

Supporting Statement for Paperwork Reduction Submission:
Out Proud and Healthy Fitness Project

A.1. Circumstances Requiring the Collection of Data

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". 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. Yet despite these benefits, almost two-thirds of the women in the U.S. are of an unhealthy weight, 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. 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.

To respond to this health care issue in older LB women (and lack of related information), OWH is requesting approval for a new data collection on the effects of a randomized prevention study that promotes healthy weight in lesbian and bisexual (LB) women through group support programs and community approaches tailored to sexual minority women for its contractor NORC at the University of Chicago (NORC) and the University of Missouri – Columbia (MU). The pilot interventions proposed by NORC and MU are culturally relevant to lesbian and bisexual women through having support groups for social support, addressing stress and its role in lifestyle choices, and providing a safe and welcoming environment for creating change. One intervention involves offering evidence-based personalized exercise routines with a focus on becoming healthier, a gym membership to eliminate any access barrier, and encouraging acceptable alternatives to unhealthy food and drink choices. Another intervention involves providing a cost-effective tool, a smart pedometer, which has been designed to motivate users to increase physical activity through several strategies. The final intervention group will receive health-education classes. To measure the effects of the intervention, the intervention groups will be followed over time, with an initial baseline assessment and a 4 and 12 month follow-up assessment (See Appendix A: Survey Instruments). A study assessing improved weight and

fitness to this extent has not been conducted before among LB women. This demonstration project will help add to the literature on health, weight, and fitness among LB women specifically. The cited law for this collection is Section 301 of the Public Health Service Act (42U.S.C.241).

A.2. Purposes and Uses of the Data

Secretary of Health and Human Services Kathleen Sebelius established the Department-wide LGBT Issues Coordinating Committee co-chaired by Assistant Secretary of Health and Human Services Dr. Howard Koh, Assistant Secretary for Aging Kathy Greenlee, and Deputy General Counsel Ken Choe to improve the health and well-being of lesbian, gay, bisexual, and transgender (“LGBT”) individuals and families. As part of this initiative, the Office of Women’s Health (OWH) contracted with NORC and its subcontractor, the University of Missouri – Columbia (MU), to develop and pilot test interventions that promote healthy weight in lesbian and bisexual (LB) women through group support programs and community approaches tailored to sexual minority women as part of the contract, “Healthy Weight in Lesbian and Bisexual Women: Striving for a Healthy Community.” NORC and MU have developed a randomized prevention study including a Full Gym Intervention Group, Smart Pedometer Intervention Group, and an Attention Control Group. Data will be collected at Baseline, Month 4 and Month 12 through direct assessments and surveys of the participants.

The project will aim to obtain the following primary and secondary SMART objectives:

- **PRIMARY**
 - **Weight Goal 1: Reduction in BMI of LB women**
 - o Objective 1.1: The gym intervention group will have a 10% decrease in BMI from baseline to final evaluation (~12 months post baseline).
 - o Objective 1.2: The smart pedometer intervention group will have a 7% decrease in BMI from baseline to final evaluation (~12 months post baseline).
 - **Weight Goal 2: Reduction in waist circumference to height ratio of LB women**
 - o Objective 2.1: The gym intervention group will have a 5% decrease in waist circumference to height ratio (WCHR) from baseline to final evaluation (~12 months post baseline).
 - **Fitness Goal: Improved fitness in LB women**
 - o Objective 3.1: The gym intervention group will have an increase in VO2 max of 20% from baseline to final evaluation (~12 months post baseline).
 - o Objective 3.2: The smart pedometer intervention group will have an increase in VO2 max of 5% from baseline to final evaluation (~12 months post baseline).
- **SECONDARY**
 - **Diet Goal: Increase healthy diet of LB women**
 - o Objective 4.1: The combined intervention groups will have a 25% reduction in consumption of sugar-sweetened beverages from baseline to final evaluation (~12 months post baseline).
 - o Objective 4.2: The combined intervention groups will have a 10% reduction in consumption of alcohol from baseline to final evaluation (~12 months post baseline).

- o Objective 4.3: The combined intervention groups will have a 10% increase in fruit and vegetable consumption from baseline to final evaluation (~12 months post baseline).
- **Physical Activity Goal: Increase physical activity in LB women**
 - o Objective 5.1: The combined intervention groups will increase the proportion by 75% of LB women meeting or exceeding the 2008 Physical Activity Guideline for Americans of 150 minutes of moderate-intensity or 75 minutes of vigorous intensity physical activity per week, or an equivalent combination of moderate- and vigorous-intensity activity from baseline measurement to final evaluation (~12 months post baseline).

