

## **Supporting Statement MOVE: Making Our Vitality Evident**

### **A. Justification**

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

National and regional research indicates that lesbian and bisexual (LB) women have higher rates of overweight and obesity than heterosexual women. HHS Secretary Kathleen Sebelius has indicated that overweight and obesity among this population is among the top 10 LGTB priorities for HHS for FY12.<sup>i</sup> The differences between LB rates and heterosexual rates have been reported over the last 10 years in the National Survey of Family Growth (Cycle 6)<sup>ii</sup>, the Nurse's Health Study<sup>iii</sup>, the NIH funded Women's Health Initiative<sup>iv</sup>, and several national and regional lesbian health surveys<sup>v,vi,vii</sup>. In the 2002 National Survey of Family Growth, which is a population-based survey of persons between the ages of 15 and 44, lesbians had more than twice the odds of overweight and obesity as heterosexual women. In the Women's Health Initiative sample of women aged 50-79 years, lesbian/bisexual women were 25% more likely to be obese than heterosexual women, with 51% of lesbians being overweight or obese.

Although the causes of obesity and overweight among the general population in the U.S. have been the subject of much research over the past several decades, the causes of obesity and overweight among LB women have not been well researched and are not clearly understood, although they seem to be linked to complex social, psychological, cultural and behavioral influences as well as genetics, calorie intake, lack of physical activity and lack of support for weight loss efforts. In 1999, the Institute of Medicine report, "Lesbian Health: Current Assessment and Directions for the Future," identified lesbians as a medically underserved population. The IOM recommends additional research to understand obesity and weight issues with the LB population as well as the provision of cultural competency and sensitivity training for health care providers.

The importance of cultural competency training as a tool to make health care more accessible and effective has been widely noted by medical professionals and bodies appointed by the U.S. Government.<sup>viii,ix</sup> However, clinicians are often uncomfortable and untrained to discuss sexuality or sexual identity with their patients, creating a barrier for providers to discuss overweight and obesity with their LB patients.

This program will address the need for greater knowledge and increased practice of sound nutrition and exercise among lesbian and bisexual women (LB) in the metropolitan area surrounding the District of Columbia, including DC, Maryland and Virginia, and the need for greater knowledge and sensitivity of medical professionals for working effectively with LB women patients.

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

The purpose of this project is to evaluate interventions that promote healthy weight in LB women through a 16-week group support program, including physical activity and

nutrition, tailored to sexual minority women.

The contractor, The Jacobs Institute of Women's Health of the George Washington University School of Public Health and Health Services (GW), working with Mautner Project: The National Lesbian Health Organization (MP), will evaluate interventions that promote healthy weight in lesbian and bisexual women. Interventions will include: 1) culturally competent group support system (including regular meetings with nutrition information, social support, exercise, as well as on-line support and information) and 2) culturally competent curricula for health care providers to address issues of overweight and obesity with LB patients. The contractor will evaluate a curriculum for medical and nursing professionals based on the already-tested cultural competency curriculum developed by Mautner Project in partnership with the Centers for Disease Control and Prevention (CDC) in 2001 for the project "Removing the Barriers™." x The contractor will collect information on how to have effective conversations with patients who are either lesbian or bisexual about the benefits of achieving healthy weight, and to provide resources that will enable physicians and nurses to help their LB patients succeed. Results of the evaluation will inform the development of a §508-compliant curriculum that can be posted on the HHS website and that can be easily replicated.

As evaluative testing, this project will allow HHS to assess the effectiveness of initiatives designed to address healthy weight in LB populations. This data collection effort will serve three major purposes.

1. Determine effectiveness of the delivery of a culturally competent group support program in promoting healthy weight in lesbian and bisexual women. Aspects of the intervention include:
  - a. regular group meetings that includes provision of nutrition information by a nutrition specialist
  - b. regular individual meetings between participants and a nutrition specialist that includes provision of nutrition information
  - c. social support
  - d. regular group exercise sessions
  - e. regular individual exercise sessions
  - f. on-line support and information
2. Determine effectiveness of provider training on how to have effective, supportive conversations with patients who are lesbian/bisexual about the benefits of achieving healthy weight.
  - Professional education trainings for providers, including doctors and nurses, will be held 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.

