PROMOTING HEART HEALTH IN MIDLIFE AND OLDER WOMEN
RESEARCH PROTOCOL

I. Central Objective and Specific Aims
Cardiovascular disease is the number one cause of death for women in the U.S., claiming approximately 500,000 female lives a year – six times as many as breast cancer. Overall, nearly 8 million women nationwide live with the disease and its devastating consequences.

Research shows that a lifestyle including a healthy diet, weight control, and appropriate physical activity can dramatically reduce the risk of heart disease in women; those who most need to adopt such a lifestyle, however, are not heeding the message. Currently, no major programs exist to help them develop the strategies and tools to reduce that risk.

The StrongWomen – Healthy Hearts Program is designed to potentially help midlife and older women make lifestyle changes to reduce their risk of heart disease. The central objective of this proposal is to rigorously evaluate the dissemination of the StrongWomen – Healthy Hearts Program in order to achieve maximal public health impact.

AIM 1: To conduct an in-depth quantitative and qualitative evaluation of the dissemination of the StrongWomen – Healthy Hearts Program using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework in Pennsylvania. To achieve this goal, we partner with Pennsylvania State University Cooperative Extension. Extension educators will serve as program leaders. We will collect data from a number of sources to address the following questions:

• Reach:
  ▪ What is the participation rate?
  ▪ How representative are participants?
  ▪ What key factors determined who in the target audience were reached successfully and who were not?

• Effectiveness:
  ▪ Is the program effective in a variety of settings?

• Adoption:
  ▪ What percentage of extension educators, begin a program within one year?
  ▪ What key factors determined adoption?

• Implementation:
  ▪ What is the extension educators’ fidelity to the various elements of the Program curriculum?
  ▪ Were key components of the intervention modified? How were they modified?
  ▪ Was the Program modified specifically to meet the needs of a particular audience? How was it modified?
  ▪ Did modifications alter effectiveness?

• Maintenance:
  ▪ How sustainable is the program at the setting level?

AIM 2: To conduct an evaluation of the first wave of national dissemination using the RE-AIM framework. To achieve this goal, we will partner with the National Extension Association of
Family and Consumer Sciences to conduct a training of 100 extension educators at their annual meeting in Fall 2010. Data will be collected from several sources to address RE-AIM questions.

II. Background and Rationale
Cardiovascular disease (CVD) is the leading cause of death for women in the United States and disproportionately affects underserved populations. The StrongWomen – Healthy Hearts Program has the potential for positive impact on this public health issue. The 12-week intervention has demonstrated effectiveness in increasing physical activity, improving diet quality, and decreasing body weight in a controlled, randomized trial in two states. The results of the pilot study have been published in a peer-reviewed journal.

This project seeks to evaluate the dissemination of the StrongWoman - Healthy Hearts Program through partnership with the USDA National Institute of Food and Agriculture (NIFA), formerly the Cooperative State Research, Education, and Extension Service (CSREES), our partner in the effectiveness trial. The project plan leverages a successful five-year collaboration between Pennsylvania State University, Tufts University, and NIFA. We will work with collaborators at Tufts University to conduct an in-depth evaluation in Pennsylvania according to the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework using quantitative and qualitative methods.

The PDF version of the SWHH curriculum may be viewed at: http://jhrc.nutrition.tufts.edu/publications/StrongWomenHealthHeartsToolKit.html. Briefly, the program is designed to take place two days per week for 12 weeks. Thirty minutes of each class includes aerobic dancing to a DVD created for the project or walking outside if location and weather permit. During the 12 weeks, subjects progress from approximately 20 minutes of low-to-moderate intensity physical activity (plus 5 minutes of gentle stretching) to 25 minutes of moderate-to-vigorous intensity physical activity (plus stretching), which is safe and appropriate for this population. The other thirty minutes includes leader-directed and hands-on discussion and activities to modify dietary intake patterns, as well as weight control strategies. The Program emphasizes an eating pattern that is rich in fruits, vegetables, low-fat or nonfat dairy, fish, whole grains, and legumes; it encourages leaner meats and poultry, and fewer refined carbohydrates and saturated and trans fats. The theoretical basis for the intervention is Social Cognitive Theory. Behavioral strategies include self-monitoring of food intake and physical activity, goal-setting, and skill-building around food preparation, supermarket shopping, and restaurant eating. For example, hands-on skill-building activities include preparation of recipes in small groups. Thorough formative research helped inform development of the curriculum.

III. Research Plan
A. Experimental design: This dissemination study is essentially a longitudinal study, in which various aspects of dissemination will be monitored prospectively. Effectiveness will be measured pre-post on all subjects (there will not be a control group).

B. Sample size and statistical analysis: Sample size summary. There are two different “Participant” groups in this research study. The first research participant group is Extension Educators. These professionals are already program
leaders with Penn State Cooperative Extension or are already program leaders in the state-wide StrongWomen Program. Extension Educators will be recruited to participate in the StrongWomen – Healthy Hearts project. If interested, Extension Educators will receive a day-long training (after providing informed consent) to provide them with the tools necessary to run classes in their county. Extension Educators are research participants in this study since data will be collected from them to inform the RE-AIM framework.

The Extension Educators will in turn recruit the second research participant group, the Program Participants. The Extension Educators will conduct the StrongWomen – Healthy Hearts classes and obtain outcomes measures on the Program Participants.

A sub-set of the Program Participants are the Eligible Non Participants. Eligible Non Participants are women who go through screening, are eligible, but do not end up participating in the StrongWomen – Healthy Hearts program. A random sample of 20 Eligible Non Participants will be interviewed (after signing informed consent) in order to better understand why they did not enroll in the program despite being eligible.

Sample size was calculated and an analysis plan was developed for each of the RE-AIM components, for each Specific Aim. Overall, we expect to recruit 20 extension educators and 270 participant subjects for Specific Aim #1 (in Pennsylvania) and 100 CSREES educators and 1200 participant subjects for Specific Aim #2 (for the first wave of national dissemination).

**REACH Sample Size and Analysis Plan for Specific Aim #1.** To determine Reach, we will obtain data to answer three questions: What is the participation rate? How representative are participants? What were the key factors that determined who in the target audience were reached? These questions are critical to achieving full representation from priority subpopulations. By answering them, we will be able to determine which recruitment strategies, site characteristics, and extension educator characteristics are significantly associated with their full inclusion.