A.3. Use of Information Technology to Reduce Burden

This study will use a NORC-proprietary software application to collect and store data. It is a data tool to build a web-based portal for surveys, assessments, and administrative data.

Participants will benefit from completing the surveys using the system because it will allow for faster and more convenient self-reporting. For example, participants who would like to complete the survey online, and have access to a computer and internet will be provided with a secure log-in to complete the survey online as opposed to waiting to receive a hardcopy in the mail.

Participants who do not have computer and/or internet access but would like to complete the survey online will be provided with a secure log-in with the option to come into a location (i.e., the community center) where a computer station is available to complete the survey online.

Lastly, for participants who may not feel comfortable completing the survey online will have the option to fill out a hardcopy of the survey. When participants complete the survey via hardcopy, project staff will enter their information into the online system. It is expected that the majority of the participants will opt for completing the survey electronically, which will significantly reduce response burden with the elimination of having to follow specific skip patterns and/or fill out a hardcopy form in a specific way. The electronic, web-based survey will have skip patterns built-in and will provide the respondent with minimal distraction from the question on the screen.

Additionally, completing the survey online will eliminate the burden of having to mail-in the survey upon filling out the hardcopy version.

A.4. Efforts to Identify Duplication

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

A.5. Small Business

No small businesses are involved as participants in the proposed data collection effort.

A.6. Consequences of Not Collecting the Information

This submission is to collect data for a pilot test intervention that promotes healthy weight in lesbian and bisexual (LB) women. Without these data, we will not be able to determine the results and effectiveness of the intervention on weight loss, physical activity, healthy eating, and social support aimed at LB women. These data will help add to the scant literature on healthy weight interventions specifically tailored for lesbian and bisexual women and will help develop interventions that support weight loss, physical activity, healthy eating, and social specifically tailored to LB women. The de-identified data will be shared, upon request, with individuals and groups with the research community in order to continue to enhance the literature. In addition to sharing the data, the research protocols and intervention criteria will be available in order for others in the research community to replicate an already tested intervention. Further, once all data analyses are complete, the data will be archived in a data archive consortium, such as ICPSR.

Tested intervention materials from this project will be provided to other LB community members. For example, at the conclusion of the project, NORC staff will produce the workout routines into a visually appealing (and culturally relevant), easy to download format for other community members to use. This will be disseminated on the study website as well as on partner websites and distributed to LB communities via listservs and distribution lists. Additionally, the LB community partner sites will post a resource guide containing information about LB friendly gyms and recreational facilities where staff has completed LB cultural competency training; offer gay teams and/or competitions; and low cost or free options for physical activities. The reach of the data and protocols in the research community as well as the reach of the intervention and materials to the OB community has the capability to be disseminated to thousands of individuals.

A.7. Special Circumstances Justifying Inconsistencies With Guidelines in 5 CFR 1320.6

There are no special circumstances required for the collection of information in this baseline data collection.

A.8. Consultation Outside the Agency

In accordance with the paperwork Reduction Act of 1995, OWH published a notice in the *Federal Register* announcing the agency's intention to request an OMB review of data collection activities. This notice was published on March 22, 2013, in volume 78, pages 17674 and provided a 60-day period for public comments. There no public comments received.

The research project utilizes several national and existing standardized and validated instruments which are listed in the Table of Measures in Appendix A. NORC worked with Catherine Jefcoat (LB Intervention Specialist), Sherrill Wayland (SAGE St. Louis), and invited advisory group members (see Table 1 below) to develop the measures and forms being used in the interventions. NORC also

worked with the project sites (The Lab Gym and Optimus) in order to obtain several of their fitness assessment measures and intake forms.

