"Management of Antipsychotic Medication Associated Obesity - 2"

Informed Consent Form, IRB-approved 10/13/2011

ClinicalTrials.gov Identifier: NCT01052714

Principal Investigator: Donna Ames, MD

Version date: 03/30/2011

VA Department of Veterans Affairs VA RESEARCH CONSENT FORM

Subject Name: **Date:**

Title of Study: Management of Antipsychotic Medication Associated Obesity – 2

Principal Investigator: Donna Ames, MD Phone:310-268-3037

Co-Investigators: Phone:

VAMC: VAGLAHS

INTRODUCTION

You are being invited to take part in a research study at the VA Greater Los Angeles Healthcare System under the direction of Dr. Donna Ames and her research team. Before you decide to take part, it is important for you to know why the research is being done and what it will involve, to include any potential risks to you as well as any potential benefits you may receive.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

1. BACKGROUND AND PURPOSE

The purpose of this study is to determine the effectiveness of our behavioral weight management program to fight obesity associated with antipsychotic medications. This behavioral weight management program will consist of educational classes, coaching to help you improve eating and exercise. The goal of these changes will be weight loss improvement in your mental health, quality of life, and your ability to stick with your treatment. This study is designed to find out what the barriers are to achieving weight loss and how we can help you overcome these barriers. The long-term objective of this study is to decrease obesity-related medical complications such as heart disease and diabetes.

You are asked to participate in this research study because you have been diagnosed as having a severe mental illness (e.g., schizophrenia, schizoaffective disorder, other psychotic disorders, PTSD, or bipolar disorder) and you have experienced a clinically significant increase in weight on your current antipsychotic medication. This study is designed to randomize 120 participants and we anticipate randomizing 30 from this medical center. Your participation in this study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

2. DURATION OF THE RESEARCH

Your participation in this study is expected to last approximately 12 months.

3. STUDY PROCEDURES

If you volunteer to participate in this study, you will be asked to do the following things:

Screening Appointment:

You will be asked to sign a separate document to give us permission to review your medical records and speak with your treating physician about your possible participation and to make sure that you qualify for the research study. During the screening session, we will ask you to watch a 16-minute videotape about participating in research and informed consent. We will then explain to you the research study procedures described in this Consent Form and we will ask you questions to determine if you understand the research.

If you decide to participate and sign this informed consent form, you will be asked to do the following:

1) During the first visit, you will undergo a complete physical exam and a painless test of your heart rhythm known as an electrocardiogram (or ECG).

2) If you have 3 or more risk factors for heart disease you may need to have an exercise tolerance test prior to starting an exercise program. An exercise tolerance test involves walking on a treadmill for a few minutes while your heart is monitored by an electrocardiogram machine. An exercise tolerance test will be repeated when you terminate the study to assure your safety to continue an exercise program.

3) At every visit, your vital signs (blood pressure and heart rate), temperature, weight, and waist size will be recorded. You will also have the percent of fat in your body measured by a small painless machine that you hold in your hands for one minute.

4) During the first visit, week 8, 26, 38, and 52, you will be asked to do the following: You will be asked not to eat or drink anything for 12 hours prior to having your blood drawn (about 29 mL or about 5.8 teaspoons) for levels of blood sugar and fats in your blood (e.g., cholesterol and triglycerides). We will also measure for levels of vitamins B1, B12, folate, vitamin D l, ferritin, and homocysteine. Your urine will be collected and tested for diabetes. You and your doctor will complete questionnaires about your physical and mental functioning.

5) During the first visit and at the end of the study, you will be asked if we can take a photograph of your body from the neck down. Your face will not appear so your identity will not be known.

If you are physically and mentally healthy enough to participate in a diet and exercise program, you will be randomized to either "usual care" or to a behavioral weight management program. Randomization means that you are put into a group by chance. It is like the flip of a coin. Neither you nor the researcher will choose what group you will be in. You will have an equal chance to be placed in either group. If you are not physically healthy to participate in a diet and exercise program (i.e., you have a bad back or heart problems) you may participate in other elements of the program, such as attending classes.

