

## **B. Collection of Information Employing Statistical Methods**

Please see Form 83-I attached in Appendix F.

### **1. Respondent Universe and Sampling Methods**

Data collection will target a particular demographic, defined as women who:

- Are over the age of 40 years old;
- Self-identify as lesbian or bisexual; and
- Are at risk for obesity-related health problems (body mass index is 27 or greater).

Data will be collected from the respondent universe of women who participate in the intervention program (N=128) and from an equal number of comparison group members (women from a similar target population but who will not participate in program, N=128).

For the participants, women will be recruited through various methods and will participate in the intervention program being evaluated. Recruitment methods will include the following contacts and resources:

- LezDyke listserv
- Night OWL News
- The Last Drag (a State of California funded LGBT-specific smoking cessation intervention in San Francisco, originally funded by the Centers for Disease Control)
- Open House (housing services for LGBT seniors)
- Older Lesbians Organizing for Change (OLOC)
- Equality California's LGBT health coalition
- LB-friendly churches
- Lyon Martin Health Services
- Local lesbian physicians to conduct broad outreach throughout San Francisco

In addition, we will recruit using fliers and postings at the SF LGBT Community Center and other community organizations, and through word of mouth and snowball methods. Women will also be recruited from the Oakmont Rainbow Women, a lesbian group in a retirement community in Santa Rosa, California, two hours north of San Francisco. Comparison group members will come from the same target population (women over age 40 who self-identify as lesbian or bisexual and have a BMI of 27 or greater).

Women who express interest will be directed to an information and recruitment website, where they will complete a recruitment screening form (Appendix C). After a woman completes the form, a DIFO researcher will contact her and place her in either the program or a comparison group.

Comparison group members will be recruited using multiple methods:

- During the screening process (see recruitment screener, Appendix C) to determine if women are eligible for the program, they will review the program description and decide if they want to participate. Women will be enrolled in the program on a first-come, first served-basis. If the number of women choosing to participate exceeds

program capacity, women who do not get into the program will be invited to be part of the comparison group, for which they will be asked to complete two surveys and receive a \$25 gift card for each survey administration. In addition, women may want to participate and meet eligibility criteria, but may not be able to participate for a variety of reasons (e.g., schedule conflicts). They will also be considered for the comparison group.

- Using the “name a friend” approach, we will ask participants to nominate a close friend for the comparison group who meets the study criteria and has similar characteristics, such as socioeconomic status or environment. This approach is used for identifying comparison groups because close friends often share factors that can cause confounding, but are hard to measure and adjust for.

It is preferable to survey the entire universe of women being served by this intervention program because this universe is of sufficient size to measure key indicators described above (Part A). The objectives stated as individual indicators call for 75-80% of women in the intervention group to achieve the specified targets. For example, the first SMART objective stated above:

- Increase the number of minutes of physical activity/movement by 20% by nine-month follow-up for at least 75% of DIFO participants.

The sample size needed to test the hypothesis that women in the intervention group will be more successful than the comparison group depends on our assumptions about how many women are likely to achieve those outcomes in the absence of the intervention. Power analysis shows that if only 60% of the treatment group achieves the desired outcome compared to 40% of the comparison group, a sample size of 107 would be sufficient to test the hypothesis (at power=0.80, two-sided alpha at 0.05). In fact, we would expect the difference between groups to be greater than a 60% to 40% distribution, so even with some attrition in the sample between baseline and nine-month follow-up, we are confident that the study will be able to detect significant differences between the two groups. Using this analysis as guidance, we designed the DIFO program to serve 128 participants. Therefore, we plan to collect data from all participants (i.e., the universe) rather than sampling from within that universe.

## **2. Procedures for the Collection of Information**

The following types of information will be collected as part of this evaluation:

- Baseline and follow-up program surveys;
- Waist circumference and height measures; and
- End-of-program focus group.

### *Participant and Comparison groups:*

The **baseline survey** (Appendices B.1 and B.2) will be administered in multiple ways in order to make survey completion most convenient for the respondent and to maximize response rate. The primary method of administration will be online (via SurveyMonkey, a user-friendly and commonly used platform for electronic surveys). First, the informed consent form (Appendix E) will be emailed to respondents and they will be asked for an electronic signature, ensuring they

agree to the parameters of the research study.<sup>1</sup> A link will then be emailed to respondents one week before the intervention begins so they can complete the survey online ahead of time. Participants who have not completed and submitted the survey before the start of the program will be asked to come in 30 minutes before the first session begins to complete the survey at the intervention site. Computers will be made available for respondents at the sites, and paper surveys will be available for those who prefer to complete the surveys on paper by hand. The survey will be emailed to comparison group members with an option for a paper survey to be mailed to them if preferred.

The **follow-up survey** (Appendices B. 3 and B.4) will be administered nine months after the intervention has begun. One week before the nine-month mark, investigators will email a link to a SurveyMonkey survey (much like the baseline survey). Respondents will also have an opportunity to take the survey during an administration session at their site (SF LGBT Community Center or Oakmont in Santa Rosa), where both online and hard copy surveys will be available. Participants and comparison group members will also have the option of having a paper survey mailed to them.

