186 Phone: 404-657-2700
Summary of problems not resolved during consultation	No problems arose during consultation that were not addressed at that time. One issue of concern raised during discussions with Dr. Redding was whether the local BCCP could absorb additional women who may present for screening as a result of this project's current efforts or a phase III campaign for this project. It was decided that if this work and/or a phase III intervention/campaign caused a significant increase in eligible women seeking screening, the study would revisit a discussion about additional funding or consider placing eligible women on a waiting list for screening services.

A9. Explanation of Any Payment or Gift to Respondents

Incentives serve as an acknowledgment that the information and time provided by respondents are valuable (Salant & Dillman, 1994). Multiple studies using a variety of data collection methodologies have shown that offering incentives increases response rates (Davis et al., 1998; Salant & Dillman, 1994; Church, 1993; Groves & Couper, 1998; Singer, Gelber, Van Hoewyk, & Brown, 1997; Singer, Van Hoewyk, & Maher, 2000). Incentives are offered to increase the likelihood of participation and to thank respondents for their time and input to the study. Although the incentive amount may vary (e.g., by the type of interviewees, the length and burden of the interview), the impact of an incentive on the response rate does not vary by data collection type (Salant & Dillman, 1994).

In the phase I study (OMB number 0920-0652), a $65 incentive was given to respondents for their participation in the focus groups. In addition, a light meal was served. Of the eight focus groups conducted in phase I, seven were filled to capacity, with 10 participants each. The remaining group consisted of eight participants.

For the phase II study, focus group participants will again be given $65 for their participation. As before, a light meal will be provided.

A10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act does not apply to this data collection. Response data will not be identified, stored or retrieved by respondent name.

Efforts will be made to ensure that respondents' personal information is secure at every step of the protocol, including recruitment and focus group discussions. Although full names and contact information of respondents will be recorded for tracking purposes throughout recruitment (see p.8), identifiable information will be destroyed after recruitment is completed and participation is confirmed. The identifiers used for recruitment and scheduling purposes are not linked to response data at any time.

Full names and contact information for follow-up correspondence during the recruitment protocol will be kept in locked file cabinets or password-protected computer files. All recruitment activities will be recorded and updated in a recruitment tracking database in Microsoft Access. Audiotapes of the focus groups will not be transcribed and all will be destroyed at the end of the study.

All study results will be presented in aggregate form. In every instance, respondents will be told that the information they provide in the focus groups and on the PDIS will be treated in a secure manner and will not be disclosed except as required by law.

The full names of focus group participants will be recorded for tracking purposes throughout recruitment, but they will not be identified in the notes or in any of the analysis or written reports. Only the Contractor, ORC Macro, and the LSRs facilitating recruitment of the respondents will have access to respondents' full names. CDC will see only participants' first names on name tents during the focus group.

Check In Process. At the time of the focus groups, ORC Macro staff will check in each focus group respondent using a roster of participant names provided by the LSRs who conducted respondent recruitment. Following check-in, each respondent will be provided with a name tent indicating their first name only. Respondents will be directed to a waiting area where they will be provided light refreshments before the focus group convenes. Once all respondents are checked in, the focus group hostess will direct them to the focus group room where they will meet the moderator and start the focus group discussion.

Access to and Protection of Respondent Names*.* At the time of the groups only ORC Macro staff and the LSRs will have access to respondent names. After the focus groups have been conducted, the LSRs will provide all screeners, original copies of the recruitment logs and any lists of respondent names or other identifying information to ORC Macro. ORC Macro staff will then be the only persons with access to respondent names and will store all materials with identifying information in locked file cabinets or password-protected computer files. At the conclusion of the project, all identifying information and audiotapes of the groups will be destroyed.

To further protect identifying information, all focus group observers (ORC Macro and CDC researchers) will be asked to sign an observer confidentiality form (Attachment J), stating that they will treat all information they hear in a secure manner, unless otherwise required by law. The local site recruiters subcontracted by ORC Macro are also being required to complete a confidentiality agreement (Attachment K).

The focus group discussion notes will be recorded in such a way that respondents cannot be identified, directly or through identifiers linked to them. In addition, identifiable, potentially sensitive screening data are maintained separately from the response data collected during focus group discussions.

Focus group participants will be asked to complete an informed consent form (Attachment C). At the start of each focus group, the consent form will be read out loud by the focus group moderator. The consent form details the limited risks and benefits of their participation, the purpose of the group, the expected duration of the group, their rights as respondents, and contact information of study personnel. The form also informs the respondents that participation is voluntary. Respondents will be asked about any concerns or questions they might have, before they are asked to provide their signature, indicating consent. The moderator will serve as a witness and will also sign the consent form of each respondent.

Respondents will be given a copy of the informed consent form to take with them. The form includes contact information for the Project Manager, who can be contacted by respondents if they have any questions once the groups are over. Consent is an ongoing process, and respondents may withdraw at any time and still receive the full incentive.

ORC Macro will maintain continual communication with the LSRs throughout the recruitment process. LSRs will be instructed to ask all questions in the recruitment screener before terminating due to ineligibility. LSRs will be instructed to complete a daily log documenting their recruitment efforts and will fax the logs to ORC Macro staff daily. The logs will capture the date, type of activity (such as attending a church social), and time spent in each attempted recruitment location. First and last names as well as contact information will only be recorded for women who are screened and eligible to participate in a focus group. LSRs will be instructed not to record names and contact information for women who are screened but found to be not eligible for focus group participation.

ORC Macro staff will then conduct reminder calls; mail reminder cards and directions to respondents; and ensure that respondents check-in at the time of the groups.

Per their required confidentiality agreement (Attachment K), LSRs will keep all screeners and original copies of the logs used to track recruitment in a secure place until meeting with ORC Macro on the first day of the focus groups. At that time, all screeners and original copies of the logs will be given to ORC Macro.

ORC Macro will record and update all recruitment activities in a Microsoft Access database. In order to protect respondents' confidentiality, ORC Macro will keep all identifying information about participants in locked cabinets and password protected computer files which will be destroyed at the end of the study.

On May 26, 2006, the project obtained notice from CDC's Human Research Protection Office that this protocol was exempt from IRB review. The expiration date is May 25, 2007. A copy of the notice of exemption is included in Attachment L.

A11. Justification for Sensitive Questions

Respondents will provide limited personal (i.e., demographics) information. The questions in the PDIS or moderator guides ask about respondents' opinions and thoughts regarding the message concepts and appropriateness. Questions are designed to determine if the concepts and messages are clear and understandable to the target audiences; are personally relevant to the target audiences; have sensitive or controversial elements; capture the audience's attention; match the audience's preferences for wording and format; and confirm that selected settings and activities are appropriate. Other questions are about opinions and thoughts regarding message concepts and appropriateness; participants will not be asked about their own personal health in focus groups.

This data collection involves requesting information on several topics that may be viewed as sensitive by a portion of respondents. These topics include race/ethnicity, income, educational level, and previous diagnosis of cancer. Although potentially sensitive, these questions are necessary because the research investigates a health disparity related to African American women's use of breast cancer screening services, and seeks input about concepts and messages aimed at promoting mammography in a specific target population. The questions are a necessary part of the screening process to ensure 1) eligibility to participate and 2) to ensure that the focus groups are racially homogeneous, which facilitates group interviewing.

A12. Estimates of Annualized Burden Hours and Costs

A12a. Burden

Burden for this effort is based on an 80% response rate (i.e. 80% of persons who are recruited to participate, are eligible, and agree to participate). Therefore, of the 150 women who are approached during recruitment for the 8 focus groups, a total 120 (15 per group) will be eligible and agree to participate. These 120 eligible women will be scheduled to attend groups to account for attrition, however only 80 women will actually participate in the groups in total (10 per group). Additionally, of the 120 eligible women scheduled to attend the focus groups, 20% (24 total, 3 per group) will be re-screened by ORC Macro for quality assurance purposes.

The recruitment screener will take approximately 5 minutes to complete, the completion of the PDIS will take approximately 30 minutes, and the focus group discussion will take approximately 90 minutes. Table A12a shows the total burden hours, using this information. The Attachments include one version of the PDIS adapted for focus group respondents (Attachment D) and one version of the PDIS adapted for the moderator's use (Attachment E).

Table A12a. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
African American women, aged 40–64 years	Recruitment Screener (initial)	150	1	5/60	13
	Recruitment Screener (spot-check)	24	1	5/60	2
	Pre-discussion Information Sheet	80	1	30/60	40
	Moderator's Guide (used to facilitate Informed Consent and Focus Group Discussion)	80	1	90/60	120
				TOTAL	175

A12b. Respondent Cost

Table A12b presents the calculations for cost of annualized burden hours. Georgia State minimum hourly wage rate information is from the Web site of the U.S. Department of Labor (http://www.dol.gov/esa/minwage/america.htm#Georgia). The total annualized respondent cost of burden hours is estimated at $898.00.

Table A12b. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage Rate	Total Cost

African American women, aged 40–64 years	**Recruitment Screener (initial)**	150	1	5/60	$5.15	64
	Recruitment Screener (spot-check)	24	1	5/60	$5.15	10
	Pre-discussion Information Sheet	80	1	30/60	$5.15	206
	Focus Group Discussion	80	1	90/60	$5.15	618
					TOTAL	$898

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

Respondents will incur no capital or maintenance costs to complete this data collection.

A14. Annualized Cost to the Federal Government

Table A14 presents the costs to the Federal Government. Two types of Government costs will be incurred:

1. Government personnel. The Technical Monitor is assigned for 50% of their FTE. Assuming an annual salary of $85,000 for the Technical Monitor, the total amount paid to Government personnel is $42,500.

2. Contracted data collection. The project design and data collection is being conducted under a contract with ORC Macro. The contract is for a total of $147,500 and includes costs for subcontracting to local site recruiters and conducting the focus groups.

Therefore, total annualized cost to the Federal Government for this data collection is $190,000.

Table A14. Estimates of Annualized Cost to the Government

Item	Annualized Cost
Technical Monitor at 50% of their FTE	**$42,500**
Contractor	**$147,750**
TOTAL	**190,000**

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

Analysis Plan

The analysis plan for this study was developed by taking into account the resources available for analysis, the anticipated quantity of data that will be generated from eight focus groups, and the anticipated use of the findings.

Data from the PDIS will be analyzed with Statistical Package for the Social Sciences (SPSS), version 13.0. PDIS data will be entered into an SPSS database, and frequencies will be run for each of the questions on the PDIS. The resulting analyses will be used only as a means of describing the study participants and drawing comparisons between groups or segments. Data obtained from the PDIS will not be used to make generalizations about any larger population and will be reported and analyzed in aggregate form.

Once the focus groups are completed, the notetakers will analyze the field notes across the groups for a specific segment and enter their notes into a data table prepared for analysis of the phase II focus group data. A sample data table is attached (Attachment O). The data table will be organized by the sections of the moderator guide, divided into age and enrollee versus non-enrollee segments. This will allow for the easy recording of age and enrollee/non-enrollee themes and differences and will guide notetakers in how to record details in each section of the table.

The ORC Macro team will use a rigorous, systematic process when completing the data tables, to ensure reliability and consistency among the notetakers in how the data are summarized and to ensure neutrality in the reporting and interpretation. The ORC Macro analysis team will meet on a regular basis to compare findings and discuss the interpretation of the data. Should differences in interpretation occur, team members will reexamine and discuss the data tables and field notes until they reach agreement in their findings and interpretation of the data.

Particular attention will be given to capturing the frequency of topics, extensiveness of the response across participants, and the intensity of the response. For example, the analysis team will identify patterns or themes that are clearly and frequently expressed within each group, as well as those that are more subtle or less often voiced. The team will consider ideas or thoughts that are voiced once or several times and nonverbally supported by group members, but not necessarily repeated frequently by others in the groups. On the basis of these discussions, the themes that are common across the segments and themes that distinguish among the segments will be identified. The themes from the focus groups will be either articulated directly by participants or identified by the analysis team.

