

# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

## CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Study Title:** SHINE Study –Supporting Healthy by Integrating Nutrition and Exercise

Dr. Frederick Hecht, Dr. Elissa Epel, and Dr. Jennifer Daubenmier at the UCSF Osher Center for Integrative Medicine and the Center for Health and Community are doing a research study to examine the effects of two different weight loss programs on weight, body fat, and psychological well-being. Some of the key areas of interest include comparing the effects of the two groups on the following:

- weight loss and maintenance
- body fat distribution
- insulin sensitivity
- psychological well-being
- stress hormones
- immune function

I am being asked to participate in this study because I am an overweight adult and have no history of diabetes.

Research studies include only people who choose to take part. I understand that I can take my time to make my decision about participating, and I can discuss my decision with my family or friends if I wish. If I have any questions, I may ask the researchers.

### **Who pays for this study?**

This study is funded by a grant from the National Institutes of Health.

### **How many people will take part in this study?**

About 230 people will take part in this study.

### **What will happen if I take part in this research study?**

If I agree, the following procedures will occur:

#### Overview:

I will speak to a study staff member to see if I am eligible to participate. I will be asked questions about my current and past medical history, height and weight, and medication use. If it appears that I am eligible to participate and am still interested, I will schedule a 2-3 hour appointment at UCSF to enroll in the study for further screening and testing. I may be asked to see my physician for an evaluation to begin an exercise program prior to my first study visit. At this visit, I will sign a consent form, have some body measurements taken, have a blood draw, and complete questionnaires to confirm my eligibility. If I am eligible to participate in the study after my initial screening visit and blood draw, I will be scheduled for a baseline visit, which is described in detail below. I will have follow-up visits approximately 3, 4, 5, 6, 12 and 18 months after the start of my class. If I agree, I will have a fat aspirate at baseline and 6 months, which involves drawing some cells from under the skin on my abdomen into a needle. I will have a separate visit at baseline and 6 months for an MRI to measure abdominal fat. I will also get an influenza vaccination about 3 months after the start of the study to test my immune responses. The total time required for study visits is approximately 20 hours over 20 months. More detailed information about what tests will be done and what will happen at study visits is described below.

After I complete the baseline assessments, I will be randomly assigned to participate in one of two different weight loss group programs. Each group will use a somewhat different approach, but both will include diet and exercise components aimed at long-term weight loss. Both groups will meet 16 times on weekday evenings over about 6 months for 2-2.5 hours each time, and will also meet 2 times on weekend days for approximately 7-hours. More detailed information about what group participation will involve is described below.

Location: Study visits and group sessions take place on the UCSF campus. Study visits will take place at the Mt. Zion CCRC located at 1600 Divisadero St., 6<sup>th</sup> floor. MRI visits will be done at the UCSF China Basin campus. The group sessions will take place at the Osher Center for Integrative Medicine (1701 Divisadero St.). The all-day weekend classes may be held at the Osher Center or at alternative locations in the Bay Area

Consent/Screening Visit: This visit will take about 2-3 hours to complete and will take place in the morning. The night before this visit, I will not eat or drink anything (except water) after midnight and will not eat breakfast in the morning in order to measure hormones in my blood related to metabolism, such as glucose and insulin. If I was required to see my physician for an evaluation and authorization to begin an exercise program, I will bring this letter with me to the visit.

I will review the consent form with study staff, and, if I wish to participate, I will sign these forms. I may be asked whether I am willing to participate in a pre- and post intervention abdominal fat fine-needle aspiration. This procedure involves inserting a needle under the skin on my abdomen and drawing cells into a needle. A local anesthetic (Lidocaine 2%) will be injected into the tissues where the needle will be inserted for the aspirate in order to numb the area. This procedure is very helpful scientifically but is not a required part of the study. If I choose not to allow this, it will not affect my participation in the study. If I agree now, but change my mind in the future, I can notify study staff and withdraw this agreement. I will circle my choice and initial at the end of this form to indicate whether or not I am willing to have a fat aspirate at baseline and 6 months. Additional details regarding this procedure are described below.

After I complete the consent form, I will do the following at this visit:

- a. My blood pressure will be measured using an appropriate blood pressure cuff and my heart rate will be assessed using a heart rate monitor. My ear temperature will also be measured using an infrared digital ear thermometer.
- b. I will have a brief medical history which will be reviewed by a study physician or nurse practitioner to evaluate my cardiovascular risk and physical ability to carry out an exercise program. If there are concerns about whether it is safe for me to begin an exercise routine, I may be required to get further evaluation and clearance by my own physician prior to enrolling in the study.
- c. I will have my height and weight measurements taken with a gown on. These measurements will be used to calculate my Body Mass Index (BMI). If my BMI is too low or too high, I will not be eligible to continue in the study, and the visit will be ended.
- d. My hip and waist measurements will be taken using a measuring tape. In order to ensure the accuracy of the measurements, I will be asked to remove all clothing except my undergarments. If my waist is too small, I will not be eligible to continue in the study, and the visit will be ended.
- e. I will have a (fasting) blood draw of about 90cc (about 7 tablespoons) to measure glucose, hemoglobin A1c (HbA1c), insulin, cholesterol, and thyroid stimulating hormone (TSH). My fasting glucose must be no higher than 126 mg/dl, and my HbA1c and TSH results within a certain range in order to participate in the study. It will take about one week to get the results.
- f. A drop of this blood will be used to get an immediate reading of my blood glucose using a glucose meter. Glucose meters are not as accurate as laboratory testing, so this immediate result will not be used to determine my eligibility for the study. However, if the glucose meter result is 126 mg/dl or higher, the rest of the consent visit may be postponed until my results are received from the lab and eligibility is confirmed. Study staff will call to tell me the result.

