

**Supporting Statement for Living Healthier, Living Longer  
Submitted by the Office on Women's Health (OWH)**

**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".<sup>1</sup> 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.

Maintaining a healthy weight lowers the risk of heart disease, stroke, diabetes, high blood pressure, various cancers, and early death, and improves quality of life.<sup>2</sup> Yet despite these benefits, almost two-thirds of the women in the U.S. are of an unhealthy weight,<sup>3</sup> and this proportion is even more staggering when looking specifically at lesbian and bisexual (LB) women. For example, studies have identified a higher rate of unhealthy weight among lesbian women (as compared with heterosexual or all women), with one study suggesting more than twice the likelihood of being an unhealthy weight.<sup>4,5,6</sup> Unfortunately, there is limited information available on the potential causes of unhealthy weight in LB women, and few programs have been undertaken to improve the issue. Indeed, to the best of our knowledge, no Federal intervention programs have addressed this issue to date.

To respond to this health care issue in older LB women (and lack of related information),

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1 Department of Health & Human Services Office of the Secretary. HHS LGBT Issues Coordinating Committee 2012 Report. Available online at [http://www.hhs.gov/secretary/about/lgbthealth\\_objectives\\_2012.html](http://www.hhs.gov/secretary/about/lgbthealth_objectives_2012.html).

2 The nutrition source. How to get to your healthy weight. Harvard School of Public Health. Accessed online on August 15, 2012 at <http://www.hsph.harvard.edu/nutritionsource/healthy-weight/healthy-weight-full-story/index.html>.

3 Roger V L, Go AS, Lloyd-Jones D, et al. Heart Disease and Stroke Statistics 2011 Update: A Report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2011; 121:e1-e192.

4 Rates of unhealthy weight in bisexual women are less clear.

5 Boehmer U, Bowen DJ, Bauer GR. Overweight and Obesity in Sexual-Minority Women: Evidence From Population-Based Data. *American Journal of Public Health*. 2007 June; 97(6): 1134-1140.

6 Aaron DJ, Markovic N, Danielson ME, et al. Behavioral Risk Factors for Disease and Preventive Health Practices Among Lesbians. *American Journal of Public Health*. 2001 June; 91(6): 972-975.

OWH will implement a healthy weight demonstration project in the New York City area and measure the demonstration's effects. The demonstration will include educational meetings (regarding physical activity and nutrition) and will encourage independent and group physical activity. To measure the effects of the demonstration, we will collect data on:

- Demographics and Background
- General health and health history
- Physical activity
- Food and beverage consumption
- Program experience

Nearly all of the data collected will be through questions that have been previously validated and used in other government-sponsored studies or recommended by government task forces. 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**

There is currently very limited information available regarding weight and obesity among LB women; thus, a critical component of this demonstration project is the collection of information pertaining to the topic. This information will be analyzed by our study team and used by OWH and HHS to identify and understand the effects of our healthy weight demonstration project, and to inform the applicability of the program to other sites across the United States.

Specifically, the demonstration has the following primary objectives:

- Decrease respondent waist circumference by at least 5%, on average
- Increase the average number of steps/day by 2,000
- Decrease the percentage of individuals who consume sugar-sweetened beverages on a daily basis to 5%
- Increase the percentage of individuals meeting dietary guidelines for fruit and vegetable consumption to 50%

Secondary objectives include increased frequency of resistance training and minutes of aerobic exercise, decreased blood pressure, increased water consumption, improved cardiovascular fitness, and improved energy and stress levels.

Based on the success of the demonstration (as measured through the objectives listed above), we will disseminate the program to other organizations across the U.S. for its sustained use in older LB women (similar to programs such as Sisters Together<sup>7</sup>). Without this information collection, we will not know whether the demonstration is in fact effective and if it should be disseminated across the U.S. (see the following table).

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<sup>7</sup> Sisters Together is a program run through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which offers "evidenced-based, age-appropriate, and culturally relevant" information to encourage regular physical activity and health eating among overweight and obese black women. More details about the program are available at <http://www.win.niddk.nih.gov/sisters/>.