A publishable hardcopy report of findings will be produced at the end of the study as well as an electronic §508-compliant version for online publication on the HHS

Website. In addition, one or more manuscripts will be produced suitable for publication in a peer-reviewed journal describing the methodology and results of the project. A PowerPoint slide presentation will also be produced, that is §508 compliant and suitable for on-line distribution and replication. Reports and presentations will only include high level results that will not contain the identities or identifying information of study participants.

If this study is not performed, OWH will not know whether interventions under the "Healthy Weight in Lesbian and Bisexual Women: Striving for a Healthy Community" programs are effective and whether they should be disseminated nationally to address the issue of obesity and overweight in the LB population. General findings from this research will inform future initiatives to improve outreach to LB populations on healthy weight, nutrition and exercise and to improve cultural competency training for physicians and nurses on the care of LB populations. Results of the health professional training program evaluation will also inform the development of a §508-compliant curriculum that can be posted on the HHS website and be replicable around the country.

This package includes a description of data collection and description of the sample required to perform the evaluation.

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

This project will collect minimal data from study participants to evaluate the effectiveness of the programs. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

Evaluation criteria are based on outcome measures, including height and weight (to calculate Body Mass Index (BMI)) and waist circumference. We will also evaluate demographic information, nutrition, physical activity, general health status, and quality of life, as they relate to risk of increased weight and weight loss. 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.<sup>xi</sup> Participants will be given the opportunity to complete the pre- and post- survey instrument on hard copy or on an electronic version through a survey software application in SurveyMonkey®. Providers participating in the study to assess curricula for health care providers to address overweight and obesity with LB patients will also be given the opportunity to complete the survey on an electronic version through SurveyMonkey®.

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

The OWH reviewed existing published literature and unpublished qualitative evaluation reports, and also consulted with outside experts to identify information on

the assessment of LB healthy weight initiatives. 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 CDC, HRSA and NIH.

Information collected for this project will start to fill the gaps in knowledge that are currently unknown around effective delivery methods for promoting healthy weight in lesbian and bisexual women and cultural competencies of healthcare providers in caring for LB populations. OWH is working with multiple contractors to evaluate different healthy weight programs directed at LB populations to determine which programs are effective.

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

This evaluation will have a beneficial impact to the Mautner Project by improving its research capacity and abilities.

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

Data (height, weight and waist circumference) will be collected from group support program participants at the beginning of the program and at the conclusion of the program to establish pre and post intervention measurements. Pre and post intervention measurements are necessary in order to determine effectiveness of the program. Curriculum and training participants (physicians and nurses) will be asked to complete two short surveys, one prior to the training and one at the end of the training. Both measurements are necessary to determine effectiveness of the training program. The performance of this analysis is needed to determine if the healthy weight program is performing optimally. Findings will hopefully lead to thousands of women receiving culturally competent care and treatment to achieve and maintain a healthy weight.

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. The group support program and curriculum and training activities fully comply with the regulations and guidelines in 5 CFR 1320.5.

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

The 60-day Federal Register Notice was published in the Federal Register on March 22, 2013, VOL. 78, PAGE 17675.

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

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

Participants in the program will receive free gym membership, free one-on-one

nutrition counseling, free participation in group support meetings, and a free fitness assessment at the gym for participating in the intervention. There are no direct monetary incentives to participants, but we anticipate the in-kind incentives will be effective and appropriate motivators for participation.

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

All informed consent documents, tapes and transcripts will be kept in a locked file in Mautner Project offices, and will remain there no later than March 1, 2015, or 6 months after the completion of the project in order to conduct post-project analyses. By this date they will be securely destroyed. The consent forms will be stored separately from the transcripts and tapes, and will be accessible only to the Principal Investigator, so that no identifying information can be connected. Each participant will be assigned a unique identifier, and the code to the unique identifier will be stored separately from the data. There will be no connection between consent forms, participant numbers and transcripts. Contractor has submitted the evaluation to the GW Institutional Review Board (IRB), which is HHS-certified. Before data are collected, contractor will obtain full approval from the GW IRB, a process that is expected to be complete by March 2013. All reports to HHS and published reports will include qualitative and quantitative data that are de-identified and will not allow for identification of program participants.

## **11. Justification for Sensitive Questions**

The majority of questions asked for the evaluation will not be of a sensitive nature. There will be no request for a respondent's Social Security Number (SSN), financial, or residential information. It will be necessary to ask a few questions considered to be of a sensitive nature in order to recruit individuals into the study including whether individuals self-identify as lesbian or bisexual. The contractor will interview individuals on the phone during recruitment and will also ask about height and weight. This information is needed because inclusion criteria for study participation are: individuals are lesbian and/or bisexual, have a BMI of 27 or greater, and are aged 18 or over. Interviewers will be trained to ask questions in a sensitive manner and to handle any subsequent discussion skillfully.