If the results from the lab test show that my fasting glucose is less than 126 mg/dl, I will schedule an appointment to complete the rest of the procedures (items g-i). If the lab test glucose is 126 mg/dl or higher, or the HbA1c or TSH results are too high I will not be eligible to continue in the study and no further visits will be scheduled.

- g. I will complete questionnaires on a computer. These questionnaires will be about my demographics, personality, mood, emotions, stress, health behaviors, and physical and emotional well-being. These will take approximately 45 minutes to complete.
- h. I will be given a home saliva sampling and dexamethasone suppression test (DST) kit and instructions about how to use the kit. These tests will be used to check my body's regulation of stress hormones. I will complete this home saliva sampling before my baseline stress visit. I will complete a logbook to record the time of my home-based saliva collections, as well as my mood, at each sample. I will also record my daily use of tobacco, alcohol, and other health behaviors as well as my stress level and how I coped with stress each day. I will take 4 saliva samples (waking, 30 minutes post-waking, 5pm and bedtime) on 3 consecutive days prior to my baseline visit, and 2 samples on the morning of the 4<sup>th</sup> day. On the evening of the third day of saliva sampling, I will take a low dose (0.5 mg) dexamethasone pill (a synthetic hormone similar to cortisol, a hormone my body produces naturally). Because dexamethasone is similar to cortisol, taking a small dose usually decreases the amount of cortisol the body makes the next morning. By measuring the cortisol level in my saliva on the morning after I take the dexamethasone pill, the researchers will be able to see how well my body regulates stress hormones. I will collect my saliva by drooling through a straw into a small plastic labeled tube. I will freeze each sample as soon as possible; if I am not at home when I take a sample, I can refrigerate or leave the sample at room temperature until I am able to put it in the freezer. The saliva will need to be stored in my home freezer until I bring it in. I will be reminded when to start the saliva collection when I am called with my fasting glucose result.
- i. Dietary intake assessment: I will be given a copy of a questionnaire about the foods I typically eat, along with a portion size booklet, and instructions about how to complete this questionnaire at home. I will be given a postage-paid envelope in which to return the completed questionnaire by mail. This questionnaire will take approximately 30 - 45 minutes to complete. I can call study staff, including a study nutritionist, if I have questions when I am completing this form. My completed questionnaire will be reviewed by a trained study nutritionist for completeness and consistency, and if needed, I will be contacted by phone for clarification.

The blood draw will be used to confirm that I am eligible for the study. It will take about a week to get these test results. Study staff will call me to tell me the results and whether I am eligible for the rest of the study. I may go through this screening visit and not be eligible for the study. If I am eligible for the study and still interested in participating, I will schedule a baseline visit.

The total time to complete the consent/screening visit will be about 2 hours.

- 2. Baseline afternoon visit: This visit will usually happen 2-4 weeks after the screening visit. This visit will take about 2.5 hours to complete and will occur in the afternoon. At this visit, I will do the following:
  - a. I will bring my saliva kit back with me to this visit.
  - b. My blood pressure will be measured using an appropriate blood pressure cuff and my heart rate will be assessed using a heart rate monitor. My ear temperature will also be measured using an infrared digital ear thermometer.
  - c. I will have my weight measurement taken with a gown on.
  - d. I will complete questionnaires on a computer. These questionnaires may be about my mood, emotions, stress, health behaviors, and physical and emotional well-being. Study staff will remain nearby and will be available to help if I have questions or need technical assistance. If I need help, I can ask the staff for assistance. These questionnaires will take approximately 20 minutes to complete.

- e. Autonomic Nervous System (ANS) monitoring: I will have a number of sensors placed on my skin in order to measure my heart rate, blood pressure, cardiac output (i.e. the amount of blood pumped on each beat of my heart), and perspiration measured. The sensors are like those used for EKG recordings. Sensors will be attached to my arms, legs, neck, and chest. I will have to lift my shirt enough to allow placement of the sensors.
- f. I will be asked to do tasks that involve thinking and talking. I will be given instructions about what to do before doing these tasks. I will be videotaped while doing the tasks. I will give saliva samples and have ANS monitored during this part of the visit. I will complete paper and pencil questionnaires about my response to the tasks I am asked to do. I will be quietly resting for about 45 minutes of this visit. I may be given headphones to listen to music or audiorecordings during the visit. At the end of the visit, study staff will discuss the experience of the visit with me. I can choose not to have my tape used for research purposes at any time.

The total time to complete this visit will be about 2.5 hours.