Table 1: Invited Advisory Group Members*	
Name	Affiliation
Jeanette Mott Oxford	Former State Representative
Nancy Novak	Bar Owner (Lesbian bar)
Mo Costella	Owner of MoKaBe's (SGM hang out spot)
Nancy Fowler Larsen	Reporter with the Beacon
Carol Robinson	Lesbian of Color Community Advocate
Marcia Daab	SAGE Board Member
Audrey Pearson	Lesbian of Color and Community Advocate
Christina Meneses	YWCA rape crisis center
Stacy Snow	Community Member
Leigh Lockhart	Main Squeeze
Mandy Schick	Schick Training
Melinda Hemmelgarn	Food Sleuth LLC
Annette Triplett	PedNet Coalition
Marshall Newman	SoCo Club
Ellen Dugger	Community Member
Martha Pickens	Community Member
Stacia Riley	Health Department
Linda Cooperstock	Health Department
Kerri yost	Citizen Jane Film Festival
Lise Saffran	MU Masters of Public Health Program
Anna Lingo	Markel & Lingo Law Firm
Linda Hayes	PFLAG
Cindy Foley	Wellness Resource Center
Patty Clover	Clovers
Laura Hacquard	MU Women's Center
Sara Michelle	The Center Project
*This list is the group of individuals who have been invited to participate on the Advisory Group; but have not yet confirmed their participation.	

A.9. Payments or Gifts to Respondents

Church found in a meta-analysis of 38 experimental and quasi-experimental studies that implemented some form of mail survey that those surveys that included monetary or non-monetary rewards in the initial mailing yielded statistically significant participant response rates.¹ We will be offering monetary incentives to the participants to complete assessments for the intervention. The CDC also mentioned the importance of using incentives in its July 2010 evaluation brief, *Using Incentives to Boost Response Rates*, to: Improve response rates; Demonstrate respect and appreciation for respondent time and effort; and Convey trust that the respondent will complete the survey.

The attention control group will receive \$25 for completing each fitness assessment (at baseline, at the end of the intervention phase (16-weeks), and at the end of the study (12-months), totaling \$75. There will be a post-intervention focus group in which up to 20 individuals across intervention groups will be invited to participate. The focus group participants will receive \$25 for their participation. **Therefore, the total compensation for each attention control group participant is \$75 with a maximum total of \$100 (for those who participate in the focus group).** No other compensation will be provided.

Participants in the Smart Pedometer Group will receive \$25 for completing the 12 month follow-up evaluation. There will be a post-intervention focus group in which up to 20 individuals across intervention groups will be invited to participate. The focus group participants will receive \$25 for their participation. **Therefore, the total compensation for each Smart Pedometer Group participant is \$25 with a maximum total of \$50 (for those who participate in the focus group).** No other compensation will be provided.

Participants in the Full Gym Intervention Group will receive \$25 for completing the 12 month follow-up evaluation. There will be a post-intervention focus group in which up to 20 individuals across intervention groups will be invited to participate. The focus group participants will receive \$25 for their participation. **Therefore, the total compensation for each Full Gym Intervention Group participant is \$25 with a maximum of \$50 (for those who participate in the focus group).** No other compensation will be provided.

A.10. Assurance of Confidentiality

The data collection plan has been submitted for approval by the NORC at the University of Chicago (NORC) and University of Missouri – Columbia Institutional Review Boards. Every effort will be made to maintain the privacy and confidentiality of respondents. Data will be kept private to the extent allowed by law. The confidentiality procedures adopted for this study during baseline data collection, data processing, and analysis will consist of the following:

- All baseline study respondents will be assured that participation in the study is voluntary and the information they provide is confidential and will be used only for the purpose of this research. Each participant will be assigned a subject ID for the purposes of data collection and storage. All participant information received through the online data collection and storage system will be stored using this subject ID.
- To ensure data security, all individuals hired by the NORC at the University of Chicago and University of Missouri – Columbia, are held to strict standards and are required to sign an oath of confidentiality as a condition of employment.
- Hard-copy data collection forms will be delivered to a locked area for receipt and processing at NORC. These will be entered into online data collection and storage system by an authorized research staff member. The hardcopy forms will be destroyed and disposed of once they have been entered electronically. NORC at the University of Chicago and University of Missouri – Columbia maintain restricted

access to all data preparation areas (receipt, coding, and data entry). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a “need-to-know” basis only.