**Sample Size.** Sample size calculations are based on data from the StrongWomen strength training program (Seguin 2008 [1] and unpublished data). We calculated sample size based on a representative site characteristic (equipment availability) for which we had data. Based on this, we will need 17 extension educators/sites to detect any associations between site characteristics and participation rate and 41 to determine the association between site characteristics and representativeness (based on race). We are assuming that % reach, which will have the same numerator as participation rate, will have a similar sample size. We expect an actual sample of approximately 18 sites (extension educators that run a program). We will therefore have a large enough sample for participation rate at a power level of at least 0.8. However, we will have a power level of only approximately 0.5 for representativeness.

We used the same approach to determine sample size for the association between extension educator characteristics (using a representative characteristic) and participation rate/Reach, and representativeness, which yielded samples sizes of 10 and 53, respectively. So we will similarly have a large enough sample for participation rate at a power level of 0.8, and only a power level of approximately 0.5 for representativeness.
While we will have insufficient power to test for associations between site and extension educator characteristics and representativeness, these calculations provide only an estimate and it still may be possible to detect true associations. If we find that we truly lack power, we will pool this data with national data from Specific Aim #2.

**Statistical Analysis.** We will do the following calculations:

- % who respond to recruitment = (# in target population that contact educator/# exposed to recruitment) x 100
- % Reach into target population = (# who begin program/# in target population) x 100
- % eligible = (# eligible/total # who contact extension educator) x 100
- % participation among eligible = (# who participate/# eligible) x 100

Representativeness will be determined at the county and state levels. At the county level, each group of participants (representing one class with one extension educator) will be compared with the overall county population of women age 40 and over based on education, income, race, marital status, and work status. At the state level, all participants will be similarly compared with the overall state population of women age 40 and over. A chi-square test will be used since demographic factors will be reported categorically.

To test for associations between site characteristics and participation rate (a continuous variable), Pearson correlations will be used for continuous site variables and t-tests will be used for dichotomous site variables. The same approach will be used to determine associations between site characteristics and reach. For representativeness, we will first compile a representativeness score. Each of the 5 demographic factors (education, income, race, marital status, and work status) will receive a score of 1 if there is no significant difference between participants and the overall target population in that county. Therefore the representativeness score will range from 0 to 5, with 0 indicating very little similarity between program participants and the overall population, and 5 representing high similarity. This score will then be dichotomized, with 0-3 represented by 0 (low representativeness) and 4-5 represented by 1 (high representativeness). Associations between site characteristics and representativeness will be tested using t-tests for continuous site variables and chi-square tests for dichotomous site variables.

The same approach will be used to determine the association between EXTENSION educator characteristics and participation rate, reach, and representativeness.

**EFFECTIVENESS Sample Size and Analysis Plan for Specific Aim #1.** A controlled, randomized trial has already demonstrated the effectiveness of the StrongWomen – Healthy Hearts Program. However, it will be important to continue to monitor effectiveness as the Program is more broadly disseminated. A significant impact on the cardiovascular disease burden will only be achieved if it remains effective in a wide variety of settings. We will evaluate the effectiveness of the Program on weight/BMI, fruit and vegetable intake, and physical activity using a pre-post within-subjects design.

**Sample Size.** The sample size calculation for overall effectiveness uses data derived from the StrongWomen – Healthy Hearts effectiveness study, looking at the change in weight in the intervention group. After the 12-week program, the estimated mean change in weight in this
group was -2.1 kg with a standard deviation of 5.3. The ICC observed in the effectiveness trial was 0.11, giving a cluster effect of 2.7, assuming an average cluster size of 15 subjects. The test of equality of means will be carried out at the 0.05 level of significance. A sample size of 33 participants accounts for the design effect and gives a probability of 0.8 of rejecting the null hypothesis. We expect 270 participants and will therefore have an adequate sample.

We were not able to determine sample sizes to test for associations between site and extension educator characteristics and effectiveness. The StrongWomen studies did not evaluate pre-post changes in participants’ weight (or other outcomes of interest for this study), and we did not obtain site and extension educator characteristics in the StrongWomen – Healthy Hearts effectiveness trial. However, because the analyses are similar, we expect sample sizes to be within the same range as for other RE-AIM components.

**Statistical Analysis.** Pre-post data for the entire state of Pennsylvania will be analyzed using a paired samples t-test which adjusts for the clustering of participants within a county (site).

Effectiveness will be defined as a change in weight of a magnitude at least equal to that seen in the effectiveness trial, -2.1 kg. To test for an association between site characteristics and effectiveness (a dichotomous variable), t-tests will be used for continuous site variables and chi-square tests will be used for dichotomous variables. The same approach will be used to determine the association between extension educator leadership characteristics and effectiveness.

**ADOPTION Sample Size and Analysis Plan for Specific Aim #1.** If the number of EXTENSION educators and type of site that adopts a program is limited, then the number of women that can be reached is also limited. It is important to ensure that a program will fit in a variety of sites. We will collect the data needed to determine the rate of adoption and the key factors that may have influenced adoption. Adoption will be defined as an extension educator beginning a StrongWomen – Healthy Hearts Program in her community within one year of being trained. This is based on our experience with the StrongWomen program.

**Sample Size.** Based on data from the StrongWomen strength training program (Seguin 2008 [1] and unpublished data), we will need 45 extension educators who do or do not adopt to detect any associations between site characteristics and adoption, should they actually exist, at a power level of 0.8. This would give us an actual power level of approximately 0.5. While this is our best estimate based on previous work, it still may be possible to detect true associations. Should we in actuality lack the power to do so, we will pool this data with national data from Specific Aim #2.

We used the same approach to determine sample size for the association between extension educator characteristics and adoption, which yielded a sample size of 18 extension educators. We therefore expect a large enough sample to test for associations at a power level of 0.8.

**Statistical Analysis.** We will do the following calculations:

- Overall % adoption = # who adopt/# eligible in state
- % adoption among trained = # who adopt/# trained
To test for associations between site characteristics and adoption among those trained (a dichotomous variable), t-tests will be used for continuous site variables and chi-square tests will be used for dichotomous site variables. The same approach will be used to test for associations between EXTENSION educator characteristics and adoption, and perceived costs, importance of cost and adoption.