- 3. **Baseline Fat Aspirate visit:** If I agree, I will have a 45 minute visit for a fine-needle aspirate of abdominal fat. This involves drawing some cells from under the skin on the abdomen into a needle. This is similar to a blood draw, but the needle is put into tissue rather than a vein. I will lie on a bed, and local anesthetic will be used to numb a small area of skin on my abdomen. A needle and syringe will then be used to take a small amount of fat tissue from under the skin in my abdomen near my belly button. During the fat aspirate, there is usually minimal discomfort. To reduce the discomfort, a local anesthetic (Lidocaine 2%) will be injected into the tissue where the needle will be inserted for the aspirate in order to numb the area. This is the same type of injection that is used by dentists when numbing teeth for dental work. If I am allergic to Lidocaine, or similar drugs used to numb the skin or mouth, I will not have a fat aspiration. Once the aspirate has been taken, manual pressure will be held at the site until bleeding stops. After the anesthetic wears off, the area may be sore for about 1 day. I should not be left with a scar but the area may be slightly bruised for a week or two afterwards. The fat aspirate will be used to measure the activity of an enzyme (11  $\beta$ -HSD 1), that may be related to where excess fat is deposited in the body. Removing the fat itself typically takes 10 minutes or less, but the whole procedure, including set up and applying the local numbing agent may take up to 45 minutes. This visit will be in the morning, as I will be asked to fast for about 8 hours before the procedure. Under certain circumstances it may be possible to have this procedure at another visit (e.g. consent or MRI). I may have my weight measurement taken at this visit

The fat aspirate is very helpful scientifically, but is not a required part of the study. If I choose not to allow this, it will not affect my participation in the study. If I agree now, but change my mind in the future, I can notify study staff and withdraw this agreement. I will circle my choice and initial at the end of this form to indicate whether or not I am willing to have this.

- 4. **Baseline MRI visit:** I will have a separate visit to measure the amount and location of my abdominal fat. This step will not be done if I have metal implants in my body. People with metal implants can be injured by MRI, so I will be screened for this and warned of the risk to avoid undergoing MRI if I have metal implants. If I pass the safety screen for participating in MR imaging, I will go to the UCSF Radiology research center at China Basin for a baseline magnetic resonance imaging (MRI) scan to measure the amount of fat in my abdomen. This visit will take about 30 minutes and will ideally occur after completion of the baseline visit and prior to randomization. This MRI machine uses a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an x-ray CT scan. I will be asked to lie on a long narrow bed for approximately 15 minutes while the machine gathers data. During this time there will be a loud banging noise. I may feel warm during this procedure. During this time I will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields. I will not feel either. I will be given earplugs or headphones that I will be required to wear. The space within the large magnet in which I lie is somewhat confined. The procedure will be done by trained technicians. I can stop the procedure at any time if I experience excessive distress or discomfort.

5. Randomization. After my baseline assessments are complete, I will be randomized to one of two groups. I will have a 50/50 chance (like flipping a coin) of being placed in one of the two groups. Neither study staff nor I will make the choice.
6. Interview with group leader: I will be scheduled for an individual 30-45 minute interview with the group leader prior to the start of class. The interview will last 30 minutes. The purpose of the interview is for the group leader to learn my goals and for me to have an opportunity to discuss any issues or concerns I may have about the class. I will meet individually with the dietician to review my progress and goals two other times during the 22-week intervention. I may have my weight measurement taken at this visit or on the first night of class, as my weight may have changed since my last CCRC visit. My weight will be recorded in private by a study research assistant.
7. Study Classes: Regardless of which group I am assigned to, I will participate in a 6-month weight-loss program. I will have 12 weekly classes over 12 weeks, followed by 3 classes every two weeks, then a final class one month later. In total, I will attend 16 classes over 5.5 months. The final four classes are spaced out in order to help me learn to maintain the diet, exercise and other changes that I made during the weekly classes so that I might achieve and maintain long-term weight loss. I will also have two all-day (7-hour) classes on a Saturday or Sunday around the 7<sup>th</sup> and 14<sup>th</sup> week of the program. Study staff will go over the exact dates of the classes with me. It is understandable that I may have a schedule conflict for one or two of the classes, but I should only participate if I can attend nearly all of the classes. Each class will last 2-2.5 hours (and the first class may last as long as 3 hours). Study staff will go over the exact schedule with me when I am randomized. There will be about 15 other study participants in the group with me. Following the last class, if I am willing to provide an email address, I may receive suggestions and ideas for continued and maintained weight loss. I may get up to two emails a month.

There will be differences in curriculum between the two groups, but both will include state-of-the art diet and exercise approaches to losing and maintaining weight loss. In the classes we will discuss healthy diet practices to encourage weight loss, and how to incorporate more exercise into my daily life. I will be asked to complete 30-60 minutes per day of home assignments 6 days per week during the course. The home assignments will include gentle exercise practices (like walking) as well as other activities to help support weight loss. Each week, I will be asked how many minutes I practiced the homework activities during the past week. I will be given a pedometer and asked to wear it and record the amount of walking I do as well as complete some questionnaires about my general diet and exercise over the week. The total amount of out-of-class time will be about 5 hours a week.

Depending on the group I am in, I may do some gentle yoga. I may also have some stress reduction exercises.