- Individuals identifying information will be maintained separately from completed data collection forms and from computerized data files used for analysis.
- All data will be collected and stored using a NORC-built software application. Participants will have the option to complete the survey online or via hard copy. To complete the survey online, participants will be provided with a secure log-in. For participants who complete the survey via hardcopy, authorized project staff will replace participant names with the assigned participant ID numbers. The data on the hardcopy form will then be entered into the online system by project staff. Once the data has been transferred to electronic format, the hardcopy data will be destroyed and disposed of properly. -
- All direct identifiers between the participants and the ID numbers will be encrypted before they are stored in the database to ensure that the information is not accessed by unauthorized users.
- All database servers are password protected and only a select few authorized research staff and NORC developers will be able to obtain access to the data. Project staff at the project sites, including personal trainers and support group facilitators, project participants, and research staff will have the ability to enter data into the Liberty system, although each type of user will have varying levels of read/write access to the system. The different users of the Liberty system will be provided with either admin-level access, respondent-level access, or site-level access to ensure that only authorized users can view direct identifiers to help ensure that data remain confidential. Each user will be able to use their credentials to log-in to the system. They will only have access to the information that they are authorized to view, which is granted by their user-level access.

A.11. Questions of a Sensitive Nature

Some of the OPAH Fitness Project research topics related to fitness and weight include potentially sensitive questions. In the informed consent procedure, all sample persons are advised of the voluntary nature of their participation in the survey or any of its components. Participants are informed that they can choose not to answer any individual questions and may stop the interview 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. All questions and procedures are reviewed by NORC at the University of Chicago and University of Missouri Research Ethics Review Board for issues of sensitivity. The potential sensitivity of questions was an evaluation criterion in determining content of the survey.

The following questions are thought to be of a sensitive nature

Alcohol Use: When LB population status is ascertained in population-based studies, lesbians and bisexual women drink at higher rates than the general population.²⁻⁵ One primary goal of the study is to reduce caloric intake from alcohol among the participants. The three alcohol questions are recommended by the National Institutes of Health's National Institute on Alcohol Abuse and Alcoholism.

Tobacco Use: Smoking prevalence in the SGM population has been reported up to twice that of the heterosexual population.⁶⁻¹⁰ Smoking has been linked to an increase in individual's body fat distribution, weight, and risk of metabolic syndrome.¹¹ Some studies have shown smoking, and particularly heavy smoking, may be related to weight gain, contrary to the population opinion.¹² Smoking status will be included to characterize our population and as a potential covariate in models used to explain project outcome of weight loss or improved fitness. The two smoking questions will obtain information to determine smoking status (current, former, never) and these questions are recommended by the Centers for Disease Control and Prevention.

Mental health: Another area of strong positive correlation is depression and unhealthy weight in the general population of women¹³ and in a population-based studies of sisters, with one being lesbian or bisexual, the bisexual sister experienced higher prevalence of depression than their heterosexual sister.¹⁴ Lesbian and Bisexual women also tend to have a greater prevalence of generalized anxiety disorder than heterosexual women;¹⁵ however, in a study comparing gay men to lesbian women, gay men have lower depression and high anxiety than lesbian women,¹⁶ indicating that lesbian women suffer from higher rates of depression compared to gay men. Participants will take a 4-question established depression screening module called the Center for Epidemiology Studies Depression Scale (CES-D). Depressive symptoms score will be included to characterize our population and as a potential covariate in models used to explain project outcome of weight loss or improved fitness. The participants will complete the questionnaire before their respective sports physical evaluation. They will then have an opportunity to discuss any health issues with their health care provider.

Sexual and Gender Minority (SGM) status: Eligibility criterion to participant in this project requires self-reported sexual orientation as lesbian or bisexual female. Further, VanKim et al (in the New Mexico's routine statewide public health survey: Behavioral Risk Factor Surveillance Study) tested the refusal rate of asking SGM status compared to other known sensitive questions and found refusal rates as similar to refusal rates for race/ethnicity and significantly lower than rates for questions on household income.¹⁷ The National Health Interview Study has included extensively tested SGM status question in their 2013 survey and we are using these in our screening module.¹⁸

Race/Ethnicity: Race and ethnicity differences are associated with perceptions of healthy weight and self-reported weight^{19,20} with non-White women more likely to report a healthy weight with a higher body mass index (BMI: weight/height²).²¹ Prevalence of overweight and obesity among

lesbians varies by race/ethnicity.²² Race and ethnicity will be included to characterize our population and as a potential covariate in models used to explain project outcome of weight loss or improved fitness. In addition, this is a very important characteristic to describe the proportion of study participants by race and ethnicity. Per the OMB standards, race and ethnicity are separate questions and we are using the National Health and Nutritional Examination Survey's (NHANES) race and ethnicity questions.

