

**Supporting Statement
(DIFO) Doing It For Ourselves Program**

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 wellbeing. 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 (HHS, 2012).

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" (HHS, 2012). 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 (Harvard School of Public Health, 2012). Yet despite these benefits, almost two-thirds of the women in the U.S. are of an unhealthy weight (Roger et al., 2011), 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 (Aaron et al., 2001; Boehmer, Bowen & Bauer, 2007). 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.

The Office on Women's Health (OWH) has contracted with five organizations across the United States to respond to the HHS objective of addressing healthy weight among lesbian and bisexual women. "Doing It For Ourselves" (DIFO), one of the five healthy weight projects, is a community-based collaboration of, by, and for LB women. It addresses barriers to health for the LB community, and promotes overall health and well-being by means of health-related and LB-relevant discussions, physical activities, and mindfulness activities. The specific purpose of the DIFO program is to improve overall health in LB women over 40 who are at risk for weight-related health problems. This section describes why our measurement tools are necessary for achieving our goals and addresses their psychometric qualities when that information is available.

Researchers around the world have advocated for local community-driven approaches to health problems that capture the needs and norms of specific subpopulations, and have been critical of applying generic "evidence-based" interventions to oppressed minority populations without considering the culturally specific needs of those groups (Minkler & Wallerstein, 2008; Sandoval et al., 2011). Therefore, the DIFO intervention has been developed from the ground up to address what we know about local LB women's community norms, common barriers to health, patterns of physical and mental health access, and preferences for health services and health outcomes.

This focus on a culturally specific subpopulation means that sometimes we need to develop new measures to address the specific experiences of the group. Very few mainstream assessment tools have been validated for use with LB women, and in the few studies that compare sexual minority and heterosexual populations, some significant differences have been found (e.g., Birnholz & Young, 2012).

Weight is a complex phenomenon for all individuals (Institute of Medicine [IOM], 2012), and cannot be addressed via generic individual-level interventions alone. In public health, a useful theoretical framework for addressing complex health problems is the social ecological model (Bronfenbrenner, 1999, 2005; Krieger, 2005, 2012). DIFO is based on an ecological model (Appendix A), a comprehensive review of the literature on sexual minority women's health, and community input. In public health applications of the ecological model, typically at least four levels of influence are included in the design of interventions: individual-, interpersonal-, community-, and broader societal-level influences.

The evaluation of the DIFO program will address the following research questions:

Primary Research Question:

- Does an intervention based on an ecological model of LB women's health result in improved health, as defined by:
 - quality of life,
 - decreased weight,
 - improved nutrition, and
 - increased physical activity?

Secondary Questions:

- What components of an ecologically-driven intervention are effective for different types of LB women?
- What demographic (age, race/ethnicity, income level) and LB-specific factors (age of coming out, partner status, gender expression, level of outness) predict success in the program?
- Do higher-level factors related to sexual minority stress such as internalized homophobia or experiences of discrimination affect success in the program?
- How does a mindful eating focus influence overall well-being and nutrition?

The cited law for this collection is Section 301 of the Public Health Service Act (42U.S.C.241). The primary outcome measures are individual behavior change measures, but in order to test our model and answer the secondary research questions, we must also assess other components of the ecological model that are featured in the intervention. In the discussion below, we include one section on individual-level measures; we then group interpersonal-, community-, and societal-level factors into a single section on higher-level influences.

Individual Level

At the individual level, several studies have identified higher rates of overweight and obesity and/or higher body mass indexes (BMI) among LB women than among the general population of women (Roberts, Dibble, Scanlon, Paul, & Davids, 1998; Case et al., 2004; Aaron & Hughes, 2007). Individual-level factors that influence weight in the general population include age, race/ethnicity, physical activity patterns, alcohol use, smoking, presence of health problems or disability, nutrition, and mindfulness related to nutrition (IOM, 2012). Therefore, we include questions about all of these factors on the baseline survey, mostly drawn from standardized health surveys.

Lesbian-specific factors that might influence weight include internalized negativity and stress related to sexual orientation, gender, or other stigmatized identities. We draw questions about lesbian identity from previous research studies. One potential factor that appears to underlie the health disparities among lesbians is internalized shame and guilt related to the stigma of minority sexual identification, often referred to as internalized homophobia. Thus, we include the only scale in the literature that has been used in more than one study and has strong psychometric properties, the ***Lesbian Internalized Homophobia Scale (LIHS)***.