8. Audiotaping: Class sessions will be audio recorded in order to ensure adherence to the structure of the program to which I have been assigned. A recorder will be placed in front of the class, nearest to the instructor. The purpose of the recording is to capture the instructor's voice and assess his/her effectiveness in teaching the class materials. However, there is a possibility that my voice may be recorded. I have the option to either sit in the back of the room, or stop the tape while I am speaking if I do not want to be audio taped. All tapes will be destroyed after they have been completely transcribed. Any information that links my identity to the voice on the tape will not be included in the transcribed data. The recordings will be made available for me to listen to on a secure website if I miss a class.
9. 3 Month Visit: This visit will occur in the morning and will take approximately 2 hours to complete. The night before this visit, I will not eat or drink anything (except water) after midnight and will not eat breakfast in the morning in order to measure hormones in my blood related to metabolism, such as glucose and insulin. The following procedures, previously completed at the consent and baseline visits (and described more fully in those sections) will be repeated at this visit:
  - a. Blood pressure, heart rate, and ear temperature measurement.
  - b. Height and weight measurement.
  - c. Hip and waist measurements.

- d. Fasting blood draw of 90cc (about 6 tablespoons).
  - e. Questionnaires on the computer: these will take approximately 45 minutes. I may choose to complete some of these questionnaires from home prior to the visit.
  - f. Autonomic Nervous System (ANS) monitoring: I will have a number of sensors placed on my skin in order to measure my heart rate, blood pressure, cardiac output (i.e. the amount of blood pumped on each beat of my heart), and perspiration for about 5 minutes. The sensors are like those used for EKG recordings. Sensors will be attached to my arms, legs, neck, and chest. I will have to lift my shirt enough to allow placement of the sensors.
  - g. Influenza vaccination: I will be given influenza vaccination. This will be done to test my immune responses to vaccination. The most current available vaccine will be used. I will receive the vaccine even if I enroll at a time when the vaccine is not typically given. This step will not be done if I have a history of allergies to eggs (which increases the risk of allergic reactions) or allergic reactions to influenza vaccination. If I have already received this year's flu vaccine, I will not be given the flu vaccine as part of the study. If I feel strongly about not getting the vaccination, I can also opt out of this step by informing study staff.
10. Vaccination follow-up visit: If I received an influenza vaccination, I will come back 4 to 8 days later for a small blood draw. I will have 40 cc of blood (about 2.5 tablespoons) drawn in order to measure my immune response to the vaccine. The visit will take about 20 minutes and will take place at the Mount Zion CCRC
11. Follow-up afternoon visit: This visit will happen around 4.5 months after the class start date. It will last approximately 2.5 hours and will occur in the afternoon. The following procedures, previously completed at the baseline stress visit (and described more fully in that section) will be completed at this visit:
- a. My blood pressure, heart rate and ear temperature will be measured.
  - b. Height and weight measurement.
  - c. I will complete questionnaires on a computer. These questionnaires may be about my mood, emotions, stress, health behaviors, and physical and emotional well-being. Study staff will remain nearby and will be available to help if I have questions or need technical assistance. If I need help, I can ask the staff for assistance. These questionnaires will take approximately 20 minutes to complete.
  - d. Autonomic Nervous System (ANS) monitoring: I will have a number of sensors placed on my skin in order to measure my heart rate, blood pressure, cardiac output (i.e. the amount of blood pumped on each beat of my heart), and perspiration measured. The sensors are like those used for EKG recordings. Sensors will be attached to my arms, legs, neck, and chest. I will have to lift my shirt enough to allow placement of the sensors.
  - e. Similar to my baseline visit, I will be asked to do tasks that involve thinking and talking. I will be given instructions about what to do before doing these tasks. I will be videotaped while doing the tasks. I will give saliva samples and will have ANS monitored during this part of the visit. I will complete paper and pencil questionnaires about my response to the tasks I am asked to do. I will be quietly resting for about 30 minutes of this visit. I may be given headphones to listen to music or audiorecordings during the visit. At the end of the visit, study staff will discuss the experience of the visit with me, and I will be told about the purpose of and the scientific basis for the procedures. I can choose not to have my tape used for research purposes after I find out more about what is being studied.
  - f. If I received the flu vaccine at my 3 month visit, I may have a small blood draw (40cc or about 3 tablespoons) at this visit to further examine my immune response to the vaccine.
12. 6 month CCRC visit: This visit will last approximately 2 hours and will occur in the morning. The night before this visit, I will not eat or drink anything (except water) after midnight and will not eat breakfast in the morning in order to measure hormones in my blood related to metabolism, such as glucose and insulin. The following procedures, previously completed at the baseline visits (and described more fully in that section) will be completed at this visit:

- a. I will bring my second set of saliva and urine kits back with me on this visit. I will be called and reminded when to begin these collections.
- b. My blood pressure, heart rate and ear temperature will be measured.
- c. Height and weight measurement.
- d. Hip and waist measurements.
- e. Fasting blood draw: I will have a blood draw of about 90cc (about 6 tablespoons).
- f. I will complete questionnaires on a computer. These questionnaires will be about my mood, emotions, stress, health behaviors, and physical and emotional well-being. These questionnaires will take approximately 45 minutes to complete. I may choose to complete some of these questionnaires from home prior to the visit.
- g. Autonomic Nervous System (ANS) monitoring: I will have a number of sensors placed on my skin in order to measure my heart rate, blood pressure, cardiac output (i.e. the amount of blood pumped on each beat of my heart), and perspiration measured. The sensors are like those used for EKG recordings. Sensors will be attached to my arms, legs, neck, and chest. I will have to lift my shirt enough to allow placement of the sensors.
- h. Similar to my baseline visit, I will be asked to do tasks that involve thinking and talking. I will be given instructions about what to do before doing these tasks. I will be videotaped while doing the tasks. I will give saliva samples and will have ANS monitored during this part of the visit. I will be quietly resting for about 30 minutes of this visit. At the end of the visit, study staff will discuss the experience of the visit with me, and I will be told about the purpose of and the scientific basis for the procedures. I can choose not to have my tape used for research purposes after I find out more about what is being studied.
- i. If I had a fat aspirate done at baseline, and I am willing to have this procedure done again, it will be repeated at this visit. The procedure will add an additional 30 minutes to the visit.

The total time to complete the 6-month CCRC visit will be about 3 hours; If I have a fat aspirate, the visit will be about 3.5 hours.

13. Follow-up fat-aspirate visit: If I had a fat aspirate done at baseline, and I am willing to have this procedure done again, it will be repeated about 6 months after the class start date. This visit will take place at the CCRC and will last 45 minutes. Under certain circumstances it may be possible to have this procedure at another visit (e.g. consent or MRI)
14. 6 month MRI: If I had a baseline MRI and again pass the safety screen for participating in MR imaging, I will return to the UCSF Radiology research center at China Basin for a second magnetic resonance imaging (MRI) scan to measure the amount of fat in my abdomen. This visit will take about 30 minutes to complete, and the scanning procedure will be the same as the first one. I will be asked to lie on a long narrow platform for about 15 minutes while the machine gathers data. I may have my weight measurement taken at this visit.
15. 12 month CCRC visit: This visit will occur in the morning and will take approximately 2 hours to complete. The night before this visit, I will not eat or drink anything (except water) after midnight and will not eat breakfast in the morning in order to measure hormones in my blood related to metabolism, such as glucose and insulin. Similar to the 3 and 6 month visits where I had a fasting blood draw, the following procedures will be repeated at this visit:
  - a. Blood pressure, heart rate, and ear temperature measurement.
  - b. Height and weight measurement.
  - c. Hip and waist measurements.
  - d. Fasting blood draw of 60cc (about 4 tablespoons).
  - e. Questionnaires on the computer: these will take approximately 45 minutes. I may choose to complete some of these questionnaires at home before the appointment.
  - f. Autonomic Nervous System (ANS) monitoring: I will have a number of sensors placed on my skin in order to measure my heart rate, blood pressure, cardiac output (i.e. the amount of blood pumped on each beat of my heart), and perspiration for about 5 minutes. The sensors are like those used for EKG recordings. Sensors will be attached to my arms, legs, neck, and chest. I will have to lift my shirt enough to allow placement of the sensors.

- g. I will bring my third saliva kit back with me on this visit. I will be called and reminded when to begin these collections.
16. 18 month CCRC visit: This visit is very similar to the 12 month visit, but I will not be asked to provide saliva samples. This visit will occur in the morning and will take approximately 2 hours to complete. The night before this visit, I will not eat or drink anything (except water) after midnight and will not eat breakfast in the morning in order to measure hormones in my blood related to metabolism, such as glucose and insulin. Similar to the 12 month visit, the following procedures will be repeated at this visit:
- a. Blood pressure, heart rate, and ear temperature measurement.
  - b. Height and weight measurement.
  - c. Hip and waist measurements.
  - d. Fasting blood draw of 60cc (about 4 tablespoons).
  - e. Questionnaires on the computer: these will take approximately 45 minutes. . I may choose to complete some of these questionnaires at home before the appointment.
  - f. Autonomic Nervous System (ANS) monitoring: I will have a number of sensors placed on my skin in order to measure my heart rate, blood pressure, cardiac output (i.e. the amount of blood pumped on each beat of my heart), and perspiration for about 5 minutes. The sensors are like those used for EKG recordings. Sensors will be attached to my arms, legs, neck, and chest. I will have to lift my shirt enough to allow placement of the sensors.

### **How will my blood, saliva, and fat tissue samples be stored and used?**

Some of my blood will be sent for to Quest laboratories immediately for testing (e.g. for glucose, insulin, cholesterol, and hormones). Some of the blood, and all of the saliva and fat tissue that is collected from me will be stored at the UCSF Biological Specimen Bank (BSB) for research tests for this study. These stored samples will be used to learn more about my metabolic and immune system and stress. Storing blood, saliva, and fat aspirate (if I have this procedure) for these tests is a required part of the study. If I choose to leave the study early I can request that my stored samples be destroyed by contacting study staff or Dr. Hecht at any time. After I complete the study, I can also request that any remaining samples be destroyed. All specimens will be coded, and only study staff will have access to the key that links my name with my study code.

