

**B. Collection of Information Employing Statistical Methods If statistical methods will not be used to select respondents and item 17 on Form 83-I is checked "No" use this section to describe data collection procedures.**

**1. Respondent Universe and Sampling Methods**

Information collection activities will target two groups – 1) lesbian and bisexual women 40 and over who have a BMI of 27 or greater and 2) healthcare providers located at participating organizations. This evaluative research of a small scale research project will be based on a convenience sample. For the group support program, participants will be based on a self-selected sampling strategy of LB women interested in participating in the project. The contractor will undertake recruitment through their Website and Email list (of 5,000 individuals, mostly in the DC metro area) as well as advertisements in newspapers, church bulletins, Facebook, Twitter, and the Websites of LGBT and health-focused colleague organizations located in metropolitan DC, including Maryland. The contractor will evaluate the results of this intervention on two groups of 20 women for a total of 40 women.

*Individual Intervention: Making Our Vitality Evident (MOVE)*

The information collected from the individual intervention will permit the GW/Mautner team to assess the effectiveness of the MOVE intervention according to the following primary and secondary SMART (Specific, Measurable, Appropriate, Realistic, and Time-Specific) objectives:

Primary

SMART Objective 1: Increase exercise by a minimum of 150 minutes per week of moderate intensity exercise or 75 minutes per week of the vigorous intensity exercise.

*Power Analysis of SMART Objective 1:*

Using McNemar's test for paired proportions for the power analysis (see <http://www.medcalc.org/manual/mcnemartest2.php>), and estimating a cohort of 40 participants, there would be .83 power at the .05 level with an increase of 11 people reaching the goal of increased exercise over baseline.

SMART Objective 2: During the course of the program, participants will be asked to complete a daily sheet or on-line tool recording (e.g., <http://www.myfitnesspal.com>) quantitative data about healthy food intake. Participants will be given food diaries with categories for ease of keeping track of "healthy food" (e.g., fruits, vegetables, whole grains, legumes, nuts, lean protein) and "less healthy" food (e.g., white bread, pasta, whole fats, alcohol, sugar-added drinks). The objective is for participants to use this food diary at least once.

*Power Analysis of SMART Objective 2:*

Using McNemar's test for paired proportions for the power analysis (see <http://www.medcalc.org/manual/mcnemartest2.php>), and estimating a cohort of 40 participants, there would be .83 power at the .05 level with an increase of 11 people reaching the goal of using a food diary over baseline

Secondary

Objective: Decrease weight by 5% in LB women over the course of the 16-week intervention.

Objective: Decrease the ratio of waist circumference to height (waist/height) by 5% in LB women over the course of the 16-week intervention.

The primary outcomes that our demonstration project is designed to evaluate are increased exercise and the use of journaling through My Fitness Pal. My Fitness Pal is an online, interactive exercise-focused website that allows a participant to communicate with others in the group and to document the amount of time she spends exercising, foods eaten, changes in weight and waist, etc. The GW/Mautner team will not monitor the site as a measurement tool for each of these outcomes, but will use the site as a measurement tool to record how often each participant engages in the act of journaling her progress. We will examine the relationship between each outcome (percent change) and the following predictors: (1) patient baseline (pre-intervention) characteristics, including demographics, general health, nutrition, physical activity, resiliency, and social isolation; (2) Fulfillment of the MOVE intervention.

Measurements for the primary outcomes will be analyzed using Stata software to determine any correlation with Likert scale variables that women will report on the pre-post questionnaires. The validated Likert scales include the World Health Organization's Quality of Life Scale, the Behavioral Risk Factor Surveillance System (BRFSS 2009), the Connor-Davidson Resilience Scale (10Q), and the Lubben Social Network Scale (LSNS6). Respectively, these validated scales measure one's quality of life, nutrition, resiliency to adverse experiences, and social isolation or ability to connect with others. We will categorize each calculated summary scale into good, fair and poor (depending upon the distribution). The main outcomes will be compared among each patient baseline characteristics category. Expecting a normal distribution of the data, the team will conduct nonparametric statistical tests to determine these variables' strength of association with the primary and secondary outcomes of interest: increased exercise, the use of food journaling, a 5% decrease in weight, and a 5% decrease in waist circumference/height. Paired T test or Wilcoxon signed-rank test will be conducted to determine whether the MOVE intervention has a significant effect on the mean percent change of the weight and waist/height ratio between participants who are adherent or not.

### *Community-Level Intervention: Health Professional Trainings*

In order to evaluate the curriculum and training exercises, the contractor will train and evaluate doctors and nurses at George Washington University School of Medicine and Health Sciences, Georgetown University Medical Center, Howard University College of Medicine, Vanderbilt University School of Nursing, and the Vanderbilt University Program for GLBTI Health. These organizations are collaborating on this project and will recruit doctors and nurses as well as medical and nursing students for the training program.