Topic	Purpose of Collected Information	Effects of Not Collecting Information
Demographics and Background	<p>It is important to understand the characteristics of those women for whom the demonstration does/does not work. For example, obesity rate, diet, and ability to lose weight vary based on factors such as age and whether an individual is pre-, peri-, or post-menopausal.</p> <p>Understanding these various demographic factors will inform the applicability of the program to other LB populations across the United States.</p> <p>Additionally, the educational piece of the demonstration will be tailored based on demographic information collection. For example, one piece of the program includes providing a resource directory of local, LB-friendly establishments such as gyms and health markets. This directory will be organized by ZIP code.</p>	<p>Not collecting demographic information on the study respondents will make it difficult to generalize study findings to older LB women not enrolled in the study. Additionally, we will not be able to tailor the demonstration project in the most effective way without knowing basic demographic information. For example, if some respondents in our program are currently working, group sessions may have to be scheduled outside normal working hours. In another example, ethnic/racial background may inform some of the nutritional education provided in that the types of foods discussed can be culturally relevant.</p>
General Health and Health History	<p>To know whether the demonstration project is successful in achieving healthy weight and improving health in older LB women, certain health metrics will be collected. The health metrics we selected represent both general health measures as well as those related directly to weight, and will be measured by trained individuals (e.g., nurse). Research has shown that LB women are more responsive to “improved health” messaging rather than “weight loss” messaging; thus, health metrics we collect will focus on general health and improved well-being.</p> <p>Additionally, health history questions will be asked in order to identify potential limitations to weight loss,</p>	<p>If these measures are not collected, we will not know the effects of the demonstration on healthy weight and health of older, LB women. Additionally, it will be difficult to establish an overall emphasis on “improved health”, which is necessary to gain support of the program by older LB women. Furthermore, some of the questions asked will be to motivate continued participation in the study (by demonstrating less obvious health improvements, such as improved energy).</p> <p>Without responses to many of the health history questions, we will not be able to most effectively tailor the program (e.g., if an individual has physical</p>

Topic	Purpose of Collected Information	Effects of <i>Not</i> Collecting Information
	increased physical activity, and dietary modification, as well as to tailor the program.	limitations that we can accommodate).
Physical Activity	Physical activity is an essential component of weight loss and improved health. Physical activity metrics will be used to identify how successful the program is at encouraging increased physical activity. In 2011, only 16% of older Americans met recommended guidelines for aerobic and muscle strengthening exercises. <sup>8</sup>	If these measures are not collected, we will not know whether the demonstration resulted in increased physical activity in study respondents, or the relationship between physical activity and improvements in weight and health. OWH will use this information to inform whether successful weight loss program in older LB women should emphasize increased physical activity.
Consumption	As with physical activity, food and beverage consumption is an essential component of weight loss and improved health. We will measure consumption of a limited sample of foods/beverages to identify how successful the program is at encouraging improving healthy eating.	If these measures are not collected, we will not know whether the demonstration encouraged improved consumption in study respondents, or the relationship between consumption and improvements in weight and health. OWH will use this information to inform whether successful weight loss programs in older LB women should emphasize improved food and beverage consumption.
Program experience	In order to ensure the most effective program and assure that research translates into a meaningful experience for respondents, it is important to understand respondent experience during and after the demonstration. The program design is multi-faceted, including group sessions, educational pamphlets, an online social experience, walking groups, health screenings, healthy reminders, and other components; thus, it is important to understand which of these individual pieces was	Without soliciting information from respondents regarding their experience of the demonstration, we will not know what made the program succeed or fail. It is important to understand these factors to know how to effectively tailor the program so that it might be used in other communities across the US (e.g., if all respondents agreed that the provided therabands were not useful, then other communities would not want to invest in therabands).

8 Behavioral Risk Factor Surveillance System. Prevalence and Trends Data, 2011. Available online at <http://apps.nccd.cdc.gov/BRFSS/age.asp?cat=PA&yr=2011&qkey=8291&state=UB>

Topic	Purpose of Collected Information	Effects of <i>Not</i> Collecting Information
	received well by respondents or if changes are necessary.	