Analysis team members will also review the field notes to flag any specific quotes that were recorded, to illustrate the themes and primary patterns and capture additional group dynamics. If possible (from the quotes recorded in the notes), quotes will be included in each segment to illustrate common themes.

The analysis of field notes will serve as the basis of the bullet-point topline summary of general themes and patterns from the focus groups. The topline summary will include the terms “several,” “a lot of support,” and “not a lot of support” to describe focus group discussions. Other acceptable terms to use to describe participants’ comments and ideas include “some,” “many,” “most,” and “a few.” Setting numerical parameters to quantify terms such as “some,” “many,” “most,” and “a few” is not a standard practice when describing qualitative data, and every

attempt will be made to ensure that all comments and insights are reported in a consistent and accurate manner.

ORC Macro will meet with CDC to obtain feedback and comments on the topline summary, then revise it accordingly.

Publication
Results from this data collection will likely be disseminated in peer-reviewed publications.

Study Timeline
Table A16 presents the estimated timeline for this study. A 1-year clearance is requested.

Table A16. Study Timeline

Study Activity	Estimated Date of Completion
Recruit participants in location 1	3 to 6 weeks after OMB clearance
Conduct groups in location 1	6 to 8 weeks after OMB clearance
Recruit participants in location 2	6 to 8 weeks after OMB clearance
Conduct groups in location 2	8 to 10 weeks after OMB clearance
Analyze data	14 weeks after OMB clearance
Produce topline summaries	14 to 18 weeks after OMB clearance

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

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

A18. Exemptions to Certification for Paperwork Reduction Act Submissions

There are no requested exemptions to the certification.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. RESPONDENT UNIVERSE AND SAMPLING METHODS

The target audience for this project is African American women aged 40 to 64 years who are eligible for participation in the NBCCEDP in Macon and Savannah, Georgia. The focus groups will be composed of women from this population. Half of the participants will be women who have received a mammogram in the past 24 months (medically screened), and the other half will be women who meet the eligibility criteria for enrollment but have not had a mammogram in the past 3 years (unscreened). They will be asked to provide information about their opinions and thoughts regarding concepts and messages being tested in the focus groups.

There will be a total of eight focus groups. Four groups will be conducted in Macon, Georgia, and four groups will be conducted in Savannah, Georgia. In each city, the four groups will be conducted with NBCCEDP-eligible African American women who have never been diagnosed with breast cancer, live within a specific set of ZIP Codes, and do not have any family members who have been recruited for this study. The focus groups will be segmented by age (40 to 49 years and 50 to 64 years) and screening status (screened within the past 24 months and not screened within the past 3 years). Segmentation by age allows the study to explore any differences about how younger and older women view breast cancer and potential differences in response to concepts and messages tested. Segmenting by age will also help maintain a greater level of group homogeneity (Patton, 1990). Table B1 shows the focus group segmentation plan for the eight focus groups.

Table B1. Segmentation Plan

City	Screened (Women Screened in the Past 24 Months)		Unscreened (Women Not Screened in the Past 3 Years)	
	40–49 years	50–64 years	40–49 years	50–64 years
Macon	1 group	1 group	1 group	1 group
Savannah	1 group	1 group	1 group	1 group

The unit of analysis for this study is the focus group segment, and the segmentation plan for this focus group study allows the investigators to analyze the data by each unit. The study will contain eight segments of analysis:

1. African American women who have been screened within the past 24 months, aged 40 to 49 years, in Macon, Georgia
2. African American women who have been screened within the past 24 months, aged 40 to 49 years, in Savannah, Georgia
3. African American women who have been screened within the past 24 months, aged 50 to 64 years, in Macon, Georgia
4. African American women who have been screened within the past 24 months, aged 50 to 64 years, in Savannah, Georgia

5. African American women who have not been screened within the past 3 years, aged 40 to 49 years, in Macon, Georgia
6. African American women who have not been screened within the past 3 years, aged 40 to 49 years, in Savannah, Georgia
7. African American women who have not been screened within the past 3 years, aged 50 to 64 years, in Macon, Georgia
8. African American women who have not been screened within the past 3 years, aged 50 to 64 years, in Savannah, Georgia

This is an exploratory focus group study; therefore the unit of analysis is each focus group. The PDIS will be used only as a means of describing the study participants and drawing comparisons between groups or segments. These data will be reported and analyzed only in aggregate form. Data obtained from the PDIS will not be used to make generalizations about any larger population. The number of participants per focus group will be approximately 6 to 10. Therefore, for eight focus groups, the estimated number of participants is between 48 and 80 women.

B2. Procedures for the Collection of Information

The Persuasive Health Message Framework (Witte, 1995), an integrated approach to generating audience-specific messages, was used to guide data collection efforts in phase I and continues to guide data collection efforts in phase II. Phase II of the study involves concept and message testing through focus groups with the target population. The objective of the concept testing is to evaluate the effectiveness of the basic ideas (or concepts) for the radio messages created. This study's goal is to determine whether the ideas or concepts that were developed on the basis of the phase I research findings are clear and understandable to the target audiences; are personally relevant to the target audiences; have sensitive or controversial elements; capture the audience's attention; match the audience's preferences for wording and format; and confirm that selected settings and activities are appropriate.

The specific research question (RQ) and subquestions for concept testing are as follows:

RQ1: What are the audience's general thoughts about the concepts presented?
- Are the concepts understandable to this audience?
- Are the concepts believable to this audience?

The objective of message testing is to explore participants' thoughts about radio messages identified and developed on the basis of the findings from phase I formative research. Moderators will ask participants questions about message comprehension, source credibility, approval of the voices, and message ability to reinforce and/or motivate desired behaviors (e.g., breast cancer screening/mammography). The specific research questions and subquestions for message testing are as follows:

RQ2: What are the audience's general thoughts about the radio ads?
- What is the audience's initial reaction to this radio ad?
- Does the radio ad catch the audience's attention?
- If the audience heard this ad on the radio, would they listen/pay attention to it? Why/why not?

RQ3: Are the radio ads understandable?
RQ3a: Does the audience interpret the ads correctly?

- What does this radio ad say to the audience?
- What does the audience think is the main message it is trying to communicate?
- Is there anything confusing about this ad?

RQ4: Does the audience relate to the radio ads?

RQ4a: Does the audience feel like the ads speak to them, or to someone else (e.g., other types of people)?

- Did the audience relate to what this radio ad is saying? Why/why not?
- Whom does the audience think this radio message is meant for?
- Does the ad speak to the audience? Why/why not?

RQ4b: Does the audience believe what the radio ads are saying?

- Does the audience believe what this radio ad says? Why/why not?
- Does the audience think there is a better way to say what this ad is trying to say? If yes, what is the better way to say what the ad is trying to say?
- What else would the audience want to hear in this ad? Why?

RQ5: How does the radio ad affect the audience?

RQ5a: What emotional impact does it have on the audience?

RQ5b: What behavioral impact does it have on the audience?

- How does this radio ad make the audience feel?
- Is it encouraging or motivating? Why/why not?
- Does the ad make the audience think twice about the topic? Why/why not?
- Does the ad motivate the audience to call the number provided? Why/why not?
- Does the audience think they would get a mammogram after hearing this on the radio? Why/why not?

All focus group protocols and instruments are included in the following attachments:

- Attachment C: Informed Consent Form
- Attachments D and E: Pre-discussion Information Sheets (participant and moderator versions, respectively)
- Attachment F: Focus Group Moderator Guide
- Attachment J: Observer Confidentiality Form
- Attachment K: Confidentiality Agreement With Local Site Recruiters
- Attachment M: Recruitment Flyer
- Attachment N: Recruitment Screener

Selecting Recruiters

The local site recruiters (LSRs) will be African American women who received recruitment training and recruited women for participation in the phase I focus groups. These women will conduct recruitment for all of the phase II focus groups and work closely with ORC Macro and CDC staff to recruit women for the study.

Recruitment of Focus Group Participants

ORC Macro will subcontract with one LSR in Macon and one LSR in Savannah to identify and recruit eligible women to participate in the focus groups. LSRs will participate in a conference call that will provide an overview of focus group research, tips regarding recruiting, how to and how not to approach potential participants, where to conduct recruitment, and overall

recruitment protocol. The LSRs previously participated in an intensive 2-day in-person recruitment training during phase I of this study. The training session was conducted with all recruiters to ensure consistent protocol implementation. The two current LSRs are well versed in the process of recruitment, particularly for this population of women, because of their previous work as LSRs during phase I of this project.

NBCCEDP-eligible women who self-report that they have received a mammogram within the past 24 months (screened) or have not received a mammogram within the past 3 years (unscreened) will be recruited through in-person intercept recruitment techniques at a variety of community locations, including community centers, faith-based organizations, and malls. Intercept recruiting is a common approach to sampling in focus group research. The process entails recruiting participants by contacting them in locations frequented by members of the target population desired to participate in the study. The focus group is then held after recruitment in a convenient location (Krueger & Casey, 2000). In their intercept recruiting efforts, LSRs will use a recruitment flyer (Attachment M) and a recruitment screener (Attachment N) provided by ORC Macro.

Once screened and unscreened potential participants are identified, the LSR will fax or e-mail participants' names and contact information to ORC Macro staff members, who will conduct reminder calls; mail reminder cards and directions to participants; and ensure that participants check in at the time of the groups. To secure participants' confidentiality, the LSRs will complete a confidentiality agreement (Attachment K). Per their required confidentiality agreement, LSRs will keep all screeners and original copies of the logs used to track recruitment in a secure place until meeting with ORC Macro on the first day of the focus groups. At that time, all screeners and original copies of the logs will be given to ORC Macro. In addition, all identifying information about participants will be kept in locked file cabinets and password-protected computer files, which will be destroyed at the end of the study.

It is anticipated that the recruitment process will begin 1 to 2 weeks after OMB approval, and 1 to 2 weeks before the scheduled focus groups, to allow ample time to assess how recruitment is progressing and whether any focus group needs to be rescheduled.

All recruitment activities will be recorded and updated in a recruitment tracking database maintained by ORC Macro in a password-protected computer file to protect the confidentiality of all recruited participants. Screened but nonrecruited individuals will not have their names included in the database.

Informed Consent

Focus group participants will be asked to complete an informed consent form (Attachment C). At the start of each focus group, the consent form will be read out loud by the focus group moderator. The consent form details the limited risks and benefits of their participation, the purpose of the group, the expected duration of the group, their rights as participants, and contact information of study personnel. The form also informs the women that participation is voluntary. Participants will be asked about any concerns or questions they might have, before they are asked to provide their signature, indicating consent. The moderator will serve as a witness and will also sign the consent form of each participant.

Participants will be given a copy of the informed consent form to take with them. The form includes contact information for the ORC Macro project manager, who can be contacted by participants if they have any questions once the groups are over.

Pre-discussion Information Sheet

After obtaining consent, the moderator will administer parts 1 and 2 only of the PDIS (Attachment D). The moderator will first explain the purpose of the PDIS (Attachment E) and then read out loud each of the questions and responses in part 1 of the PDIS to gather background information about the focus group participants. Participants will be instructed to record their answers on the sheet given to them. Following part 1 of the PDIS, the moderator will administer part 2 of this instrument, which is a three-step pretest of radio messages. The moderator will play the first radio message, then read aloud each of the questions and responses in part 2a of the PDIS. Participants will be instructed to record their answers on the sheet they were given. The same three-step process will follow for the second and third radio messages.

- **Step 1:** Play the message
- **Step 2:** Read aloud questions and responses
- **Step 3:** Participants record answers on the PDIS

Focus Group Discussion

After participants have completed parts 1 and 2 of the PDIS, the moderator will conduct a 90-minute focus group discussion, using the moderator guide (Attachment F). The focus group discussions will be led by an African American female moderator to make participants feel more at ease. Standard focus group methodology recommends matching the moderator's race/ethnicity to that of the participants to encourage open discussion and increase participants' comfort (Krueger & Casey, 2000; Morgan, 1998).