The LIHS was developed by Szymanski and Chung (2001a) and consists of 52 items representing five dimensions: (a) Connection with the Lesbian Community (CLC); (b) Public Identification as a Lesbian (PIL); (c) Personal Feelings about being a Lesbian (PFL); (d) Moral and Religious Attitudes Toward Lesbianism (MRATL); and (e) Attitudes Toward Other Lesbians (ATOL). Each statement is rated on a seven-point Likert scale from "strongly disagree" to "strongly agree." The LIHS includes reverse-scored items to reduce response sets. Higher scores indicate more internalized homophobia. The five subscale scores have internal reliabilities (coefficient alpha) of .87, .92, .79, .74, and .77 (.94 for the total score). The inter-scale correlations ranged from .37 to .57. Content validity was supported by five expert raters and construct validity was supported by significant correlations between the LIHS subscales and measures of self-esteem, loneliness, depression, various social support, passing for straight, membership in a LGB group, and conflict concerning sexual orientation (Szymanski & Chung, 2001a; Szymanski, Chung, & Balsam, 2001). We plan to use the short form to keep the length of the survey administration time reasonable. The short form has 31 items and the same factor structure. Validity of the LIHS-Short form was supported by exploratory factor analysis and correlating the LIHS with measures of depression, self-esteem, and psychosexual adjustment. Reported alpha for scores on the LIHS- Short full scale was .93 (Piggot, 2004). This scale measures a critical concept that underlies, in part, the health disparities found among sexual minority women (along with external experiences of discrimination). Thus far, no studies have examined internalized homophobia as a factor in the greater weight of sexual minority women, although several authors hypothesize its importance in the development of both mental and physical health problems (Eliason, Dibble, DeJoseph, & Chinn, 2009; Meyer, 2003). Because our curriculum addresses minority stress, we expect to see a change in the scores from baseline to follow-up.

Another individual factor that could influence health and weight is mental health, specifically depression. Depression is an underlying factor in many physical health problems and a possible factor in whether women are successful in an intervention. We use a four-item version of the ***Center for Epidemiological Studies-Depression (CES-D; Radloff, 1977)*** to collect information

about depression-related factors. The CES-D is one of the few instruments to have been scrutinized for differential responding by sexual orientation. Birnholz and Young (2012) did find subtle differences in responding, but not on the four-item version that we choose to use, developed by Melchior and colleagues (1993). Women who are currently depressed may be less likely to fully engage in a health intervention, or alternatively, those with mild depression may show decreases in depression as a result of improved overall health. We include this measure on both the baseline and follow-up surveys.

We also assess the history of weight loss attempts, using the scale developed by Fogel, Young, Dietrich, and Blakemore (2012). Understanding the frequency and success of previous attempts will help us to tailor the intervention to LB women's lived experiences. We also include standard health history questions about presence of chronic health problems, disability, alcohol use, and smoking.

In addition, several studies now have identified that LB women are more likely to seek out alternative and complementary health services such as meditation (Smith et al., 2010; Matthews, Hughes, Osterman, & Kodl, 2005) and might be drawn to group interventions (Jessup & Dibble, 2012; McCabe, West, Hughes, & Boyd, 2012), suggesting a willingness to seek out group alternative interventions. We are developing a culturally-specific approach to mindfulness in our intervention, and will assess whether the program increases mindful eating via baseline and follow-up measures using a scale derived from the literature review on mindfulness, the **Mindfulness Eating Questionnaire** (Framson et al., 2009). This 28-item scale was generated from the research literature to measure the extent to which people are aware of their own eating habits and emotional responses to food. Exploratory factor analysis revealed five subscales: disinhibition, awareness, external cues, emotional response, and distraction. Each item is rated on a four-point scale, with higher scores signifying greater mindfulness. The overall scale has a Cronbach's alpha of .64, with subscale alphas ranging from .64 to .83. In the initial validation studies, greater mindfulness was associated with lower BMI, independent of sex, race, and education. The initial studies did not include sexual orientation measures, so we do not have data for LB women on this measure. Mindful eating is a relatively new concept and this is one of the few scales with empirical support for its reliability and validity. We need a measure to determine whether women increase their mindfulness around eating as a result of our intervention, and thus will include this measure on both baseline and follow-up surveys.

Primary Outcome Variables

The primary outcome variables for the study include quality of life, nutritional status, physical activity levels, and weight, and waist circumference to height ratio (WC/H). We selected quality of life as our primary outcome variable because studies of sexual minority women's definitions of health find them closely aligned with the concept of quality of life, such as wishing for more energy, vitality, and overall physical, emotional, social, and spiritual well-being (Fogel, Calman, & Magrini, 2012; Roberts, Stuart-Shor, & Oppenheimer, 2010).

