BRIGHAM AND WOMEN'S HOSPITAL
Program for Weight Management

INFORMED CONSENT FOR TREATMENT

A. GENERAL DESCRIPTION

The Program for Weight Management (PWM) is affiliated with the Brigham and Women's Hospital and utilizes physician-directed weight control programs. These programs have been developed to treat obesity in adult patients, particularly when such therapy can assist in the management of weight-related health problems. The PWM has determined that for most obese patients who seek professional help, the most reliable way to achieve significant weight loss is to use a nutritionally adequate, medically supervised low calorie diet with exercise. This may be combined with prescription medicine and/or surgery to achieve optimal and durable weight loss.

I understand that the PWM offers no medical care other than weight reduction and may periodically provide regular reports to my personal physician. I understand that I cannot remain on a medically supervised low-calorie diet indefinitely. Accordingly, I also understand that the PWM requires a careful, gradual transition from a medically supervised low-calorie diet to a weight-maintenance lifestyle. I recognize that it is pointless to expect permanent weight loss from involvement in the PWM in the absence of active participation in a strong weight-maintenance program in association with an appropriate exercise regimen.

It is understood that I will undergo a medical history, physical examination, electrocardiogram (as recommended), laboratory blood tests and other measurements to determine my suitability for the PWM and to plan individualized treatment and maintenance programs. I will be seen by a physician and a physician assistant regularly as indicated, undergo laboratory testing at regular intervals and attend a unique series of behavioral, nutritional and counseling sessions on a weekly basis. I understand that attendance at these follow-up visits is important to ensure safe weight loss in a medically supervised environment and that the behavioral program continues after the weight loss goal has been achieved.

I understand that I may participate in **one** of four treatment plans, depending on what is appropriate for me. These are:

1. CALORIE-CONTROLLED DIET
2. PRESCRIPTION MEDICINE AND CALORIE-CONTROLLED DIET
3. LIQUID FORMULA DIET
4. FOOD AND LIQUID FORMULA DIET

B. BENEFITS

The potential medical benefits of these forms of treatment have been explained to me. These may include decreased blood pressure, lowered blood sugar, lowered blood cholesterol and triglycerides, lowered risk of heart disease and stroke, as well as enhanced psychological wellbeing. The decreased risk of developing obesity-related disease may increase my longtime survival. However, I understand that no guarantees have been made to me concerning the results of any of these forms of treatments.

C. ASSOCIATED SIDE EFFECTS AND RISKS

The PWM has been designed to minimize the undesirable side effects associated with therapeutic weight loss. However, the PWM cannot guarantee that side effects will never occur. Thus, it has been explained to me that weight reduction on the PWM program may be associated with the following side effects: anemia, feeling cold, dry skin, temporary skin rash, dizziness upon sudden standing, fatigue, muscle cramps, bad breath, hair loss, bowel changes, and increased uric acid level in the blood. In rare cases, rapid weight loss subjects a nerve in the leg to unusual pressure leading to numbness or loss of muscle power. This is usually temporary and I can prevent it by avoiding activities that compress the nerves, such as prolonged crossing of the legs. Other rare

effects are the appearance of previously undetected gallstones or gout. In addition, it is conceivable that other side effects could occur which have not been observed to this date.

DRUG RISKS:

I understand that the drugs used for assisting weight reduction may cause me to have a wide variety of symptoms, including dry mouth, anxiety, nervousness, insomnia, drowsiness, fatigue, depression, tremor, lightheadedness, dizziness, rapid heart beat, irregular heart rhythm, increased blood pressure, low sodium level in the blood, altered sexual function, and stomach complaints such as nausea, pain, loss of appetite, and diarrhea. I also understand that a small number of patients have become depressed and manic disorders occurred in others, but the relationship to the drugs is not clear. Obesity drugs are classified as having addiction or abuse potential, but the risk is thought to be very small. If I take phentermine on a long-term basis, I may feel tired for several days after its discontinuation.

I understand that with administration of any drug, there is the possibility of an allergic reaction that may cause skin rash, difficulty breathing, collapse, or even death. Such reactions are very rare with all the drugs used in this treatment program.

The possibility always exists in medicine that the combination of any significant disease with methods employed for its treatment may lead to previously unobserved or unexpected ill effects. Some reports have suggested a relationship between programmed diets and sudden death, probably due to irregularities of the heart. I understand that participation in this weight reduction program may entail an extremely low risk of fatal heart irregularities. Regular checkups, including EKG monitoring as indicated, are designed to keep this risk at a minimum.

