

**Supporting Statement for Paperwork Reduction Submission:  
WHAM: Women's Health and Mindfulness**

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

In April 2010, President Obama requested that the Department of Health and Human Services (HHS) identify opportunities to improve the health of lesbian, gay, bisexual, and transgender (LGBT) individuals. In response to this request, HHS Secretary Kathleen Sebelius initiated an LGBT Coordinating Committee, tasked with developing objectives and recommended actions to improve LGBT health and well-being. Additionally, in June 2011, Secretary Sebelius announced that HHS would increase its efforts to collect health data on LGBT populations to help identify and address health disparities affecting the LGBT population.

To respond to the LGBT Coordinating Committee and HHS' goal of collecting health data on LGBT populations, HHS recently noted the objective to "identify and test effective and innovative ways of reducing obesity in lesbian and bisexual women" in their coordinating committee 2012 report. The Office on Women's Health (OWH) has contracted with five organizations across the United States to respond to this HHS objective; this information collection review (ICR) details one of the five studies and information collection approaches.

The Women's Health and Mindfulness (WHAM) program aims to develop and pilot test interventions that promote healthy weight in lesbian and bisexual (LB) women age 40 years and older on two levels: a systems-level change via healthcare provider training to increase chronic disease preventive health counseling and appropriate referrals; and an individual-level change with a group-based 12-week mindfulness-based intervention.

Mindfulness-Based Stress Reduction (MBSR), has been effective in treating both physical and psychological health issues, including depression, anxiety, cardiovascular improvements and disordered eating<sup>1-3</sup>. MBSR is a group program that focuses upon the progressive acquisition of mindful awareness, or mindfulness. Mindfulness is characterized by dispassionate, nonevaluative and sustained moment-to-moment awareness of perceptible mental states and processes.<sup>1</sup> Although MBSR has been used in a variety of clinical and non-clinical populations, there is no current research on its use within lesbian, gay, bisexual, or transgender populations who might benefit from the intervention's improvements in coping with both daily and minority-related stressors.

The 2011 IOM report on *The Health of LGBT People* noted that lesbians and bisexual women are at greater risk for obesity and related chronic health conditions.<sup>4</sup> According to national population health studies,<sup>5-7</sup> national studies of older women, and medical chart reviews in regional samples<sup>8</sup>, lesbian and bisexual women tend to be heavier than heterosexual women. Population-based surveys have shown that lesbians had more than twice the odds of overweight and obesity as heterosexual women.<sup>5</sup> The Women's Health Initiative sample of women aged 50-79 years found that lesbian/bisexual women were 25% more likely to be obese than heterosexual women, with 51% of lesbians being overweight or obese.<sup>7</sup> A meta-analysis of obesity and sexual orientation supported this association and called for the health care system to respond with more culturally sensitive care, which has been identified as a barrier to appropriate care for lesbian and bisexual women<sup>9,10</sup>.

More research is needed in this understudied area to inform the development of evidence-based strategies that address the disproportionately higher burden of overweight and obesity in this population. This program will be the first federally funded initiative from the Office of Women's Health (OWH) to develop and pilot test interventions for LB women on healthy weight. The cited law for this collection is Section 301 of the Public Health Service Act (42U.S.C.241).

## **2. Purpose and Use of Information Collection**

The Office of Women's Health was established in 1991 to improve the health of American women by advancing and coordinating a comprehensive women's health agenda throughout HHS to address health care prevention. This project is the first of its kind to focus specifically on LB women aged 40 and older and reflects the Office on Women's Health's determination of need for research on this target population.

To address the scarcity of work in healthy weight among LB women, this demonstration project includes two research activities: (1) a community-level health system intervention that responds to Goal 4, Strategy 4-1 of the 2012 Institute of Medicine (IOM) report "Accelerating Progress in Obesity Prevention: Solving the Weight of the Nation;" and (2) an innovative group support program that combines mindfulness-based stress reduction, nutrition, and physical activity that will be evaluated for its feasibility and evidence of effect on short-term outcomes. The information collected from this research will allow HHS to assess the feasibility of interventions focused on achieving a healthy weight in LB women age 40 years and older, as well as build the evidence base of effective approaches for clinical providers to use with LB women aged 40 and older in community settings.

