

**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

**Health Systems Intervention.** The health systems intervention targets clinic providers (through training and standard operating procedures) to improve preventive health counseling and referrals regarding healthy weight. The effectiveness of this intervention will be evaluated first and foremost through examination of provider behavior as evidenced by patient medical record review. The design of the medical record abstraction component of the study consists of repeated sampling of patients in the target population (LB women aged 40 and older considered overweight/obese) seen at the LMHS clinic during the three-month period prior to and the three-month period after implementing the clinic intervention. The pre-/post-training Knowledge and Attitudes Assessment for providers and clinic staff will include all participants in the training.

**Group Intervention.** The intervention is being evaluated with 80 women who reside in the San Francisco Bay Area, are aged 40 and older, identify as LB, and are overweight or obese at enrollment (based on self-reported height and weight to calculate body mass index). A convenience sample of women in the San Francisco Bay Area will be recruited. The primary recruitment venue will be LMHS, our community-based health clinic partner with a patient population of sufficient size from which to draw the study sample. Additional recruitment will take place through community organizations that serve the target population as well as through print advertisements and electronic list-serves.

### Sample size and power analysis

**Health Systems Intervention.** The rationale for the proposed target sample size for abstraction of patient records was based on power calculations for a design with pre- and post-intervention estimates of the proportion of overweight and obese LB women who receive preventive health counseling. Power calculations were based on a two-tailed  $\alpha=0.05$  level test for comparing two independent proportions, assuming the pre-intervention proportion who receive preventive health counseling is 20%. If we abstract 150 randomly selected patient visit records at both time periods (pre and post-intervention), we will have 80% power to detect a 15% difference in proportions and 99% power to detect a 25% difference.

**Group Intervention.** The rationale for the proposed target sample size for the number of LB women in the group intervention study component was based on power calculations for comparing pre-post changes in HgA1c between the intervention and control groups. Our proposed sample size of 40 women per group will provide 80% power to detect a 0.44 unit difference (or 0.6 standard deviation units) in mean level of hemoglobin A1c assuming a two-tailed  $\alpha=0.05$  level test. The Look AHEAD trial (The Look AHEAD Research Group. Reduction in weight and cardiovascular disease risk factors in individuals with type 2 diabetes. *Diabetes Care*, 2007; 30: 1374- 1384) corroborates the potential to find an effect of this size as they found that individuals in the diet and exercise arm had significant greater decrease in hemoglobin A1c than in the control arm (-.64 vs. -.14, respectively; difference of 0.5).

## 2. Procedures for the Collection of Information

**Health Systems Intervention.** The data collection activities for the health systems intervention involves: 1) medical records abstraction done by project staff employed by LMHS and recorded electronically into a standardized data collection tool; 2) pre- and post-training Knowledge and Attitudes Assessment. This will be a self-administered pencil and paper questionnaire that does not exceed one-page. The patient visits included in the medical records abstraction will be identified by searching the LMHS patient visit database for LB women aged 40 and older. Then, these charts will be reviewed for study eligibility based on BMI >25.

**Group Intervention.** The data collection activities for the group-based evaluation will follow standard methods.

Screening procedures for the study will be conducted two ways to minimize participant burden: 1) electronically through a web-based screening survey that describes the intervention and includes the minimum number of screening questions to determine eligibility; and 2) interviewer-administered either in-person or via telephone.

Once eligibility has been determined (regardless of whether the screening interview mode was web-based or in-person), a study interviewer will talk directly with the eligible individual to describe the study further, answer questions, and invite the individual to enroll. For eligible and interested individuals, written informed consent will be obtained, the baseline Evaluation Questionnaire (including health assessments) will be conducted and then randomization assignment will be made. The interviewer will be blind to the randomization.

Evaluation Questionnaires conducted at baseline and follow-up will be interviewer-administered and will be conducted in a private room at LMHS. The questionnaire administration will be followed by a health assessment where biomarkers associated with chronic diseases (e.g., hemoglobin A1c, blood pressure) will be measured to provide evaluation endpoints.

Interim behavioral data collection at 1-month (Interim Behavioral Assessment survey) will be conducted through a web-based survey and can be completed either in-person during an intervention session or elsewhere where the web is accessible and completion is convenient to the participant.