Quality of Life

Quality of Life is assessed via the **Veteran's RAND-12 (VR-12) Health Survey** (Kazis et al., 1998). The VR-12, is a 12-item survey that measures quality of life, both in terms of physical and mental health. The VR-12 was developed from a longer version of the survey, the VR-36,

which has been in use since 1996, with almost 2 million surveys completed in a series of large Veteran’s Health Administration (VHA) studies. This survey covers eight domains:

- Physical functioning;
- Role limitations due to physical problems;
- Bodily pain;
- General health perceptions;
- Vitality;
- Social functioning;
- Role limitations due to emotional problems; and
- Mental health.

These eight domains yield two summary scores, a Physical Component Score (PCS) and a Mental Component Score (MCS). The VR-12 contains the 12 most crucial items from the VR-36—some from each of the eight domains. In addition, it includes two “change” items intended to measure changes in physical and emotional health over the last year. The VR-12 has been administered to over 400,000 respondents through VHA projects, to many Medicare recipients, and to patients in the managed care system (Kazis et al., 1998).

The VR-12 instrument is an excellent fit for the DIFO Campaign because one of the primary individual objectives of our study is to measure overall quality of life—both physical and psychological—and not just physical function or physical measures such as waist circumference and BMI.

We chose to include a quality of life measure as the primary outcome variable because of qualitative research showing that overweight sexual minority women define health in terms of energy, strength, and vitality, rather than weight or body mass indicators (Fogel, Calman, & Magrini, 2012; O’Hara & Gregg, 2012; Roberts et al., 2010); however, we also measure nutrition, weight, WC/H, and physical activity, as they are standard methods of assessing outcome of weight-related health interventions.

Nutrition

We chose to measure improvements in nutrition via assessing the consumption of fruits and vegetables and sugar-sweetened beverages. These items were drawn from the Behavioral Risk Factors Surveillance Survey (BRFSS, 2011 version). They have been widely used in population studies for many years. Only a few states include sexual orientation questions on their BRFSS administration, so there is not yet data available for LB women.

Physical Activity

One of our secondary individual objectives of the “Doing It For Ourselves” (DIFO) campaign is to increase minutes of physical activity among our participants. The ***International Physical Activity Questionnaire*** (Booth, 2000) or IPAQ, is a measure of physical activity that has been extensively validated, used in over a dozen different countries, and has served as the basis for well over 100 peer-reviewed journal articles. This instrument is designed for a diverse audience, which is important to our study of LB women—in general an extremely understudied minority

population. In addition, the IPAQ measures both vigorous and moderate exercise and thus is well suited to participants who might not be particularly physically active, which may be the case for many in our target population of 40-and-over LB women with a BMI of 27 or above. The IPAQ also asks participants to reflect on their level of physical activity for the previous week only, which reduces the likelihood of recall bias. For all of these reasons, the IPAQ very well suits the purposes of the DIFO project.

Weight

Because the focus of the funded projects is healthy weight in LB women, another indicator we will measure is weight. Participants who enroll into the intervention will be asked for their self-reported weight and height. Investigators will calculate each woman's body mass index (BMI) to determine if she meets the program's eligibility criteria (BMI of 27 or greater). Weight will be taken at baseline and again post-intervention, when individuals will again be asked for their self-reported weight.

Waist Circumference to Height Ratio

Because weight alone (and even BMI) tells only part of the story about why someone may be at risk for weight-related health problems, we will also collect data on each program participant's waist circumference (WC), in order to compute a WC-to-height ratio. WC has recently been shown to be a more accurate predictor of health problems because it is an indicator of where on the body an individual carries extra weight (Ashwell, Cole, & Dixon, 1996; Wang et al., 2003). Waist circumference and the ratio of waist circumference to height have been proposed as better indicators of the need for management of weight than the classic BMI, and there is increasing understanding that body fat distribution may be more important than weight per se as it relates to health. Specifically, individuals with higher central adiposity (i.e., abdominal fat) have been shown to have greater health risks than those who simply have higher BMI. As Wang et al. (2003) states, "in a guide about obesity treatment recently published by the National Institutes of Health (NIH), WC and BMI were suggested as the most available and reliable means of identifying obesity, establishing the risks related to it, and monitoring its treatment." Waist circumference is measured commonly using one of four sites on the body: immediately below the lowest ribs (WC1), the narrowest waist (WC2), the midpoint between the lowest rib and the iliac crest (WC3), and immediately above the iliac crest (WC4). The Wang (2003) study found that the most reliable measurement is below the lowest rib. For the DIFO program, we plan to have personal health coaches (a personal trainer and a physical therapist trained in WC measurement) measure each participant's WC for the baseline assessment. The health coach will demonstrate to participants how to measure WC for themselves so that we can rely on self-report for the follow-up measurement.