The specific objectives of the work are as following:

### **Health Systems Intervention**

#### **Primary Objective**

1. Three months after implementing the health systems intervention at LMHS, a 25% increase will be observed in the proportion of visits in which lesbian/bisexual patients receive counseling related to healthy weight (i.e., improved nutrition, physical activity and stress reduction).

#### **Secondary Objective**

2. Three months after implementing the intervention at LMHS, the percentage of referrals to community services that assist in and support the achievement and maintenance of healthy weight will increase by 25%.

## Group Intervention

### Primary Objective

1. At the end of the 3-month intervention period, a 0.5 mean decrease in Hemoglobin A1c level, indicating improved glycemic control, will be observed.

### Secondary Objectives

2. *Improved nutrition:* At the end of the 3-month intervention period a 40% increase in the proportion of participants who adhere to 2010 Dietary Guidelines for Americans will be observed.
3. *Increased energy expenditure:* At the end of the 3-month intervention period an increase of 30% in the number of minutes of moderate-intensity physical activity per week will be observed.
4. *Reduced stress:* At the end of the 3-month intervention period a 40% decrease in participants' stress levels as measured by a perceived stress scale will be observed.
5. *Decreased waist circumference/height:* At the end of the 3-month intervention period a 10% decrease in the waist-to-height ratio will be observed.
6. *Decreased weight.* At the end of the 3-month intervention period, a 5% loss in weight will be observed.

The three products of the work are:

1. Systematic review of literature related to health, weight and previous health interventions targeting LB women age 40 years and older.
2. A culturally-appropriate health systems intervention targeting health care providers to strengthen capacity to address healthy weight and chronic disease prevention with their patients. This intervention, which includes a provider training and implementation of standardized operating procedures, will be pilot-tested in a community clinic in San Francisco (Lyon-Martin Health Services [LMHS]) that serves the target population. Its effectiveness will be evaluated through assessments of provider knowledge/attitudes prior to and following the training, and through evidence of increases in the proportion of patients receiving appropriate preventative health counseling and targeted community referrals for services related to nutrition, physical activity and stress reduction.
3. An evaluation of whether a novel 12-week group mindfulness-based nutrition and exercise intervention (WHAM group intervention) provides short-term evidence that it improves key biomarkers associated with chronic disease. Furthermore, effects of the intervention on healthful diet as defined by the 2010 Dietary Guidelines for Americans, and on physical activity will be used to inform the pilot evaluation.

This study will provide the OWH with information to inform decisions about which types of health interventions are properly suited for LB women aged 40 and older and that show promise in improving health biomarkers and behaviors associated with reduced risk of weight-related chronic disease. The results of this project will inform the developments of future interventions designed for LB women. In addition, the development and pilot testing of a health center intervention will contribute to the design of clinical interventions aimed at improving the delivery of chronic disease preventative counseling and referrals within a health care setting for LB women. The research

findings are expected to offer data to support efforts to address health disparities in weight-related chronic disease for older lesbian and bisexual women in the U.S.

### **3. Use of Improved Information Technology and Burden Reduction**

The WHAM program will use advanced technology, when appropriate and feasible, to collect and process data to reduce respondent burden and to make data processing and reporting maximally efficient. We have also kept assessment frequency and length to a minimum to reduce burden. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

**Health Systems Intervention.** Providers and clinic staff who participate in the training designed to strengthen capacity for preventative health counseling and referrals will complete a pre-/post-training Knowledge and Attitudes Assessment. It will be self-administered on paper and is designed to be a single page in length. Medical records abstraction to evaluate the effects of the health systems intervention on the proportion of LB patients who receive chronic disease preventive health counseling and appropriate referrals targeted toward overweight and obese older LB women will be done using an electronic database so that data abstracted will be entered directly into the computer, reducing the need for paper-based forms.