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

Information technology will be used where possible to collect respondent information. Across the different categories of topics addressed (and across a 14 week timeframe), respondents will be required to answer a total of 109 survey questions, 83 of which will be part of an online survey and 26 of which will be part of PDF-form for email (i.e., 100% of the survey questions asked will employ online information technology methods). In the current study, online information technology will be an improvement over paper administration due to the following:

- Consolidation of various forms into a single online tool
- Reduced respondent burden
  - No requirement to return a survey
  - Easier use of skip-patterns in surveys
- Increased collection efficiency through elimination of data entry requirements
  - Less data entry required
    - Fewer/no opportunities for error
    - Less time required
- Improved data management
  - Increased security/protection of responses due to fewer researchers required and elimination of paper copies
  - Data available “real-time”

However, print versions of the surveys will also be available to respondents who choose not to use information technology.

An additional 24 “questions” will require respondent time but are in fact physical measurements (e.g., waist circumference, blood pressure); thus, these “questions” will involve a trained professional and will occur in person. Finally, 12 questions will be asked at focus group meetings. Including physical measurements and focus group questions, a total of 75% of questions in this study will employ information technology, if available to the respondent.

<b>Mode of Collection</b>		<b>Baseline of Study</b>	<b>Midpoint of Study</b>	<b>End of Study</b>	<b>Total Questions</b>
Information Technology:	Online	45	-	38	<b>83</b>
	PDF-form	26	-	-	<b>26</b>
In-person	Physical Measurement	8	8	8	<b>24</b>
	Focus Group	-	6	6	<b>12</b>

In addition to standard information technology (e.g., online survey completion), we will employ Bluetooth technology to further reduce respondent burden. Specifically, daily steps taken will be measured for each respondent, and, rather than require respondents to complete this information manually, we will provide technology to

allow passive collection. Each respondent will receive a pedometer equipped with Bluetooth technology that saves seven days' worth of data and automatically downloads daily steps taken whenever the individual is within 15 feet of an "activated" Smart phone or computer. We will provide an "activated" computer kiosk at the local community center where group sessions will be held to facilitate passive collection of steps taken. All respondents will be informed of this technology upon receipt of the pedometer.

In all evaluative approaches, the number of questions will be held to the absolute minimum required for the intended use for the evaluation. Skip patterns will be used where available to further reduce the number of questions individuals will have to complete.

- *Survey of demographic/background information:* response completion via online survey tool (computer-assisted self-interview)
- *General health and health history:* health metrics data will be collected by a nurse and other trained professionals; survey questions will be made available via an online survey tool and computerized PDF-form for emailing/ mailing
- *Physical activity:*
  - *General physical activity:* response completion via online survey tool (computer-assisted self-interview) and computerized PDF-form for emailing
  - *Steps taken:* steps data are collected passively through a Bluetooth relationship between pedometer and computer
- *Consumption:* response completion via online survey tool (computer-assisted self-interview)
- *Program Experience:* respondents will engage in focus group discussion moderated by a trained professional

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

Although a small number of studies have been conducted to identify potential characteristics of a successful healthy weight program in LB women, a review of the literature suggests that no studies have been completed where an LB-specific program was implemented and evaluated. Additionally, 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 CDC, HRSA, or the NIH, outside of this current initiative within OWH. This demonstration project is the first of its kind.

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

No small businesses will be involved in this study.

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

There are no legal obstacles to reduce the burden. The following table details the frequency of collection for each of the topics addressed.