- **Alcohol consumption:** Questions will be asked to associate weight gain with caloric intake due to alcohol consumption.<sup>xii,xiii,xiv</sup>
- **Disability status:** Questions will be evaluated to determine if the participant has the ability to engage in physical exercise activities appropriate to the intervention.<sup>xv, xvi, xvii</sup>
- **Race/Ethnicity:** Questions duplicated from the BRFSS survey will be asked to ascertain any differences in program outcomes between members of different races and/or ethnicities because of the vast array of established

literature that demonstrates health disparities, including overweight and obesity, between races and ethnicities.<sup>xviii</sup>

- **Mental health:** Questions will be asked to associate depression and the ability to engage in health weight and weight loss activities.<sup>xix, xx, xxi</sup>
- **Weight loss history:** Questions will be asked to evaluate if this program has the ability to succeed in ways other weight loss efforts have not or to evaluate whether a history of weight loss efforts alters the outcome of women in this population.<sup>xxii</sup>

Questions included in recruitment interviews have been pretested and used in pilot programs with a minimal number of individuals matching the characteristics of the target audience. Questions regarding the cultural competency of providers regarding LB care and weight management approaches may potentially be considered sensitive to some providers. These questions are necessary to evaluate providers' knowledge of LB-specific care before and after the trainings.

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

This section summarizes the total burden hours for this information collection in addition to the cost associated with those hours.

### **12A. Estimated Annualized Burden Hours**

The contractor anticipates two groups of 20 women each for the group support healthy weight program. The contractor anticipates 150 participants for the curriculum and training program. Beyond the time required responding to the survey, no additional cost is expected on behalf of the respondent. The annualized burden hours were calculated based on a pretest of a minimal number of individuals that resulted in an average of 17 minutes to complete the survey and 5 minutes to measure weight and waist circumference for LB adult women participating in the study. We calculated, based on our previous experience, providers would spend 5 minutes completing a short survey directly before and after curriculum training.

Forms (If necessary)	Number of Respondents	Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours
Pre-Test Women's Survey	40	1	23/60	15
Post –Test Women's Survey	40	1	23/60	15
Pre- Test Physician's/Nurses Survey	150	1	5/60	13
Post –Test Physician's/Nurses Survey	150	1	5/60	13
<b>Total</b>				<b>56</b>

## **13. Estimates of other Total Annual Cost Burden to Respondents or Record**

**keepers/Capital Costs**

None.

**14. Annualized Cost to Federal Government**

The average estimated annual cost to the federal government for conducting this data collection is \$197,000. This figure includes costs for a contract with a research firm and OWH staff time. OWH has a 24-month contract with George Washington University School of Public Health and Health Services (GW), working with Mautner Project: The National Lesbian Health Organization (MP) for evaluation, data collection, analysis, and reporting. The annual cost of that evaluation component of the contract is \$89,000. In addition, two OWH staff members will oversee the five projects relating to LB women and healthy weight. For our evaluation, the two OWH staff members will receive \$21,600 total.

**14A. Annualized Cost to Federal Government**

Contract with George Washington University/Maunter Project	\$89,000
Federal staff oversight	\$21,600
<b>TOTAL</b>	<b>\$110,600</b>

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

This is a new data collection effort.

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

The results of evaluation activities in this project will be shared with HHS officials responsible for women's health initiatives and may be published in a peer-review journal. The information will be used to inform future health programs across OWH, as well as other public health campaigns that influence the health of LB women and LB communities. Reports and presentations of evaluation findings will only include high level results that will not contain the identities or identifying information of study participants. Data collection for the evaluation will occur throughout the program lifecycle. This evaluation is anticipated to conclude in August 2014. The contractor will submit a publishable report to HHS in September 2014.

**1. 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.

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

There are no exceptions to the certification.