During the focus groups, participants will be asked questions to test the three concepts (Attachment G) and three messages (Attachment H) to determine whether the concepts and messages (1) are clear and understandable to the target audiences, (2) are personally relevant to the target audiences, (3) have sensitive or controversial elements, (4) capture the audiences' attention, (5) match the audiences' preferences for wording and format, and (6) confirm that selected settings and activities are appropriate.

The focus group discussion will begin with questions related to three conceptual messages. The first concept board will be shown to participants, then the moderator will ask specific questions from the moderator guide about the concept board presented. The same process will follow for the second and third concept boards.

Next, the discussion will focus on the three radio messages already played during administration of part 2 of the PDIS. The first message will be played for participants, then the moderator will ask specific questions from the moderator guide about the message. Following the questions in the moderator guide, the moderator will administer the part 3 message posttest section of the PDIS. The moderator will read aloud each of the questions and responses in part 3a of the PDIS and instruct participants to record their answers on the sheet provided. Then, the moderator will move back to the moderator guide, play the second message, ask the corresponding questions from the moderator guide, and ask the corresponding posttest questions in part 3 of the PDIS. This same three-step process will follow for the third message.

After participants complete the message posttest for the last message, the moderator will ask the final questions in the moderator guide before ending the focus groups.

For the focus group data, two trained notetakers from ORC Macro will record the group discussions in field notes. The notetakers will also observe and record participant interactions

and the intensity of discussions in the form of gesticulations, head nodding, and other nonverbal communication. Each notetaker will be responsible for a particular audience segment (e.g., one notetaker will be responsible for the screened groups and another notetaker will be responsible for the unscreened groups). The detailed field notes will be used to perform a note-based analysis of the focus group data.

B3. Methods to Maximize Response Rates and Deal With Nonresponse

We expect an 80% response rate based on experience from Phase I. A number of measures are being taken to optimize recruitment of women to participate in the focus groups. ORC Macro will again subcontract with two previously contracted LSRs in Macon and Savannah, Georgia, to identify and recruit both screened and unscreened women to participate in the focus groups. This is to ensure that the recruiters are familiar with the localities and the community. LSRs previously participated in a conference call that included a thorough orientation to Phase I of the study, an update of the project goals and expectations, an overview of focus group research, tips regarding recruiting, how to and how not to approach potential participants, where to conduct recruitment, and overall recruitment protocol. This past experience will contribute to successful recruitment during Phase II.

All recruitment activities were monitored in Phase I and successful recruitment locations and strategies were identified and can be replicated for Phase II. ORC Macro staff will conduct reminder calls and spot checks with random screened and unscreened participants via telephone to rescreen them and ensure that participants check in at the time of the groups.

B4. Tests of Procedures or Methods to Be Undertaken

A trained moderator has reviewed the focus group protocol. In addition, all instruments and methods have been reviewed extensively by CDC/National Center for Chronic Disease Prevention and Health Promotion staff, including the Technical Monitor for this project, and LSRs from each of the two sites in which data are being collected. Staff from ORC Macro, the evaluation and research firm, also reviewed all instruments and methods for this study. All instruments were pilot-tested with fewer than 9 staff from ORC Macro to determine burden estimates.

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

No statistical sampling or estimation procedures will be used in this data collection. The Technical Monitor and CDC project consultant reviewed the protocol for this data collection:

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Study design, data collection, and analysis will be conducted by the following individuals (all persons listed below participate in all activities):

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ATTACHMENT A
BREAST AND CERVICAL CANCER MORTALITY PREVENTION ACT

TITLE 42
THE PUBLIC HEALTH AND WELFARE

Chapter 6a. The Public Health Service

Preventive Health Measures with Respect to Breast and Cervical Cancers
42 U.S.C. § 300k (1996)

§ 300k. Establishment of Program of Grants to States

(a) In general. The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States on the basis of an established competitive review process for the purpose of carrying out programs—

(1) to screen women for breast and cervical cancer as a preventive health measure;

(2) to provide appropriate referrals for medical treatment of women screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;

(3) to develop and disseminate public information and education programs for the detection and control of breast and cervical cancer;

(4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancer; (5) to establish mechanisms through which the States can monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures; and

(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program-monitoring activities.

(b) Grant and contract authority of States

(1) In general. A state receiving a grant under subsection (a) may, subject to paragraphs (2) and (3), expend the grant to carry out the purpose described in such subsection through grants to, and contracts with, public or nonprofit private entities.

(2) Limited authority regarding other entities. In addition to the authority established in paragraph (1) for a State with respect to grants and contracts, the State may provide for screenings under subsection (a)(1) through entering into contracts with private entities that are not nonprofit entities.

(3) Payments for screenings. The amount paid by a State to an entity under this subsection for a screening procedure under subsection (a)(1) may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act [42 U.S.C. § 1395j et seq.] if payment were made under such part for furnishing the procedure to a woman enrolled under such part.

(c) Special consideration for certain States. In making grants under subsection (a) to States whose initial grants under such subsection are made for fiscal year 1995 or any subsequent fiscal year, the Secretary shall give special consideration to any State whose proposal for carrying out programs under such subsection—

(1) has been approved through a process of peer review; and 2

(2) is made with respect to geographic areas in which there is—

(A) a substantial rate of mortality from breast or cervical cancer; or

(B) a substantial incidence of either of such cancers.

[(d)](c) Coordinating committee regarding year 2000 health objectives. The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to coordinate the activities of the agencies of the Public Health Service (and other appropriate Federal agencies) that are carried out toward achieving the objectives established by the Secretary for reductions in the rate of mortality from breast and cervical cancer in the United States by the year 2000. Such committee shall be comprised of Federal officers or employees designated by the heads of the agencies involved to serve on the committee as representatives of the agencies, and such representatives from other public or private entities as the Secretary determines to be appropriate.

§ 300l. Requirement of Matching Funds

(a) In general. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under subsection (b)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(b) Determination of amount of non-Federal contribution.

(1) In general. Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(2) Maintenance of effort. In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State involved toward the purpose described in section 1501 [42 U.S.C. § 300k] for the 2-year period preceding the first fiscal year for which the State is applying to receive a grant under such section.

(3) Inclusion of relevant non-Federal contributions for Medicaid. In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary shall, subject to paragraphs (1) and (2) of this subsection, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act [42 U.S.C. § 1396 et seq.] by the State involved toward the purpose described in paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)].

§ 300l-1. Requirement Regarding Medicaid

3.

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] for a program in a State unless the State plan under title XIX of the Social Security Act [42 U.S.C. § 1396 et seq.] for the State includes the screening procedures specified in subparagraphs (A) and (B) of section 1503(a)(2) [42 U.S.C. § 300m(a)(2)(A), (B)] as medical assistance provided under the plan.

§ 300m. Requirements With Respect to Type and Quality of Services

(a) Requirement of provision of all services by date certain. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)], including making available screening procedures for both breast and cervical cancers;

(2) subject to subsection (b), to ensure that—

(A) in the case of breast cancer, both a physical examination of the breasts and the screening procedure known as a mammography are conducted; and (B) in the case of cervical cancer, both a pelvic examination and the screening procedure known as a pap smear are conducted;

(3) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in section 1501(a) [42 U.S.C. § 300k(a)] is provided; and (4) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.

(b) Use of improved screening procedures. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that, if any screening procedure superior to a procedure described in subsection (a)(2) becomes commonly available and is recommended for use, any entity providing screening procedures pursuant to the grant will utilize the superior procedure rather than the procedure described in such subsection.

(c) Quality assurance regarding screening procedures. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the State will, in accordance with applicable law, assure the quality of screening procedures conducted pursuant to such section.

§ 300n. Additional Required Agreements

(a) Priority for low-income women. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that low-income women will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)].

4.

(b) Limitation on imposition of fees for services. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any woman with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981 [42 U.S.C. § 9902(2)].

(c) Statewide provision of services.

(1) In general. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that services and activities under the grant will be made available throughout the State, including availability to members of any Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act [25 U.S.C. § 450b]).

(2) Waiver. The Secretary may waive the requirement established in paragraph (1) for a State if the Secretary determines that compliance by the State with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in section 1501(a) [42 U.S.C. § 300k(a)].

(3) Grants to tribes and tribal organizations.

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to tribes and tribal organizations (as such terms are used in paragraph (1)) for the purpose of carrying out programs described in section 1501(a) [42 U.S.C. § 300k(a)]. This title applies to such a grant (in relation to the jurisdiction of the tribe or organization) to the same extent and in the same manner as such title applies to a grant to a State under section 1501 [42 U.S.C. § 300k] (in relation to the jurisdiction of the State).

(B) If a tribe or tribal organization is receiving a grant under subparagraph (A) and the State in which the tribe or organization is located is receiving a grant under section 1501[42 U.S.C. § 300k], the requirement established in paragraph (1) for the State regarding the tribe or organization is deemed to have been waived under paragraph (2).(d) Relationship to items and services under other programs. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

5.

(e) Coordination with other breast and cervical cancer programs. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the services and activities funded through the grant shall be coordinated with other Federal, State, and local breast and cervical cancer programs.

(f) Limitation on administrative expenses. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(g) Restrictions on use of grant. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(h) Records and audits. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that—

(1) the State will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section; and

(2) upon request, the State will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the State of the grant.

(i) Reports to Secretary. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

§ 300n-1. Description of Intended Uses of Grant

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless—

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the State with a need for the services or activities described in section 1501(a) [42 U.S.C. § 300k(a)];

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public and nonprofit private entities; and (4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

§ 300n-2. Requirement of Submission of Application

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless an application for the grant is submitted to the Secretary, the application contains the description of intended 6 uses required in section 1505 [42 U.S.C. § 300n-1], and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this title [42 U.S.C. § 300k et seq.].

§ 300n-3. Technical Assistance and Provision of Supplies and Services in Lieu of Grant Funds

(a) Technical assistance. The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to section 1501 [42 U.S.C. § 300k]. The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(b) Provision of supplies and services in lieu of grant funds.

(1) In general. Upon the request of a State receiving a grant under section 1501 [42 U.S.C. § 300k], the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such section and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in payments. With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant under section 1501 [42 U.S.C. § 300k] to the State involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

§ 300n-4. Evaluations and Reports

(a) Evaluations. The Secretary shall, directly or through contracts with public private entities, provide for annual evaluations of programs carried out pursuant to section 1501 [42 U.S.C. § 300k]. Such evaluations shall include evaluations of the extent to which States carrying out such programs are in compliance with section 1501(a)(2) [42 U.S.C. § 300k(a)(2)] and with section 1504(c) [42 U.S.C. § 300n(c)].

(b) Report to Congress. The Secretary shall, not later than 1 year after the date on which amounts are first appropriated pursuant to section 1509(a) [42 U.S.C. § 300n-5(a)], and annually thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this title [42 U.S.C. § 300k et seq.] as the Secretary determines to be appropriate, including recommendations regarding compliance by the States with section 1501(a)(2) [42 U.S.C. § 300k(a)(2)] and with section 1504(c) [42 U.S.C. § 300n(c)].

7.

§ 300n-4a. Supplemental Grants for Additional Preventive Health Services

(a) Demonstration projects. In the case of States receiving grants under section 1501 [42 U.S.C. § 300k], the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to not more than 3 such States to carry out demonstration projects for the purpose of—

(1) providing preventive health services in addition to the services authorized in such section, including screenings regarding blood pressure and cholesterol, and including health education;

(2) providing appropriate referrals for medical treatment of women receiving services pursuant to paragraph (1) and ensuring, to the extent practicable, the provision of appropriate follow-up services; and

(3) evaluating activities conducted under paragraphs (1) and (2) through appropriate surveillance or program-monitoring activities.

