Brief Title: Optimizing an Online Behavioral Weight Loss Intervention and Novel Culturally Tailored Components for Sexual Minority Women

Official Title: Optimizing an Online Behavioral Weight Loss Intervention and Novel Culturally Tailored Components for Sexual Minority Women: MOST Optimization Phase

PI: Emily Panza, PhD

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Research Consent and Authorization Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital, Newport Hospital, and Gateway HealthCare

Name of Study Participant: _____

Principal Investigator: Emily Panza, Ph.D.

Using the Multiphase Optimization Strategy to Optimize a Culturally Tailored Online Behavioral Weight Loss Intervention for Sexual Minority Women

OPTIMIZATION PHASE

KEY STUDY INFORMATION

You are being asked to take part in a research study. A research study helps scientists learn new information to improve medical practice and patient care. This form contains information that will help you decide whether to take part in the research. Taking part in this study is completely voluntary. **Even if you decide to take part in the study, you are free to leave at any time if you change your mind**. The researcher will explain the study to you and answer any questions you may have. We encourage you to discuss this study with others (your family, friends or other doctors) before you agree to participate in the research. If you agree that you would like to participate in this research study, you will be asked to review and sign this consent. A copy will be given to you.

A. What is the purpose of the research?

We developed an online behavioral weight loss treatment (*Rx Weight Loss: PRIDE)* specifically for cisgender sexual minority women (e.g., women who self-identify a minority sexual orientation such as lesbian, bisexual, or queer). **This goal of this study is to identify which parts of *Rx Weight Loss: PRIDE* are most effective for cisgender sexual minority women (and which are not).** Data from this study will help us decide which parts of this program to include in a finalized treatment to be offered to cisgender sexual minority women on a wider scale.

B. What is experimental/new in this study

Rx Weight Loss: PRIDE is a 3-month online behavioral weight loss program that includes a **core program** (changes to diet and exercise) and **3 new components** that address weight loss barriers known to affect many sexual minority women: (1) stigma due to sexuality, gender, and weight; (2) lack of social support, and (3) negative body image.

All participants in this study will receive the core 3-month program. Past research shows that this program is an effective weight loss treatment. Participants may also receive 0, 1, 2, or 3 of the new treatment components, in addition to the core program. The program is delivered online and involves watching video lessons and applying the skills they teach. No medications are involved. The number of new components each participant receives is decided at random by a computer.

C. What do I have to do in this research?

It will take you about 6 months to complete this study, including 3 months of active participation in the treatment and a 3-month follow-up period. Most of your participation during this time will be online. We will ask you to make 3 short in-person study visits and 1 virtual visit. Appropriate

COVID-19 mitigation protocols (e.g., sanitization, mask wearing, social distance) will be followed.

If you decide to join this research study, the following things will happen:

- Baseline Assessment Visit: You will complete a baseline visit. During this visit, we will review the informed consent form, which you may choose to sign. We will assess your height and weight and ask you to complete brief questionnaires (~10 minutes) to confirm your eligibility. If you consent to participate, you will complete questionnaires. Compensation for your time is $10. Only participants who complete all aspects of the study visit will receive compensation.
- Randomization Visit (Virtual): Within one week following the baseline visit, you will complete a 15-20 minute online visit with research staff where you will be randomized to receive the weight loss program and 0-3 additional components (stigma, social support, body image). You will also receive training in how to use the online weight loss program website during the visit.
- Online Weight Loss Treatment: You will complete a 3-month online behavioral weight loss program and 0-3 additional treatment components (stigma, social support, body image).
- Follow-up Assessment Visits: You will complete 2 in-person follow-up visits (3 and 6 months after starting the program). During these visits, we will measure your height and weight and you will complete questionnaires. Compensation for your time is $15 at the 3 month visit and $25 at the 6 month visit. Only participants who complete all aspects of the study visit will receive compensation.