**IMPLEMENTATION Sample Size and Analysis Plan for Specific Aim #1.** As a program is widely disseminated, there is ongoing tension between fidelity and flexibility. Fidelity to key components is critical to maintaining effectiveness, yet flexibility is also essential to effective translation in the local setting. The goal in evaluating implementation is to help determine which components must be adhered to and which can, and should, be modified.

*Sample Size.* Sample size was determined based on the StrongWomen – Healthy Hearts effectiveness study, for which an overall fidelity score was determined by the Project Manager based on weekly check-ins and site visits. Fidelity score was associated with change in weight in that study. Based on that data, we will need 20 extension educators/sites to detect any associations between fidelity and effectiveness, should they exist, at a power level of 0.8. The 18 EXTENSION educators/sites will provide nearly that (power of 0.78).

*Statistical Analysis.* We will test for an association between overall fidelity score and effectiveness at the site level (using mean change in weight for the site) using Pearson correlations, since both variables will be continuous.

We will determine the cost of the program by compiling extension educators’ weekly reports of cost, and adding up costs for the entire program. We will calculate summary statistics (mean and standard deviation) for costs per site.

**MAINTENANCE Sample Size and Analysis Plan for Specific Aim #1.** The full public health impact of a program will be realized only if it is sustained within an organization, giving it the ability to reach significant numbers of people over time. The goal of the Maintenance evaluation is to determine the extent to which this happens within extension in Pennsylvania. Consistent with the organizational structure of extension, we will monitor individual sites to determine collective maintenance. We will also identify the factors that affect Maintenance so that this information can be used to adapt the program if necessary.

*Sample Size.* Based on data from the StrongWomen strength training program (Seguin 2008 [1] and unpublished data), we will need 41 extension educators, including both those who do and do not maintain, to detect any associations between site characteristics and maintenance, should they actually exist, at a power level of 0.8. Based on this, we will only have approximately 50% power to detect any associations that actually exist, given the expected sample size of 18 (those who adopt who may or may not maintain, see Figure 1). Our actual power may be higher than this estimate, and we may still detect true associations. However, if we find we do not have sufficient power, we will pool this data with national data from Specific Aim #2 (see section D.2.k).
We used the same approach to determine sample size for the association between extension educator characteristics and maintenance, which yielded a sample size of 21 extension educators. We will therefore have close to 80% power (actual power = 76%) with 18 expected sites.

Statistical Analysis. We will calculate % Maintenance as follows:
% Maintenance = # of educators who re-run the program/# initial adopters

To test for associations between site characteristics and maintenance (a dichotomous variable), t-tests will be used for continuous site variables and chi-square tests will be used for dichotomous site variables. The same approach will be used to test for associations between extension educator characteristics and maintenance, and perceived costs, importance of cost and maintenance.

REACH Sample Size and Analysis Plan for Specific Aim #2. The larger number of extension educators/sites that we will have for Specific Aim #2 compared to Specific Aim #1 (approximately 100 compared to 20) will allow us to use regression models, rather than bivariate statistics, to test for associations between site and leader characteristics and participation rate, reach, and representativeness. It will also ensure adequate power to test these associations. By including all variables and determining the best model, we will be able to determine more robustly the characteristics that are most important for participation rate, reach, and representativeness.

Sample Size. Sample size is calculated similarly to Specific Aim #1, yielding initial sample sizes of 17 and 41 extension educators (county sites) for testing the association between site characteristics and participation rate/reach and representativeness, respectively. These sample sizes are increased by 10 for each predictor in the regression model [2]. Similarly, the sample sizes of 10 and 53 needed to test for associations between extension educator characteristics and participation rate/reach and representativeness will be increased by 10 for each covariate. We will add no more than 4 covariates to ensure that our sample is sufficient (80 sites that run programs) to conduct the analysis at a power level of at least 0.8.

Statistical Analysis. Percent eligible and % participation among eligible will be calculated as for Specific Aim #1. To determine representativeness, participants will be compared to the total target population in their state and within the United States, using a chi-square test since demographic data will be reported categorically.

To test for an association between site characteristics and participation rate, stepwise regression analysis will be used. The hypothesized model is specified as: % participation = site characteristic 1 + site characteristic 2 + site characteristic 3, etc. Site characteristics will include factors like resource level and accessibility as determined by the Site Questionnaire. The model will include an adjustment for clustering of sites within states. A similar model will be set up for reach, with % reach as the dependent variable, and for representativeness, using the representativeness score (see section D.1.g, Statistical Analysis) as the dependent variable.

Similar regression models will be constructed to test for associations between extension educator characteristics and participation rate, reach, and representativeness. The hypothesized models
will be specified as: [participation rate, reach, or representativeness] = age + sex + race + education.

**EFFECTIVENESS Sample Size and Analysis Plan for Specific Aim #2.** Overall effectiveness results will confirm and augment those from Specific Aim #1. To test for associations, as with reach, the larger number of extension educators/sites compared to Specific Aim #1 will allow us to use a regression model, rather than bivariate statistics. It will also ensure adequate power to test these associations.

**Sample Size.** Sample size calculation for overall effectiveness will be the same as for Specific Aim #1. We are unable to determine a sample size for tests of associations between site and extension educator characteristics and effectiveness, but expect ranges similar to other RE-AIM components.

**Statistical Analysis.** To test for overall effectiveness of the Program, paired t-tests will be used just as for Specific Aim #1. To test for an association between site characteristics and effectiveness, regression analysis will be used. The hypothesized model is specified as: pre-post weight change (site mean) = site characteristic 1 + site characteristic 2 + site characteristic 3, etc. Site characteristics will include factors like resource level and accessibility (as determined by the Site Questionnaire). The model will include an adjustment for clustering of sites within states. Similarly, regression models will be constructed to test for associations between extension educator characteristics and effectiveness. The hypothesized models will be specified as: pre-post weight change = age + sex + race + education.

**ADOPTION Sample Size and Analysis Plan for Specific Aim #2.** The larger number of extension educators/sites that we will have for Specific Aim #2 compared to Specific Aim #1 (80 compared to 18) will allow us to use a regression model, rather than bivariate statistics, to test for associations between site characteristics, leader characteristics, cost, and adoption. By including all variables and determining the best regression model, we will be able to determine more robustly the characteristics that are most important for adoption.