Higher-Level Influences

At the interpersonal level, factors related to weight include one's significant other's health and lifestyle, social network health and lifestyle behaviors, social support, and level of "outness." These variables may impact both support around sexuality and potential stresses from family of origin, coworkers, and others. The "outness" scale has been used in several recent studies (Eliason, DeJoseph, Dibble, Deevey, & Chinn, 2011; Eliason & Schope, 2001; Eliason, Dibble, & Robertson, 2011; Meyer, 2006), and social support network questions designed specifically for this study assess the respondent's satisfaction with community and significant other support.

Community and partner support has been found to predict better mental health and well-being in a number of studies (e.g., Szymanski & Chung, 2001b).

At the community level, subpopulation community norms impact lifestyle behaviors. Lesbian and bisexual women's communities have been influenced by feminist critiques of body expectations for women, tend to critique femininity, and are more invested in fat-positive movements (Bowen, Balsam, & Ender, 2008; Yost & Chmielewski, 2011). These issues are part of our intervention, but we do not have corresponding questions on the surveys. Instead, focus groups during the first session will evaluate the role of LB community norms on women's current conceptions of health and well-being through open-ended questions about the influence of community on individual lesbian/bisexual women's health.

Finally, stress for lesbian/bisexual women stems from the societal stigmas of sexism and heterosexism. These conditions create minority stress (Meyer, 2003), and can manifest in the individual as internalized homophobia (already described as an individual-level factor) and experiences of discrimination. At the level of discrimination, we use the ***Everyday Discrimination Scale*** (Meyer, 2006). This scale was modified from an eight-item questionnaire developed by Williams, Yu, Jackson, and Anderson (1997) based on their qualitative research with African Americans, and was validated by Krieger, Smith, Naishadham, Hartman, and Barbeau (2005). The scale is designed to measure chronic, routine, and less overt experiences of unfair treatment, and was adapted by Meyer to apply to all minority groups. Each experience is rated on a four-point scale from often (1) to never (4). Respondents are then asked whether the experiences were related to sexual orientation, gender, ethnicity, race, age, religion, physical appearance, income level, or some other form of discrimination. We have modified this section to reduce the overall number of questions by not linking the social identities to each of the eight separate items. Cronbach's alpha for the scale has been reported at .83 or higher across several studies (Krieger, et al., 2005). This scale measures the second component of minority stress (the first is internalized homophobia) that may be the greatest predictor of mental and physical health disparities among sexual minority women (Kelleher, 2009; Lehavot & Simoni, 2011; Meyer, 2003). This scale will be administered only at baseline, as the intervention would not be expected to affect the experiences of discrimination that participants might have outside the program.

2. Purpose and Use of Information Collection

The information collected from this intervention will allow the DIFO team to assess the effectiveness of the DIFO program in terms of achieving the following individual and community SMART (Specific, Measurable, Appropriate, Realistic, and Time-specific) objectives:

For individual participants:

Primary objective:

1. Increase health-related quality of life by 10% by the end of the three-month intervention, as measured by score on VR 12 Scale, for at least 75% of participants.

Secondary objectives:

1. Increase number of minutes of physical activity/movement by 20% by the end of the three-month intervention for at least 75% of participants.
2. Increase the proportion of fruit and vegetable consumption by at least 10% by the end of the three-month intervention for at least 80% of participants.
3. Reduce waist circumference to height ratio by 5% for at least 75% of participants by the end of the three-month intervention.
4. Decrease weight by 5% of body weight by the end of the three-month intervention for at least 80% of participants.

For the San Francisco Bay Area LGBT Community:

1. Develop a package of web-based tools and materials that can be used by lesbians in more remote areas without access to LB community resources (disseminated via the Lesbian Health and Resource Center of UCSF and Lavenderhealth.org.)
2. Increase the number of community recreation resources in San Francisco and Santa Rosa that are inclusive of sexual minority women, measured by number of individuals who complete an online training and apply for a Safe Zone sticker.

This study aims to pilot and test a culturally-specific health intervention for an underserved population. If successful, it represents a cost-effective, community-driven health program that could be applied more broadly to lesbian/bisexual women's communities, thought to represent conservatively 4% of the U.S. female population (Gates, 2012). In addition to allowing us to assess the accomplishment of the seven SMART objectives listed above, the data will be used to address the primary research question and four secondary research questions listed in Section 1 above.