Topic		Collection Frequency	Justification for Frequency
Demographics and Background		1x	These data are collected at baseline to understand characteristics of respondents, which will be used to tailor and evaluate the program.
General health and health history	Health history	1x	These data are collected at baseline to identify potential limitations that may have to be accounted for in the development of physical activity and nutrition regimens.
	General health	2x	These data are collected at baseline and the end of the study (14 weeks apart) to identify any changes in general health after participation in the study (e.g., change in the amount of physical pain an individual experiences and the effects of this pain on everyday functioning).
	Health screening	3x	<p>These data are collected at three points in the study, 7 weeks apart:</p> <p><b>Baseline:</b> To identify current health status of respondents.</p> <p><b>Midpoint:</b> To identify midpoint-health status of respondents, and also to encourage continued participation (by providing results feedback).</p> <p><b>Completion:</b> To identify final effects of study on health status.</p> <p>Collection of data less frequently than this will result in lack knowledge whether the program is actually effective, as well as decrease respondent motivation to participate in the study.</p>
Physical Activity	General activity level	2x	<p>Increased physical activity will be encouraged as a part of this demonstration, including through available exercise classes at the program site. General activity level will be collected at baseline and completion (14 weeks apart) to capture any changes that might occur during the demonstration.</p> <p><b>Baseline:</b> To determine current physical activity level of respondents.</p> <p><b>Completion:</b> To identify final effects of study on physical activity level.</p> <p>Collection of data less frequently than this will result in the inability to determine whether the program in fact increased physical activity.</p>
	Steps taken	1x	The pedometer being used to collect steps is equipped with Bluetooth technology, and automatically “logs” steps taken on behalf of the respondent (whenever she is near a Smart phone or activated computer). Thus, after initial account set-up, respondents will have no added burden.



Topic	Collection Frequency	Justification for Frequency
Consumption	2x	One component of our program design includes nutritional education as it relates to healthy eating and weight loss. To measure the effects of this education, we will measure certain food and beverage consumption levels at baseline and again at study completion. Collecting this information less frequently would result in the inability to determine whether the program improved healthy eating.
Program experience	2x	<p>Focus groups will be held at two different points in the study to identify what pieces of the demonstration contributed to its success or failure:</p> <p><b>Midpoint:</b> Understanding what is working and what is not (after respondents have had 7-weeks of experience with the program) will allow us to modify the program accordingly to ensure success.</p> <p><b>Completion:</b> After respondents have completed the program, we will solicit feedback on elements that may have aided or hindered the respondents' ability to meet their health and fitness goals.</p>

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

No special circumstances exist.

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

- A 60-day Federal Register Notice was published in the Federal Register on 3/12/2013, Volume 78, Number 48, pages 15725-15726 (See Attachment "Living Healthier Living Longer 60-day notice").
- No comments were received from the public during this notice period.
- To better understand potential respondent burden and reaction, we consulted with the following individuals/organizations during November – December, 2012 and January 2013:
  1. *Danielle Brittain*  
University of Northern Colorado, Assistant Professor  
Researcher; expert in lesbian women and physical activity  
[Danielle.brittain@unco.edu](mailto:Danielle.brittain@unco.edu)
  2. *JoEllen Wilbur*  
Rush University College of Nursing, Associate Dean for Research  
Researcher, expert in pedometer-based programs in minority female populations  
[Joellen\\_wilbur@rush.edu](mailto:Joellen_wilbur@rush.edu)
  3. *Brenda Davy*  
Virginia Polytechnic Institute (VirginiaTech), Associate Professor

Researcher and Registered Dietician, expert in improving health behaviors and data collection

[bdavy@vt.edu](mailto:bdavy@vt.edu)

4. *Jessica Albere*

FitBit, Inc. (pedometer-supply company)

[jalbere@fit.com](mailto:jalbere@fit.com)

5. *Ken Bishop*

National Cancer Institute, Diet History Questionnaire Technical Support

[DHQ@imsweb.com](mailto:DHQ@imsweb.com)

Additionally, as this OWH effort was funded to five separate organizations and includes five unique healthy weight demonstrations, the five teams have collaborated to review the appropriateness and validity of many of the questions asked. Through this collaboration, the five teams decided on approximately 54 “core” questions to be asked across all of the teams in their studies. Core questions are denoted in column J (Group Core) of Appendix G with “Yes”.