SMART Objective 3: The team will measure the numbers and professional profiles of staff trained in RTB™. We will conduct pre-testing to determine a baseline of knowledge, skills, and attitudes, and post-testing immediately after each training, to judge the level of improved knowledge, skills and attitudes, as well as improved comfort in communicating with patients about sexual identity and about weight issues with patients who are lesbian or bisexual women. The pre-test/post-test evaluation instruments will include multiple-choice, yes/no, and Likert-scale questions in order to facilitate measurement of quantitative changes in providers' knowledge, attitudes, and skills. Open-ended questions will also be included with answers to be qualitatively analyzed to identify primary common and divergent themes. Providers will also be asked to provide feedback on the training modules themselves in order for the team to incorporate changes to reflect providers' experiences in participating in the training modules.

#### *Power Analysis for SMART Objective 3:*

Using McNemar's test for paired proportions for the power analysis (see: <http://www.medcalc.org/manual/mcnemartest2.php>), and estimating a cohort of 150 health professional participants, a power of .80 at the .05 level with a change/increase of knowledge of at least 12 participants.

Using Stata software, we will conduct nonparametric testing of the categorical and Likert-scale questions to determine if there is a statistical increase in knowledge gained from pre-test to post-test.

## **2. Procedures for the Collection of Information**

The contractor will evaluate the group support program both qualitatively and quantitatively. The overall goal of the group support program is for women to lose 5% - 10% of their current weight over six months. According to the National Heart, Lung and Blood Institute at NIH, this is a healthy weight loss goal as a first step to losing weight and maintaining healthy weight<sup>1</sup>. Our key measures are dietary changes to include more healthy eating and increased physical activity. Evaluation criteria are based on outcome measures, including height and weight (to calculate Body Mass Index (BMI)) and waist circumference. This information will be collected from participants at the beginning of the program and at the conclusion of the program to establish pre- and post-intervention measurements. In order to collect accurate data research

staff will take measurements of program participants, including weighing participants using a scale and taking waist circumference using a tape measure. Study participants will be asked to complete a survey before and after the program that includes demographic information, physical activity, nutrition, general health and quality of life questions.

The contractor will conduct at least 6 trainings of medical professionals during the two-year period, reaching approximately 150 medical professionals including doctors, nurses, residents and medical students. Trainings will be from 60 to 90 minutes long and will take place at George Washington, Georgetown, Vanderbilt, and Howard universities. The trainings will be an adaptation of Mautner Project's Removing the Barriers™ cultural competency training, with the focus on how providers can most effectively communicate with and support their lesbian and bisexual women patients in achieving a healthy weight and improved nutrition habits and exercise.

The contractor will measure the number and type (profession, specialty, etc.) of providers trained in Mautner Project's Removing the Barriers™ cultural competency training and will conduct pre-testing to determine a baseline of knowledge, skills, and attitudes, and post-testing immediately after each training, to judge the level of improved knowledge, skills and attitudes, as well as improved comfort in communicating with patients about sexual identity and about weight issues with patients who are lesbian or bisexual women. The pre-test/post-test evaluation instruments will include yes/no and Likert scale questions in order to facilitate measurement of quantitative changes in providers' knowledge, attitudes, and skills. Open-ended questions will also be included in the post-test with answers to be qualitatively analyzed to identify primary common and divergent themes. Providers will also be asked to provide feedback on the training modules in order for the team to incorporate changes to reflect providers' experiences in participating in the training modules for improving the training for future efforts. All data collection and analysis will be performed in compliance with OMB, Privacy Act, and Protection of Human Subjects requirements.

Questions on lesbian and bisexual women are taken from Mautner Project's Removing the Barriers Training. It is certified by Corexcel for continuing education credits. Corexcel is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation (ANCC). Corexcel is accredited as a provider of continuing education in nursing by the State of Florida, Board of Nursing (provider no. 50-452) and the State of California, Board of Nursing (provider no. CEP 13687). Corexcel is an Authorized CEU Sponsor of the International Association for Continuing Education and Training (IACET). This program is approved for 2.30 nursing contact hours. This program is approved by the National Association of Social Workers (Approval # 886447440-9907) for 1.5 Social Work continuing education hours. IMNE designates this educational activity for a maximum of 2.25 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

### **3. Methods to Maximize Response Rates and Deal with Non-response**

The contractor will encourage recruited individuals to adhere to the program and complete data gathering activities. The contractor will offer a structured group experience, with individual as well as group support, gym access, Pilates, yoga or other instruction, and nutritionist consultation as part of the intervention. The contractor will contact participants who miss sessions required for data collection by phone and/or email to ensure maximum data collection.

#### **4. Tests of Procedures or Methods to be Under Taken**

We have piloted the survey instrument with individuals at the Mautner Project for both time and usability. Before the group support program begins, a contractor will conduct a focus group with a small number of individuals. The contractor will also test the provider curriculum with the participation of GW Residents in Internal Medicine, and other GW-based providers (nurses, PAs), public health professionals, and GW School of Public Health students. After incorporating feedback from testing of the intervention, the contractor will arrange similar trainings with clinicians and students at the institutions that have already agreed to participate.

#### **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

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*MOVE: Making Our Vitality Evident*

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