I understand that withdrawal from normal eating can be emotionally stressful, and an individual's reaction to this form of therapy for obesity cannot be predicted. It is possible that I may develop symptoms of depression, agitation, or excessive anxiety.

If I am taking any medications for any other reasons besides weight loss, i.e., for depression, migraines, or colds/allergies, I understand that weight loss may affect the dosage or need for the medication, and that my personal physician may want to adjust my medication and associated treatments.

D. PROGRAM PROCEDURES

1. I understand that it is essential that I consume no less than the total amount of formula diet and/or food prescribed, as well as the recommended amount of fluids, and that failure to consume the total amount may be harmful to my health. Moreover, I understand that if I interrupt the prescribed low-calorie formula diet program by abruptly consuming a meal of regular foods, I may develop some gastrointestinal distress, bloating, diarrhea, and/or constipation.

2. I understand that successful weight loss includes not only the diet plan I have chosen but also participation in a regular, structured exercise program. I must obtain written clearance from my personal physician before participating in an exercise program.

3. I understand that there is a staff member on call and available by telephone 24 hours/day, with physician backup. Should I have any problems I feel are associated with the PWM program, I will call the office immediately.

4. My general medical problems will continue to be treated by my personal physician. My personal physician can obtain my progress and laboratory results while I am in the PWM program.

5. If at any time the PWM physician feels that it is in my best interest, he/she may discontinue my participation in the PWM program. I understand that it is my responsibility to be present at all office sessions. My failure to attend any session(s) will be cause for the supervising physician to reevaluate my continued participation. Since such absences may be detrimental to my health, I may be discharged from the PWM program.

6. All medical, surgical, psychiatric or hospital expenses incurred by me as a part of, or resulting from, any participation in the PWM program, will be my sole responsibility. Neither my physician, staff, nor the PWM will assume responsibility for any of my medical expenses at any time.

7. FOR PATIENTS WHO MAY BE PREGNANT OR CONSIDERING PREGNANCY: I understand that caloric restriction may have damaging effects on a fetus. To the best of my knowledge, I am not pregnant and have been made aware that I should not become pregnant while under treatment in the PWM program. If I become pregnant or suspect that I am pregnant, I will notify the PWM physician immediately and will also notify my personal physician. If I become pregnant or suspect that I am pregnant, I will begin a regular diet until it is determined that I can safely resume my prescribed weight loss regimen. Also, I declare that I am not breast feeding a child at this time.

8. I will consent to data obtained during my treatment being used in scientific presentations and publications with the condition that I am not identified by name in the published material and my anonymity will be preserved.

E. PROGRAM POLICIES

1. I understand that ALL program fees are **NOT** covered by insurance and are my responsibility. If my insurance does agree to pay for the program, I agree to pay all program fees up front to the Program for Weight Management and have the insurance company reimburse me directly.

2. I understand that all HMR products are **NOT** returnable. Once I have purchased any of these products I will be unable to receive a refund or exchange.

3. I understand that laboratory fees are **NOT** included in the enrollment fee. These fees will be submitted directly to my insurance company by the laboratory. I will check with my insurance company to determine if regular blood draws are covered by my plan. Any portion of the lab fees that are not covered by my insurance plan are my full responsibility.

4. I understand that any medication prescribed by a PWM physician is **NOT** included in the enrollment fee. I am responsible for the full cost of all medications prescribed to me.

5. I understand that the enrollment fee to the Program for Weight Management covers eight visits within a ten week period. (My 8 week program fee allows that I may be absent twice in a ten week period for any reason) I understand that extended absence considerations will be made in the case of medical illness or bereavement. I agree that extended absence considerations for any additional circumstances will be made per the discretion of PWM staff. I understand that dates when clinic is closed due to holidays or inclement weather will not count towards my 8 purchased weeks.

6. All enrollment fees must be paid within **ONE WEEK** of their due date. If these fees go unpaid for 2 or more weeks, I understand that I will be unable to participate in the Program for Weight Management until the fees are paid.

7. I understand that formula sales are made at the discretion of the medical staff. The Program for Weight Management will not sell formula to anyone if they have not been seen in the clinic for three or more weeks.

I have read and understand the above information and hereby agree and consent to treatment. I understand I may revoke this voluntary consent and discontinue my participation in the PWM program at any time, but that this consent will be valid until revoked in writing by me.

_____ _____

Name (Please Print) Signature

_____ _____

Witness Date