### **Will my blood, saliva or fat tissue be saved for future use?**

If I agree, any of my blood, saliva, or fat tissue that is collected from me and not needed for the planned research tests may be stored at the UCSF Biological Specimen Bank and used for future research, including new tests that become available. Results of any future tests will not be given to me unless the test results are thought to be important to my medical care. Examples of the type of future research that stored specimens might be used for include studies to better understand the effects of stress on the body, how the hormonal and immune systems interact, and factors that may influence diabetes risk. Blood, urine, and saliva specimens will be kept for up to 30 years after the end of the study unless I ask to have them destroyed. I can ask to have stored specimens destroyed after I am finished participating in the study by contacting either study staff or Dr. Hecht. No additional information will be collected for specimen storage, but data from other study measures such as weight, questionnaire answers, and blood test results will be retained along with the specimens. This data can be destroyed when the study is complete by contacting study staff. Otherwise, this study data will be retained until specimens are destroyed. Future work with study specimens is primarily intended for UCSF researchers who collaborate with the research team. Specimens may also be used to address important research questions that can be better studied by non-UCSF investigators at other Universities or medical research companies, Use of specimens by other investigators must be reviewed and approved by study investigators. Specimens and other data that are saved for future research use will have only a study ID number. My name and other ways to identify who the specimens or data came from will be destroyed after the study is complete. These samples will not be sold. I will not receive any payment or financial benefit from any findings or commercial products that might be developed. Having samples saved for future research is voluntary. If I choose not to allow this, it will not affect my participation in the study. I should circle my choice and initial at the end of this form to indicate whether or not I am willing to allow storage of my blood, saliva, and urine for future research.

## **Will genetic testing be done on my blood or other specimens?**

Some blood and fat tissue will be used for genetic testing. Genetic research can look at diseases that are passed on in families. This is not the aim of the genetic testing that will be done in this study. Genetic testing may be done to look at my tissue type (HLA). This is useful in studying the immune system. Other testing will be done to test whether certain genes are active in making substances that serve as messengers for turning on inflammation (cytokine gene expression). Researches may also use genetic testing to see if there are genetic factors that that tend to mean the weight loss program will work better, or not as well. Researchers will not put the results of any of these tests in your medical record

## **Will I receive my test results?**

If I wish, I will receive results of standard health measures: fasting glucose, insulin, cholesterol, and blood pressure. Other lab results will not be given to me because the results are for research purposes and generally would not have direct clinical meaning.

The MRI scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators and UCSF are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merits further investigation, in which case the investigator will contact me to inform me of the finding. If I wish, this information will also be provided to my primary care physician. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and UCSF are not responsible for any examination or treatment that you undertake based on these findings

## **How long will I be in the study?**

My participation in the study will take about 20 months.

## **Can I stop being in the study?**

Yes. I can decide to stop at any time. I will just tell the study researcher or staff person if I wish to stop being in the study.

Also, the study researcher may stop me from taking part in this study at any time if he or she believes it is in my best interest, if I do not follow the study rules, or if the study is stopped.

## **What side effects or risks can I expect from being in the study?**

1. Venipuncture: The risks of drawing blood include temporary discomfort from the needle stick, localized bleeding and bruising, lightheadedness, and rarely, fainting or localized infection.
2. Weight, waist, hip measurements: There is no risk involved in measuring body size (weight, height, circumferences), though it does require measurement while wearing only a T-shirt and underclothes which may cause me to feel uncomfortable. Measurement will be done by a trained, research assistant in a private room.
3. Questionnaires: Some of the questions may make me uncomfortable or upset, but I am free to decline to answer any questions I do not wish to answer or discontinue my participation at any time.
4. Randomization: I will be assigned to a group by chance. The group I am assigned to may prove to be less effective or to have more side effects than the other group or than other available programs. This will not be known until after the study is completed and the data have been analyzed.

5. Exercise: The exercise is designed to have low risk of injuries, but any exercise program may result in muscle soreness or strains, particularly if there are substantial increases in activity levels. Exercise reduces the risk of heart attacks, but there can be a temporary increase in the risk of heart attacks during exercise itself, particularly if I have not been exercising regularly. If I experience significant pain, particularly pain that limits exertion, study investigators recommend stopping the exercise until pain is improved. If significant pain persists after stopping the exercise, I should contact my regular physician. If I develop any chest pain during exercise, I should notify my doctor as soon as possible, as well as notifying group leaders and/or study staff. If I develop severe chest pain during exercise, I should call 911 immediately. Approaches for addressing difficulties experienced during any activities involved in study participation will be discussed further in the group.
6. Audiotaping: My voice might be recorded in the audiotapes. If I do not wish my voice to be recorded on the audiotapes, I have the option to sit in the back of the room where there is less likelihood that my voice will be recorded, or I can ask to have the audiotaping stopped when I am speaking.
7. Flu Vaccine: Receiving the flu vaccine may cause soreness or swelling in my arm where the shot is given. A vaccine may rarely cause a severe allergic reaction. People who have ever had a severe allergic reaction to eggs or to a previous flu shot should not receive the flu vaccine as part of this study.
8. Home assignments: I may find it inconvenient to complete the home assignments for the class. Also, I could experience distressing emotions during some of the home assignments. If this happens, I can stop the exercise and speak to the instructor or study staff either by phone or at the next class. Suggestions for how to handle difficult emotions that come up during home assignments will be discussed in the first class, and throughout the course as needed.
9. Home Saliva Collection: There are no significant risks involved in giving a saliva sample, but I may find the procedure inconvenient. If I am having trouble with completing the collection, I can call study staff for help.
10. Dexamethasone: The low dose dexamethasone pill that I will take during home saliva sampling typically has no side effects or interactions with medications.
11. Thinking and talking tasks: I may be anxious or uncomfortable doing the thinking and talking tasks at the baseline and 6 month visits. I may refuse to do the tasks or stop the testing at any time. If I feel uncomfortable at any time during the thinking and talking tasks, I should tell the study staff immediately so that they can either correct the problem or stop the testing. At the 6 month visit, the purpose and scientific basis for the study procedures will be fully explained to me.
12. ANS monitoring: These tests are not painful and will cause me no physical harm. The sensors are applied and feel like band-aids. Redness or irritation of the skin may occur when they are removed. This usually goes away within a few hours. A skin cream will be available for me to use when the sensors are taken off. If I begin to have discomfort such as redness or itching while wearing the sensors, I can choose to end the test. If I feel uncomfortable at any time during the testing, I should tell the study staff immediately so that they can either correct the problem or stop the testing.
13. Fat aspirate: The risk of this procedure includes infection (a slight risk any time the skin is broken), bleeding at the site, bruising of the area, and a small risk of scar tissue under the skin would form small firm area under the skin. I should not be left with a visible scar but the area may be slightly bruised for a week or two afterwards. Most people will get some visible bruising from bleeding under the skin. I should not do vigorous physical activity involving my abdominal muscles for at least a few hours after the procedure, as this may increase bruising. There is usually minimal discomfort. I will be given the option of not participating in this procedure. The smallest needle will be used. I will be given a local anesthetic (Lidocaine) to minimize my discomfort (the risks of this anesthetic are