(b) Status as participant in program regarding breast and cervical cancer. The Secretary may not make a grant under subsection (a) unless the State involved agrees that services under the grant will be provided only through entities that are screening women for breast or cervical cancer pursuant to a grant under section 1501 [42 U.S.C. § 300k].

(c) Applicability of provisions of general program. This title [42 U.S.C. § 300k et seq.] applies to a grant under subsection (a) to the same extent and in the same manner as such title applies to a grant under section 1501[42 U.S.C. § 300k].

(d) Funding.

(1) In general. Subject to paragraph (2), for the purpose of carrying out this section, there are authorized to be appropriated $ 3,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(2) Limitation regarding funding with respect to breast and cervical cancer. The authorization of appropriations established in paragraph (1) is not effective for a fiscal year unless the amount appropriated under section 1510(a) [42 U.S.C. § 300n-5(a)] for the fiscal year is equal to or greater than $ 100,000,000.

§ 300n-5. Funding for General Program

(a) Authorization of appropriations. For the purpose of carrying out this title [42 U.S.C. § 300k et seq.], there are authorized to be appropriated $ 50,000,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, $ 150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(b) Set-aside for technical assistance and provision of supplies and services. Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 1507 [42 U.S.C. § 300n-3].

ATTACHMENT B
LEGISLATION

TITLE III
GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

Sec301 (241.)

(a) Research and investigations generally
Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to:

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section. The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)

(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains:

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and (D) a description of (i) each request received during the year involved:

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Source: U.S. Code Title 42, Chapter 6A, Subchapter II, Part A

ATTACHMENT C
INFORMED CONSENT FORM

PHASE II
INFORMED CONSENT FORM

ORC Macro is conducting discussion groups on behalf of the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. These groups are being held to help CDC develop more effective health promotion and communication campaigns aimed at African American women aged 40-64 who may qualify for free breast cancer screening.

Breast cancer screening can help to find cancer earlier. When cancer is detected early, women have a better chance of survival. Many women do not know that they qualify for low- or no- cost breast cancer screening. This study will provide information to CDC on how to better inform African American women about available breast cancer screening services.

You were asked to participate in these focus groups with other women who like you who met the eligibility criteria and qualify for low- or no-cost screening through your local screening program. The discussion group will take no more than two hours of your time. If you agree to be in the group, here are the things you should know:

- Your participation in the study is voluntary. If you do not participate, you will not lose any health care service that you expect to get apart from this study.
- You may choose to leave the group at any time for any reason with no penalty or consequence.
- Each discussion group will consist of six to ten women.
- You can choose not to answer any question at any time for any reason.
- You will not be asked any questions about your personal health.
- ORC Macro staff will take notes during the focus group discussion.
- We will record the discussion on audiotape. Only study staff will be able to use the tapes. The tapes are to help ensure our notes accurately capture what is said by all of you as you discuss the topics.
- Your answers in the group will be kept secure and we do not plan to disclose your name or any personal information about you to anyone outside this room, except as required by law. Identifying information will not be disclosed to anyone but the researchers conducting this evaluation. The information that we report to CDC will not contain any identifying information and we do not plan to use your name in any reports about this evaluation. We ask that you also respect the privacy of your fellow group members.
- To secure your personal information, we will keep the records and tapes in a secure location in secure files and only study staff will be allowed to use them.
- ORC Macro staff and CDC staff will observe the group.

- Your input in this discussion group poses few, if any risks to you. You can choose not to answer any question for any reason.

- Your participation in this focus group will not directly benefit you. However, the benefit of this group to you is that your input will help CDC develop more effective health promotion and communication campaigns aimed at African American women like you. What you have to say could help increase the number of women who get screened for breast cancer and reduce the number of women who die from this disease.

- We will give you $65.00 for your time. We will give you this $65 whether you finish the focus group or decide to withdraw before it ends.

- You will be given a copy of this form to keep.

Contact Information: If you have questions about the study, please call Ashani Johnson-Turbes, ORC Macro Project Manager at 404-321-3211. If you have concerns about your rights in this research study, contact the CDC Human Research Protection Office at 1-800-584-8814.

Please sign below to indicate that you have read the above and agree to take part in this discussion group.

Please Print Your Name:	
Please Sign Your Name:	
Witness Signature:	
Date:	

THANK YOU

ATTACHMENT D
PRE-DISCUSSION INFORMATION SHEET (PDIS)
RESPONDENT VERSION

Form Approved
OMB No.: _____
Exp. Date: _____

PHASE II
PRE-DISCUSSION INFORMATION SHEET

PART 1: GENERAL QUESTIONS (10 minutes)

Please do not write your full name on this form.

1. What is your date of birth? (Month/Day/Year)_____

2. What is your highest education level completed?

- ❑ 6th Grade or less
- ❑ 7th – 8th Grade
- ❑ 9th – 11th Grade
- ❑ 12th Grade without a High School diploma
- ❑ 12th Grade with a High School diploma
- ❑ GED
- ❑ Some college
- ❑ Associate degree
- ❑ Completed college (4 year degree)

3. What is your employment status? *(Check all that apply)*

- ❑ Full-time
- ❑ Part-time
- ❑ Presently not employed outside the home, looking for work
- ❑ Presently not employed outside the home, not looking for work
- ❑ Student
- ❑ Laid Off
- ❑ On Strike
- ❑ Disabled

4. What do you do for a living? What is your occupation/profession? _____

5. How often do you listen to the radio?

- ❑ Never or rarely
- ❑ 1-2 days a week
- ❑ 3-4 days a week
- ❑ 5-6 days a week
- ❑ Every day

6. During what time of the day do you most often listen to the radio?

- ❑ In the mornings (5am-12pm)
- ❑ In the afternoons (12pm-6pm)
- ❑ In the evenings (7pm-12am)

7. ***On which days of the week are you most likely to listen to the radio?*** **(Check all that apply)**
   - ❑ Monday
   - ❑ Tuesday
   - ❑ Wednesday
   - ❑ Thursday
   - ❑ Friday
   - ❑ Saturday
   - ❑ Sunday

8. **Which of the following types of radio stations do you usually listen to?** ***(Check all that apply)***
   - ❑ Talk Stations
   - ❑ Music Stations
   - ❑ AM
   - ❑ FM

9. **When you listen to the radio, which station or stations do you listen to most often?**
   Write in station dial location and name:_____

PART 2: PRETEST OF MESSAGES (10 minutes)

PART 2a: MESSAGE ONE PRETEST

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn? _____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

PART 2b: MESSAGE TWO PRETEST

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn? _____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

PART 2c: MESSAGE THREE PRETEST

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn? _____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

PART 3: POSTTEST OF MESSAGES (10minutes)

PART 3a: MESSAGE ONE POSTTEST

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn? _____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

PART 3b: MESSAGE TWO POSTTEST

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn? _____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

PART 3c: MESSAGE THREE POSTTEST

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn? _____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

ATTACHMENT E
PRE-DISCUSSION INFORMATION SHEET (PDIS)
MODERATOR VERSION

Form Approved
OMB No.: _____
Exp. Date: _____

PHASE II
PRE-DISCUSSION INFORMATION SHEET—MODERATOR VERSION

Moderator: "To get started today we would like you to take a moment and give us some background information about you for the group and respond to a series of questions about three demo radio messages that I will play for you shortly.

Let's begin. I'm first going to ask you some questions about yourself. Please listen carefully as I read aloud each of the questions and answers on the paper in front of you. You will record your own responses to each question right on your paper. Remember that our discussion and what you record on this paper will be maintained in a secure manner and that there are no right or wrong answers."

PART 1: GENERAL QUESTIONS (10 minutes)

Please do not write your full name on this form.

1. What is your date of birth? (Month/Day/Year)

2. What is your highest education level completed?

- ❑ 6th Grade or less
- ❑ 7th – 8th Grade
- ❑ 9th – 11th Grade
- ❑ 12th Grade without a High School diploma
- ❑ 12th Grade with a High School diploma
- ❑ GED
- ❑ Some college
- ❑ Associate degree
- ❑ Completed college (4 year degree)

3. What is your employment status? *(Check all that apply)*

- ❑ Full-time
- ❑ Part-time
- ❑ Presently not employed outside the home, looking for work
- ❑ Presently not employed outside the home, not looking for work
- ❑ Student
- ❑ Laid Off
- ❑ On Strike
- ❑ Disabled

4. What do you do for a living? What is your occupation/profession?_____

5. How often do you listen to the radio?

- ❑ Never or rarely
- ❑ 1-2 days a week
- ❑ 3-4 days a week
- ❑ 5-6 days a week
- ❑ Every day

6. During what time of the day do you most often listen to the radio?

- ❑ In the mornings (5am-12pm)
- ❑ In the afternoons (12pm-6pm)
- ❑ In the evenings (7pm-12am)

7. On which days of the week are you most likely to listen to the radio? (Check all that apply)

- ❑ Monday
- ❑ Tuesday
- ❑ Wednesday
- ❑ Thursday
- ❑ Friday
- ❑ Saturday
- ❑ Sunday
- ❑

8. Which of the following types of radio stations do you usually listen to? (Check all that apply)

- ❑ Talk Stations
- ❑ Music Stations
- ❑ AM
- ❑ FM

9. When you listen to the radio, which station or stations do you listen to most often?
Write in station dial location and name:_____

PART 2: PRETEST OF MESSAGES (10 minutes)

Moderator: "I am going to play for you 3 radio messages. After I play each message, please listen carefully as I read aloud each of the questions and answers on the paper in front of you. You will record your own responses on the paper. Remember that our discussion and what you record on this paper will be maintained in a secure manner and that there are no right or wrong answers.

We will conduct this exercise again near the end of our discussion."

PART 2a: MESSAGE ONE PRETEST

[Moderator: Play the first radio message and ask the following questions.]

1. Did you like the voices that were used in the radio advertisement?

- ❑ Yes
- ❑ No

2. Did you like the music that was used in the radio advertisement?

- ❑ Yes
- ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn?_____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

PART 2b: MESSAGE TWO PRETEST

[Moderator: Play the second radio message and ask the following questions.]

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn?_____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

PART 2c: MESSAGE THREE PRETEST

[Moderator: Play the last radio message and ask the following questions.]

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn?_____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

[Moderator: Move back to the moderator guide and begin with concept testing questions 1 – 7.]

PART 3: POSTTEST OF MESSAGES (10 minutes)

Moderator: "I am going to play the same 3 radio messages for you again. After I play each message, please listen carefully as I read aloud each of the questions and answers on the paper in front of you. You will record your own responses on the paper. Remember that our discussion and what you record on this paper will be maintained in a secure manner and that there are no right or wrong answers."

PART 3a: MESSAGE ONE POSTTEST

[Moderator: After playing the first radio message and asking questions 8 – 13 in the moderator guide, ask the following questions.]

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn? _____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

[Moderator: Play the second radio message, move back to the moderator guide, and ask questions 8 – 13 for the second radio message.]

PART 3b: MESSAGE TWO POSTTEST

[Moderator: After playing the second radio message and asking questions 8 – 13 in the moderator guide, ask the following questions.]

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn? _____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

[Moderator: Play the third radio message, move back to the moderator guide, and ask questions 8 – 13 for the third radio message.]

PART 3c: MESSAGE THREE POSTTEST

[Moderator: After playing the third radio message and asking questions 8 – 13 in the moderator guide, ask the following questions.]

1. **Did you like the voices that were used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

2. **Did you like the music that was used in the radio advertisement?**
   - ❑ Yes
   - ❑ No

3. **Did you learn anything new from this radio advertisement?**
   - ❑ Yes
   - ❑ No

   If yes, what did you learn? _____

4. **After hearing this radio advertisement would you call your doctor or health department about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

5. **After hearing this radio advertisement would you contact a family member or friend about getting screened for breast cancer (or getting a mammogram)?**
   - ❑ Yes
   - ❑ No

[Moderator: Move back to the moderator guide and ask questions 14 – 15.]