**Group Intervention.** Screening of participants for the group intervention will be conducted primarily through an online survey. Recruitment will occur through brochures posted in the clinic and other community sites, as well as through electronic listserves and websites of community agencies that serve LB women. Interested participants will be referred to an online survey that includes a brief screening tool consisting of the minimum number of questions required to assess eligibility. For enrolled participants, the baseline and follow-up evaluation questionnaires will be conducted through face-to-face, interviewer-administered surveys. Participants will also receive a physical health assessment as part of their baseline and follow-up study visits. (e.g., A1c, cholesterol, weight, waist circumference, and blood pressure). The Hemoglobin A1c and cholesterol testing will be conducted using blood specimens that should be collected after an 8-hour fast. This will require a visit to Lyon-Martin Health Services or to another partner laboratory in the community that may be more conveniently located for participants. The Interim Behavioral Assessment survey of core nutrition and physical activity measures that will be conducted at one-month will be administered using web-based survey tools. This will reduce participant burden because they can complete the survey at a location that is convenient to them using a computer or smart phone device. Participants may always choose to complete this survey at the clinic using a laptop computer that will be available.

### **4. Efforts to Identify Duplication and Use of Similar Information**

We have reviewed existing published literature and unpublished evaluation reports, and also

*Office on Women's Health Information Collection Request* (WHAM) *Women's Health and Mindfulness Program* consulted with outside experts to identify information that could facilitate intervention development. The project team is collaborating with local and national experts in LB health, nutrition and physical activity, including: UCSF Professor Patricia Robertson, MD (representing health care systems); San Francisco Department of Public Health (SFDPH) Director Barbara Garcia, MPA (representing local government); Marion (Mhel) Kavanaugh-Lynch, MD and Diane Sabin, DC (representing organizations focused on LB women's health); National Center for Lesbian Rights (NCLR) Sports Project Director Helen Carroll (an exercise expert); and Prajna Paramita Choudhury, LAc, DiplOM (a health and wellness expert).

The OWH has consulted with other federal agencies and no other project is being funded to collect data on LB overweight women by other agencies such as the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and the National Institutes of Health.

#### **5. Impact on Small Businesses or Other Small Entities**

No small businesses or other small entities are anticipated to be affected by these research activities.

#### **6. Consequences of Collecting the Information Less Frequent Collection**

If the data are not collected as proposed the evaluation will be compromised. Data collection has been designed for minimum burden, while ensuring that analyses yield clear results that can inform models of healthy weight interventions for older LB women in the U.S. Currently, few data exist on effective interventions related to improved chronic disease outcomes in this population. This project focuses specifically on a high-risk group of women and will also provide data on subgroups within the LB women population.

As described in #3 above, the health systems intervention will be evaluated two ways. First, providers and clinic staff who receive training will be asked to complete a pre-test/post-test assessment of knowledge and attitudes. Time will be allotted for this during the training session. They will not be recontacted for additional data collection. Second, the medical records abstraction will be done by research staff to minimize clinic staff burden. To ensure sufficient statistical power to detect effects of the health systems intervention on patient care practices, records will be abstracted for patient visits during the three-month period prior to the intervention roll-out and the three-month period following its implementation.

Individuals participating in the group-based healthy weight intervention (N=80 women) will be asked to respond at study enrollment and exit to the evaluation questionnaire. Those respondents randomized to complete the intervention during the second sequence, will complete this same assessment prior to initiating the intervention in order to have a time-matched comparison with the first sequence participants who will be exiting the study. One month after enrollment, respondents will be asked to respond to an interim behavioral assessment that assesses a subset of core behavioral measures tied to the study's core objectives.

There are no legal obstacles to reduce the burden.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances. This request fully complies with the regulations and guidelines in 5 CFR 1320.5.

**8. Comments in Response to the Federal Register Notice/Outside Consultation**

A 60-day Federal Register Notice was published in the Federal Register on March 20, 2013, VOLUME 78, PAGE17209.

Comments were not received from the public during this notice period.

National experts provided input on the design of each data collection method. In addition to members of our own research team, these include Dr. Suzanne Haynes, of OWH, as well as the research teams from the other four sites funded through this contract. Our Advisory Committee members (named in #4 above) were also consulted in design of the interventions.

OWH consulted with relevant Federal agencies and national associations that conduct chronic disease prevention research in women, including CDC and HRSA. They determined that focused research designed to identify effective individual- and health systems-level interventions for lesbian and bisexual women aged 40 and older was needed to address elevated levels of overweight and obesity in this population.

**9. Explanation of any Payment/Gift to Respondents**

Training of clinic staff and providers at LMHS (N=25), including the pre- and post-training knowledge/attitudes assessment will take place during regular paid working hours. No additional incentive payments will be provided for clinic staff and providers.