#### *Participant group only:*

One of the most accurate and innovative ways to measure weight change related to health factors is to assess **waist circumference (WC)-to-height ratio** (Wang et al., 2003). At the beginning of the health program, each participant will meet one-on-one with a health coach (e.g., physical therapist, personal trainer). The coach will work with the participant to develop personalized health (nutrition, exercise) goals. During the first meeting, the trained coaches will measure each participant's waist (using measuring tape) and gather their height (self-reported) in order to compute a ratio. At this time, the coaches will train each participant how to accurately measure their WC. Measuring tape will be provided to each participant. Each coach will be trained to take the same type of measurement by wrapping the tape measure around the waist at the narrowest part, just below the rib cage. At the nine-month follow-up, participants will be asked to measure their own WC, as they were trained to do so by their coach during the baseline data collection. During the last session of the 12-week program, a **focus group** (Appendix B.5) will be conducted to gather feedback about how well the program worked, what could be improved, what aspects participants found most helpful, what was missing, and so on. The focus group will be moderated by the facilitator who runs the groups each week, and will be audio recorded with the permission of the participants.

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

Several procedures proven effective in previous studies will be used to maximize response rates:

- Potential respondents will be informed about the importance of this study and encouraged to participate through a variety of methods. Investigators will motivate survey completion by presenting each participant and comparison group member with information explaining the importance of this innovative and historic program, which could contribute to the health of women like them in their community.
- Survey respondents will each receive a \$25 gift card for completing the baseline

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<sup>1</sup> The DIFO investigators are currently undergoing IRB review with San Francisco State University and seeking approval to use electronic consent for individuals who participate in the research study.

program survey and a \$25 gift card for completing the follow-up program survey. Gift cards can be emailed or mailed to respondents; they can also be provided in person if surveys are completed by hand at one of the program sites.

- We will offer online and paper health resources to the comparison group members (as well as the \$25 gift cards for each survey completion), and enter both participants and comparison group members in raffles, with chances to win prizes such as gym discounts and health/nutrition books.

It will be challenging to ensure a high response rate for the nine-month follow-up survey. In order to maximize survey completion, investigators will contact (first by email, then by telephone) all participants and comparison group members at three-month intervals to ensure that our team has current and accurate contact information, and that participants/comparison group members plan to complete the follow-up survey at the nine-month mark. Once surveys are emailed to respondents, a reminder email will be sent if surveys are not returned within a week. If there is no response within one week, the potential respondent will be reminded by phone. In addition, a follow-up email will be sent explaining the importance of the survey and reminding potential respondents that they will receive a gift card for survey completion and will be entered into a raffle to win prizes (e.g., gym discounts, health/nutrition books).

#### **4. Tests of Procedures or Methods to be Undertaken**

The baseline and follow-up surveys will be administered to a small pilot group of nine women to determine face validity, assess how long it takes participants to complete surveys, and determine whether items are clear and understandable and item ordering is appropriate. The women who pilot the instrument will be friends and acquaintances of the investigators who are part of the target population (over age 40, lesbian/bisexual, overweight or obese).

We expect only very minor changes will be made to the survey after this small pilot.

Portions of the surveys have been used, in part or as a whole, in previous studies. Survey items were pulled from:

- CDC's Behavioral Risk Factor Surveillance System (BRFSS)
- Center for Epidemiological Studies-Depression (CES-D) scale (Radloff, 1977)
- History of weight loss attempts (derived from Fogel, Young et al., 2012)
- International Physical Activity Questionnaires (IPAQ)
- Lesbian Internalized Homophobia Scale (LIHS) (from Syzmanski & Chung, 2001)
- Mindful Eating (Framson et al., 2009)
- Minority Stress/Everyday Discrimination Scale (Meyer, 2006)
- National Health Interview Survey (NHIS)
- Veterans RAND 12 Item Health Survey (VR-12)

#### **Data Analysis**

Guided by the SMART objectives outlined in Section 2 above, quantitative analysis will include descriptive analysis of outcomes, comparison between intervention and comparison groups using a difference-in-differences estimation analysis, and multivariate regression analysis controlling

for individual characteristics including age, race, ethnicity, education, immigration status, income, employment, and insurance status. Subgroup analysis will be used to explore outcomes for groups of women with different characteristics and health statuses at baseline, and to examine relationships between outcomes and intervention sites, cohorts, or “dosage” (as documented by attendance and Session Activity logs). NVivo software will be used to facilitate the qualitative analysis, including coding the data collected from focus groups.

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**Appendices:**

**Appendix A. Ecological Model**

**Appendix B. Evaluation Tools**

***B.1 Baseline Program Survey***

***B. 2 Baseline Comparison Survey***

***B.3 Follow-Up Program Survey***

***B. 4 Follow-Up Comparison Survey***

***B. 5 End-of-program Focus Group***

**Appendix C. Recruitment Screener**

**Appendix D. Survey Items and Sources**

**Appendix E. Informed Consent Form**

**Appendix F. OMB Form 83**