The results of the evaluation will provide valuable data to inform future health interventions designed for LB women. If this analysis is not performed, it will not be possible to establish the effectiveness of the program, and many LB women could potentially miss out on an evidence-based practice for delivering LB-specific services to significantly improve their health and well-being. This is particularly noteworthy because not only are 3-5% of women estimated to be lesbian/bisexual, but evidence suggests that they are more likely to be overweight (Cochran et al., 2001; Struble, Lindley, Montgomery, Hardin, & Burcin, 2010) than other women. Research also shows that a major barrier for LB women is that they are likely to find existing weight loss programs unfriendly towards lesbian women (Fogel, Young, et al., 2012). The information gained from the collection of data for this study will inform LB-specific health programming throughout the San Francisco Bay Area (including the ability to compare effectiveness between urban and rural/suburban settings, and between peer-led and clinician-led support groups), and may yield findings generalizable to other parts of the nation. Findings will be disseminated

nationally, and the evaluation report will be drafted for publication in peer-reviewed health journals.

3. Use of Improved Information Technology and Burden Reduction

We have two primary strategies to reduce burden to respondents:

- We will do our utmost to comply with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII. In all cases, the number of survey questions will be held to the minimum required for the intended use of the data.
- In addition, we will encourage respondents to complete surveys online to minimize burden to them and to maximize the efficiency of the research process.

However, some percentage of our participants may not be able to complete surveys online. Our target population includes low-income women who might not have personal computers, as well as older women who may not be computer literate and/or may be more comfortable with paper surveys. To reduce burden and broaden the options for such potential participants, we will:

- Provide paper and pencil versions of the surveys as needed so that respondents can complete them at the intervention site and/or fill them out and mail them to us; and
- Provide computers at the intervention site where participants who may not have computers at home can complete their surveys.

4. Efforts to Identify Duplication and Use of Similar Information

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

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

The Doing It For Ourselves program provides an historic and unique opportunity to collect data about the health of lesbian and bisexual women as it relates to weight-related health issues, and to craft and evaluate the effectiveness of an intervention that is specifically tailored to this population. There is currently very little detailed data about this population, particularly about health-related interventions geared towards sexual minority women. All data collection involved in this project is designed to fill in these gaps in the literature, to enhance our understanding of program outcomes, and to provide insights regarding the issues and preferences of various subgroups (women of color, bisexuals, and so on) within the community of sexual minority women. At the same time, we recognize the importance of minimizing burden on participants. As shown in Table 1, our participants will complete:

- One baseline survey at program start before groups are randomized to treatment and control conditions;
- One survey at month 4 (for “immediate start” treatment group, survey will be taken immediately after the 3 month program is complete; for control or “delayed treatment” group, another survey will be administered at month 4 to establish comparability between groups);
- One follow-up survey at month 8 for “immediate start” group and a post program survey for “delayed start” group; and
- A 3 month follow up survey at month 10 *only* for “delayed start” group (roughly half of all participants).

Table 1. Timetable for Data Collection

Time in Study	Month 0	Months 1–3	Month 4	Months 5-7	Month 8	Month 10
Sequence 1: “Immediate Start” Group	Baseline survey	Intervention	Post-program survey		3 month follow-up survey	
Sequence 2: “Delayed Start” Group/control	Baseline survey	No Intervention	End-of-Sequence 1 survey	Intervention	Post-program survey	3 month follow-up survey

Participants will also participate in one end-of-program focus group—a discussion designed for participants to provide feedback on the program and how it could be improved. This focus group will take place during the last group session of the 3 month program.

If data are collected less frequently, investigators will not be able to understand changes in women’s lives due to program effects (information provided by surveys). In addition, if the end-of-program focus groups are not conducted, researchers will not have the information necessary to: 1) understand program implementation and processes, enabling program providers to make modifications and improvements along the way to better serve the needs of participants; and 2) understand the transferability and adaptability of approaches to other LBGTT communities throughout the country.

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 message-testing activities fully comply 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 published in the Federal Register on March 28, 2013, VOL.# 78,, Pg. 18982.

No comments were received.