The CDC's 2010 brief, *Using Incentives to Boost Response Rates*, noted that incentives improve response rates; demonstrate respect and appreciation for respondent time and effort; and convey trust that the respondent will complete the survey. Modest incentive payment amounts have been chosen to minimize the possibility of undue influence (Grady, Am J Bioethics, 2001). Yet, to recognize the participants' contributions to the research the remuneration is provided to improve response rates and retention.

Participants in the group intervention will receive \$25 cash remuneration for completion of each data collection study visit (40 women complete two visits [baseline and 5 months]; 40 women complete three visits [baseline, 5 months, 10 months]). To provide biomarker data as objective measures of our intervention effects on health, participants will be asked to provide fasting blood specimens (8-hour fast) for the Hemoglobin A1c and cholesterol testing. For most women, this will necessitate a separate visit to the clinic or a partner laboratory after their baseline and follow-up interview visits since individuals prefer having these fasting blood draws done early morning. Thus, we will offer a cash remuneration of \$25 for completing the blood draws for testing to compensate participants for the second in-person visit requirement.

The 40 women (20 in the sequence one "immediate start" group; 20 in the sequence two "delayed start" group) who will be randomly selected to wear an accelerometer at three points during study participation to provide an objective measure of physical activity (baseline, mid-intervention, post-intervention) will be paid \$20 for each period of use. This amount was chosen to compensate them for receiving instructions from research staff about how to use the device and for completing the accompanying physical activity diary.

## **10. Assurance of Confidentiality Provided to Respondents**

The data collection plan, study protocol and consent forms have been approved by the Institutional Review Board (IRB) at RTI. The RTI IRB number for this research project is 13243.

**10A. Privacy Act Determination.** OWH has determined that the Privacy Act does apply to this project and appropriate systems to ensure participant protection and data safety will be implemented as described below. **The applicable System of Records Notice is xx-xx-xxxx.**

**10B. Safeguards.** All staff involved in data collection will be trained in procedures for ensuring privacy of participant information. Participant data extracted from medical records will be entered directly into a computer database designed for this purpose. Data collected from the participant at study visits (Evaluation Questionnaires at baseline and follow-up) will be collected initially on paper and then keyed into a computerized study database. The interim behavioral assessment data (collected one-month into the intervention period) will be entered by the participant directly into a web-based survey. A unique study identification number will be assigned to each participant and included on all data collection forms. No personally identifiable information such as the participant's name will ever appear on data collection forms. In publications, the individual identities of participants will not be disclosed, and data will be reported only in the aggregate.

The study data collection and management system will adhere with IRB-requirements for participant protection and data security. The data management system will include features such as user authorization (i.e., requirement of username and password to access the system) and encryption of sensitive data. Only the Project Manager and Project Director will be given authorization to enter data into the study database. Project files and databases will be available only to research personnel through the authorization of the Project Manager. Staff who will have access to data or interact with participants must sign confidentiality agreements and will be informed of their responsibility to maintain confidentiality once they have left the study or the study has ended. Staff will be trained on the policies and procedures for data management and transmission, and will also receive instructions on how to report any violations of those policies and procedures. In addition, staff will be trained on the ethics of human subjects research and the procedures to minimize risk.

The study database will reside on secure network servers in the RTI data center with daily backups. RTI security professionals are experienced with all security documentation and processes necessary to obtain an Authority to Operate, and with all applicable Health and Human Services, CDC, Federal Information Security Management Act, Health Insurance

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 Portability and Accountability Act, NIST, and other federal policies and regulations that may apply. RTI project team members and security professionals will ensure that all OWH-related technical and security standards, processes, and procedures are followed.

**10C. Consent.** The informed consent form will be reviewed with the participant and must be signed before the participant is enrolled in the study. A copy of the consent document will be provided to the participant for their records. The consent document will include a comprehensive description/purpose of the study, statement emphasizing the voluntary nature of the study, duration of the follow-up visits, incentives, risks or benefits to participants, and confidentiality procedures. The consent documents will also clearly state that participation in each component of the study is completely voluntary and participants can discontinue the study and opt out of any part of the study without penalty at any time. All consent documents will follow the guidelines outlined by RTI’s IRB and ethical guidelines set forth by the state and federal governments. Documentation and proof of participant consent will be stored at RTI. Participant contact information and other paper documents will be stored in a locked file cabinet located in a secure room at RTI or in a locked room in the community-based study clinic.