ATTACHMENT F
FOCUS GROUP MODERATOR GUIDE

Form Approved
OMB No.: _____
Exp. Date: _____

FOCUS GROUP MODERATOR GUIDE

TABLE OF CONTENTS

[Moderator: Before participants enter room, write on flip chart visible to all participants:]

- "Topic of Discussion: Thoughts about concepts and messages to educate women about breast cancer and increase breast cancer screening (mammography) among African American women."
- Focus group ground rules.

INTRODUCTION TO GROUP PROCESSES AND PROCEDURES (10 minutes)

Thank you for taking the time to be here. My name is _____ and I work for ORC Macro, a research and consulting firm in Atlanta, Georgia. As you may remember when you were recruited, we are conducting this focus group on behalf of the Centers for Disease Control and Prevention (CDC) to learn about your thoughts about concepts and messages designed to educate women about breast cancer and increase breast cancer screening among African American women. First, I want to take a few minutes to tell you about my role and what to expect from our discussion and then I'll give everyone the chance to introduce herself.

My role is simply to facilitate the discussion, make sure we stay on topic, and keep us within our 2-hour time limit. I am not here to push any particular agenda or point of view, but rather to hear your frank and honest opinions. There are no right or wrong answers. We all have our own likes and dislikes, our own thoughts and feelings.

I want to remind everyone that the discussion here will be maintained in a secure manner. Please use only your first name. We will not report your comments by name, and we ask that you respect each other's privacy in the same way. We do not expect you to tell us anything that you would be uncomfortable sharing with the group. But we do hope that you will be honest with your responses to the questions I ask.

Before we begin, I need to give you the informed consent form. Let's read it together and then I'll ask you to sign it. Most importantly, I want to make sure that you understand your participation in this study is completely voluntary. That means you can leave at any time.

[Moderator: Review, collect informed consent form, and answer any questions.]

I'm going to ask a series of questions, but mainly I want to hear from you. As I mentioned, my role is simply to guide the discussion. Sometimes we may really get going on one question, and I'll have to move you onto the next question so that we may cover everything. Please do not take it personally! We just need to hear from everyone about several topics.

There are also a few ground rules that I would like us to adopt for our discussion:

- You have been asked here to offer your views and opinions.
- Everyone's input is important. I may call on you if you are being quiet.
- Avoid side conversations.
- Let one person speak at a time.
- I may need to cut a discussion short to get through the whole discussion.
- Please turn off all cell phones!
- There are no right or wrong answers.
- All answers are will be maintained in a secure manner, so feel free to speak your mind.

- Respect one another at all times.
- It's okay to disagree.

Most importantly, please try to speak up, speak clearly, and one at a time. We are audiotaping the discussion so that we can have an accurate record of the discussion. Do you have any questions before we get started?

PARTICIPANT INTRODUCTIONS AND WARM-UP EXERCISE (5 minutes)

So we can get to know each other a little, let's go around the room and introduce ourselves. Please say your first name only and your favorite type of music.

MESSAGE PRE-TEST (15 minutes)

[Moderator: Refer to the PDIS and administer Part 1 (General Questions) and Part 2 (Pretest of Messages)]

DISCUSSION QUESTIONS (40 minutes)

Conceptual Message Testing (20 minutes)

Moderator: "Now I'd like us to focus on a few conceptual messages. I have a few examples that I would like to show you and we will discuss each. We are interested in your thoughts about these concepts. Remember that you are the experts and your opinions are important to us. We're interested in providing information that is as useful as possible, so I really want your honest and frank responses to what we present you."

Show one conceptual message at a time and ask the following questions for each.

1. **What do you think about this phrase?**
   - ❑ Probe: What does it make you think about?
   - ❑ Probe: What do you like about this phrase? Why?
   - ❑ Probe: What do you dislike about the phrase? Why?

2. **What do you think the phrase means?**
   - ❑ Probe: What is the main idea it is trying to communicate?

3. **Is there anything confusing about the phrase? Please explain.**

4. **Do you believe what the phrase is telling you? Why/Why not?**
   - ❑ Probe: Who do you think this phrase is meant for?

[Moderator: We are trying to gather information about what group of people they think the phrase is meant for, e.g. African Americans, young people, etc]

5. **What would be a better way to say what is in meant by this phrase?**
   - ❑ Probe: What else (or other types of information) would you want to hear in this phrase?

[Moderator: After asking the questions above for each of the three phrases, say "Now let's take a look at all 3 phrases together…"]

6. **Which of these phrases appeals to you the most? Why?**

7. **Why do you like/dislike one more than another?**

MESSAGE TESTING (20 minutes)

Moderator: "Okay. Now I'm going to play three radio spots for you that CDC has developed to educate African American women like you about breast cancer and breast cancer screening. I want to hear what you think about each of these radio advertisements."

Play one radio spot at a time and ask the following questions for each.

1. **What do you think about this ad?**
   - ❑ Probe: Would you stop and listen to it if you heard it? Why or why not?
   - ❑ Probe: What do you like about this ad? (e.g., voices, music, tone, etc.)
   - ❑ Probe: What do you dislike about the ad? (e.g., voices, music, tone, etc.)

2. **What do you think is the main message of the ad?**
   - ❑ Probe: What is confusing about the message?
   - ❑ Probe: What is most clear about the message?

3. **Do you believe what this ad is saying? Why or why not?**
   - ❑ Probe: Who do you think this ad is meant for?
   - ❑ Probe: What about this ad can you relate to?

[Moderator: We are trying to gather information about what group of people they think the ad is meant for, e.g. African Americans, young people, etc.]

4. **What is the most striking thing about this ad?**
   - ❑ Probe: What do you think about the: (a) tone, (b) voices (c) music (d) length

5. **How could the ad be improved?**
   - ❑ Probe: What might be a better way to say what this ad is trying to say?
   - ❑ Probe: What would you change in this? Please explain why.
   - ❑ Probe: What else would you want to hear in this ad? Why?

6. **After listening to this ad would you be motivated to do anything? Please explain.**

MESSAGE POST-TEST (15 minutes)

[Moderator: After playing each radio ad and asking the above questions, refer to the PDIS and administer Part 3 (Posttest of Messages). Complete the PDIS post-test exercise before you play the following ad. Conduct the Posttest for each ad.]

CLOSING (5 minutes)

Moderator: "As a closing activity, I just want to briefly go around the room and ask each one of you…"

1. **Out of the last three radio messages we just listened to, which do you like the most? Explain why.**
   - ❑ Probe: Which was most informative? Why?
   - ❑ Probe: Which was most motivating? Why?

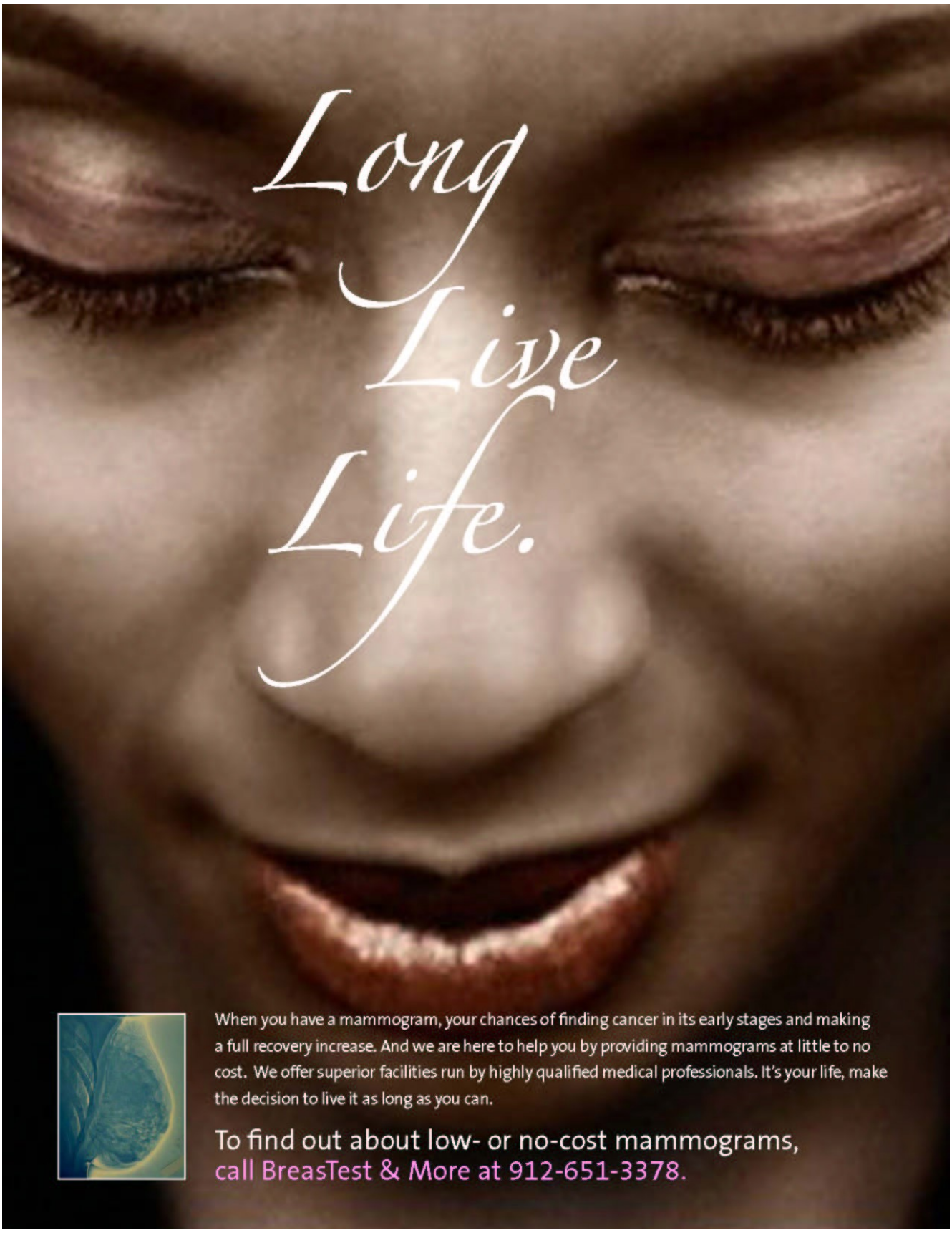
2. **Well, that's the last of my questions. Do you have any questions?**

[Moderator: "On the table behind me, you'll see that we have brought some educational materials about breast cancer, mammography and clinical breast exams. Please feel free to help yourselves to any of this information.]

For Women in Unscreened Groups Only:
We also have a health educator here who can answer any immediate questions you may have.

Thank you again for taking the time to participate in this discussion. We sincerely appreciate and value your input!"