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

In its July 2010 evaluation brief, *Using Incentives to Boost Response Rates*, the CDC discussed the use of incentives to increase survey response. As stated in this brief, incentives:<sup>9</sup>

- Improve response rates;
- Demonstrate respect and appreciation for respondent time and effort; and
- Convey trust that the respondent will complete the survey.

Research has supported the use of incentives to increase response rates, with monetary incentives having the largest effect. Additionally, research has shown that incentives can be cost effective in their ability to reduce overall sample size as well as interviewer time.<sup>10,11</sup> Furthermore, research has shown that providing incentives *prior* to survey completion (i.e., non-contingent, or prepaid) is much more successful than providing incentives after survey completion (i.e., contingent, or promised) in increasing response rates.<sup>12,13, 14</sup> Thus, gift cards in the amount of \$10 will be provided to respondents for the completion of surveys (at two points in the study), in advance of administration of the surveys.

9 The Centers for Disease Control and Prevention. Evaluation Briefs: Using incentives to boost response rates. No. 22, July 2010.

10 Dykema J. Presentations and discussion: Incentives part 1. Incentives and research-based best practices. University of Wisconsin Survey Center. 2011. Available online at [www.uwsc.wisc.edu/2011fd/Dykema\\_2011\\_IFD&TC.pdf](http://www.uwsc.wisc.edu/2011fd/Dykema_2011_IFD&TC.pdf).

11 Lavrakas, Paul J. 2011. “The Use of Incentives in Survey Research.” Short course presented at the annual meeting of the American Association for Public Opinion Research, Phoenix, AZ.

12 Church AH. Estimating the effect of incentives on mail survey response rates: a meta-analysis. *The Public Opinion Quarterly*. 1993; 57(1): 62-79.

13 Delnevo CD, Abatemarco DJ, Steinberg MB. Physician response rates to a mail survey by specialty and timing of incentive. *American Journal of Preventive Medicine*. 2004; 26(3): 234-236

14 James KM, Ziegenfuss JY, Tilburt JC et al. Getting physicians to respond: the impact of incentive type and timing on physician survey response rates. *Health Services Research*. 2011; 46(1 Pt 1):232-242.

We anticipate as the total remuneration costs:

- \$10 per survey completion at two points in the study, for 40 respondents, for a maximum remuneration of \$800.

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

Respondents will not be required to share personal identifiers (e.g., full names) with other respondents and no identifiable data will be made public. We will use name information solely to link study outcomes with factors such as demographics, general health, etc. Data will be de-identified prior to evaluation, described below.

Additionally, in advance of study participation, respondents will be asked to sign an Informed Consent form, which will include a statement on the private nature of the program and will clarify that the study is voluntary. It will also state that all data collected will be kept private to the extent allowed by law.

We will follow relevant World Medical Association Declaration of Helsinki ethical principles for research involving human subjects. Specifically:

- We will ensure that the well-being of the individual research subject takes precedence over all other interests, for example, by minimizing risks through sound research design
- We will protect the dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects
- Only individuals with the appropriate scientific training and qualifications will conduct this research and collect respondent information
- We will take every precaution to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity
- We will ensure that the importance of our objectives outweighs the inherent risks and burdens to the research subjects
- Participation by competent individuals as subjects will be voluntary
- Each potential subject will be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study.

Protecting respondent and subject confidentiality is of central concern in our study. All collected data will be encrypted and stored in a password-protected database on a secured drive, with access provided only to those individuals responsible for data analysis. Additionally, within our database, unique identifiers will be assigned to each participant to help protect confidentiality. These unique identifiers may consist of a combination of numbers and letters and will not contain any information that may be used to identify a participant (e.g., "OWH100," "OWH101,"). Thus, we will create a de-identified data set. Such a data set is stripped of all elements that might enable someone to deduce the identity of the participant. A crosswalk of unique identifiers will be archived in a separate, password-protected database on a secured drive.

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

The majority of questions asked will not be sensitive in nature; however, 11 questions that may be perceived as sensitive will be asked of respondents involving the following topics: alcohol consumption, disability, mental health, race/ethnicity, sexual minority status, and weight. The responses to these questions will be used by OWH to tailor the program, and to better understand the effects of the program (more specifically, to understand for whom the program did/did not work). This information will improve OWH's ability to disseminate the program to a broader population of older LB women across the United States.