If you are randomized to the behavioral weight management program ("Lifestyle Balance Program"), you will do the following:

a) You will meet with your psychiatrist and your case manager and you will receive nutritional counseling. You will be given suggestions to improve your eating habits and increase your exercise with the goal that you will lose 7% of your body weight. If you are an inpatient, your diet will be adjusted accordingly. Our goal is to assist you to obtain a 500-calorie reduction per day that will result in roughly one pound of weight loss per week.

b) You will be asked to exercise 30 minutes per day for at least 5 days per week. You will be provided with a pedometer to encourage walking, as walking is the easiest exercise. You will be encouraged to participate in

other types of exercise and we will schedule supervised exercise activities at our clinic. These will be run by the Lifestyle Balance Program group leaders and/or an exercise instructor.

c) You will be asked to maintain food and exercise diaries to discuss individually on a weekly basis with your case manager for the first 8 weeks, and then once per month.

d) You will be asked to answer questions about your knowledge of healthy eating habits and nutrition. These questionnaires will be given at the beginning and end of the initial 8 weeks of classes, at 6 months and at 12 months.

e) You will participate in 16 classes over the first 2 months (approximately 2 classes per session). These classes will be offered weekly, but will accommodate whatever schedule you need. The goal is to complete 16 classes in 8 weeks, but additional time will be given if necessary. The classes on Lifestyle Balance (based largely upon the "Lifestyle Balance classes" utilized in the Diabetes Prevention Program) are the following:

Welcome to the Lifestyle Balance Program	Fat Facts
How Antipsychotic Medications Affect Me	What's On Today's Table
Becoming Active: A Way of Life	Take Charge of What's Around You
Mindful Eating	Tip the Calorie Balance
Moving those Muscles	Your Food Away from Home
Weighing the Risks	Delicious Decisions
You Can Manage Stress-Mindfulness, Yoga, Taichi	Variety on Your Plate
Carbs: Simply Complex	Ways to Stay Motivated

f) Booster classes will be given to you on a once per month basis following the 16 classes over the first 2 months.

g) You will receive small rewards for achieving weight loss and exercise goals throughout the study period. These rewards may include pedometers and canteen books for non-food items.

h) You will be asked if you prepare your own foods according to the eating behavior recommendations presented to you. If you are unable to prepare your own foods, we will ask if we can meet with you and your caregivers together to discuss eating behavior recommendations. These meetings will occur during the first visit, every 3 months, and as needed. We will provide pamphlets and information about healthy eating to you and to your caregivers.

Additional Interventions:
In the event that you are not losing weight or are having trouble adjusting to your exercise or diet, you may be asked to do the following: (All are optional)

Additional Exercise Procedures

a)Your physician will review your medical chart to determine if your current medications may be contributing to fatigue or sedation. If necessary, your physician may adjust your medications to increase your energy.
b)Your rewards may be reviewed and changed to improve your motivation to exercise.
c)If your exercise demands are too high, we will adjust these demands to a more comfortable level.
d)We may assist you in finding a safe exercise location. You will be given the opportunity to take our exercise classes or you may be given a membership to a safe exercise facility.
e)We may provide you transportation or bus fare so that you may attend the exercise classes.
f) If you are injured, or have any other physical problem, your exercise regimen and goal expectations may be adjusted to fit your needs.

Additional Diet Procedures

a)Your case manager may request to attend meals with you at your home in order to observe your eating patterns and make positive suggestions.
b)We may work with your Board and Care and/or caregiver and discuss with them ways to help you with healthy eating.
c)You may be asked to substitute a meal or snack for a Slimfast, energy bar, or other food substitute.
d)If your dietary goals are too difficult, we may adjust them to a more comfortable level.
e)You may be asked to repeat some classes and take additional booster sessions to relearn the material taught in class.
f) You may be reeducated about the risks and negative impact of obesity on your health.
g)You may be given take-home reminders such as pamphlets, fat counters, and other materials.

All the additional exercise and eating behavior interventions mentioned above are optional.

If you are randomized to the "Usual Care" group, you will do the following:
You will receive pamphlets about Lifestyle Balance, starting exercise, and general nutritional information regarding food pyramids and the amount of calories in fast foods. You will be encouraged to exercise and eat healthy, and will be weighed at each visit. No classes on nutrition and exercise will be given to you. However, you will be seen every week for 8 weeks and once a month for the remainder of the year-long program to be interviewed by your assigned psychiatrist and case manager, and you will answer questions about your knowledge of healthy eating habits and nutrition. If you are randomized to usual care, you may be eligible for participation in the behavioral weight management program if in the opinion of the investigator your weight and/or metabolic changes require intervention that is more rigorous after 6 months of study participation.