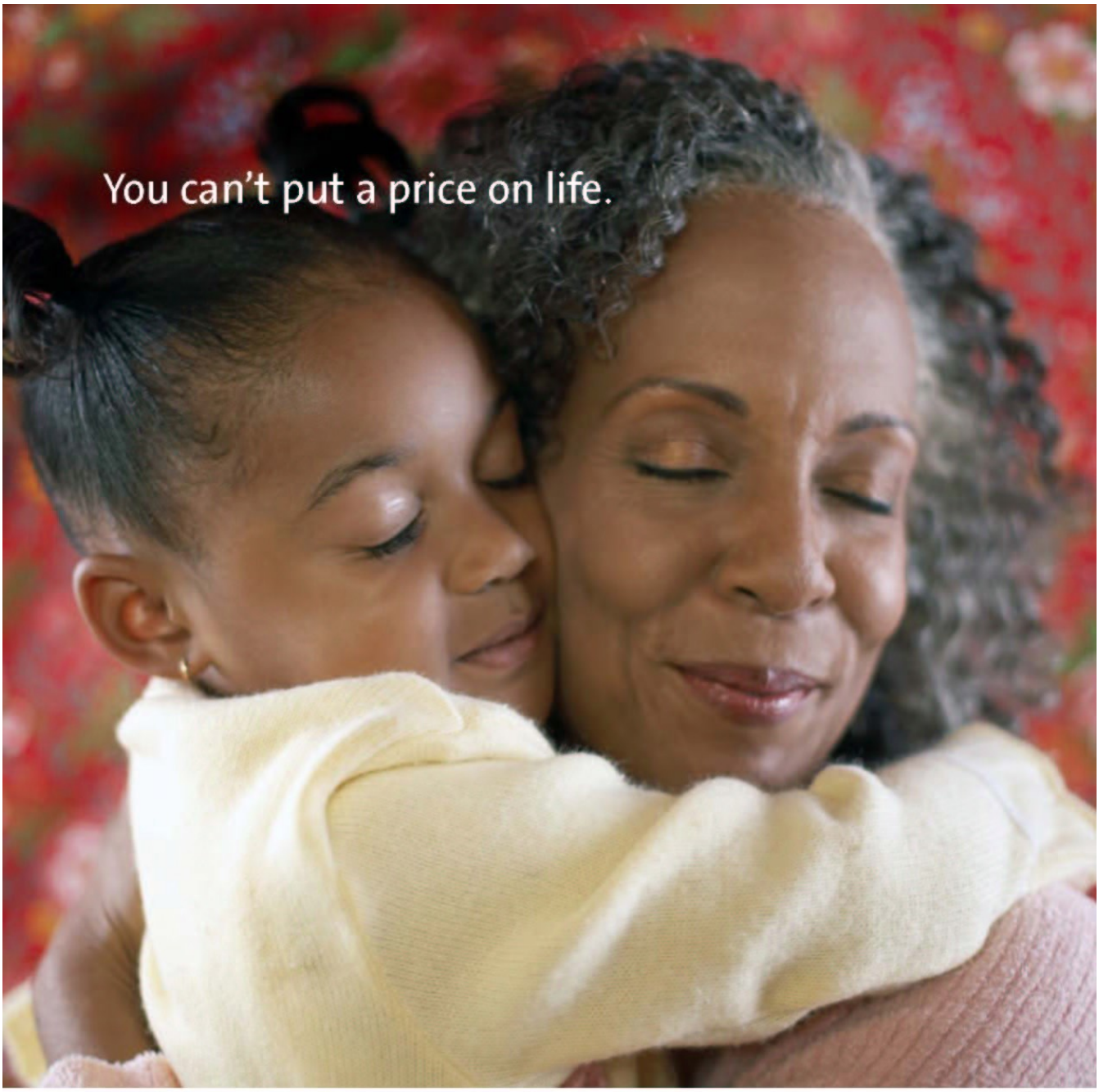
ATTACHMENT G
CONCEPTS


Long
Live
Life.
When you have a mammogram, your chances of finding cancer in its early stages and making a full recovery increase. And we are here to help you by providing mammograms at little to no cost. We offer superior facilities run by highly qualified medical professionals. It's your life, make the decision to live it as long as you can.
To find out about low- or no-cost mammograms,
call BreasTest & More at 912-651-3378.

Think about what you're not doing.

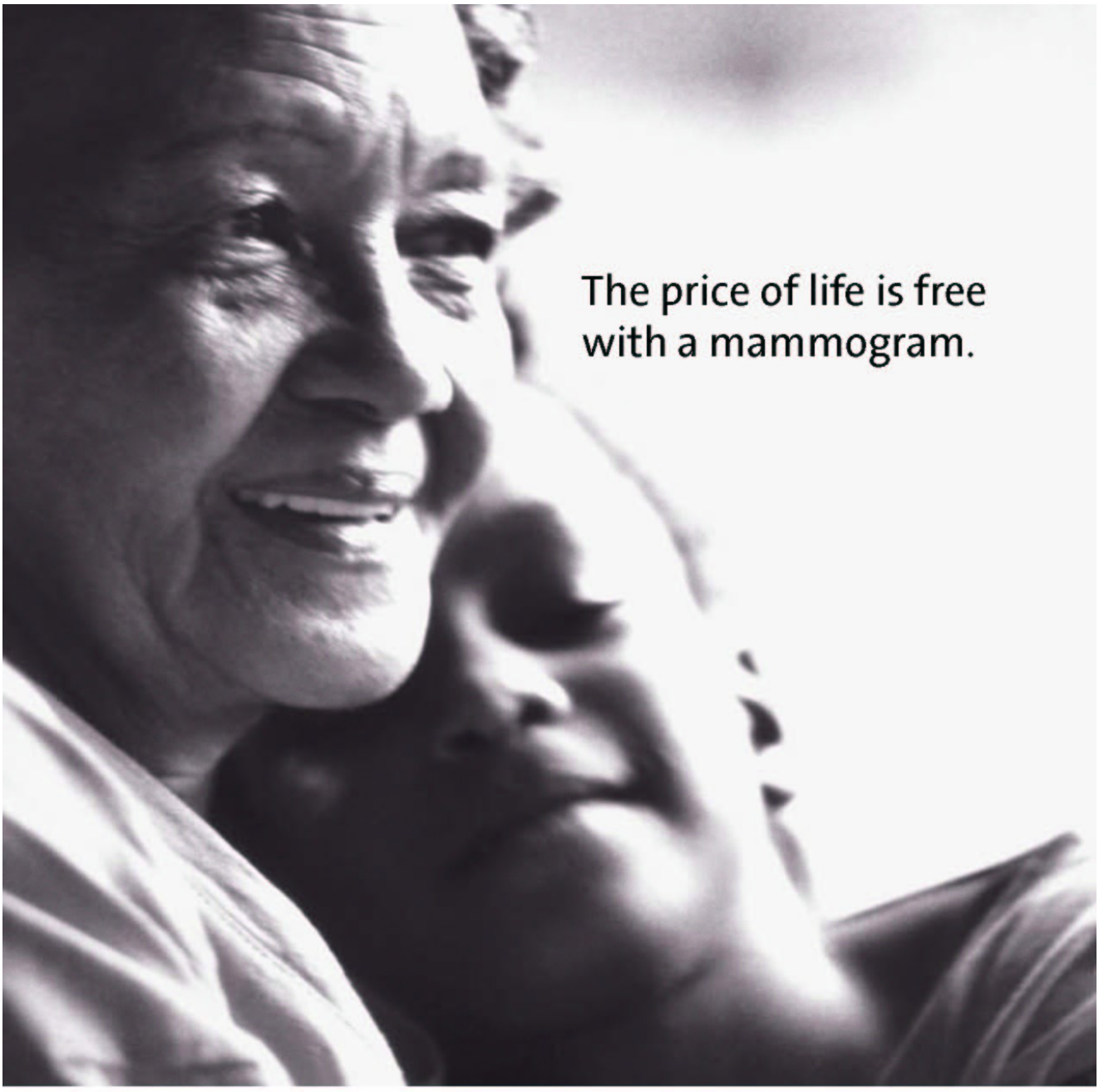
The sooner you have a mammogram, the greater your chances of finding cancer in its early stages and making a full recovery. We are here to help you by providing mammograms at little to no cost at our facilities run by qualified medical professionals. It's a small price with big benefits for your life.

To find out about low- or no-cost mammograms,
call BreasTest & More at 912-651-3378.



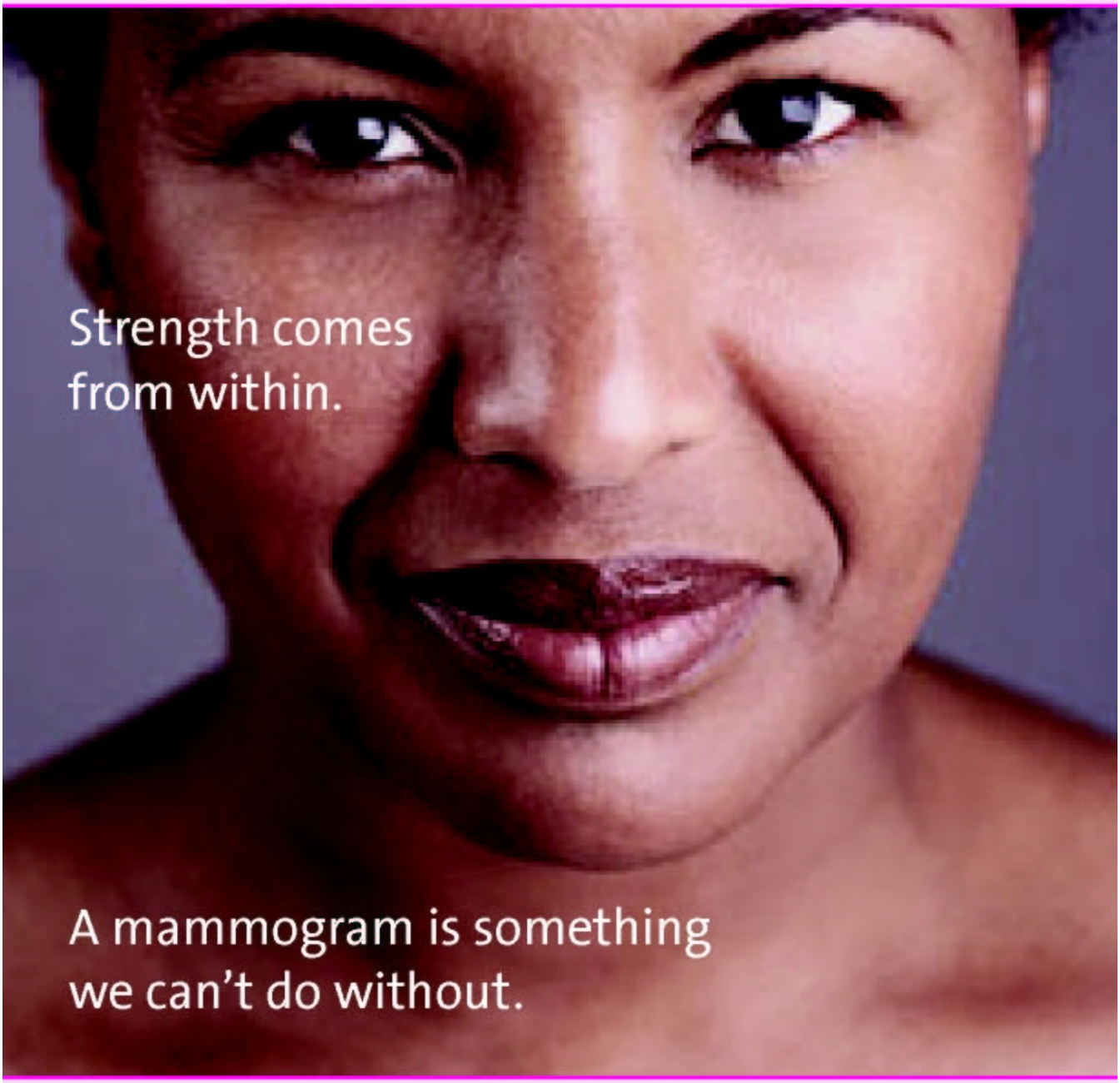
The sooner you have a mammogram, the greater your chances of finding cancer in its early stages and making a full recovery. We are here to help you by providing mammograms at little to no cost at our facilities run by qualified medical professionals. It's a small price with big benefits for your life.

To find out about low- or no-cost mammograms,
call BreasTest & More at 912-651-3378.



The sooner you have a mammogram, the greater your chances of finding cancer in its early stages and making a full recovery. We are here to help you by providing mammograms at little to no cost at our facilities run by qualified medical professionals. It's a small price with big benefits for your life.

To find out about low- or no-cost mammograms,
call BreasTest & More at 912-651-3378.