Income: Income is commonly used to assess a person's socio-economic position. It is also possibly the most sensitive of commonly asked demographic questions. Paeratakul et al reported weight difference by socio-economic status.¹⁹ Using NHANES data, Wang reported that low-socioeconomic status groups are heavier.²³ Although SGM women may be more likely to have higher education attainment, Rothblum reported that this does not translate into higher income.²⁴ Income levels will be included to characterize our population and as a potential covariate in models used to explain project outcome of weight loss or improved fitness. The one income question uses a standardized question and to improve participation proportion, provides closed-categories to increase response rate.²⁵ Further, a self-administered survey, used in this project, compared to face-to-face interviews has also been shown to improve the response rate.²⁶

Weight history: History of weight cycling, repeated loss and regain of weight have been shown to be associated with weight regain after weight loss intervention.²⁷⁻²⁹ We are unaware of any published studies on evaluating weight cycling in the lesbian and bisexual female population though we would expect weight cycling to be equally predictive of weight loss maintenance as found in the general population. Weight history will be included to characterize our population and as a potential covariate in models used to explain project outcome of weight loss or improved fitness. We are using the 14 NHANES' weight history questions.

Disability Status: 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. As a result, we created two questions to capture disability status by using the Americans with Disability Act regulations' (29 C.F.R. 1630.2(i).) definition, "a physical or mental impairment that substantially limits a major life activity." Have one or more self-reported disability (e.g., limitations in lifting or carrying groceries; climbing several flights of stairs; bending, kneeling or stooping; walking for several blocks; and walking for one block) will be included to characterize our population and may be included as a potential covariate in models used to explain project outcome of weight loss or improved fitness.

Lesbian Internalized Homophobia Scale: Szymanski developed an internalized homophobia scale for use in the lesbian population. It is intended to measure the extent to which negative attitudes and beliefs about homosexuality are internalized and integrated into one's self-image and identity as SGM.³⁰ Shidlo suggests one reason to assess one's internalized homophobia is because this is an important cause of psychological distress.³¹ Levels of psychological distress

have been shown to be associated with abdominal adiposity and weight^{32,33} as well as poorer weight loss treatment outcomes in intervention studies.³⁴ Scores on this validated scale will be included to characterize our population and as a potential confounder in models used to explain project outcome of weight loss or improved fitness.

Discrimination Scale: Perception of discrimination is strongly associated with stress. Whether the causal pathway is related to biochemical change (e.g., red blood cell oxidative stress³⁵) or excessive eating as a mal-adaptive coping strategy,³⁶ stress is positively associated with obesity.^{37,38} Meyer and others have posited that LB individuals face stigma-related prejudice and discrimination, also known as minority stress, which constitutes chronically stressful events.³⁹ Scores from this validated scale will be included to characterize our population and as a potential confounder in models used to explain project outcome of weight loss or improved fitness.

Medical questions: Participants will be asked to obtain medical clearance to participate in the study. To assess their health status, one of our family doctors at University of Missouri Family and Community Medicine Department provided the medical form of pertinent information she felt was needed to assess the patient for medical clearance. In addition to her specific questions about the patient's and patient's family medical and psychosocial history, a few other questions were added to this form since these questions fit well within the health history. For example the Center for Epidemiology Studies Depression Scale (CES-D) was placed within this instrument. Place of these kinds of questions within this instrument also allowed the patient to discuss any questions or concerns that might arise from answering the questions with her physician.

A.12. Estimate of Response Burden

Number of Respondents, Frequency of Response, and Annual Hour Burden

Approximately, 160 lesbians and bisexual women will be enrolled in the study for a target number of 120 individuals completing all phases of the intervention. We estimate an attrition rate of approximately 17%. Each participant will respond to survey questions at four time periods (enrollment, baseline, 4-month, and 12-month). The estimated annual hour burden per respondent is 3.08 hours. Time estimates are based on previous studies with the LB population and a pre-test of the measures with 5 adults.

Hour Burden Estimates by Each Form and Aggregate Hour Burdens

At enrollment, the eligibility screener will be given to 160 individuals and will take an average of 8 minutes (.13 hours) to complete. The eligibility screener will be administered one time. The individuals will also complete a physical at enrollment that will take approximately 20 minutes (.33 hours) and a blood panel that will take approximately 10 minutes (.16 hours) Total time at enrollment is .62 hours.