D. What could go wrong?

The most important potential risks to know about are:

(1) Participants may have difficulty losing weight in the program.
(2) Risks of physical exercise may include being injured or feeling pain or discomfort.
(3) Risks of changing your diet may include feeling hungry and more rarely, experiencing low blood sugar.
(4) Participants may feel distress when answering questions about topics like social stigma.
(5) Risks of using an online program include the possibility that private data from a computer or mobile device may be intercepted during transmission.
(6) If someone sees a participants' study communications referencing sexual minority status, it is possible that one's sexual orientation may be unintentionally revealed.
(7) Although study staff take all possible precautions, participants who attend an in-person study visit during the COVID-19 pandemic have a risk of contracting COVID-19 as a result of the study visit.

E. What are the benefits?

The most important potential benefits to know about are: Participants will receive information about weight loss, healthy eating, and physical activity, which may help you lose or maintain weight. However, there is no guarantee that you will lose weight.

F. Other things I should know about this research?

If we find out about new information from this research that may affect your health, safety or willingness to stay in this research, we will let you know as soon as possible.

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G. If I don't want to take part in this research what are my other choices?

You do not have to be in this research study to receive weight loss treatment. To learn more about weight loss programs that may be available, you can ask your doctor to discuss with you what weight loss treatment(s) might be right for you considering your medical history.

- **Please carefully read this form, additional detail about each item just described is below.**
- **Please listen to the study team explain the study and this form to you.**
- **Please ask questions about anything that is not clear.**

COMPREHENSIVE STUDY INFORMATION

1. Nature and Purpose of the Study

We developed an online behavioral weight loss treatment (*Rx Weight Loss: PRIDE)* specifically for sexual minority women. The goal of this study is to determine which parts of *Rx Weight Loss: PRIDE* are most effective for sexual minority women and which are not.

You are being asked to take part in this research project because you are an adult who self-identifies having a sexual minority sexual orientation (e.g., lesbian, bisexual), you identify as female and were assigned female at birth, you are interested in losing weight, and you have a body mass index (BMI; this measures the ratio of your height to weight) between 25-50 kg/m^2. We expect to enroll 120 subjects into this study. The study is sponsored by The National Institute of Minority Health and Health Disparities.

2. Explanation of Procedures:

Baseline Assessment Visit

First, you will complete a baseline visit in-person at the Weight Control and Diabetes Research Center, 196 Richmond St, Providence, RI lasting 15-60 minutes (length will depend on whether you choose to complete study questionnaires during the visit, or at home).

- **Informed Consent:** During this visit, we will review the informed consent form with you, which you may choose to sign. Please take all the time you need to review the form. You will receive a copy of the form for your records.
- **Screening:** If you decide to join the research study, we will measure your height and weight to confirm your eligibility for this study. This research study is recruiting cisgender women with a BMI (the ratio of your height to weight) that falls in the overweight or obese category (BMI = 25-50kg/m^2). If your BMI is within this range and you meet all other eligibility criteria, then you will be eligible for this study and the baseline visit will continue. If your BMI is under 25 or over 50, then you cannot be in the research study and the research investigator will discuss other options with you.
- **Questionnaires**: If you consent to participate and you meet all study criteria, next you will be asked to complete a series of online questionnaires. The questionnaires will take between 30-45 minutes to answer. You will have the option to complete these questionnaires using a laptop in a private room at our research center, or you can complete them on your own at home. These questionnaires ask questions about your eating and physical activity patterns, your health and quality of life, your familiarity with

technology, the social support in your life, and aspects of your medical history. They also ask about certain sensitive topics, such as your experiences with depression, anxiety, and stress, and your experiences with social stigma due to your weight, sexuality, and other aspects of your identity. You have the option to skip any questions that you do not feel comfortable answering.

- **Compensation**: You will receive $10 as compensation for your time when you complete all aspects of the study visit (including questionnaires). Participants will have the option to receive compensation in the form of cash or electronic gift card.