Medical management of other conditions related to obesity from psychiatric medications: Your doctor will assure proper treatment for any medical conditions that are discovered during this study. For example, if it is discovered that you have a heart problem, you will receive a referral to a cardiologist. You will not be required to make any changes in your medications, as part of this study. However, your doctor may need to recommend usual treatments if it is discovered during this study that you have changes in your blood sugar or cholesterol. No medications will be provided as part of this study, and you may need to pay usual co-pay for medications recommended.

4. POSSIBLE RISKS OR DISCOMFORTS

You may experience the following risks and discomforts as a result of participating in this research study:

Discomforts and inconveniences: You will come to clinic one time per week for the first 8 weeks and then once per month for the remainder of the 12 months of the study. You may find these frequent visits inconvenient. If you are randomized to the behavioral weight loss program, you will be offered educational lectures and materials to assist you with developing a healthy lifestyle. You may find this information and the questionnaires boring or irritating and the clinicians will be sensitive to this possibility. In some cases, talking about your weight and health could be embarrassing, stressful, or depressing, particularly in a group setting. If participation in small group classes is uncomfortable to you, every effort will be made to provide the class material to you in an individual basis.

Risk of symptom worsening or relapse: One risk is the worsening of your symptoms of schizophrenia which may result from the following: changing your diet and/or restricting your calories as well as exercising. Most data support the beneficial effects of weight loss and exercise, however, we cannot guarantee that. Some people feel irritable and grumpy when they make dietary and exercise changes. Because schizophrenia and schizoaffective disorder are illnesses that can be affected by stress, it will be very important that you and your doctor meet so your psychiatric symptoms can be carefully monitored. If exercise and diet changes as well as class participation are proving too stressful for you, your doctor may recommend discontinuing you from the program. You understand that some symptoms of your schizophrenia illness (for example: auditory hallucinations or hearing "voices," visual hallucinations or seeing "visions," delusions – highly unrealistic thoughts or beliefs, or paranoia—unreasonable fears or suspiciousness) may increase and this may be unpleasant or distressing to you. Your symptoms may worsen to the point that you might begin to have thoughts of hurting yourself or others. It is possible that you might act on these thoughts and actually hurt yourself or somebody else. Death is possible if you act on these thoughts.

If, in the opinion of the study doctor, there are problems caused by your participation in the healthy lifestyles program, your doctor may need to stop your participation. If your psychiatric symptoms worsen, you may need to be hospitalized for your safety. If you are hospitalized you do not have to stop participation in the protocol unless your doctor and you think it is unwise to continue. If you become very ill and your behavior becomes life-threatening, and it is considered unwise for you to continue in the study, your doctor will discontinue your participation in the study and make sure that you receive proper follow up care. At any time you can decline to participate in the study, as study participation is voluntary.

If you think your symptoms are getting worse, please contact Dr. Donna Wirshing at 310-278-3037. If after business hours, you can call 310-478-3711 and ask that the investigator be paged.

Risks of blood tests: When having blood drawn, you may experience some discomfort as a result of the needle prick in your arm. Some bruising or slight bleeding may occur. Although infection is possible, it is extremely rare because the needle is sterile and disposable. Occasionally, people feel lightheaded or faint when blood is drawn.

Risk of exercise: Although exercise will be recommended in order to promote weight loss and improve your overall health, exercise could result in injury or worsening of certain medical problems that you might have. It is possible that you could become sick or even die if you have certain medical conditions, such as coronary artery disease, that could be made worse by exercise. You should inform the study doctor of your medical history and any conditions that could be made worse with exercise such as preexisting injuries to your muscles or bones, asthma (trouble breathing), angina (chest pain), or heart disease. If you experience severe chest pain or severe physical discomfort and need immediate assistance, do not hesitate to contact us, come to the Emergency Room 24 hours a day seven days a week, or call 911. Do not drive if you are experiencing chest pain.

Risk of losing confidentiality: A risk of study participation is loss of confidentiality of your private information. Every effort will be made to protect your confidentiality throughout every procedure of the study including subject recruitment. A certificate of confidentiality has been obtained for this study. The certificate of confidentiality protects you from having the records related to your study participation reviewed by others who are not given permission by you to view these records.

Risk of conflict of interest: If any of the doctors listed on this consent form is your treating physician, he (or she) is also an investigator on this study. As an investigator, he (or she) is interested not only in your clinical welfare, but also in the results of this study. It is possible that occasionally these two goals may be in conflict. At any time during this study, you may ask for a second opinion from another doctor who is in no way associated with this study.