Doing It For Ourselves is also consulting with outside experts in the health of lesbian and bisexual women. The project has established a seven-member advisory committee representing a range of different types of expertise such as research methods, community-based services with lesbian and bisexual women, connection to specific racial/ethnic or sexual identity subpopulations, and lesbian health care in general. All members have deep connections to the LB community and work or have worked in health care communities. This committee will meet quarterly and will provide feedback on our focus group protocol, literature review, intervention, and evaluation. Advisory committee members include the following:

Name	Position/Community
Diane Sabin	Director, Lesbian Health and Research Center, University of California San Francisco
Patty Robertson, Michelle Alcedo	OB/Gyn physician; lesbian health expert at UCSF Open House (San Francisco organization devoted to older LGBT individuals)
Jeanne DeJoseph	Retired, Department of Family Health Care Nursing, UCSF; resident of Oakmont, Santa Rosa
Migdalia Reyes	Faculty member in Social Work at San Jose State University; deep connections with Latina lesbian communities
Sue Dibble	Retired, Institute of Health and Aging, UCSF; resident of Oakmont
Gloria Soliz	Co-Founder and facilitator of The Last Drag, an LGBT-specific smoking cessation program. Has worked with both Lyon Martin and LGBT Community Center.

9. Explanation of any Payment/Gift to Respondents

Participants in the “DIFO” intervention and research study will receive a \$25 gift card for completion of each survey they complete. Approximately half of the participants will complete three surveys and the other half will complete four surveys (see Table 1 above). Therefore, approximately half of the women will receive a total of \$75 over the course of the study and the other half will receive \$100 in gift cards. We believe this gift is essential in order to achieve a satisfactory response rate, yet not large enough to constitute a threat to participant autonomy or to unduly exploit vulnerable populations. It is unlikely that the relatively small payments (of \$25 or \$50) will influence participants’ decision to engage in a 12-week program (London, Borasky, & Bhan, 2012). After the program, and only upon completion of the post-program surveys, participants will receive the additional gift cards. These “promised incentives” will reward individuals for participating and ensure that investigators gather the critical data needed for the study (CDC, 2010).

10. Assurance of Confidentiality Provided to Respondents

We will collect limited personal information (name, phone number and/or email, and possibly mailing address if paper surveys are requested) to contact participants and send them resources and surveys as needed. Surveys will ask for respondents' names so that individual data can be tracked to assess changes in health behaviors. However, names will be converted to unique identification numbers, and names will never be reported or used in data analysis or reports. All data will also be reported in the aggregate so that no individuals can be identified. Respondents will be advised of the nature of the activity, the length of time it will require, and that participation is purely voluntary. Respondents will be assured that no penalties will occur if they choose not to respond to the information collection as a whole or to any specific questions. Data will be kept in secure Berkeley Policy Associates (BPA) facilities; paper or hard copies of surveys and other documents containing data and respondent information will be kept in a locked file cabinet. Electronic data will be housed as encrypted files on a password-protected computer. These materials will be stored at BPA in Oakland, California for a period of three years after the completion of the study.

The DIFO project is currently in the process of obtaining IRB approval from San Francisco State University.

11. Justification for Sensitive Questions

Most of the questions on the data collection instruments were drawn from standardized health surveys or past research projects conducted by the principal investigator, and they did not pose any risk to participants in those studies. However, we will ask some questions that might be considered sensitive on our surveys in order to evaluate changes in health-related behavior and to understand for which subgroups of participants the intervention is most effective. Our informed consent procedure emphasizes the voluntary nature of their participation in the survey and any of its components. Participants are informed that they can choose not to answer any individual questions and may stop participating at any time. To avoid fear of disclosure of sensitive information, participants will be told that all data provided by participants will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

In this section we list potentially sensitive questions and our justification for including them.

Race/ethnicity:

Questions 2-3 (see Appendix B1) of our baseline survey ask about race and ethnicity. It is important to know the racial/ethnic composition of our respondents for two reasons: 1) there are differences in cultural norms about weight and body ideals based on race/ethnicity (Wilson, Okwu, & Mills, 2011) that must be addressed in any intervention; and 2) we plan to conduct subgroup analyses to determine not only whether the DIFO program is effective, but for which types of women it is most effective.

Income:

Questions 6-7 (Appendix B1) ask for the respondents' income and how many people rely on that income. These are based on the Current Population Survey, a joint effort between the U.S. Census Bureau and the Bureau of Labor Statistics. Income level is a standard demographic question used in social science research (e.g., U.S. Census) and will be used in subgroup

analyses to determine whether DIFO program effectiveness varies by income level of the participant.

Sexual/gender identity:

Three questions (15-17) on the survey (Appendix B1) ask about how the participant identifies herself in terms of her sexual orientation and gender identity. Questions 15-16 come from the Centers for Disease Control and Prevention (CDC) and the National Health Interview Survey (HHS, 2013). Question 17 has been used by the principal investigator in previous unpublished studies. It is important to understand how participants define themselves because the DIFO intervention has been developed with a focus on a culturally specific subpopulation (LB women). Very few mainstream assessment tools have been validated for use with LB women, and in the few studies that compare sexual minority and heterosexual populations, some significant differences have been found (e.g., Birnholz & Young, 2012).