**Sample Size.** As for Specific Aim #1, we will need 45 extension educators including those who do and those who do not adopt to detect any associations between site characteristics and adoption, should they exist, at a power level of 0.8. In addition we will need 10 extension educators/sites per covariate [2], with no more than 4 covariates anticipated. We will therefore have sufficient power (at least 0.8) with 100 extension educators.

We used the same approach to determine sample size for the association between extension educator characteristics and adoption, which yielded a sample size of 58 extension educators (accounting for the multiple covariates in the model). We will therefore have sufficient power to test these associations.

**Statistical Analysis.** Percent adoption will be calculated as follows:
% adoption among trained = # who adopt/# trained
To test for an association between site characteristics and adoption, logistic regression analysis will be used. The hypothesized model is specified as: adoption (yes or no) = site characteristic 1 + site characteristic 2 + site characteristic 3, etc. The model will include an adjustment for clustering of sites within states. Similar models will be set up to test the association between extension educator characteristics and adoption, and perceived cost and adoption.

**IMPLEMENTATION Sample Size and Analysis Plan for Specific Aim #2.** The larger sample size will allow us to examine associations between each component of fidelity (physical activity, cooking exercise, preparedness, etc.) and effectiveness. This will help determine which specific components must be adhered to and which can, and should, be modified.

*Sample Size.* Sample size calculations are the same as for Specific Aim #1 (section D.1.j), except that we must add 10 extension educators/sites for each covariate in the model [2], expected to be no more than 4. We will therefore need a sample size of 60, which we expect to achieve.

*Statistical Analysis.* Regression analysis will be used to test for associations between fidelity for the various curriculum components and effectiveness. The hypothesized model is specified as: pre-post weight change (mean for site) = fidelity_component 1 + fidelity_component 2 + fidelity_component 3 + fidelity_component 4. The model will include an adjustment for clustering of sites within states.

We will determine the cost of the program by compiling extension educators’ monthly reports of cost, and adding up costs for the entire program. We will calculate summary statistics (mean and standard deviation) for costs per site.

**MAINTENANCE Sample Size and Analysis Plan for Specific Aim #2.** Similar to Adoption, the larger number of extension educators/sites that we will have for Specific Aim #2 compared to Specific Aim #1 (80 compared to 18) will allow us to use a regression model, rather than bivariate statistics, to test for associations between site characteristics, leader characteristics, cost, and maintenance. By including all variables and determining the best regression model, we will be able to determine more robustly the characteristics that are most important for maintenance.

*Sample Size.* Based on data from the StrongWomen strength training program (Seguin 2008 [1] and unpublished data), we will need 41 extension educators, including both those who do and those who do not maintain, to detect associations between site characteristics and maintenance, should they exist, at a power level of 0.8. We used the same approach to determine sample size for the association between extension educator characteristics and maintenance, which yielded a sample size of 21 extension educators. We must add 10 for each covariate in the model, for final sample sizes of 81 for site characteristics and 61 for extension educator characteristics. We expect a sample of 80 extension educators who do or do not maintain (see Figure 2), and therefore will have an adequate sample.

*Statistical Analysis.* We will calculate % Maintenance as follows:

\[ \text{% Maintenance} = \frac{\text{# of educators who re-run the program}}{\text{# initial adopters}} \]
To test for an association between site characteristics and maintenance, logistic regression analysis will be used. The hypothesized model is specified as: maintenance (yes or no) = site characteristic 1 + site characteristic 2 + site characteristic 3, etc. The model will include an adjustment for clustering of sites within states. Similar models will be set up to test the association between extension educator characteristics and maintenance, and perceived and actual cost and maintenance.

C. Subject characteristics:

Extension Educators. Again, there will be two types of subjects in this study. Extension educators will be involved both as researchers and as subjects. As researchers, they will be responsible for collecting some of the data, screening, obtaining informed consent, and implementing the program. Human subjects research will be conducted in Pennsylvania and at other extension sites across the country. Extension educators are associated with universities and all extension educators have or will have received human subjects training in compliance with the IRB at their institutions prior to the start of the program. IRB approval for all aspects of the study, including informed consent, will be obtained from Pennsylvania State University after we have received approval from Tufts University.

As subjects, extension educators will be asked to provide basic information (demographics) about themselves and about their leadership style. They will also provide information about the extension site. They will document various aspects of recruitment and participation. They will participate in key informant and in-depth interviews. Extension educators are almost entirely female (over 90%). All are over the age of 21.

Inclusion criteria for Extension Educators:

• Current Extension Educators and/or trained program leaders of existing StrongWomen Programs
• Interest in conducting a StrongWomen – Healthy Hearts class in their county
• Up to date on IRB human subjects training
• CPR certified
• Willingness to participate in research study and provide informed consent
• Clearance on the Par-Q and You questionnaire or a Physician’s clearance letter

Exclusion criteria for Extension Educators:

• Not a current Extension Educator or trained program leader for existing StrongWomen Program
• No interest in conducting a StrongWomen – Healthy Hearts class in their county
• Not up to date on IRB human subjects training
• Not CPR certified
• Not willing to participate in research study

Although Program Participants will be excluded on the basis of pregnancy (see below), Extension Educators will not be. The intensity and duration of the physical activity that they will be leading in the classes is completely in line with current recommendations for physical activity during pregnancy. They can still teach weight loss components of the classes, but will be advised not to attempt to lose weight during pregnancy.
Program Participants. The second type of subject (the one on whom most outcomes will be assessed) will be those who participate in the StrongWomen – Healthy Hearts Program. Inclusion criteria for Program Participants:

- Female
- Age ≥40
- BMI ≥24
- Living independently
- Sedentary lifestyle
- Willingness to participate in research study and provide informed consent
- Clearance on the Par-Q and You questionnaire or a Physician’s clearance letter

Exclusion criteria for Program Participants:

- Failure to provide informed consent
- Failure to provide permission letter from healthcare provider if deemed necessary by the PAR-Q
- Participation in any other lifestyle modification program
- Unstable medical condition that would preclude participation in exercise
- Cognitive impairment
- Planning to move outside of area before completing the 12-week program
- Pregnancy

Potential Program Participant subjects will be initially screened by telephone for all inclusion and exclusion criteria except cognitive impairment. All subjects <69 will be screened for safety and appropriateness to begin an exercise program using the Physical Activity Readiness Questionnaire (PAR-Q). Women over 69 and those who respond affirmatively to any question on the PAR-Q will be required to obtain a signed permission letter from her healthcare provider that indicates that physical activity is safe and appropriate. Once enrolled, subjects will discontinue the intervention if there are any changes in their medical status that would make exercise unsafe. Every effort will be made to obtain measurements on these subjects for the remainder of the study, provided it is safe and appropriate to do so.