Randomization Visit

- This visit (15-20min) will be conducted virtually/online within 1 week of the baseline visit.
- **Randomization**: All participants will receive the core online weight loss program. Participants will also be randomly assigned, or "randomized", to receive 0, 1, 2, or 3 additional treatment components that address weight loss barriers known to affect cisgender sexual minority women. Randomization means that you are put into a group by chance. It is like flipping a coin. A computer decides which group you are put in. Neither you nor the researcher can choose what group you will be in. You will have a 1 in 8 chance of being placed in any group. You will find out your experimental condition during this visit.
- **Training in Using Online Weight Loss Treatment:** All participants in this study will complete a 3 month online behavioral weight loss program. During this visit, a research assistant will assist participants in creating a log-in for the online program portal, and will provide training in using the portal. This will take 15 minutes.

<u>Online Weight Loss Treatment</u>

All 120 participants will complete a 12-week (3 month) online behavioral weight loss program (*Rx Weight Loss: PRIDE).* **All aspects of the online weight loss program will occur in a private, secure, online portal that was created specifically for this research study.** Each participant will create their own unique username and password to access the portal. When new content has been added for you to view in the portal, we will e-mail you to let you know. *Rx Weight Loss: PRIDE* includes 3 main components:

- **Diet, exercise, and weight loss goals and tracking.** Participants set goals for weight loss during the program, daily calorie intake, and weekly physical activity minutes. <u>These goals are flexible and can be tailored to suit each participant's unique goals</u>.
    - *Weight Loss Goal*. The goal is for participants to lose 10% of their starting body weight over the course of the program.
    - *Daily Calorie Goal*. The goal for daily calorie intake ranges between 1200-1800kcals per day, depending on the participant's body weight.
    - *Daily Physical Activity Goal*. The weekly physical activity goal starts at 50 minutes per week of physical activity (e.g., brisk walking), which gradually increases to 200 minutes per week by the end of the program.
    - *Tracking*. To measure progress towards goals, participants are asked to weigh themselves daily, to track the foods they eat every day using an online program (e.g., *My Fitness Pal*) or paper diaries. Participants also track their daily minutes of physical activity. Once per week, participants are asked to enter their daily weight,

calorie intake, and activity minutes into the study's online portal.

- **Weekly online video lessons**. Every week, participants receive an e-mail containing a weekly video lesson to watch, a reminder to enter their tracking data, and personalized feedback on their progress. Online lessons discuss healthy eating, physical activity, and behavioral skills like goal-setting and problem-solving. These lessons are interactive and use audio and video. Each weekly video lesson lasts 10 minutes.
- **Personalized feedback e-mailed to you**. Each week, participants receive automated feedback on progress towards weight, calorie, and activity goals. Feedback is designed to provide encouragement, praise for meeting goals, and constructive feedback.
- **Reminders**: Participants who do not view the weekly lesson or enter monitoring data receive e-mail reminders to re-engage.

<u>Component 1: Coping with Stress and Stigma Intervention</u>
Half of participants will receive the Coping with Stress and Stigma Intervention, in addition to the core *Rx Weight Loss: PRIDE* program. The intervention will be 3 months long (delivered Weeks 1 – Week 12) and will be delivered online. As part of the intervention, you will be asked to watch weekly online video lessons lasting approximately 10 minutes each. These lessons discuss both general stress and specific stressors affecting cisgender sexual minority women (i.e., social stigmas like heterosexism and weight stigma), how they can affect your weight loss, and teaches concrete skills for reducing stress so you can meet your health-related goals.

<u>Component 2: Social Support Intervention</u>
Half of participants will receive a Social Support Intervention in addition to the main *Rx Weight Loss: PRIDE* program. The intervention will be 3 months long (delivered during Week 1 – Week 12). Social support describes the support and encouragement you receive from people in your life. The goal of this intervention is to provide online opportunities for you to receive more social support as you work toward improving your health. As part of this intervention, we will provide you with access to a private, online forum (hosted on the *Rx Weight Loss: PRIDE* portal) where you can interact with other women participating in this study and working toward their weight loss goals. The intervention will begin in Week 1 with a 12-minute online video lesson describing the importance of social support for weight management and providing training in how to use the online networking platform. For the next 12 weeks, you will have access to the social support platform. It features a discussion forum where you can share your strategies for success, get support and guidance about your challenges, and encourage others. Our research staff will also post topics for the group will discuss 3-4 times per week. You will also have the opportunity to earn badges for meeting program goals (e.g., losing 5 pounds) and you can compete for a place on the weight loss and physical activity leaderboard.