All research staff, including LMHS staff who are members of the project team and who are involved in data collection activities, will be trained in human subjects research protections as required by the RTI IRB (CITI training is required).

**11. Justification for Sensitive Questions**

**Group Intervention.** It will be necessary to ask questions considered to be of a sensitive nature to evaluate a change in health-relevant behavior and physiological changes that may be a result of the group intervention. Questions concerning lifestyle (e.g., diet, physical activity, including alcohol use) as well as demographic questions regarding sexual orientation and race/ethnicity could be considered sensitive. There will be no request for a respondent’s Social Security Number (SSN). To avoid fear of disclosure of sensitive information, respondents will be told that all data provided will be treated in a private manner and will not be disclosed, unless otherwise compelled by law.

The following questions are thought to be of a sensitive nature. The question topic and a rationale for its inclusion, including a statement about the specific measure, are included in the table below.

Sensitive Question	Rationale
Race/ethnicity	Race and ethnicity differences are associated with perceptions of healthy weight and self-reported weight <sup>22</sup> , with non-White women more likely to report a healthy weight with a higher body mass index (BMI: weight/height <sup>2</sup> ). Prevalence of overweight and obesity among lesbians varied by race/ethnicity <sup>23</sup> . Race and ethnicity will be included to characterize our population and as a potential confounder in models used to explain project outcome of weight loss or improved fitness. Required to ensure group-based intervention is culturally appropriate and provides evidence of feasibility and effectiveness for LB women in multiple racial/ethnic groups. African-American and Latina women have higher rates of chronic disease. Per OMB standards, race and ethnicity are separate



	questions. We are using the National Health and Nutritional Examination Survey's (NHANES) race and ethnicity questions.
Sexual orientation	Eligibility criterion for study entry: self-identify as lesbian or bisexual female. The National Health Interview Study has included extensively tested sexual orientation question in their 2013 survey and we are using these in our instruments.
Income	Income is commonly used to assess a person's socio-economic position. It is also possibly the most sensitive of commonly asked demographic questions. Paeratakul et al. <sup>22</sup> reported weight difference by socio-economic status. Using NHANES data, Wang <sup>24</sup> reported that low-socioeconomic status groups are heavier. Although SGM women may be more likely to have higher education attainment, Rothblum <sup>25</sup> reported that this does not translate into higher income. Income levels will be included to characterize our population and as a potential confounder in models used to explain evaluation outcomes.
Disability Status	As noted in the 2011 US DHHS Assessing the Need for a National Disability Survey: Final Report, there is a lack of valid standardized questions to use for assessment of disability status. As a result, we created two questions to capture disability status by using the Americans with Disability Act regulations' (29 C.F.R. 1630.2(i).) definition. Have one or more self-reported disability (e.g., limitations in self-care, performing manual tasks, walking/standing, lifting/reaching, seeing, hearing/ speaking/ communicating, learning/thinking/concentrating, or working) will be included to characterize our population and may be included as a potential confounder in models used to explain evaluation outcomes.
Diet	Improved nutrition is a secondary outcome of the intervention. Stress has been shown to play a role in food choice and weight gain <sup>21</sup> , and may cause eating behavior changes, including disinhibition. In this context, disinhibition is the tendency to overeat in response to different stimuli, including emotional distress, and has been associated with excess body weight. <sup>6</sup>
Physical activity	Increased energy expenditure is a secondary outcome of the intervention and is an important contributor to healthy weight.
Alcohol use	Studies of LB women show that sexual minority stress is linked to increased substance use <sup>18</sup> . Further, evidence suggests that moderate alcohol consumption is a risk factor for obesity <sup>19</sup> and weight gain <sup>20</sup> . When LB population status is ascertained in population-based studies, lesbians and bisexual women drink at higher rates than the general population <sup>22, 26-27</sup> . One primary goal of the study is to reduce caloric intake from alcohol among the participants. The three alcohol questions are recommended by NIAAA of NIH.
Tobacco use	Smoking prevalence in the LB population has been reported up to twice that of the heterosexual population <sup>28-29</sup> . Smoking status will be included to characterize our population and as a potential