Note that in our pretest, none of the seven volunteers found any questions sensitive.

- **Alcohol Consumption:** Research has shown various effects of alcohol on weight gain. Specifically, low to moderate consumption of alcohol has been found in numerous studies to have a protective effect on weight gain (particularly in women), with consumers gaining less weight than non-consumers.<sup>15,16,17</sup> However, excessive drinking, and in particular binge-drinking, has been shown to have the opposite effect on weight gain, with studies demonstrating increased risk of metabolic syndrome<sup>18</sup> and being overweight.<sup>19,20</sup> Additionally, LB women may have different alcohol consumption patterns than heterosexual women, with research showing LB women consuming a higher number of alcoholic drinks in general, as well as more frequently participating in "heavy" drinking.<sup>21</sup> Given these patterns of alcohol consumption in LB women and the potential effects on weight and weight gain, it is important to measure alcohol consumption in the current study. Respondents will be asked a maximum of three questions in this study to measure drinking frequency. The questions are from the National Institute on Alcohol Abuse and Alcoholism (NIAAA).
- **Disability Status:** The American with Disabilities Act (ADA) defines disability (with respect to an individual) as "a physical or mental impairment that substantially limits one or more major life activities of such individual", including activities such as walking, standing, lifting, reading, and communicating.<sup>22</sup> Because our healthy weight demonstration is focused on increasing increased physical activity and improved nutrition, an individual

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15 Wang L, Lee, IM, Manson JE, et al. Alcohol consumption, weight gain, and risk of becoming overweight in middle-aged and older women. *Archives on Internal Medicine*. 2010; 170(5): 453-461.

16 Thomas CA, Wertheim BC, Hingle M, et al. Alcohol consumption and body weight change in postmenopausal women: results from the Women's Health Initiative. *International Journal of Obesity*. 2012; 36(9):1158-1164.

17 Arif AA, Rohrer JE. Patterns of alcohol drinking and its association with obesity: data from the Third National Health and Nutritional Examination Survey, 1988-1994. *BMC Public Health*. 2005; 5(5):126.

18 Fan AZ, Russell M, Maimi T, et al. Patterns of alcohol consumption and the metabolic syndrome. *The Journal of Clinical Endocrinology & Metabolism*. 2008; 93(10):3833-3838

19 Forman MR, Trowbridge FL, Gentry EM, et al. Overweight adults in the United States: the behavioral risk factor surveys. *The American Journal of Clinical Nutrition*. 1986; 44(3)410-416.

20 Arif AA, Rohrer JE. Patterns of alcohol drinking and its association with obesity: data from the Third National Health and Nutritional Examination Survey, 1988-1994. *BMC Public Health*. 2005; 5(5):126.

21 Drabble L, Trocki K. Alcohol consumption, alcohol-related problems, and other substance use among lesbian and bisexual women. *Journal of Lesbian Studies*. 2005; 9(3):19-30.

22 42CFR12102(1) and 12102(2).

with certain disabilities might need accommodations to facilitate their participation in our study. For example, an individual with the inability to walk will likely be unable to participate in study walking groups. Thus, we will ask a maximum of two questions to evaluate disability status and better understand accommodations that can be made. The questions were derived from the ADA definition for disability.<sup>23</sup>