Age of coming out/ "Outness":

Questions 18-24 (Appendix B1) ask the participant when she came out as a sexual minority woman, and how out she is to a variety of key social networks. These questions are included because social support and level of "outness" may impact physical and mental health, specifically the health behaviors and weight of an individual. Health is influenced by potential stresses from family of origin, coworkers, and others. The "outness" scale has been used in several recent studies (Eliason, DeJoseph et al., 2011; Eliason & Schope, 2001; Eliason, Dibble, & Robertson, 2011), and social support network questions assess the respondent's satisfaction with community and significant other support.

Internalized homophobia:

Questions 25-63 (Appendix B1) are taken from the Lesbian Internalized Homophobia Scale (LIHS) developed by Szymanski and Chung (2001a). Lesbian-specific factors that might influence weight include internalized negativity and stress related to sexual orientation, gender, or other stigmatized identities. One potential factor in the health disparities among lesbians is internalized shame and guilt related to the stigma of minority sexual identification, often referred to as internalized homophobia. Thus, we include the only scale in the literature that has been used in more than one study and has considerably strong psychometric properties. We plan to use the short form to keep the length of the survey administration time reasonable. The short form has 31 items and the same factor structure as the long form. Validity of the LIHS-Short form was supported by exploratory factor analysis and correlating the LIHS with measures of depression, self-esteem, and psychosexual adjustment.

The LIHS measures a critical concept that underlies, in part, the health disparities found among sexual minority women (along with external experiences of discrimination). Thus far, no studies have examined internalized homophobia as a factor in the greater weight of sexual minority women, although several authors hypothesize its importance in the development of both mental and physical health problems (Eliason et al., 2009; Meyer, 2003). Because our curriculum addresses minority stress, we expect to see a change in the LIHS scores from baseline to follow-up survey.

Minority stress:

Questions 70-85 (Appendix B1) ask about life stressors influenced by minority status. Stress for lesbian/bisexual women stems from the societal stigmas of sexism and heterosexism. These conditions create stress in daily living, referred to as “minority stress” (Meyer, 2003), and can manifest in the individual as experiences of discrimination. Our survey questions are pulled from the ***Everyday Discrimination Scale*** (Meyer, 2006). The scale is designed to measure chronic, routine, and less overt experiences of unfair treatment, and was adapted by Meyer from a focus on African American populations to apply to all minority groups. Each experience is rated on a four- point scale from often (1) to never (4). Respondents are then asked whether the experiences were related to sexual orientation, gender, ethnicity, race, age, religion, physical appearance, income level, or some other form of discrimination. We have modified this section to reduce the overall number of questions by not linking the social identities to each of the eight separate items. This scale measures the second component of minority stress (the first is internalized homophobia) that may be the greatest predictor of mental and physical health disparities among sexual minority women (Kelleher, 2009; Lehavot & Simoni, 2011; Meyer, 2003). This scale will be administered only at baseline, as the intervention would not be expected to affect the experiences of discrimination that participants might have outside the program.

History of weight loss:

Questions 103-118 (Appendix B1) ask respondents if they have ever attempted to lose weight in the past and, if so, what strategies they have tried. We assess the history of weight loss attempts using the scale developed by Fogel, Young, and colleagues (2012). Understanding the frequency and success of previous attempts will help us to tailor the intervention to lesbian/bisexual women's lived experiences. We also include other standard health history questions about presence of chronic health problems, disability, alcohol use, and smoking.

Alcohol use questions:

Questions 128-131 (Appendix B1) ask respondents about the frequency with which they drink alcohol, as well as the amount of alcohol they drink. Alcohol consumption, which is linked to health problems, is more prevalent among LB women than the general population (Drabble, Trocki, & Midanik, 2005); and the DIFO intervention will address alcohol use during program sessions. The survey questions are taken from the National Institute on Alcohol Abuse and Alcoholism and previous studies (Eliason, Dibble, Gordon & Soliz, 2012). Since lowering alcohol consumption can be an important step toward healthy lifestyles, our investigators will assess alcohol use in the baseline and follow-up surveys.