described in the next section). The whole procedure including recovery will be carefully executed and monitored by a nurse practitioner or physician for potential complications such as a bleeding, infection or pain. Once the aspirate has been taken, manual pressure will be held at the side until bleeding stops.

14. **Local anesthetic during fat aspirate:** A local anesthetic (Lidocaine 2%) will be injected into the tissue where the needle will be inserted for the aspirate in order to numb the area. This is the same type of injection that is used by dentists when numbing teeth for dental work. This injection commonly causes brief burning during the injection. Common minor problems include swelling and redness in the area in the injection was made. This usually goes away within 1-2 hours, or less. There can be prolonged numbness in the injection area (more than a few hours), but this is not common. If lidocaine goes into the blood stream, it can cause lightheadedness, sleepiness, and low blood pressure. It can also cause slow heart rates. To help avoid these problems, the clinician will draw back on the syringe to make sure it is not in a blood vessel before the injection is made, but sometimes this does not prevent lidocaine from going into the blood stream.
15. **Abdominal MRI:** Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during my examination, which could in the process possibly harm me. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. If I have a piece of metal in my body, such as a fragment in my eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, I will not be allowed into the MRI room and cannot have an MRI. Having an MRI may mean some added discomfort for me. In particular, I may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why I will be asked to wear ear plugs. At times during the test, I may be asked to not swallow for a while, which can be uncomfortable. Because the risks to a fetus from MRI are unknown, pregnant women cannot participate in this study.
16. **Reproductive risks:** The effects of MRI on fetuses is not known. Also, the diet and exercise programs are not designed for the particular diet considerations during pregnancy and breast feeding. If I become pregnant during the study, I may have to stop the diet and exercise program, and some of the follow up testing will be changed. For example, I will not get an MRI. If I think I could be pregnant, I should inform study staff.
17. **Study visits:** Participating in the study may be an inconvenience. Every effort will be made to schedule interviews at convenient times for me.

### **What happens if I am injured because I took part in this study?**

It is important that I tell the Principal Investigator, Dr. Frederick Hecht, if I feel that I have been injured because of taking part in this study. His email is [rhecht@php.ucsf.edu](mailto:rhecht@php.ucsf.edu) and his phone number is 415-353-9743. I may also contact Dr. Patty Moran, the Project Director, at 415-353-9745 or [moranp@ocim.ucsf.edu](mailto:moranp@ocim.ucsf.edu).

**Treatment and Compensation for Injury:** If I am injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, I may call the office of the Committee on Human Research at 415- 476-1814.

### **Are there benefits to taking part in the study?**

I will receive possible benefits of taking part in a weight loss study. These may include weight loss, reductions in risk factors for chronic diseases, such as reduced blood pressure and decreased fasting glucose, and decreased feelings of stress. The information that I provide may also help health professionals better understand how these programs can help people improve their health, mood, and lower their risk for certain diseases, such as diabetes.

## **What other choices do I have if I do not take part in this study?**

I am free to choose not to participate in this study. If I decide not to take part in this study, there will be no penalty to me. I will not lose any of my regular benefits, and I can still get care the way I usually do. If I do not participate, it will not affect my ability to participate in other programs at the UCSF Osher Center. There are a variety of weight loss programs in the community I can participate in if I choose not to be part of this study.

## **Will information about me be kept private?**

Participation in research may involve a loss of privacy, but information about me will be handled as confidentially as possible. A UCSF medical record will be created as a result of my participation in this study. My consent form and brief medical history and notes by the CCRC nursing staff during my research visits at the CCRC will be included in this record. Therefore, my other doctors may become aware of my participation. Hospital regulations require that all health care providers treat information in medical records confidentially. The results of my lab tests (i.e. glucose, cholesterol, etc.) will not be included in this medical record.