Women who pass the telephone screening protocol will sign an informed consent statement and participate in the first in-person assessment, which will include the 6-item test for cognitive impairment [3]. BMI as determined by heights and weights measured during the assessment (rather than those self-reported during the telephone screen) will be used to determine final study eligibility.

Pregnant women will be excluded because the StrongWomen – Healthy Hearts Program includes a significant section on weight loss, which is inadvisable for pregnant women. The screening instruments include a question on whether women are pregnant or planning to become pregnant. Women who respond affirmatively will be excluded from participation. Subjects who are enrolled in the study will be asked to notify their program leader immediately should they become pregnant. Any subject who becomes pregnant during the study will be terminated from the study.
D. Risk/benefit assessment:
This is a public health program that has minimal risk associated with the research activities for Extension Educators and Program Participants. While there are some risks associated with physical activity and cooking, as described below, all activities proposed in this study are designed to reduce risk of heart disease in women through safe and appropriate physical activity, good nutrition, and weight control. All recommended activities are in line with current public health guidelines (the Dietary Guidelines for Americans and the Physical Activity Guidelines for Americans).

**Extension Educators:**
There is minimal risk of psychological distress should any of personal data be revealed to anyone besides the research staff. Research staff, and no one else, will have access to Extension Educator data. The data collection forms will either be kept in a locked file cabinet or will be password protected on a computer. The measurements themselves will be made in private to minimize any discomfort.

Since Extension Educators will be leading an exercise class, they will themselves be participating in physical activity. Physical activity has some risks associated with it. There is a risk of injury, such as spraining an ankle or skinning knees, hands, or elbows. There is also some risk of muscle tenderness and soreness. Intense exercise can also cause sudden illnesses, such as stroke or heart attack. To minimize these risks, Extension Educators will take the Par-Q and You questionnaire prior to enrolling in the study. If Extension Educators have a medical issue or are over 69 years old, they will be required to provide a letter from their doctor before they can start. All Extension Educators will be thoroughly trained in the program curriculum, including safety precautions, prior to conducting the program to minimize risk.

The Extension Educators will also be leading cooking and food preparation demonstrations. The nutrition education part of the curriculum is also designed to be as safe as possible. Part of each class will be in lecture format and will not present any risks beyond those encountered in everyday life. Part will involve cooking demonstrations and lessons and includes risks typical for cooking, such as accidental burns or knife cuts. Extension Educators will be trained during the 1-day workshop training in kitchen safety precautions and adequate supplies of appropriate equipment will be available (for example, enough oven mitts) to minimize risk.

**Program Participants:**
There is minimal risk of psychological distress should any of personal data be revealed to anyone besides the Extension Educators and research staff. Assigning de-identified study numbers will minimize this risk to subjects. Research staff and the Extension Educators, and no one else, will have access to the list that links Program Participant name with unique study number. This list and the data collection forms will either be kept in a locked file cabinet or will be password protected on a computer. The measurements themselves will be made in private, so that other participants will not be able to find out other participant information during testing.

Physical activity has some risks associated with it. There is a risk of injury, such as spraining an ankle or skinning knees, hands, or elbows. There is also some risk of muscle tenderness and soreness. Intense exercise can also cause sudden illnesses, such as stroke or heart attack. To
minimize these risks, Program Participants will undergo screening to determine if it is safe for them to start an exercise program. If Program Participant has a medical issue or are over 69 years old, she will be required to provide a letter from her doctor before she can start. Extension Educators are prepared to handle sudden illnesses, sprains, and injuries from falling. All Extension Educators will have current CPR certification. Extension Educators will never be more than one minute’s walk away from any participant, and they will have a phone available at all times. If exercise is conducted outdoors, they will be required to carry a working cell phone.

The nutrition education part of the classes is also designed to be as safe as possible. Part of each class will be in lecture format and will not present any risks beyond those encountered in everyday life. Part will involve cooking demonstrations and lessons and includes risks typical for cooking, such as accidental burns or knife cuts. Kitchen safety precautions will be discussed and adequate supplies of appropriate equipment will be available (for example, enough oven mitts). Extension Educators will have a first aid kit available and are trained to provide first aid should an injury occur.

The StrongWomen – Healthy Hearts Program includes a weight control component and weight loss is an expected effectiveness outcome. Weight loss may pose some risk for older adults, as it has the potential to negatively affect muscle and bone mass. However, evidence suggests that weight loss confers the same benefits in elderly populations that it does in younger ones [4]. The position of the American Society for Nutrition and NAASO (The Obesity Society) is that “weight-loss therapy that minimizes muscle and bone losses is recommended for older persons who are obese and who have functional impairments or medical complications that can benefit from weight loss” [4]. Weight loss in this population can specifically improve the metabolic abnormalities associated with CVD risk in elderly populations. As in the effectiveness study, we anticipate that most subjects will be below the age of 75 (average age was 57.8). To reduce risk of adverse effects on muscle and bone status in older subjects caused by weight loss, the Program follows the recommendations of the American Society for Nutrition and NAASO (The Obesity Society) [4]. It includes regular physical activity, which can attenuate bone loss caused by weight loss. It is designed for gradual weight loss, with a modest reduction in energy intake and adequate amounts of all nutrients, including protein, which also helps to minimize muscle and bone loss.

Extension educators will monitor the health status of program participants throughout the study. Any participant for whom exercise becomes unsafe will discontinue her participation.

There are no risks for the Eligible Non Participants.