- **Mental Health:** Study respondents will be asked to respond to four questions regarding mental health (including energy, depression, and anxiety). Numerous studies have shown a link between weight and mental health, including the comorbidity of depression with metabolic syndrome<sup>24</sup> and lower levels of physical activity and depression/anxiety.<sup>25</sup> Additionally, studies have found that LB women tend to have higher rates of depression than heterosexual women,<sup>26</sup> and obesity and limited physical activity in older LB adults have been found to account for poor general health and depression in this population.<sup>27</sup> Given the demonstrated relationship between mental health and weight, we will use questions from the Veterans RAND 12 Item Health Survey (which has been used extensively in the Medicare population) to better understand the program experience of those individuals with mental health concerns.
- **Race/Ethnicity:** Study respondents will be asked questions about race and ethnicity in the preferred method as discussed in the OMB Directive 15 on Race and Ethnic Standards.<sup>28</sup> Specifically, two consecutive questions will be asked with Hispanic or Latino origin asked first, followed by a question on race. The response options are those provided in the OMB Directive 15 (and explicitly listed in surveys such as BRFSS and NHANES). The responses to these two questions will be used in part to tailor the program (e.g., nutritional education can be tailored to include culturally appropriate foods), as well as to inform whether the program worked differently for different ethnicities. For example, research has shown disparities in health and health behaviors among different ethnic/racial groups, such as participation in physical activity.<sup>29</sup> These racial disparities also exist among sexual minority populations. In one study of LB women in Los Angeles county (California), researchers found that the prevalence of being

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23 As noted in the US Department of Health and Human Services' Assessing the Need for a National Disability Survey: Final Report (2011), there is a lack of valid standardized questions to use for assessment of disability status. Thus, we developed two questions to capture disability status.

24 Dunbar JA, Reddy P, Davis-Lameloise N, et al. Depression: An important comorbidity with metabolic syndrome in a general population. *Diabetes Care*. 2008; 31(12):2368-2373.

25 King WC, Kalarchian MA, Steffen KJ, et al. Associations between physical activity and mental health among bariatric surgical candidates. *Journal of Psychosomatic Research*. 2013; 74(2):161-169.

26 Rothblum ED, Factor R. Lesbians and their sisters as a control group: demographic and mental health factors. *Psychological Science*. 2001; 12(1):63-9.

27 Fredriksen-Goldsen KI, Emler CA, Kim HJ, et al. The physical and mental health of lesbian, gay male, and bisexual (LGB) older adults: The role of key health indicators and risk and protective factors. *Gerontologist*; 2012 Oct 3 (Epublication).

28 Office of Management and Budget. Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity. Available online at [http://www.whitehouse.gov/omb/fedreg\\_1997standards](http://www.whitehouse.gov/omb/fedreg_1997standards)

29 Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System, Prevalence and trends data. nationwide (states and DC) – 2011 physical activity. Available online at <http://apps.nccd.cdc.gov/BRFSS/display.asp?cat=PA&yr=2011&qkey=8291&state=UB>.

overweight or obese in lesbian women varied by race/ethnicity.<sup>30</sup> Additionally, questions about race/ethnicity allow OWH to monitor compliance with anti-discrimination provisions required of Federal agencies.

- **Sexual Minority Status:** Study respondents will be asked to provide information on their sexual identity. It is essential to this study to understand sexual identity as we expect diversity in respondent experiences and outcomes based on lesbian versus bisexual self-identification. For example, both lesbian and bisexual women have a higher prevalence of unhealthy weight than do heterosexual women. However, lesbian women have an even higher prevalence of unhealthy weight than do bisexual women.<sup>31</sup> The two sexual identity questions we will ask were pulled from the National Health Interview Study (NHIS), which included extensively tested sexual and gender minority status questions in its 2013 survey.
- **Weight and Weight Loss Efforts:** Weight is often perceived by individuals as personal and private information and can be particularly sensitive in the older LB community. Thus, our “healthy weight” demonstration project will focus on general improved health (e.g., lowered blood pressure; improved cardiovascular stamina); however, to understand the effectiveness of our program, we will also measure weight change. Additionally, respondents will be asked a single question on previous weight loss efforts, as history of weight cycling and a repeated loss and regain of weight are associated with weight regain after weight loss intervention.<sup>32</sup>

All of these questions (with the exception of a physical weight measurement to occur at health screenings) will be asked in surveys at the beginning of the study. Respondents will be informed that their responses will be kept private to the extent allowed by law and will be used to tailor the program (specifically the group session) accordingly. Respondents who would prefer not to provide a response may choose to skip these questions; they will be informed of the option to “skip” in the informed consent completed prior to study participation.