A loss of privacy may occur as a result of my participation in the group intervention. In order to minimize this possibility, the research staff will request that participants do not talk to others outside the group about information disclosed by other group participants.

If information from this study is published or presented at scientific meetings, my name and other personal information will not be used. My personal information may be given out if required by law. Organizations that may look at and/or copy my research records for research, quality assurance, and data analysis include:

- UCSF Committee on Human Research
- National Institutes of Health

Research records will be kept as confidentially as possible. All specimens as well as data collected will be coded (no names will be used). Questionnaire responses are confidential and will not be shared with people outside the study. Questionnaires will be reviewed, however, and if I am experiencing suicidal thoughts Dr. Patty Moran (Project Director and clinical psychologist) may contact me to discuss my responses and refer me for further care. If I indicate during the study that I am experiencing suicidal thoughts and am thought to be at risk of harming myself, study staff may be ethically required to break confidentiality in order to ensure my safety.

Laboratory tests such as my fasting glucose, insulin, and cholesterol results will not be sent to my physician unless I sign an authorization to release these records. If I wish to receive copies of these results and/or have them sent to my physician, I can complete the necessary forms with study staff at any time.

## **What are the costs of taking part in this study?**

I will not be charged for any of the study treatments or procedures.

## **Will I be paid for taking part in this study?**

In return for my time and effort, I will be paid for taking part in this study. I will receive \$20 for completing the consent visit. If my consent visit ends early because my blood glucose is too high, I will receive \$10; if my lab glucose results come back in range and I later complete the rest of the consent procedures, I will be paid \$10 for completing the remaining consent visit procedures. I will receive \$30 for each of the following 6 visits: baseline and follow up afternoon visits, 3, 6, 12 and 18 month visits. If I have a flu vaccine, I will receive \$20 for the brief visit with blood draw that will 4-8 days after vaccination. I will receive \$50 for each

of 2 MRI visits. I will also receive \$20 for each of 3 saliva kits that I complete. If I participate in the fat aspirate, I will receive \$30 for each of 2 times I have this procedure done. So, I could receive a total of \$440 over the course of the study if I have the fat aspirate, or \$380 if I do not have the fat aspirate. I will be paid \$10 for each of six 7-day urinary incontinence diaries (\$70 total for the diaries, and a grand total of; \$510 over the course of the study).

I can also get parking vouchers or transit reimbursement up to \$10 for study visits. There is not reimbursement or parking vouchers for the group meetings, when there is street parking available, but I can get assistance with transportation costs for these sessions if this is needed, up to \$10 per session. If I wish to be paid by check, I should receive four to six weeks after my visits. I must give the researchers my Social Security number so the check can be processed.

**What are my rights if I take part in this study?**

Taking part in this study is my choice. I may choose either to take part or not to take part in the study. If I decide to take part in this study, I may leave the study at any time. No matter what decision I make, there will be no penalty to me in any way. I will not lose any of my regular benefits, and I can still get my care from UCSF the way I usually do.

You will tell me about new information or changes in the study that may affect my health or willingness to continue in the study.

**Who can answer my questions about the study?**

I can talk to the researchers about any questions or concerns I have about this study. I can either contact the Principal Investigator Dr. Frederick Hecht ([rhecht@php.ucsf.edu](mailto:rhecht@php.ucsf.edu): phone number 415-353-9743) or the Project Director, Patty Moran, Ph.D., at 415-353-9745. Her email is [moranp@ocim.ucsf.edu](mailto:moranp@ocim.ucsf.edu).

**If I have any questions, comments, or concerns about taking part in this study**, I will first talk to the researchers above. If for any reason I do not wish to do this, or I still have concerns after doing so, I may contact the office of the **Committee on Human Research**, UCSF Institutional Review Board (a group of people who review the research to protect participant rights).

I can reach the CHR office at **415-476-1814**, 8 am to 5 pm, Monday through Friday. Or I may write to: Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143.

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**CONSENT**

I have been given a copy of this consent form to keep.

**PARTICIPATION IN RESEARCH IS VOLUNTARY.** I have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which I am otherwise entitled.

If I wish to participate in this study, I should sign below. I will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about me.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature for Consent

\_\_\_\_\_

Date

\_\_\_\_\_

Person Obtaining Consent

\_\_\_\_\_

Print name of Person Obtaining Consent

Fat aspirate:

Yes, I am willing to participate in the fat aspirate

No, I do not wish to participate in the fat aspirate.

Flu vaccine:

Yes, I am willing to participate in the flu vaccine

No, I do not wish to participate in the flu vaccine

Abdominal MRI:

Yes, I am willing to participate in the abdominal MRI

No, I do not wish to participate in the abdominal MRI

Long-term Blood Banking:

Yes, I consent to have my leftover blood, saliva, and fat tissue stored for future research.

No, I do not wish to have my leftover blood, saliva, and fat tissue stored for future research.

Future contact with this study:

This consent form only covers study assessments up to 2 years. If researchers are able to follow up with participants in this study in future years, they will contact me if I check this box.

Future contact for other studies:

There are other studies that I may be eligible for in the future. UCSF may contact me to invite me to participate in other research studies if I check this box.