The Program has the potential to greatly benefit its participants, as it provides education about nutrition, diet, aerobic fitness, and a heart-healthy lifestyle. There is a great potential for psychological benefits from physical activity, friendships, and from the enjoyment of class participation. Furthermore, heart disease is of utmost public health concern for women in the U.S. From this program, we expect to gain valuable information about the Reach, Effectiveness, Adoption, Implementation, and Maintenance of the StrongWomen – Healthy Hearts Program. This information will allow us to build on strengths and to modify as necessary for nationwide dissemination that will have maximal impact on risk factors for heart disease in midlife and older
women. We also expect this study to provide critical information about how to best reach priority subpopulations (low-income, rural) so that health disparities can be addressed. With this potential, the risks to subjects are reasonable in relation to the anticipated benefits of the program.

E. Specific methods and techniques used throughout the study: Data will be collected using the following instruments and methods.

**Extension Educators**

Extension educator subjects will provide the following data. The Extension Educator Questionnaire will be completed during the Program training sessions (expected to be in March 2010 in Pennsylvania and September 2010 for national roll-out). The Recruitment Monitoring Form will be filled out during the first year after the training sessions. Participant recruitment typically lasts 6 weeks at any site, and extension educators will be recruiting at different time points during that year. It will be completed weekly during that time. Likewise the Implementation Survey will be filled out during the 12-week Program, whenever it occurs for any individual Extension educator within the year after they are trained. It will be completed weekly in Pennsylvania and monthly in the national roll-out.

**Extension Educator Questionnaire.** This questionnaire has four parts: About You, Leadership, Site Characteristics, and Perceived Costs. The questionnaire will be designed to determine the personal characteristics of extension educators that are associated with reach, adoption, and maintenance. Extension educators will complete this questionnaire on-line at the state training. It asks about basic demographic factors: age, sex, race/ethnicity, and educational attainment. They will also be asked to report the length of time that they have been at their current position. They will be asked two self-efficacy questions related to recruitment. Extension educators will be asked whether they self-identify as a leader and whether they are comfortable leading people in activities. Four primary categories from well-established leadership inventories will be used to characterize leadership style: organization, support, communication, and conflict resolution [5]. Questions will also be asked about the site where classes will take place: the availability of resources (funds available for health programming; space; equipment) and accessibility (distance from main community commerce center; accessibility by different forms of transportation). Finally, we will ask questions about fiscal costs and the importance of those costs in ability to adopt the program and implement as specified in the curriculum.

The entire questionnaire was pre-tested with our extension collaborators in Arkansas, Kansas, and Alaska (IRB #9242).

**Recruitment Monitoring Form.** To determine recruitment strategies and to estimate the number exposed to recruitment, extension educators will be asked to complete an on-line form that documents all recruitment activities. Extension educators will log the type of recruitment activity conducted (for example, fliers, newspaper ad, listserv announcement, etc.) and the approximate number exposed to each type (for example, 100 people on listserv; newspaper circulation of 5,000, and so forth).
Implementation Survey. Once they start the Program, extension educators will be asked to complete an on-line survey every week (which will take approximately 10 minutes). This survey, adapted from the one used in the effectiveness trial, will ask them to respond to questions about attendance, participant engagement, actual activities done and materials used.

Site Visits. The Penn State Project Coordinator will observe one class at each of the expected 18 sites that adopt a program in Pennsylvania. S/he will visit during weeks 6-10 of the 12 week program. During the observation, the Project Coordinator will rate the class on a number of factors using a 5-point scale [6].

Extension Educator anticipated time commitment for this study:  
- Extension Educators will participate in a 1-day SWHH training workshop.  
- Extension Educators will need to recruit Program Participants (~3 to 6 hours a week for 3 weeks).  
- Extension Educators will need to conduct an informational meeting in their county prior to starting a class (2 hours).  
- Extension Educators will need to conduct baseline and final (12-weeks) testing on Program Participants (total of 3 hours per assessment day)  
- Extension Educators will need to conduct the 12-week class (2 sessions per week, total time 6 hours/week, includes preparation time and reporting).  
- Because this is a natural experiment, Extension Educators may run more than one class over the 2-year period.

Program Participant Subjects
The following data will be collected on program participant subjects. Data will be collected twice on each participant subject, pre- and post-intervention (except for Participant Questionnaire and Height, since those items are not expected to change during the intervention period).

Participant Questionnaire. To determine representativeness, it is necessary to know the demographic characteristics of the Program participants. Participants will complete a paper questionnaire that asks for basic demographic information (age, race/ethnicity, educational attainment, income level, marital status, and work status) just prior to beginning the program. All questions are based on those used in national surveys (U.S. Census and the Behavioral Risk Factor Surveillance System).

Weight. Weight control is an important part of CVD risk reduction [7] and the Program contains a considerable weight control component. Weight will be measured, in triplicate, to the nearest 0.5 kg on a digital floor scale (Seca 880, self-calibrating with 200kg capacity).

Height. Height will also be measured so that BMI (kg/m²) can be calculated. Body Mass Index is a measure based on weight and height and is used to evaluate adult weight status [8]. Height will be measured, in triplicate, to the nearest 0.5 centimeter, using a portable stadiometer (Seca 214) according to the procedures of Lohman [9]. The Seca 214 has a flat vertical surface with an accurate measuring rule attached and measures up to 6’9”.
Fruit and Vegetable Brief FFQ. We will use the 5 A Day for Better Health brief screener to determine if there is pre-post change in this dietary factor. This instrument is brief, self-administered, and has been validated in diverse populations [10]. Servings per day can be calculated from this instrument and will be used as the outcome.

Physical Activity Questionnaire. We will use the International Physical Activity Questionnaire (IPAQ) short version (self-administered) to assess pre-post changes in physical activity. The IPAQ measures the last 7 days of activity and has been validated in a diversity of populations [11-13] and used to evaluate interventions [14, 15]. Metabolic-equivalent (MET) minutes per week will be used as the outcome and will be calculated by multiplying MET intensity for each activity by weekly duration [11].

Program Participant anticipated time commitment for this study: Program Participants will participate in the study for up to 5 months (starting at the Informational Meeting, where they will sign the informed consent, through the Orientation and Assessment Meeting, to the end of the 12-week classes).
- Extension Educators will conduct a telephone screening of potential Program Participants to ascertain eligibility.
- Extension Educators will conduct information meetings for prospective eligible Program Participants.
- Eligible and interested Program Participants will participate in baseline testing (1 to 2 hours)
- The 12-week program will meet 2-times per week for 1 hour to 1 hour and 15 minutes each class.

We will also undertake the following qualitative data collection methods.