<u>Component 3: Negative Body Image Intervention</u>
Half of participants will receive a Body Image Intervention, in addition to the main *Rx Weight Loss: PRIDE* program. The intervention will be 3 months long (delivered Weeks 1 – Week 12) and will be delivered online. As part of the intervention, you will be asked to watch weekly online video lessons lasting approximately 10 minutes each. These lessons provide education about body image that is designed specifically for sexual minority women. Body image refers to the thoughts,

emotions, and concerns you may have about your body size and shape. The weekly intervention lessons will discuss body image, what it means to have negative body image, and how negative body image can influence your eating, activity, and health. The material will be tailored specifically for cisgender sexual minority women. Lessons will teach strategies for coping with negative body image and improving your body image (regardless of your weight) to reduce its influence on your health. Participants will be asked to complete brief homework assignments involving practicing the skills taught in the intervention lessons.

Follow-up Assessment Visits

You will complete 2 follow-up visits (3 and 6 months after starting the program). These visits will occur in-person at the Weight Control and Diabetes Research Center, 196 Richmond St, Providence, RI and will last about 10–60 minutes. During the visits, we will measure your weight and you will be asked to complete online questionnaires lasting 30-45 minutes. Prior to the visit, we will ask you if you want to complete these questionnaires at home (prior to the visit) or at our center during the visit. At the end of each visit, you will receive compensation for completing all parts of the 3 month visit ($15) and 6 month visit ($25) in the form of cash or gift card. Only participants who complete all aspects of the study visit will receive compensation.

Costs for participating in this study

Some of the services you will receive are being performed only because you are participating in this research study. These 'research only' services include the online weight loss program and any of the 0 - 3 new intervention components that you may receive. These services will be paid for by the study and will not be billed to you or your health insurance company. However, the costs of any routine healthcare that you receive *outside* of your participation in this study (e.g., visits with your primary care doctor) are not covered by this study.

Contact Information:

You can call us with any concerns or questions about the research. Emily Panza, Ph.D. (Principal Investigator) can be reached at 401-793-9714 or Emily.Panza@Lifespan.org, Mon-Fri 9AM- 5PM.

Use of Study Data and Research Study Results

Your identifiable private information may be stripped of identifiers and used for future research studies, published to open data repositories consistent with NIH policies, or distributed to another researcher for future research studies without additional informed consent. Additionally, during the baseline assessment questionnaires, we will ask you if you would like to be notified of the results of this study. If you wish, we will disclose study results to you (in aggregate) when they are published.

Text Messaging

- We may use text messaging to schedule assessment visits with you as part of this research study. This may include you receiving text messages from research staff and/or you sending text messages to research staff. Lifespan takes your confidentiality seriously and will take steps to protect the information contained in the text messages to the degree permitted by the technology being used. Some of the following steps will be taken: encrypting the data during transmission, eliminating sensitive health care information from texts, & storing all data gathered on secure servers.

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- However, Lifespan can make no guarantees about the secure transmission of texts you send to us, nor can Lifespan guarantee security after you receive the text message from Lifespan. For example, text messages that display on your phone screen may be seen by someone close by or by someone you have allowed to use your phone. Also, if you do not password protect your phone and it is lost or stolen, anyone who finds it might view the information in the texts about your health or other topics. To try to lessen these risks, you should make sure your phone is password protected, only open and view messages where no one will be able to view the screen and delete messages as soon as possible after reading them. Additionally, when you trade in your phone, remember the SIM card (memory card used in cell phones) should be cleared.
- Finally, it is also possible that the mobile phone company that transmits the text messages may keep copies of ALL your texts (those from the study, and your other texts) even after the study is ended. Lifespan has no control over these companies and cannot make any guarantees about their conduct.