- <sup>i</sup> HHS LGBT issues coordinating committee 2012 report. (2012). Retrieved January/22, 2013, from [http://www.hhs.gov/secretary/about/lgbthealth\\_objectives\\_2012.html](http://www.hhs.gov/secretary/about/lgbthealth_objectives_2012.html)
- <sup>ii</sup> U.S. Centers for Disease Control and Prevention. (2012). National survey of family growth. Retrieved January/18, 2013, from [http://www.cdc.gov/nchs/nsfg/nsfg\\_products.htm#cycle6](http://www.cdc.gov/nchs/nsfg/nsfg_products.htm#cycle6)
- <sup>iii</sup> The Nurses' Health Study. Retrieved January/18, 2013, from <http://www.channing.harvard.edu/nhs/>
- <sup>iv</sup> National Institutes of Health. Women's Health Initiative. Retrieved January/18, 2013, from <http://www.nhlbi.nih.gov/whi/>. Washington, D.C.: National Heart, Blood, and Lung Institute.
- <sup>v</sup> Fogel, S. C., Young, L. and McPherson, J. B. (2009). *The Experience of Group Weight Loss Efforts Among Lesbians*. *Women & Health*. 49: 540 — 554.
- <sup>vi</sup> Fogel, S. C., Calman, L. & Magrini, D. (2010). *Lesbians' and Bisexual Women's Definition of Health*. *Journal of Homosexuality*. (In press.);
- <sup>vii</sup> Mautner Project, & Out to Market Communications. "Tackling the Lesbian Obesity Epidemic: Messaging and Images Report." Retrieved from: [www.mautnerproject.org](http://www.mautnerproject.org)
- <sup>viii</sup> Department of Health and Human Services. (March 2001). *National standards for culturally and linguistically appropriate services in health care*. Washington, D.C.: Office of Minority Health.
- <sup>ix</sup> The Joint Commission. (2011) *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals*. Oakbrook Terrace, IL.
- <sup>x</sup> Mautner Project. (2012). Removing the barriers. Retrieved January/18, 2013, from [http://www.mautnerproject.org/education/removing\\_barriers.cfm](http://www.mautnerproject.org/education/removing_barriers.cfm)
- <sup>xi</sup> Lean, M., Han, T., & Morrison, C. (1995). Waist circumference as a measure for indicating need for weight management. *BMJ*, 311(158)
- <sup>xii</sup> Wang L, Lee I, Manson JE, Buring JE, Sesso HD. (2010). *Alcohol consumption, weight gain, and risk of becoming overweight in middle-aged and older women* doi: 10.1001/archinternmed.2009.527
- <sup>xiii</sup> Wannamethee, S. G., Field, A. E., Colditz, G. A., & Rimm, E. B. (2004). Alcohol intake and 8-year weight gain in women: A prospective study. *Obesity Research*, 12 (9), 1386-1396. doi: 10.1038/oby.2004.175
- <sup>xiv</sup> Suter, P. M., & Tremblay, A. (2005). IS ALCOHOL CONSUMPTION A RISK FACTOR FOR WEIGHT GAIN AND OBESITY? *Critical Reviews in Clinical Laboratory Sciences*, 42(3), 197-227. doi: 10.1080/10408360590913542
- <sup>xv</sup> Section 902 definition of the term disability. (2008). Retrieved January/18, 2013, from <http://www.gpo.gov/fdsys/pkg/CFR-2011-title29-vol4/xml/CFR-2011-title29-vol4-part1630.xml>
- <sup>xvi</sup> United States Department of Health and Human Services. (2012). Disability and health, healthy people 2020. Retrieved 1/29, 2013, from <http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=9>
- <sup>xvii</sup> United States Department of Health and Human Services. (2012). Physical activity, healthy people

2020. Retrieved 1/29, 2013, from

<http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=33>

<sup>xviii</sup> The Centers for Disease Control and Prevention. (1/24/2013). Behavioral risk factor surveillance system. Retrieved 1/29, 2013, from <http://www.cdc.gov/brfss/>

<sup>xix</sup> Nicholson, N. R. (2012). A review of social isolation: An important but under assessed condition in older adults. *The Journal of Primary Prevention*, (33), 137-152. doi: 10.1007/s10935-012-0271-7

<sup>xx</sup> Iqbal, S. U., Rogers, W., Selim, A., Qian, S., Lee, A., Ren, X. S., Kazis, L. E. The Veterans Rand 12 item health survey (vr-12): What it is and how it is used.

<sup>xxi</sup> United States Department of Health and Human Services. (2012). Physical activity, healthy people 2020. Retrieved 1/29, 2013, from

<http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=33>

<sup>xxii</sup> United States Department of Health and Human Services. (2012). Nutrition and weight status, healthy people 2020. Retrieved 1/29, 2013, from

<http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=29>