Key Informant Interviews with Eligible Non-Participants. Structured 15-20 minute telephone interviews will be conducted with women who have responded to recruitment, are eligible for the Program, but who do not participate in it. A random sample of 10% of eligible non-participants, based on our experience in the StrongWomen – Healthy Hearts effectiveness study, should yield approximately 20 non-participants. We will ask about reasons for non-participation, and specifically about any barriers to participation. The Project Coordinator at Penn State will conduct the interviews after being trained by Dr. Folta, who has expertise and experience in qualitative methods. Phone calls will be digitally recorded and then transcribed by the Project Coordinator. Dr. Folta will analyze the data using the NVivo program (QSR International, version 8.0). Data will be coded in a two-step process: key phrases will be coded into a framework that is based on the questioning structure; and additional themes that emerge from the data will be added to the framework and coded. Key themes will then be compiled and reported. Dr. Folta and the Penn State Project Coordinator will work together to ensure that the final results accurately reflect the content of the interviews.

Key Informant Interviews with Non-Adaptors. We will interview the trained extension educators (expected to be 2 of the 20, based on input from Dr. Corbin at Penn State) who fail to adopt the Program within one year. The interviews, designed to take 15-30 minutes, will be conducted by the Project Coordinator at Penn State who will be trained on qualitative methods by Dr. Folta.
We will ask about reasons for non-adoption and barriers to adoption. Depending on the location of the extension educators, the interviews will be conducted either in-person or by telephone. They will be digitally recorded and then transcribed by the Project Coordinator. Dr. Folta will analyze the data as described above for the non-participant key informant interviews. However, the small number of interviews does not warrant use of NVivo software for analysis.

**In-Depth Interviews.** In-depth interviews will be scheduled with extension educators in conjunction with the site visits. The main purpose is to explore in depth any changes that were made to the curriculum; why those changes were made; and perceptions about whether they affected behavior change in participants. Specifically, extension educators will be asked to describe any changes that were made to increase feasibility for themselves; to increase feasibility for participants; and to meet the needs of their target population based on culture, resources available, or any other factors. This qualitative data will be transcribed and analyzed using NVivo software.

**Key Informant Interviews with Non-Maintainers.** To determine barriers to Maintenance, we will conduct key informant interviews with extension educators who do not run the program again within one year. Based on the StrongWomen strength training program, we anticipate % maintenance to be approximately 70%, yielding approximately 5 non-maintainers who we will invite to be interviewed. Interviews will take place either in person or by phone, depending on the location of the interviewees. They will be designed to take no more than 20 minutes and will be digitally recorded. We will ask about reasons for non-maintenance, and specifically about barriers to participation. The Project Coordinator at Penn State will conduct the interviews and transcribe them. Dr. Folta will analyze the data using a two-step process, using NVivo software. Key themes will then be compiled and reported. Dr. Folta and the Project Coordinator will work together to ensure that the final results accurately reflect the content of the interviews.

**F. Assessment of subject safety:** A Data and Safety Monitoring Plan will be implemented to ensure the safety of the participants, as well as the validity and the integrity of the data. Dr. Nelson (Principal Investigator), with the help of the Co-Investigators and Project Managers, will monitor all aspects of safety. All unexpected and adverse events will be reported to the Project Managers (Ms. Wiker if it is in Pennsylvania, or Dr. Folta if it is elsewhere) and Principal Investigator through the individual extension educators in a timely manner. All of the extension educators at each study site will be notified via either fax or phone of all serious adverse events. An event will be considered serious if it results in death, is life-threatening, requires inpatient hospitalization, or results in a persistent or significant disability/incapacity, or might require medical or surgical intervention to prevent one of these outcomes.

Non-serious adverse events will be monitored as well. These are defined as conditions that may be unpleasant to the participant, such as sore muscles, that do not require termination of participation. Should these occur, extension educators will immediately notify the Project Manager. This notification can occur at any time, as all extension educator will have access to the Project Managers’ cellular and land-line telephone numbers. The Project Manager (Ms. Wiker and/or Dr. Folta) will then immediately notify the Principal Investigator, who will then review study protocol to assess the event. Any subject who experiences an adverse event has the option to continue participation in the study, if she so chooses. Any problems will be reported
immediately to the Tufts IRB and the Pennsylvania State University’s IRB if it occurs there. These events will be logged by the individual extension educator.

G. Subject participation:
**Extension Educator Recruitment, Screening, and Informed Consent**
Extension educators will be recruited through email announcements, listserves, and by word-of-mouth. All extension educators will be required to complete an informed consent statement prior to participation in the study. Research personnel at Pennsylvania State University will screen extension educators in Pennsylvania, and research personnel at Tufts University will screen national extension educators. Extension educators may participate in other research studies while participating in this one.

Extension educators will be screened for eligibility by the Penn State Project Manager (Ms. Wiker) in Pennsylvania and by Tufts Project Manager (Dr. Folta) nationally. They will be screening using a tool that has both on-line and paper versions. Screening will take place over the telephone. Consent to participate in the screening will be obtained verbally before commencing the screening process. It will be stated that there are no consequences to refusing to participate in the screening except that they will not be able to participate in the study.

Informed consent will be obtained from Extension Educator subjects during the one-day training sessions on the StrongWomen – Healthy Hearts Program, either in Pennsylvania or at the national training. Study personnel (Principal Investigator, Project Director or Project Managers) will obtain consent. Ample time will be allotted during the training for the extension educators to read through the form, ask any questions, and decide whether or not to participate. It will be made clear to all extension educators that participation in the study is voluntary. It will also be made clear that whether or not the extension educator participates in the study will not have an impact on their current or future employment. The informed consent will be the culmination of a long process of recruitment and screening during which the study, its objectives, and their role will be explained at several points.

**Program Participant Recruitment, Screening, and Informed Consent**
Program participant subjects will be recruited using fliers, which will be placed at local community centers, libraries, restaurants, grocery stores, Laundromats, houses of worship, banks, and other places where midlife and older adults gather or visit frequently. In addition, announcements may be placed on the extension educators’ county websites. A subset of eligible program participants, the eligible non-participants, will be recruited by phone call to see if they are willing to participate in an interview on reasons for non-participation.