	<p>confounder. The two smoking questions will obtain information to determine smoking status (current, former, never) and these questions are recommended by the CDC.</p>
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To avoid negative reactions to these questions, several steps will be taken:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Participants will be provided with local and toll-free numbers to call in case they have a question or concern about the sensitive issue.
- Interviewers will be trained, as part of a study-specific research training, to ask questions in a sensitive manner and to handle any subsequent discussion skillfully. All interviewers will be women.
- Questions included in these interviews will be pilot-tested with a minimal number of individuals matching the characteristics of the target audience (LB aged 40 and older recruited from LMHS).

**12. Estimates of Annualized Hour and Cost Burden**

This section summarizes the total burden hours for this information collection and cost burden to respondents.

**12A. Estimated Annualized Burden Hours**

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours
<b>Health Center Systems Intervention Evaluation</b>				
Knowledge and Attitudes Assessment Pre-training)	40	1	5/60	3
Knowledge and Attitudes Assessment Post-training)	40	1	5/60	3
<b>Group Intervention</b>				
<i>Assessments for All Participants: Sequence 1 (Immediate Intervention Start) and Sequence 2 Comparison Group (Delayed Intervention Start at Month 4)</i>				
Group Intervention Screening Questionnaire	120	1	10/60	20
Evaluation Questionnaire: -Baseline-	80	1	45/60	60
Interim Behavioral Assessment -Month 1-	80	1	10/60	13

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Accelerometer: Activity Diary and Reminder	40	3	20/60	40
Evaluation Questionnaire: Follow-up -Month 4-	80	1	30/60	40
<i>Assessments for Sequence 2 Comparison Group Participants Only (Delayed Intervention Start at Month 4)</i>				
Interim Behavioral Assessment -Month 5-	40	1	10/60	7
Evaluation Questionnaire: Follow-up -Month 8-	40	1	30/60	20
<b>Total</b>				<b>179</b>

\*40 “immediate start” intervention participants will complete one follow-up visit at month 4; 40 “delayed intervention start” comparison group participants will complete two follow-up visits: at months 4 and 8 (see B.2 for exhibit depicting phased roll-out/stepped wedge study design). All participants will complete the 1-month core behavior questionnaire one-month into the intervention period (and into the “observational control” period for the delayed start group).

**12B. Estimated Annualized Burden Costs.** No costs on behalf of the respondent are required except for the time it takes for the respondent to answer the surveys.

**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

None.

**14. Annualized Cost to Federal Government**

The average estimated annual cost to the federal government for conducting this data collection is \$238,250. This figure includes costs for a contract with a research firm, RTI International that includes a sub-contract with a community-based clinic that is a partner in this research, LMHS (total annualized cost of RTI award: \$216,650). OWH has a 24-month contract for the amount of \$433,301 with RTI International for developing the data collection instruments and protocols, designing the intervention components, implementing the interventions, conducting their evaluation, analyzing study data and reporting results. LMHS is a sub-contractor on this award for the 24-month period of performance.

The government costs include personnel costs for federal staff involved in project oversight and development of this Information Collection Request. These efforts involve 10% FTE of a Program Specialist in the Division of Program Coordination, DHHS/OS/OASH/Office on Women's Health; and 10% FTE of the Senior Science Advisor in the DHHS Office on Women’s Health. The estimated annualized cost of federal personnel is \$21,600.

**15. Explanation for Program Changes or Adjustments**

This is a new data collection.

## **16. Plans for Tabulation and Publication and Project Time Schedule**

The results of evaluation activities in this study will be shared with the OWH Program Officer, other HHS officials, as guided by the OWH Program Officer, and published in a peer-review journal. The information will be used to inform future public health interventions directed toward lesbian and bisexual women to address healthy weight and reduce chronic disease burden associated with overweight and obesity.

The health systems intervention will be implemented initially at LMHS with clinic providers and staff. This is planned for July 2013. Chart review data will be abstracted starting in August 2013. After fine-tuning the training based on this initial implementation and results of the Knowledge and Attitudes Assessment completed by participants pre- and post-training, the training will be offered starting in September 2013 to medical school faculty and students. Participants will complete the Knowledge and Attitudes Assessment for CME units offered through their institutions. Analyses of data and reporting of findings will take place in Spring 2014.