No questions will be asked about Social Security Number (SSN).

## **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**

A maximum total hour burden of 129 hours and 20 minutes is expected in this study, for an average annualized burden of 3 hours and 14 minutes per respondent. Because the current project includes various types of respondent data

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30 Yancey AK, Cochran SD, Corliss HL, Mays VM. Correlates of overweight and obesity among lesbian and bisexual women. *Preventive Medicine*. 2003; 36:676-683

31 Boehmer U, Bowen DJ, Bauer GR. Overweight and obesity in sexual-minority women: Evidence from population-based data. *American Journal of Public Health*. 2007;97(6):1134-1140.

32 Garip, G. Yardley, L. A synthesis of qualitative research on overweight and obese people's views and experiences of weight management. *Clinical Obesity*. 2011;1(2-3): 110-126.

collection (survey completion, physical measurements, and focus group discussion), we further stratified this burden:

- Survey Completion: 44 minutes per respondent
- Physical Measurements: 30 minutes per respondent
- Focus Group Discussion: 2 hours per respondent

Hour burdens for survey completion were derived through a formal pretest (i.e., pilot sample) of seven individuals. Lesbian and bisexual women volunteers were asked to complete each form and provide feedback on:

- The length of time to complete;
- Comprehension of questions and response options;
- Perceived sensitivity of questions; and
- Preferred question version to gather identical information (3 questions)

In response to this pretest, we modified 25 questions on our original survey. For 12 questions, we clarified instruction (e.g., “select all that apply”) or added a “None” or “N/A” response option. Thirteen questions were deleted (from the World Health Organization Quality of Life Scale) and replaced with the OMB-approved Veterans Rand 12 Item Health Survey.

Hour burdens for physical measurements were determined by speaking with experts trained in taking the measurements that will be collected (e.g., registered nurse; physical trainer). Hour burdens for the focus groups were determined based on a pre-defined meeting time: the focus groups will occur during regularly-schedule group sessions that the respondents will already be attending. These group sessions are an hour in length.

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Baseline Survey	40	1	15/60	600/60 (10 hours)
Study Completion Survey	40	1	15/60	600/60 (10 hours)
Pedometer Profile	40	1	2/60	80/60 (1 hour)
Health Screen (physical measurement)	40	3	10/60	1,200/60 (20 hours)
Health History Questionnaire	40	1	12/60	480/60 (8 hours)
Focus Group (study midpoint)	40	1	1	40 hours
Focus Group (study completion)	40	1	1	40 hours
<b>Total</b>				<b>129 hours</b>

No costs on behalf of the respondent are required except for the time it takes the respondent to answer the survey.

**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 this data collection is \$189,465. This amount includes the cost for a contract with a professional research organization and OWH staff time. OWH has a 2-year contract with the organization The Lewin Group to design, implement, and evaluate the healthy weight demonstration project, which includes developing and administer study questions, analyzing responses and their relationship to the broader program, and reporting on these results. The annual cost of that contract is \$167,865 with an estimated 1,200 anticipated hours. Additionally, two OWH staff oversee the project, for a total 20% FTE, approximately \$21,600 per year.

	Annual Cost
<i>Contract with The Lewin Group</i>	\$167,865
<i>Federal staff oversight</i>	\$21,600
<b>Total</b>	<b>\$189,465</b>

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

This is new data collection.

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

The results of this study will be shared with HHS officials as well as published in a peer-reviewed journal. The information will be used to fill a gap in the information available regarding healthy weight in LB women. Specifically, the findings will inform potential healthy weight programs in older, LB women that can be used by organizations and entities across the United States. This information has the capacity to improve the health and save lives of older LB women across the United States. Additionally, the results will further Secretary Sebelius' and President Obama's goal to identify steps that HHS can take to improve the health and well-being of LGBT individuals and families.

This evaluation is anticipated to take at least 14 weeks to field, and field date is expected to be September 2013. The evaluation will span the duration of the demonstration with analysis and reporting to occur eight weeks after the end of the demonstration.

**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