The baseline assessments will be given to approximately 150 individuals and will take an average of 23 minutes (.4 hours) to complete. Several of the baseline measures will be administered again at the 4-month and 12-month follow up assessments although the baseline assessment will only be administered once. The direct physical fitness assessments will take approximately 30 minutes to complete (.5 hours). In addition, the participants will set up access to a social media site for the intervention groups (approximately 5 minutes, .1 hours). Total time at baseline is 1.0 hours.

The 4-month follow up assessment will be given to 120 individuals and will take an average of 5 minutes (.1 hours) to complete. Several of the measures included in these assessments will be administered again at the 12-month follow up assessments although the 4-month follow-up assessment will only be administered once. The direct physical fitness assessments will take approximately 30 minutes to complete (.50 hours) and a blood panel that will take approximately 10 minutes (.16 hours). Total time at baseline is .76 hours.

The focus group will occur after the 4-month assessment and prior to the 12-month assessment and will ask only a subset of the study individuals (up to 20 individuals) to participate in a post-intervention focus group. The post-intervention focus group will ask about the strengths and weaknesses of the intervention. This focus group will include up to 20 individuals and the total time will be up to 1.50 hours.

The 12-month follow-up assessment will be given to 120 individuals and will take an average of 12 minutes (.2) hours to complete. The 12-month follow-up assessment will only be administered once. The direct physical fitness assessments will take approximately 30 minutes to complete (.5 hours). Total time at baseline is .7 hours.

12A Estimated Annualized Burden Hours

Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Enrollment Survey	160	1	37/60	99
Baseline Survey	150	1	60/60	150
4-month Follow-up Assessment Survey	140	1	46/60	106
Post Intervention Focus Group	20	1	90/60	30

12-month Follow-up Assessment Survey	120	1	42/60	84
Total				470

12B Estimates of Annualized Cost to Respondents for the Hour Burdens

There are no annualized monetary costs to the respondents for participating in this study other than the time it will take to complete the surveys and assessments. Respondents are able to complete the surveys at their convenience.

A.13. Estimate of Total Capital and Startup Costs/Operation and Maintenance Costs to Respondents or Record-Keeper

There are no annualized capital/startup or ongoing operation and maintenance costs involved in collecting the information. Other than their time to complete the surveys, which is estimated in Exhibit 1, there are no direct monetary costs to respondents.

A.14. Estimates of Costs to the Federal Government

The estimated cost to the Federal Government for the *Out Proud and Healthy Fitness Project* data collection activities is \$21,600 for 2 staff members at 10% FTE each.

A.15. Explanation for Program Changes or Adjustments

No change in burden is requested. This submission to OMB is for an initial request for approval.

A.16. Plans for Publication, Analysis, and Schedule

NORC at the University of Chicago and the University of Missouri – Columbia in conjunction with OWH will develop several reports and manuscripts based on the project’s findings.

In year one, NORC, MU, and OWH will develop the first manuscript which will describe the methodology and results of the focus groups during the design phase of the project.

In year two, NORC, MU, and OWH will develop the following publications. The second manuscript will describe the final protocol for the proposed interventions. The third paper will descriptively describe the rationale, methods and materials used for the intervention. The fourth paper will describe the results from the evaluation of the intervention including the evaluation method, results, lessons learned, and prospects for sustainability.

In addition, our team will present the findings from this study at key professional conferences such as Gay and Lesbian Medical Association (GLMA), American Public Health Association (APHA), and Society of Epidemiology Research (SER) during year two.

A.17. Approval to Not Display Expiration Date

No exemption is requested.

A.18. Exceptions to Item 19 of OMB Form 83-1

This submission describing data collection requests no exceptions to the Certificate for Paperwork Reduction Act (5 CFR 1320.9).