3. Discomforts and Risks

Potential risks to participating in this study include the following:

1. Participants may experience distress or discomfort when answering survey questions or watching video lessons about sensitive topics such as weight loss or stigma.
2. There are possible risks of completing the *Rx Weight Loss: PRIDE* program:
    a. The program encourages participants to gradually increase time spent exercising. Risks of exercising include potential joint or muscle injury, musculoskeletal discomfort, or rarely, symptoms like chest pain, dizziness, or shortness of breath.
    b. The program recommends a balanced diet and sticking to a daily calorie goal of 1200-1800 calories. Risks of making dietary changes may include feeling hungry, hypoglycemia, hypotension, and loss of lean muscle mass due to weight loss.
    c. Participants may have difficulty losing weight in the program.
    d. *Rx Weight Loss: PRIDE* is delivered using an online portal. As with all use of technology, it is possible that private data from a computer or mobile device may be intercepted during transmission, resulting in breach of confidentiality.
3. Finally, if someone else in a participant's social network sees study communication or content that references having a sexual minority orientation, it is possible that participants' sexual orientation may be unintentionally revealed.
4. Unforeseeable risks: because this study involves testing new components of a weight loss treatment for sexual minority women, these new treatments may involve risks to the participant that are currently unforeseeable.

4. Benefits

Potential benefits to participating in this study include the following:

1. All participants in this study will receive information about weight loss, healthy eating, and physical activity.
2. Participation in this program may help you lose or maintain weight, though there is no guarantee that this program will help you lose weight.

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3. Participants may also experience improvements in skills for coping with stress, social support, and/or body image, as these are targets of the intervention being tested in this study. However, these benefits are not guaranteed.
4. Others may benefit in the future from the information that is learned in this study.

5. Alternative Therapies

There are no alternative treatments and procedures provided in this study. To learn more about weight loss programs that may be available, you can ask your doctor to discuss with you what weight loss treatment(s) might be right for you considering your medical history. These clinical treatment options may include a weight management program in your community, medications, or something else. Each clinical treatment option has known rates of being effective, known risks, as well as possible drawbacks. If you want to know more about alternative treatment options, talk with your doctor to get more information.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study, the researcher will share this information with you as soon as possible.

Reasons the researchers would take you out of the study even if you wanted to stay in:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next six months. We would appreciate if you would permit us to *get follow-up information about your health from your doctor or your medical record.*

_____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____

Signature of study volunteer Date

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You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study, please tell the Principal Investigator, Emily Panza, Ph.D. who can be reached at Emily.Panza@Lifespan.org.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact the Director, Research Protection Office in Lifespan Office of Research at (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. Federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form, you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study, you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record may be used and released for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor: The National Institute of Minority Health and Health Disparities

- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that, so it is possible they might re-release your information.
You have the right to refuse to sign this form and not participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6: Refusal/Withdrawal), no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research. You will not be allowed to see or copy the information described in this form if the research is open. You may see and copy the information when the study is completed. A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent

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disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Contact for Future Studies:

Your participation in **any research** is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.

Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ ☐ Yes, I may be contacted about participating in other research projects studying weight management or sexual minority women's health. I give permission for my contact information (name and e-mail address) to be given to other researchers working with the study investigator.

_____ ☐ No, I do not want to be contacted about other research projects. **Do not** give my contact information to the staff of any other research studies

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp. DO NOT sign this document after this expiration date.

If the expiration date is blank, this document does not expire.

The Researcher is required to provide a copy of this consent to you.

Signature of Adult Study Participant	Date (MM/DD/YEAR)	Time when signed

Signature of researcher or designate	Date(MM/DD/YEAR)	Time when signed

☐ **A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant.**