If you're over 40 or have a family history of breast cancer, it's time for you to have a mammogram. And we are here to provide you one at little to no cost. We offer superior facilities where highly qualified medical professionals will test you. Show your strength and get tested today.

To find out about low- or no-cost mammograms,
call BreasTest & More at 912-651-3378.

Side effects include knowledge.

Discover cancer early with a mammogram and increase the likelihood of making a full recovery. We make it easy by providing mammograms at little to no cost at our facilities run by highly qualified medical professionals. It's time to take your future into your own hands — we'll be here to help you along the way.

To find out about low- or no-cost mammograms,
call BreasTest & More at 912-651-3378.

ATTACHMENT H

MESSAGES

ARE AVAILABLE AS

SEPARATE AUDIO FILES

Oh Harold Transcript

Harold: And another thing, when was the last time you had a mammogram?

Woman: Oh Harold, that's sweet. Are you trying to tell me you love me?

Harold: No, I just heard, you know, you should get a mammogram every year.

Woman: Oh Harold, now you know you trying to tell me that you can't live without me.

Harold: I wouldn't read too much into it. Im just saying, you know, who would water the plants?

Woman: Oh Harold, you are a sweetheart.

To find out about low- or no-cost mammograms in your area, call 1-8004CANCER.

Birthday Party Transcript

Kid: Happy birthday, Grandma.

Grandma: Oh sweetheart, thank you.

Kid: It's a card that tells you how to get a mammogram.

Grandma: Well that's really nice, honey.

Kid: A woman your age should have one every year.

Grandma: My age? Thanks, I guess. Did your Grandpa tell you to do this?

Kid: Yeah, he gave me a dollar.

To find out about low- or no-cost mammograms in your area, call 1-8004CANCER.

Maya Angelou Transcript

As we get older, our chances of developing breast cancer increase. However, every year more women continue to live meaningful lives because their breast cancer was discovered and treated early. Every woman deserves to be healthy and a good way to make sure that you don't have breast cancer is to have a mammogram every year. If you're over 40, call about a free mammogram. Do it for yourself and the people you love. Every woman counts, every year.

PhaseI.mp3 Transcript

JR: Welcome to the Jean Ross show. Today we're going to talk about a very important message about breast cancer awareness. We have with us Sharon Reynolds who is a registered nurse and Francine D. Caldwell, a 17 yr breast cancer survivor to talk about how this disease is invading African American women and what we can do about it. Let me start with you Sharon. As a registered nurse, why do you think that the African American community seems to have a lack of awareness about BC?

SR: I think its because the incidence of BC is lower among African American women in general, however the incidence of severe disease and death is higher among African American women and so they tend to believe they are not at risk as much as other groups. I also think they are fearful of finding BC so they tend to avoid the issue.

JR: Francine, let me ask you a question. When you first found out that you had breast cancer what was your reaction?

FC: I was totally devastated. I was able to discover my cancer through breast self exam, so it does work. And of course the mammogram screening also assisted in that diagnosis. But it was discovered very, very early and with early detection your options are totally open in terms of eradicating the disease within your body. With the survival rate now at 95%, why would you not go for the mammograms early?

JR: How has life been since you've been cured?

FC: Because I was able to take advantage of discovering my cancer early and therefore having many, many options, I've been cancer free for 17 years and life has been wonderful.

JR: So the message we want to send today to every woman who is listening is first of all don't be afraid. Early detection can help your chances of survival be much greater. Do your BSE once a month and get a mammogram once a year. 1-800-4CANCER, 1-800-422-6237, that number from the American Cancer Society can save your life.

PhaseII.mp3 Transcript

JR: Welcome to the Jean Ross show. Today we're going to talk about a very important message about breast cancer awareness. We have with us Sharon Reynolds who is a registered nurse and Francine D. Caldwell, a 17 yr breast cancer survivor to talk about how this disease is invading African American women and what we can do about it. Francine, tell us about how you discovered that you had breast cancer.

FC: I discover a lump through self examination. And on follow-up with my medical professional I was diagnosed with BC

JR: We hear that mammograms are uncomfortable.

FC: You know, mammograms are a little bit uncomfortable. They do press you. However, the discomfort is very short lived. It only lasts for a few seconds and the pain of the mammogram is so much less in comparison to the pain of the treatment of the disease in its advanced stages.

JR: But there are some women who may feel they are prohibited because of the cost of a mammogram. Yet there are low and no cost mammograms available.

SR: That's true. The low cost and free mammograms are the same people, the same machines. The quality is there, the quality standards are there, the monitoring and auditing to make sure that everything is done correctly is there for every mammogram.

JR: Now we know that in the AA community faith is a major factor. Did faith influence your decision?

FC: Oh absolutely. In terms of being diagnosed with breast cancer, I had to approach my healing from more than just one perspective. My spiritual aspect was very, very significant in my healing. Also of course the medical professional, the surgeries, the treatments, and the nutritional aspects of healing my body.

JR: And Sharon isn't it true that physicians even encourage prayer to be a part of the process?

SR: Yes, fortunately many physicians are very aware of the power of faith and the power of prayer. Studies have shown that prayer positively affects healing.

JR: Ladies, remember that quality mammograms are available at no and low cost but start with the self exam. Its free. It will get you familiar with your body. Follow it up with a yearly mammogram. You can find out more information about mammograms in your area by calling the American Cancer Society hotline – 1-800-4CANCER, 1-800-422-6237. That number from the American Cancer Society can save your life.

Attachment I
60 Day FRN

causes and risk factors. State surveillance data can be used to: Identify trends in TBI incidence; enable the development of cause-specific prevention strategies focused on populations at greatest risk and monitor the effectiveness of such programs.

This project will develop and sustain injury surveillance programs including those with a focus on TBI and emergency department surveillance for mild TBI. The goal of this program is to produce data of demonstrated quality that will (a) be useful to State injury prevention and control programs, (b)enable states to produce injury indicators, (c) enable estimates of TBI incidence and public health consequences and (d) facilitate the use of TBI surveillance data to link individuals with information about TBI services.

Program recipients will collect information from pre-existing state data sets to calculate injury indicators in their state. In addition a small group of states will review and abstract medical records to obtain data for variables that address severity of injury, circumstances and etiology of injury, and early outcome of injury, in a large representative sample of reported cases of TBI-related hospitalization and mild TBI-related emergency department visits. The abstracted data will be stripped of all identifying information before submitting to CDC. States will use standardized data elements. The number of state health departments to be funded for data abstraction may be as high as 12. The only cost to the respondents is the time involved to complete the data abstraction. The estimated total burden hours are 12000.

Estimated annualized burden table

Respondents	Number of respondents	Number of responses/ respondent	Average burden/response (in hours)
State Health Departments	12	1000	60/60

Dated: February 9,2006.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc, E6-2209 Filed 2-15-06; 8:45 am] BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-06-06AII]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-4766 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Issues Related to the Use of Mass Media in African-American Women: Phase II—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Coordinating Center for Health Promotion (CoCHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Women's health programs, including the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), offer low-cost or free breast cancer screening to uninsured, low-income women. In 1991, CDC established the NBCCEDP to increase breast and cervical cancer screening among uninsured, underserved, low-income women. To date, over 1.5 million women have received services from NBCCEDP-sponsored programs. Yet NBCCEDP-sponsored programs are estimated to reach only 18% of women 50 years old and older who are eligible for screening services. A research priority for the NBCCEDP is to identify effective strategies to increase enrollment among eligible women who have never received breast or cervical cancer screening. Why women do not participate in this screening is not well understood.

As part of an ongoing study, the purpose of this task is to (1) test consumer response to concepts that arose in the Phase I formative research related to breast cancer screening and (2) test a series of radio health messages aimed at increasing mammography screening among low-income African American women for cultural appropriateness.

There are no costs to respondents except their time to participate in the survey.

Estimated annualized burden table:

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hours)
Black women, aged 40-64, GA residents	80	1	90/60	120
Total	80			120

Dated: February 10,2006.

Joan F. **Karr,**

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6-2210 Filed 2-15-06; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 18 and 19,2006, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Mimi T. Phan, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857,301-827-7001, FAX: 301827-6778, e-mail: *PHANM@cder.fda.gov*, or FDA Advisory Committee Information Line, 1-800741-8138 (301-443-0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 18,2006, the subcommittee will: (1) Receive topic updates for ongoing activities pertaining to the International Conference on Harmonisation (ICH) Q8, Q9, Q10, and future ICH quality topics; and (2) discuss and provide comments on modernized Current Good Manufacturing Practice (CGMP) approaches to process validation that encourage continuous improvement over the product life-cycle. On April 19, 2006, the subcommittee will: (1) Discuss and provide comments on the agency's new approaches to Chemistry, Manufacturing, and Control (CMC) guidance development, as illustrated by the comparability protocol guidance; (2) discuss and provide comments on the CMC Pilot Program; and (3) receive an update on the Cooperative Research and Development Agreement (CRADA) with Conformia Software, Inc., to obtain information on factors influencing pharmaceutical development. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://wwwfda.gov/ohrms/dockets/ac/acmenu.htm.* (Click .on the year 2006 and scroll down to the Advisory Committee for Pharmaceutical Science meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by April 11,2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on April 18,2006, and between approximately 11:30 a.m. and 12 noon on April 19,2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 11,2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Mimi Phan at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 9,2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6-2237 Filed 2-15-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999N-1852] (formerly 99N1852)

Guidance for Industry on Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." This guidance provides recommendations on procedures, content, and format for submitting a postmarketing study status report for an approved human drug or licensed biological product; timeframes for FDA's review of postmarketing study commitments; and information about postmarketing study commitments that will be available to the public. The guidance is intended to assist applicants in meeting the requirements of section 130 of the Food and Drug Administration Modernization Act of 1997.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling CBER at 1-800-8354709 or 301-827-1800.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See

ATTACHMENT J
OBSERVER CONFIDENTIALITY FORM

PHASE II
OBSERVER CONFIDENTIALITY FORM

ORC Macro is conducting focus groups on behalf of the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. The focus groups are to help the CDC develop more effective health promotion and communication campaigns aimed at African American women aged 40-64 who qualify for free breast cancer screening.

Because of concerns about protecting participant privacy and fostering an atmosphere of respect for the participants, it is important for all persons who intend to observe the focus groups to accept the following:

- Observers should refrain from any conduct that will disrupt the discussion or interfere with the focus group process.
- Observers are present to observe only and not to take part in the discussion process.
- Observers may enter the discussion room at the end of the session only upon the participants' request.
- After leaving the observation room, observers should not discuss who participated in the group discussion. Observers should not discuss what was said by individual participants with others who were not also observers.
- After leaving the observation room, observers should only have discussions about the session that are general and not specific in nature.
- Observers should refrain from engaging in conversations while the focus group is in session so as not to disturb the process of moderating or notetaking of the focus groups.

Your signature below indicates that you understand and accept these conditions.

Signature:		**Date:**	

ATTACHMENT K
CONFIDENTIALITY AGREEMENT WITH LOCAL SITE RECRUITERS

CONFIDENTIALITY AGREEMENT WITH LOCAL SITE RECRUITERS (LSRS)

As a Local Site Recruiter, I agree to the following conditions relating to the handling and use of screening data for ORC Macro's concept and message testing focus groups related to breast cancer screening:

- I will keep the screening data in a secure place to eliminate any access to the data by anyone not affiliated with CDC or ORC Macro.
- I will not share the screening data with any third party.
- I will not copy the screening data for any unauthorized third party (or without approval from ORC Macro).
- I will protect the identity of all participants from unapproved third parties.
- I will handle hard copies of the screening data in a secure manner to eliminate any third party access to the data.
- I will not use knowledge gained from screening data for personal gain.

My signature below indicates that I, as a Local Site Recruiter, understand the conditions stated above and that all employees involved with this project agree to comply with them.