The group-based intervention period is three months, with baseline and follow-up surveys administered at intervention end. The delayed start intervention group that serves as the control group will begin the three-month intervention four months after enrollment (see Exhibit 1). Thus, the evaluation period will be approximately 10 months in duration (allowing time for recruitment, screening and complete follow-up of all participants) and will be initiated promptly after receiving OMB approval. Analysis of baseline data will begin once study recruitment is completed; intervention evaluation will begin once follow-up data collection is completed. Initial reporting of intervention evaluation findings is anticipated to start 10 months after intervention start (approximately July 1, 2014).

Our evaluation will use a stepped-wedge design, where the intervention will be rolled out to study participants in two sequences, with the second occurring only after the first sequence completes the intervention period. The order in which individuals receive the intervention will be determined randomly, with all participants receiving the intervention by study end. For those participants randomized to start the intervention immediately (Sequence 1), in-person study visits will take place at baseline and at the end of the 3-month intervention period. Participants randomized to a delayed start (Sequence 2) will complete three in-person study visits: at baseline, at the end of the Sequence 1 intervention period (which marks the end of their period serving as a delayed-treatment control), and when the Sequence 2 intervention ends.

**Exhibit 1. Stepped-Wedge Evaluation Design for Group Intervention**

<b>Time in Study</b>	<b>Month 0</b>	<b>Months 1–3</b>	<b>Month 4</b>	<b>Months 5–8</b>	<b>Month 9</b>
Sequence 1: "Immediate Start" Group	Baseline Assessment	Intervention	Final Assessment & Study Exit		
Sequence 2: "Delayed Start" Group that serves as control	Baseline Assessment	No Intervention	End-of-Sequence 1 Assessment	Intervention	Final Assessment & Study Exit

## Statistical Analysis.

**Health Systems Intervention.** 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. A searchable electronic database of patient visits will be used by LMHS staff to identify patients whose visits are eligible for inclusion in the evaluation. This will enable the project team to compute pre-post changes at the clinic in the proportion of patients who receive chronic disease preventive health counseling and community referrals using chi-squared tests. Sub-analyses may examine whether preventive health counseling was offered differentially to particular groups of women (e.g., diabetics).

Data from the pre-/post-training Knowledge and Attitudes Assessment completed by clinic staff and providers participating in the training as well as medical school faculty and students will be used to calculate percent changes in knowledge and attitudes toward addressing healthy weight in older LB women following the training. Absolute levels of knowledge and attitudes will also be examined.

**Group-based Intervention.** Analysis of evaluation data to measure the overall effectiveness of the intervention on short-term outcomes will involve comparison of the data obtained from the Sequence 1 intervention group ("immediate start" group) at the end of their 3-month intervention period to those from the comparison group in Sequence 2 randomized to a delayed intervention start. Analytic methods will include comparisons of means, medians, and proportions using t-tests, Kruskal-Wallis, and chi-squared tests. For example, data analysis will compare the proportion of participants with high blood sugar levels (as measured by A1c) in the intervention and control groups and will also compare mean levels between groups. Comparisons in percent change from baseline to follow-up will also be made. Generalized linear mixed models will be used to estimate trends in self-reported mindfulness, stress, and health behaviors (e.g., eating, physical activity) over time within individuals and between the intervention and comparison groups. The validated scales assessing quality of life, mindfulness and perceived stress, and social isolation will be analyzed as validated by calculating mean scores.

The accelerometer data will be used in the following ways:

- Total volume of all physical activity. Mean counts per minute will be calculated by dividing the sum of activity counts by the number of minutes of wear time in that day, across all valid days.
- Time spent in differing intensities (e.g., sedentary, light, moderate, vigorous), which can be calculated using count thresholds.
- Time spent in bouts of at least 10 minutes of moderate or vigorous physical activity (MVPA), which are currently the only bouts of activity that count toward meeting national physical activity guidelines (also, the number of days per week with bouts of at least 10 minutes).
- Total number of steps per day and steps in different intensity levels.
- Time spent sitting as opposed to standing.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

Not applicable. All data collection instruments will display the expiration date for OMB approval of the information collection.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

## REFERENCES

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