Table of Measures

Measure	Enrollment	Baseline	4 Month Follow-up	12 Month Follow-up	Respondent	Source
<i>Fitness Measures</i>						
Height		•	•	•	Direct Assessment (gym staff)	Standardized Measurement Protocols
Weight		•	•	•	Direct Assessment (gym staff)	Standardized Measurement Protocols
VO2 Max		•	•	•	Direct Assessment (gym staff)	Standardized Measurement Protocols
Blood Pressure		•	•	•	Direct Assessment (gym staff)	Standardized Measurement Protocols
Waist Circumference		•	•	•	Direct Assessment (gym staff)	Standardized Measurement Protocols
Heart rate training zones		•	•	•	Direct Assessment (gym staff)	Standardized Measurement Protocols
Body Fat Percent/Body lean percent		•	•	•	Direct Assessment (gym staff)	Standardized Measurement Protocols
Trunk Flexion		•	•	•	Direct Assessment (gym staff)	Standardized Measurement Protocols
Grip Strength		•	•	•	Direct Assessment (gym staff)	Standardized Measurement Protocols
<i>Respondent Surveys/Forms</i>						
Screening Questionnaire	•				Self-respondent	NHIS 2013
Contact Information Form	•				Self-respondent	Not Applicable
Medical History Form	•				Self-respondent and signed by physician	University of Missouri Health System Medical Form
Demographics Questionnaire	•				Self-respondent	BRFSS 2011; National Lesbian Health Care Survey, http://www.icpsr.umich.edu/icpsrweb/ICPSR/studies/8991
<i>Stress & Resiliency</i>						
Center for Epidemiologic Studies Depression (CES-D) Scale	•		•	•	Self-respondent	Radloff, LS. A Self-Report Depression Scale for Research in the General Population. Applied Psychological Measurement, 1(3), 385-401.
Stress Jackson Heart Study		•		•	Self-respondent	Jackson Heart Study; instrument available on NHLB (National Heart Lung and Blood Institute):

						<p>http://www.nhlbi.nih.gov/resources/obesity/pop-studies/jhs.htm http://jhs.jsu.edu/jhsinfo/Portals/0/pdf/form1/Home%20Induction_Exam%201.pdf</p>
The Lesbian Internalized Homophobia Scale		•			Self-respondent	<p>J Homosex. 2001;41(2):37-52. The Lesbian Internalized Homophobia Scale: a rational/theoretical approach. Szymanski DM, Chung YB.</p>
Perceived Stress Scale		•	•	•	Self-respondent	<p>Cohen, S., & Janicki-Deverts, D. (2012). Who's stressed? Distributions of psychological stress in the United States in probability samples from 1983, 2006 and 2009. Journal of Applied Social Psychology. This article provides NORMATIVE DATA for the PSS-10 from large 2006 and 2009 probability samples of the U.S. (2.) Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. Journal of Health and Social Behavior, 24, 385-396. (provides RELIABILITY and VALIDITY (3.) Cohen, S., & Williamson, G. (1988). Perceived stress in a probability sample of the U.S. In S. Spacapan & S. Oskamp (Eds.), The social psychology of health: Claremont Symposium on Applied Social Psychology. Newbury Park, CA: Sage.</p>

						(provides NORMATIVE DATA from a large U.S. sample)
Lubben Social Network Scale		•				Assessing social networks among elderly populations. Lubben, James E. Family & Community Health: The Journal of Health Promotion & Maintenance, Vol 11(3), Nov 1988, 42-52.
Connor-Davidson Resiliency Scale (CD-RISC)		•	•	•	Self-respondent	Depress Anxiety. 2003;18(2):76-82. Development of a new resilience scale: the Connor-Davidson Resilience Scale (CD-RISC). Connor KM, Davidson JR.; PLoS One. 2012;7(6):e39879. doi: 10.1371/journal.pone.0039879. Epub 2012 Jun 29. Measuring resilience in adult women using the 10-items Connor-Davidson Resilience Scale (CD-RISC). Role of trauma exposure and anxiety disorders. Scali J, Gandubert C, Ritchie K, Soulier M, Ancelin ML, Chaudieu I.; A methodological review of resilience measurement scales. Windle G, Bennett KM, Noyes J. Health Qual Life Outcomes. 2011 Feb 4;9:8. doi: 10.1186/1477-7525-9-8.
Discrimination Questionnaire		•			Self-respondent	Soc Sci Med. 2005 Oct;61(7):1576-96. Epub 2005 Apr 21. Experiences of discrimination: validity and reliability of a self-report measure for