To collect data on patterns of physical activity, including duration, intensity and frequency, over a one-week time period, a subset of participants will be randomly selected for accelerometry use (N=40 total: 20 in the intervention group and 20 in the delayed-start comparison group). Physical activity and sedentary behavior will be collected using the ActiGraph CT3X monitor, a triaxial accelerometer that is sensitive to movement in multiple directions. The device is small and light-weight. Participants will be asked to wear the monitor while undertaking normal activities for one week. Random selection of participants for accelerometer assessment will be conducted within randomization block groups (5 from each block group of 10) to ensure an even roll-out of the accelerometer data collection over the study period. During this period, these participants will complete a physical activity diary to complement interpretation of the accelerometry data.

To ensure high quality data, oversight procedures will be followed for all aspects of data collection. Examples of these procedures include the following:

- Data collection will be conducted by experienced and well-trained research staff, led by Project Coordinator, Natalie Ingraham, with direct supervision by Project Director, Alexandra Minnis.
- The project director will observe field procedures at least monthly and will monitor a minimum of 10% of group intervention interviews.
- A 10% random sample of medical record abstraction data will be reviewed by a second member of the research team.
- All group intervention paper-based completed interviews will be reviewed for completeness and accuracy of administration (e.g., correct skip patterns) by a second member of the research team. Feedback will be shared with the interviewer as a training tool.

All data collection and analysis will be performed in compliance with OMB, Privacy Act, and Protection of Human Subjects requirements.

### **3. Methods to Maximize Response Rates and Deal with Nonresponse**

**Health Systems Intervention.** Non-response and retention will not be particular concerns for the evaluation of the health systems intervention given the design. Should new providers be hired, they will receive the health systems training as part of their LMHS orientation training.

#### **Group Intervention.**

**Monitoring Recruitment and Retention of Study Participants.** The following information will be recorded monthly and cumulatively: (1) number of participants enrolled; (2) contact information for all enrolled participants; (3) withdrawals from the study; and (4) losses to follow-up. Withdrawal or loss to follow-up will also be recorded. Based on these reports and in consultation with our Advisory Board, recruitment and retention methods will be revised as necessary.

Retention strategies for this study will build on successful approaches used in past research activities. Accurate contact information will be updated at every study visit and will include places where the participant spends time, place of employment (if employed), and contact information for two family members or friends with whom the participant stays in regular contact. In addition, as a participation incentive in the intervention, a monthly lottery will be offered where each week's attendance at a group session and/or exercise class results in an entry into the lottery. Lottery prizes will be valued at \$100 each. A community presence will be maintained through our community-based office at LMHS, where participants will be able to drop-in to connect with study staff. Maintaining relationships with community agencies that serve our target population will enhance our recruitment and retention, build trust with participants, and facilitate our ability to make any necessary service referrals. Reminder telephone calls or text messages will be made to try to prevent late or missed visits. At least five attempts will be made to connect via telephone, at which point alternative contact methods (e.g., home visits) will be adopted.

Additional procedures include:

- Potential respondents will be informed about the importance of this study to improving the health of lesbian and bisexual women through targeted interventions. It will be

explained that participation affords them an opportunity to provide input on this intervention and to contribute to shaping future healthy weight programs that could be offered in their and others’ communities.

- Interviewers will participate in thorough training sessions. Training topics will include study objectives, question-by-question reviews of data collection instruments, strategies for engaging respondents, role playing, and techniques for fostering respondent participation and survey completion.
- Interview staff will be able to provide respondents with the name and telephone number of an official at OWH. This official will confirm with respondents the importance of their participation.

Using these methods that build on our successful recruitment and retention strategies from past research, the project anticipates achieving a response rate of 80% and aim for 90% retention. There is the possibility of experiencing higher attrition among our Sequence 2 participants during the delayed-control period so will ensure accurate contact information is maintained and communicate with them during this period to remind them of their upcoming intervention start. The RTI research team has extensive experience retaining diverse population groups in prospective studies.

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

Before fielding the study, instruments will be pilot tested for both health systems intervention and the group intervention. Lessons from the pilot test will be identified, and changes as necessary will be incorporated into the instruments and/or data collection procedures. All pilot tests will involve fewer than 10 individuals unless OMB clearance is sought for a larger number.

The OMB will be notified of any changes to the evaluation instruments or procedures, should they be deemed necessary, before data collection begins.