Signature:		**Date:**	

Attachment L

Documentation of Exemption from IRB Review Requirements CDC Human Research Protection Office

From: Heilig, Charles (Chad) (CDC/OD/OCSO)
Sent: Friday, May 26, 2006 11:18 AM
To: Hall, Ingrid (CDC/NCCDPHP/DCPC)
Cc: Human Subjects Review-OD (CDC); Holtzman, Deborah (CDC/OD/OCSO); Redmond-Leonard, Joan A. (CDC/NCCDPHP/OD)
Subject: 4883: request for exemption

I have reviewed the request to exempt protocol 4883, "Formative Research on Issues Related to the Use of Mass Media in African American Women - Phase II". I find that this research activity is exempt under 45 CFR 46.101(b)(2). Changes to this protocol may not be implemented until they are reviewed and determined to be consistent with the exemption categories. You will be asked in one year (by 05/25/2007) to confirm that no changes have occurred in the protocol or the related science that would affect the ethical appropriateness of the research or this exemption. Please be advised that the investigators remain responsible for appropriate human research protections even for research that is exempt from regulations for protecting human subjects.

Notes:
This activity is exempt under category 2 because "disclosure of the human subjects' responses outside the research could [not] reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation" (see protocol, p 6).

Chad

Chad Heilig, PhD
Manager, Human Research Protection Office
Office of the Chief Science Officer
Centers for Disease Control and Prevention
Mail: 1600 Clifton Rd MS D73, Atlanta GA 30333
Courier: 1600 Clifton Rd MS D73, Bldg 21 Rm 8206, Atlanta GA 30333
Voice: 404-639-4601
Fax: 404-639-4901

ATTACHMENT M
RECRUITMENT FLYER

Where do you get health information?

Come share your thoughts with other African-American women!

We need your feedback on health messages about breast cancer screening

Come to an in-person discussion with 6–10 other women

Receive a free meal and $65 for participating

To find out more and join the discussions, please call:
[LSR Name] at [LSR Number]
or
[ORC Macro Staff Name]
at ORC Macro [1-800 Number]

The discussion group will take place in [Month Year]

ATTACHMENT N
RECRUITMENT SCREENER

PHASE II
RECRUITMENT SCREENER

SCREENED AND UNSCREENED

Hello. My name is _____ and I am working with ORC Macro, a consulting firm in Atlanta, Georgia and the Centers for Disease Control and Prevention (CDC) to test some ideas and messages for a health promotion campaign for African American women who may qualify for free breast cancer screening.

We are asking 6 to 10 ladies to get together and talk about these ideas and messages. The discussion will last about 2 hours and happen only once. We will not ask you any questions about your own health status or personal health issues in the discussion groups.

If you participate in the group, you will receive $65.00 cash in appreciation of your time. We will also serve a light meal prior to the discussion. Do you think that you might be interested in participating in this type of discussion?

- ❑ Yes (Continue with screener.)
- ❑ No (Thank person for his/her time and end conversation.)

Would you mind if I ask you a few questions in order to determine whether or not you can participate in the discussion group?

- ❑ Yes (Continue with screener.)
- ❑ No (Thank person for his/her time and end conversation.)

NOTE TO RECRUITER: Please continue through all questions before letting individuals know that they cannot be invited to participate at this time based on at least one of the responses they provided.

Record and Keep all Screened Data

1. Record gender

- ❑ Male (Terminate at end.)
- ❑ Female

2. Are you Hispanic/Latina?

- ❑ Yes
- ❑ No

3. How do you describe your race? Select one or more race.

- ❑ Black or African American
- ❑ White (Terminate at end.)
- ❑ American Indian or Alaska Native (Terminate at end.)
- ❑ Asian (Terminate at end.)
- ❑ Native Hawaiian or Other Pacific Islander (Terminate at end.)

RECRUITER: If an individual self-identifies as Black or African American and any other race they remain eligible for the groups.

RECRUITER: We must determine your eligibility in the Breast and Cervical Cancer Program (BCCP). To be eligible for enrollment in the BCCP and receive federally-funded breast screening:

- ❑ The woman is within the age requirements recommended breast cancer screening.
- ❑ The woman is at or below 200% of the Federal poverty guidelines.
- ❑ The woman is uninsured.

4. Record age: _____

- ❑ What is your date of birth? (Month/Year)

RECRUITER: Record which age group they belong to:

- ❑ 39 and under (Terminate at end.)
- ❑ 40-49 (Recruit to 40-49 groups.)
- ❑ 50-64 (Recruit to 50-64 groups.)
- ❑ 65 and older (Terminate at end.)

5. How many immediate family members including you live in your house?_____ [Record # of people]

6. What is your household income <u>per month</u> before taxes?_____

RECRUITER: If the woman hesitates, ask her if she thinks it is more than or less than the amount you read next to the family size she just told you.

Read the dollar figure next to the correct Family Size the person just told you.

For family of 1, read $1,497 per month	More [Terminate at end]	Less [Continue]
For family of 2, read $2,020 per month	More [Terminate at end]	Less [Continue]
For family of 3, read $2,543 per month	More [Terminate at end]	Less [Continue]
For family of 4, read $3,067 per month	More [Terminate at end]	Less [Continue]
For family of 5, read $3,590 per month	More [Terminate at end]	Less [Continue]
For family of 6, read $4,113 per month	More [Terminate at end]	Less [Continue]
For family of 7, read $4,637 per month	More [Terminate at end]	Less [Continue]
For family of 8, read $5,160 per month	More [Terminate at end]	Less [Continue]

7. Do you have health insurance coverage (includes Medicaid)?

- ❑ Yes (Terminate at end.)
- ❑ No

8. Have you had a mammogram in the last 3 years?

- ❑ Yes (Go to question 9.)
- ❑ No (Recruit to UNSCREENED Focus Groups – Go to question 10.)

9. Have you had a mammogram in the last 24 months (or 2 years)?

- ❑ Yes (Recruit to SCREENED Focus Groups – Go to question 10.)
- ❑ No (Terminate at end.)

10. Have you ever been diagnosed with breast cancer or ANY form of cancer?

- ❑ Yes (Terminate at end.)
- ❑ No

11. What is your home zip code? _____

- ❑ Is on the list of zip codes from which to recruit
- ❑ Is not on the list of zip codes from which to recruit (Terminate at end.)

12. Do you have any family members who have been recruited for this study?

- ❑ Yes (Terminate at end.)
- ❑ No

13. Are you willing to participate in a discussion to offer your thoughts about materials and messages to increase breast cancer screening in your community?

- ❑ Yes
- ❑ No (Terminate at end.)

TERMINATION SCRIPT: "We appreciate your willingness to answer each of the questions. Unfortunately, one of your answers does not meet our requirements for participation in the focus group. Thank you for your time."

14. You are eligible to participate in the group. Are you still interested in participating?

- ❑ Yes
- ❑ No (Thank person for her time, terminate and end the conversation.)

I'm glad that you will be able to join us! The discussion group will last about an hour and a half. It will be held at [INSERT LOCATION]. The group in which we would like you to participate is scheduled for:

SCREENED			
Place (Age Group)	**Date**	**Group Number**	**Time**
TBD (40-49)	TBD	Group 1	TBD
TBD (50-64)	TBD	Group 2	TBD
TBD (40-49)	TBD	Group 3	TBD
TBD (50-64)	TBD	Group 4	TBD
UNSCREENED			
TBD (40-49)	TBD	Group 5	TBD
TBD (50-64)	TBD	Group 6	TBD
TBD (40-49)	TBD	Group 7	TBD
TBD (50-64)	TBD	Group 8	TBD

15. Does this date and time work for you?

- ❑ Yes
- ❑ No (Thank person for her time, terminate and end the conversation.) [GET OTHER AVAILABLE TIMES THAT MIGHT WORK.]

You will receive $65.00 for participating in the group. Do not forget that we will serve you a light meal prior to the discussion.

We would also like to be able to send you a reminder before the group. Can you please confirm your name, address, phone number, and e-mail?

Name:			
Mailing Address:			
Home Telephone:		**Pager:**	
Work Telephone:		**Cell Phone:**	
E-Mail:			

Also, please contact [NAME] at [PHONE NUMBER] if your plans change so that we may invite someone from the waiting list to attend instead. Otherwise, we'll look forward to seeing you on [Month/Day/Year] at [Time].

RECRUITER: (Please record the location where you screened this woman:_____)

Give the woman a focus group card with her group number (1-8), the focus group location, phone number, and directions.

ATTACHMENT O
SAMPLE DATA TABLE

SAMPLE DATA TABLE

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN–AMERICAN WOMEN

CONCEPT TESTING: CONCEPT 1

1. What do you think about this phrase?
Probe: What does it make you think about?
Probe: What do you like about this phrase? Why?
Probe: What do you dislike about the phrase? Why?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

2. What do you think the phrase means?
Probe: What is the main idea it is trying to communicate?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

SAMPLE DATA TABLE

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN–AMERICAN WOMEN

CONCEPT TESTING: CONCEPT 1 (cont.)

3. Is there anything confusing about the phrase? Please explain.

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

4. Do you believe what the phrase is telling you? Why/Why not?
Probe: Who do you think this phrase is meant for?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

SAMPLE DATA TABLE

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN–AMERICAN WOMEN

CONCEPT TESTING: CONCEPT 1 (cont.)

5. What would be a better way to say what is in meant by this phrase?
Probe: What else (or other types of information) would you want to hear in this phrase?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

CONCEPT TESTING: CONCEPT 2

1. What do you think about this phrase?
Probe: What does it make you think about?
Probe: What do you like about this phrase? Why?
Probe: What do you dislike about the phrase? Why?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

SAMPLE DATA TABLE

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN–AMERICAN WOMEN

CONCEPT TESTING: CONCEPT 2 (cont.)

2. What do you think the phrase means?
Probe: What is the main idea it is trying to communicate?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

3. Is there anything confusing about the phrase? Please explain.

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

SAMPLE DATA TABLE

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN–AMERICAN WOMEN

CONCEPT TESTING: CONCEPT 2 (cont.)

4. Do you believe what the phrase is telling you? Why/Why not?
Probe: Who do you think this phrase is meant for?

	Segment	Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

5. What would be a better way to say what is in meant by this phrase?
Probe: What else (or other types of information) would you want to hear in this phrase?

	Segment	Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

SAMPLE DATA TABLE

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN–AMERICAN WOMEN

CONCEPT TESTING: CONCEPT 3

1. What do you think about this phrase?
Probe: What does it make you think about?
Probe: What do you like about this phrase? Why?
Probe: What do you dislike about the phrase? Why?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

2. What do you think the phrase means?
Probe: What is the main idea it is trying to communicate?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

SAMPLE DATA TABLE

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN–AMERICAN WOMEN

CONCEPT TESTING: CONCEPT 3 (cont.)

3. Is there anything confusing about the phrase? Please explain.		
Segment		**Themes**
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

4. Do you believe what the phrase is telling you? Why/Why not? **Probe:** Who do you think this phrase is meant for?		
Segment		**Themes**
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

SAMPLE DATA TABLE

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN–AMERICAN WOMEN

CONCEPT TESTING: CONCEPT 3 (cont.)

5. What would be a better way to say what is in meant by this phrase?
Probe: What else (or other types of information) would you want to hear in this phrase?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

CONCEPT TESTING: ALL MESSAGES

1. Which of these phrases appeals to you the most? Why?

Segment		Themes
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	

SAMPLE DATA TABLE

FORMATIVE RESEARCH ON ISSUES RELATED TO THE USE OF MASS MEDIA IN AFRICAN–AMERICAN WOMEN

CONCEPT TESTING: ALL MESSAGES (cont.)

2. Why do you like/dislike one more than another?		
Segment		**Themes**
Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	
Non–Enrollees	Savannah 40 – 49	
	Savannah 50 – 64	
	Macon 40 – 49	
	Macon 50 – 64	