5. POTENTIAL BENEFITS

No benefit can be promised to you from your participation in this study. However, some people may lose weight and feel better.

6. ALTERNATIVE PROCEDURES

You may choose not to participate in this study. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

7. CONFIDENTIALITY

Participation in this study will involve a loss of privacy, but information about you will be handled as confidentially as possible. While the VA and the researchers on the team will do everything to prevent any loss of information, in the event that there is breech of information, you will be contacted by the VA directly.

Your research records will be labeled with a code number. You will not be able to be identified by your research record. The list that matches your name with the code number will be kept in a locked file in the research team's office. This list will be protected by the research team. The research records will be kept in a password-protected computer file that only the study team has access to. Your information will be combined with information from other people taking part in the study.

We will keep confidential all research records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, someone from the Food and Drug Administration, the Office of Human Research Protections, the Government Accounting Office, the VA Office of Research Oversight, our Institutional Review Board, and our Data and Safety Monitoring Board and the Research Compliance Office may look at or copy portions of records that identify you, including your medical record; the sponsor may look at, but not copy, portions of the records that identify you, including your medical record. In addition, please note that VA policy requires that a note be written in your medical record concerning the consent process and your enrollment in this study. Thus non-research VA staff will have access to that information in the course of clinical care.

In addition, in accordance with California law, confidentiality cannot be guaranteed if the investigator becomes aware that you may be a danger to yourself or to others, or becomes aware that acts of child abuse or elder abuse may have occurred.

We may write about the combined information we have gathered, however, any presentations or publications from this information will not identify you.

At the end of this form you will be asked for your permission to allow the VA to share your Personal Health Information with the research team for use in this study. Your separate signature on that part of the consent form will reflect your official authorization.

8. COSTS TO PARTICIPANTS AND PAYMENT

You will not be charged for any treatments or procedures that are part of this study. For veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study.

You will come to clinic one time per week for the first eight weeks and then one time per month for the remainder of the 12 months, for a total of 18 visits. You will receive $10 dollars at each visit. This payment is intended as compensation for any expenses associated with participation in the study (for example, cost of transportation to the VA). In addition, the payment is intended to compensate somewhat for the time of some of the study procedures. The maximum amount of money you will receive if you stay in the study for one year is $180.00.

Weight loss Incentives: If you are randomized to the Healthy Lifestyle group, you may receive weight loss incentives. Canteen Gift Certificates with a $10 value may be provided to you as an incentive for participating in Healthy Lifestyle activities such as yoga, walking, or taichi. Ten certificates ($100 value) is the maximum number of certificates you may receive throughout your participation. In addition, a pedometer and Slimfast meal substitutes may be provided to you to facilitate meeting weight loss goals.

9. MEDICAL TREATMENT AND COMPENSATION FOR INJURY

In the event that you sustain an injury or illness as a result of your participation in this VA approved research study, all medical treatment (emergency as well as medical treatment beyond emergency care) will be provided by the VA. Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you. However, no plans or funds for additional compensation have been set aside. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

In the event of a research related injury or if you experience an adverse reaction, please immediately contact your study doctor at 310-268-3037 during the day and via pager at 310-268-3461 #5909 after business hours. If you need emergency hospitalization in a private hospital because you are unable to come to the VA, have a family member or friend contact your study doctor so that the VA can coordinate care with the private hospital.

10. VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are otherwise entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff and it will not affect the usual care that you receive as a patient.

There are no known consequences of withdrawal from this study.

11. RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The study doctor has the right to end your participation in this study for any of the following reasons:

it would be dangerous for you to continue; you do not follow study procedures as directed by the study doctors; the sponsor decides to end the study.

12. PERSONS TO CONTACT

In the event that you have a question about the research or experience a research related injury or adverse reaction, please immediately contact one of the investigators on this study: Dr. Donna Ames at 310-268-3037.

You may also contact the Associate Chief of Staff for Research and Development for the VAGLAHS at the VA Greater Los Angeles Healthcare System, 11301 Wilshire Blvd, Mail Code 151, Los Angeles, CA 90073. The telephone number is 310-268-4437.

13. SIGNIFICANT NEW FINDINGS (Include if Applicable)

We will tell you about new information that may affect your willingness to stay in the study.

14. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date
_____ Subject's Conservator** Name	_____ Subject's Conservator ** Signature	_____ Date

**If applicable

RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.