Program participant subjects will be screened in Pennsylvania and nationally by extension agents who will serve as their class leaders. All extension agents will have undergone the appropriate human subject education. Screening will take place over the telephone. The screening tool has both on-line and paper versions. Consent to participate in the screening will be obtained verbally prior to commencing the screening process. It will be stated that there are no consequences to refusing to participate in the screening except that they will not be able to participate in the study.
Extension educators will also obtain informed consent from Program Participants. This is one of the reasons that they will be required to complete basic human subjects education. Program Participants will be provided with the form at an Informational Meeting prior to the start of the program. They will have 1-2 weeks to review the form before attending the Orientation and Assessment meeting, where they will sign it. At both meetings, Program Participants will have the opportunity to ask any questions about the study and the consent form. Program Participants will be told that their participation in this study is completely voluntary and will not impact their ability to participate in any current or future programs.

In order to address the “Reach” part of the RE-AIM framework we plan to collect data from women who go through screening, are eligible, but do not end up participating in the SWHH program. We plan to interview over the phone only 20 of these “eligible non-participants.” They will be recruited by telephone using contact information provided during the screening process (note contact information will only be collected for women who pass all screening criteria). Duplicate consent forms will be sent to the prospective participant prior to the telephone interview with a stamped return envelope. Once the study office receives the signed consent form, the telephone interview will be scheduled.

Study location. The StrongWomen – Healthy Hearts classes will be conducted at various sites across Pennsylvania and the United States.

Data obtained from extension educators will be kept at the following locations:

- Data from the on-line questionnaires (Extension Educator Questionnaire, Recruitment Monitoring Form, and Implementation Forms) will be retrieved by Tufts University research personnel from the survey company’s servers and stored and secured at the Tufts University research site, 150 Harrison Ave, Boston, MA in a password protected file.
- Data obtained through one-on-one interviews (Non-Adopter Key Informant, Non-Maintainer Key Informant, or Implementation In-Depth) will be recorded on a digital audio recorder. They will then be transcribed into a written document for data analysis. The audio files and the transcripts will be stored and secured at the Tufts University research site, 150 Harrison Ave., Boston, MA and at the Pennsylvania State research site, located at the Lancaster County Cooperative Extension Office, 1383 Arcadia Road, Lancaster, PA in password protected computer files.

Data obtained from program participants will be kept at the following locations:

- Height/weight, fruit and vegetable intake, physical activity, and Participant Questionnaire data will be stored and secured at 3 possible sites: the extension educator program leader’s office (temporarily); the Penn State research site, located at the Lancaster County Cooperative Extension Office, 1383 Arcadia Road, Lancaster, PA; and the Tufts University research site, located at 150 Harrison Ave., Boston, MA.
- Data obtained from eligible non-participants (audio recordings of key informant interviews and the resulting transcripts) will be stored and secured in password protected files at the Tufts University research site, 150 Harrison Ave., Boston, MA and at the Pennsylvania State research site, located at the Lancaster County Cooperative Extension Office, 1383 Arcadia Road, Lancaster, PA.
Personnel.
- Drs. Corbin, Folta and Nelson (Project Director, Project Manager, and Principal Investigator, respectively) will be responsible for obtaining informed consent from extension educator subjects.
- Extension educators will be responsible for obtaining informed consent from program participant subjects.
- Dr. Nelson (Principal Investigator) will provide on-going information to the study sponsor and the IRB. She will have close communication with both project managers (Dr. Folta and Ms. Wiker).
- Both project managers and the Project Coordinator will be responsible for maintaining participants’ research records.

Subject fees. In Pennsylvania (Specific Aim #1), extension educators will receive $300, to be used for professional development for their participation in this research study. They will also receive a $250 stipend for attending the training workshop. Their travel and lodging expenses for the training workshop will be paid.

Pennsylvania program participant subjects will receive a $25 check once they completed all the forms and measurements at the Orientation and Assessment Meeting. They will receive a $50 gift check once they have completed all the forms and measurements at the last class.

National extension educators (Specific Aim #2), national program participant subjects (Specific Aim #2), and eligible non-participants (Specific Aim #1) will not receive any form of payment for their participation in this research.

Program participants in both Pennsylvania and nationally may be required to pay a fee for classes to cover the costs of the StrongWomen – Healthy Hearts Program. Some of the site leaders are paid volunteers, and the fee will be used to pay the instructor. Programs with an Extension Educator instructing the class may use the fee to purchase food and equipment supplies for the nutritional component of the class, but will not use the fee for instruction compensation. Counties that pay the instructor for their services will have a higher fee than those with an Extension Educator instructor. The fee is expected to range from approximately $30-$100 for the 12-week session.

Confidentiality. Participation is confidential for all subjects in this study. Only the research team and extension educator program leaders will be able to see data. Subjects will be assured in the Informed Consent Form that their employer will not see any of their study data. No personally identifiable information will be shared in any publications or presentations resulting from the research.

Extension educators will be asked to provide their name on the questionnaires that they fill out, so their data and identity will be linked. However we will take the following measures to ensure confidentiality. All questionnaires will be completed on-line. The survey data will be protected using SSL technology, the same used by on-line merchandisers to protect customers’ financial information. The company that we will use for the on-line surveys also has a robust security policy and keeps all of their servers under lock and key. The data from these questionnaires will be retrieved by Tufts University research personnel from the company’s servers and stored and secured at research sites in a password protected file.
Data obtained from extension educators through one-on-one interviews will be recorded on a digital audio recorder. They will then be transcribed into a written document for data analysis. The audio files and the transcripts will be stored and secured at the Tufts University research site, 150 Harrison Ave., Boston, MA and at the Pennsylvania State research site, located at the Lancaster County Cooperative Extension Office, 1383 Arcadia Road, Lancaster, PA in password protected computer files. The audio file will be kept for up to 1 year and then it will be destroyed.

Program participants subjects will be kept confidential by assigning a study number. Only study numbers, and not names, will appear on the data. Research staff and extension educator program leaders, and no one else, will have access to the list that links names with study numbers. This list and the data collection forms will either be kept in a locked file cabinet or will be password protected on a computer. The data will be stored and secured at 2 possible sites: the extension educator program leader’s office (temporarily); and the Tufts University research site, located at 150 Harrison Ave., Boston, MA. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Collaboration. This is a collaborative effort with Pennsylvania State University. Their Office of Research Protections will review this proposal once approval has been obtained from the Tufts IRB.

References