Tobacco use questions:

Smoking prevalence in the LGBT population has been reported up to twice that of the heterosexual population (Diamant et al., 2000; Valanis et al., 2000; Lee, Griffin, & Melvin, 2009; Pizacani et al., 2009; McElroy, Everett, & Zaniletti, 2011). Smoking has been linked to an increase in individuals' body fat distribution, weight, and risk of metabolic syndrome (Chiolero, Faeh, Paccaud, & Cornuz, 2008). Some studies have shown that smoking, and particularly heavy smoking, may be related to weight gain, contrary to the population opinion (Colditz et al. 1992). Questions 125-127 (Appendix B1) will ask about smoking habits and smoking status, and are recommended by the Centers for Disease Control and Prevention.

Mental health questions:

Another area of strong positive correlation is depression and unhealthy weight in the general population of women (Onyike, Crum, Lee, Lyketsos, & Eaton, 2003). In a population-based study of sisters, with one being lesbian or bisexual, the bisexual sister experienced higher prevalence of depression than her heterosexual sister (Rothblum & Factor, 2001). LB women also tend to have a greater prevalence of generalized anxiety disorder than heterosexual women (Cochran, Mays, & Sullivan, 2003), and show higher rates of depression compared to gay men (Cochran & Mays, 2009). Questions 121-124 (in Appendix B1) are taken from an established short form depression scale, the Center for Epidemiology Studies Depression Scale (CES-D). Depressive symptoms score will be included to characterize our population and as a potential factor in explaining program outcomes.

Disability questions:

As noted in the U.S. Department of Health and Human Services' *Assessing the Need for a National Disability Survey: Final Report* (Livermore, Whalen, & Stapleton, 2011), there is a lack of valid standardized questions used to assess disability status. As a result, we created two questions (Questions 119-120 in Appendix B1) to capture disability status by using the Americans with Disability Act regulations' (29 C.F.R. 1630.2(i).) definition. Self-reported disability status (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 to determine if disability status changes from baseline to follow-up.

Although the items described above can be considered sensitive, these specific questions have been used in past studies and deemed valid, fair, and appropriate for the purpose of a health study. Based on prior research, we do not expect that asking such questions will result in significant refusal rates.¹

In addition to the baseline, post-program, and follow-up surveys, focus group protocols (Appendix B3) will be used for data collection. While the focus group questions do not include items that are inherently sensitive, discussions may elicit comments or follow-up questions that involve sensitive topics. Individuals may share personal stories or anecdotes considered to be sensitive by others in the group.

To avoid negative reactions to sensitive 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.
- Survey respondents will be provided with a specific phone number and contact they can call in case they have a question or concern about the sensitive issue.
- Focus group moderators will be trained to ask questions in a sensitive manner and to handle any subsequent discussion skillfully.
- Respondents will be told that all data they provide will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

12. Estimates of Annualized Hour and Cost Burden

¹ For information about all survey items and their sources, see Appendix D.

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

Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Screening Tool	180	1	5/60	15
Baseline Survey	168	1	30/60	84
Follow-Up Survey	224	1	30/60	112
End-of-Program Focus Group	112	1	1	112
Total				323

12B. No costs on behalf of the respondents are required except for the time it takes to complete the surveys and participate in the focus group.

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

None.

14. Annualized Cost to Federal Government

The annualized cost to the federal government for the DIFO program is \$21,600.

This is calculated as one fifth of the sum of: .5 FTE of our OWH program officer and .5 FTE of another OWH staff member (total of \$108,000). \$108,000 divided by 5 funded projects = \$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 this intervention will be published as part of four reports; three will be suitable for peer-reviewed journal publication. The first report is associated with the participatory design phase of the project, the second report is a collaboratively written literature review (written with other OWH funded projects), the third report is associated with the intervention itself, and the final report is associated with the evaluation component of the intervention. Data collection described in this application pertain to Reports #3 and #4:

- Report #3: The Doing It For Ourselves (DIFO) intervention will begin between August and December 2013 (depending on when OMB approval is received). There

- are multiple cohorts involved in the intervention: three in San Francisco and one in Santa Rosa. While the intervention is underway, the team will prepare a detailed description of the rationale, methods, and materials used in the intervention, suitable for publication in a peer-reviewed health journal. Report #1 will be submitted to OWH and the Advisory Committee for review on August 31, 2013, and will be revised and ready for publication by September 30, 2013.
- Report #4: Data collection for the evaluation report will begin with the intervention itself. Assuming the intervention begins in September 2013, it will end by July 31, 2014 (10 months after the start date with the three-month follow-up survey for the final treatment group). The BPA team will prepare a detailed evaluation report summarizing the evaluation design, analysis, and findings in a format suitable for publication in a peer-reviewed health journal. Report #4 will be submitted to OWH and the Advisory Committee for review by August 31, 2014, and will be revised and ready for publication within 30 days of receiving feedback from OWH.

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.