Measures included in the questionnaire were selected to ensure rigorous assessment of our study objectives. Those chosen have been validated and used in previous studies. They are noted here with question numbers as ordered in the questionnaire included as an attachment:

Question #s	Measure/Domain	Sources
<i>Demographics</i>		
2.3-2.4	Ethnicity and race	Behavioral Risk Factor Surveillance Survey (BRFSS), 2011
2.5-2.7	Socioeconomic status	National Survey of Family Growth, BRFSS
2.8	Gender	LMHS patient intake form. A substantial proportion of the patient population identifies as transgender, necessitating the inclusion of this gender assessment.
2.9-2.9b	Sexual orientation	National Health Interview Survey, 2013

2.11	Disability	ADA definition for disabled 29 C.F.R. 1630.2(i)
2.12	Health care coverage	BRFSS, 2011
<i>Perceived General Health and Well-being</i>		
2.13-2.27	Health-related quality of life: physical and mental health scores	Veterans RAND 12-item Health Survey (VR-12). The 12 items in the questionnaire correspond to eight principal physical and mental health domains including general health perceptions; physical functioning; role limitations due to physical and emotional problems; bodily pain; energy-fatigue, social functioning and mental health.. The 12 items are summarized into two scores, a "Physical Health Summary Measure" and a "Mental Health Summary Measure". These provide an important contrast between physical and psychological health status. The Veterans RAND 12 Item Health Survey (VR-12) was developed from the Veterans RAND 36 Item Health Survey (VR-36) which was developed from the MOS RAND SF-36 Version 1.0.
<i>Health Behaviors</i>		
3.1-3.7	Physical activity	International Physical Activity Questionnaires-7Q version (2002). Validation study: Hagstromer M, et al. Public Health Nutrition, 2006.
3.8-3.12	Nutrition: Beverages	California Health Interview Survey 2009
3.13-3.14	Nutrition: water consumption	National Cancer Institute, Diet History Questionnaire. Categories modified to CHIS 2009.
3.15-3.20	Nutrition: fruit and vegetable consumption	Behavioral Risk Factor Surveillance Survey (BRFSS) 2012
3.21	Nutrition: daily fruit and vegetable	American College Health

	servings	Association, National College Health Assessment II Survey
3.22-3.28	Alcohol, tobacco and marijuana consumption	Alcohol: National Institute of Alcohol Abuse and Alcoholism Tobacco: 2011 BRFSS, National Cancer Institute Marijuana: adapted from 2011 BRFSS and NCI to align with tobacco assessment.
Psychosocial Assessments		
4.1-4.15	Mindful Eating Questionnaire	Framson C, et al. Development and Validation of the Mindful Eating Questionnaire. Journal of the American Dietetic Association, 2009; 109(8):1439–1444.
4.16-4.30	Mindfulness Scale	Carlson LE, Brown KW. Validation of the Mindful Attention Awareness Scale in a cancer population. J Psychosom Res. 2005; 58(1):29–33.
4.31-4.40	Perceived stress scale	Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. Journal of Health and Social Behavior 1963;24:386–396. Widely cited currently.
5.4	Partner body size	Images from: Farinah, S. Dissertation: Perception of the size, shape, and attractiveness of female body scans relative to body mass index, 2005
5.7-5.12	Social Networks/Social Isolation	Lubben Social Network Scale – 6 item, 2006.
6.1 and 6.4	Waist to height ratio (calculated from waist circumference and height measurements).	Browning, Hsieh, Ashwell. A systematic review of waist-to-height ratio as a screening tool for the prediction of cardiovascular disease and diabetes: 0.5 could be a

		suitable global boundary value Nutrition Research Reviews 2010; 23: 247-269.
6.6	Menopausal status	NHANES

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

Alexandra Minnis, PhD  
Senior Research Epidemiologist  
RTI International  
415-848-1323  
[aminnis@rti.org](mailto:aminnis@rti.org)

Jennifer Lorvick, DrPH  
Senior Public Health Researcher  
RTI International  
415-848-1315  
[jlorvick@rti.org](mailto:jlorvick@rti.org)

Diane Catellier, DrPH  
Senior Statistician  
RTI International  
919-541-6447  
[dcatellier@rti.org](mailto:dcatellier@rti.org)

Andrea Anater, PhD, MPH  
Public Health Nutrition Researcher  
RTI International  
919-541-6977  
[aanater@rti.org](mailto:aanater@rti.org)

Todd Rogers, PhD  
Senior Scientist  
RTI International  
415-848-1374  
[trogers@rti.org](mailto:trogers@rti.org)

Dawn Harbatkin, MD  
Executive Director, Lyon-Martin Health Services  
[dawn@lyon-martin.org](mailto:dawn@lyon-martin.org)

Natalie Ingraham, MA  
Project Coordinator, Lyon-Martin Health Services  
[natalie@lyon-martin.org](mailto:natalie@lyon-martin.org)

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