						population health research on racism and health. Krieger N, Smith K, Naishadham D, Hartman C, Barbeau EM.
Social Support for Diet and Exercise Behaviors				•	Self-respondent	Sallis JF, Grossman RM, Pinski RB, Patterson TL, Nader PR. <i>Prev Med.</i> 1987 Nov;16(6):825-36.
Multidimensional Body-Self Relations Questionnaire		•			Self-respondent	MBSRQ; http://www.body-images.com/assessments/mbsrq.html Cash & Pruzinsky, 1990) Only two of the MBSRQ subscales were used in this study. Appearance evaluation (7 items; range = 1-5; alpha = .83) assesses satisfaction with one’s appearance; higher scores reflect greater satisfaction. Appearance orientation (12 items; range = 1-5; alpha = .85) assesses the extent to which one believes physical appearance is important and the extent to which one engages in appearance-related activities; higher scores reflect stronger beliefs and greater activity.
Physical Activity Questionnaires						
International Physical Activity Questionnaire (IPAQ)- Short		•	•	•	Self-respondent	RAPA intro text (definition), University of Washington; Topolski TD, LoGerfo J, Patrick DL, Williams B, Walwick J, Patrick MB. The Rapid Assessment of Physical Activity (RAPA) among older adults. <i>Prev Chronic Dis</i> 2006;3(4):A118.; Q1-7

						International Physical Activity Questionnaire (IPAQ) https://sites.google.com/site/theipaq/home
Stage of Exercise		•			Self-respondent	<u>Res Q Exerc Sport.</u> 1992 Mar;63(1):60-6. Self-efficacy and the stages of exercise behavior change. <u>Marcus BH, Selby VC, Niaura RS, Rossi JS.</u>
Exercise Self-Efficacy		•		•	Self-respondent	Sallis 1996
Barriers to Exercise Scale		•		•	Self-respondent	McAuley 1992
Motivation for Exercise		•		•	Self-respondent	Ryan, R. M., Frederick, C. M., Lepes, D., Rubio, N., & Sheldon, K. M. (1997). Intrinsic motivation and exercise adherence. <i>International Journal of Sport Psychology</i> , 28, 335-354.
Sustainability Questions	Data will be collected through informal discussion at celebratory event.				Self-respondent	Not Applicable
Accelerometer Data Download	Data downloaded at each support group meeting.				Self-respondent	Not Applicable
General Health						
Veterans RAND 36 Item Health Survey (VR-36)		•		•	Self-respondent	Hays RD, Sherbourne CD, and Mazel RM. The RAND 36-Item Health Survey 1.0. <i>Health Economics</i> 1993 2: 217-227.
NHANES Weight History		•			Self-respondent	NHANES 2011, http://www.cdc.gov/nchs/nhanes/nhanes2011-2012/nhanes11_12.htm
Diet/Food Intake						
Eating Out and Food/Drink Consumption Questions		•	•	•	Self-respondent	Q1-4: NHANES 2009-2011 Flexible consumer behavior survey; Q5-9: BRFSS 2011, CDC; Q10 Hedrick VE, Savla J, Comber DL, Flack KD, Estabrooks PA, Nsiah-Kumi PA, Ortmeier S, Davy BM. Development of a Brief

						Questionnaire to Assess Habitual Beverage Intake (BEVQ-15): Sugar-Sweetened Beverages and Total Beverage Energy Intake. J Acad Nutr Diet. 2012; 112:840-849. Q11 ACHA (American College Health Association) National College Health Assessment II, 2008; Q12-15: CHIS (California Health Interview Survey) 2009; Q16: CDC recommended question; Q17-19: NIH-NIAAA (National Institute on Alcohol Abuse and Alcoholism)
Eating Patterns		•			Self-respondent	The Lab Gym client dietary assessment. St Louis MO. Compiled by Justin Thacker, MS, RD, LD, HFS, USAW, CSCS, CES, owner of the Lab Gym.
Food Log		•			Self-respondent	http://www.realsimple.com/static/pdfs/foodjournal.pdf

Total Number of Items per Survey

<i>Time point/ Survey</i>	<i>Number of Items</i>
Enrollment <ul style="list-style-type: none"> • Screening Questionnaire (4) • Contact Information Form (11) • Medical History Form (55) • Demographics Questionnaire (12) 	82
Baseline Survey <ul style="list-style-type: none"> • At Fitness Assessment (183) • At First Meeting (76) 	259
4-Month Post Intervention Survey	52
12-Month End of Study Survey	146

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