

# Informed Consent

## *We want you to know...*

When you decided to learn more about managing your weight, you took an important step toward improving your health. The health professional who is advising you can help you develop comprehensive weight management skills while you lose a meaningful amount of weight.

The calorie deficit and portion-controlled diets (including liquid formulas) were developed over 25 years ago for weight reduction. They are used with patients who are overweight and who may have significant medical problems related to obesity. Such problems may include hypertension, coronary disease, diabetes, lung, joint or bone disease, and the need for non-emergency surgery. These methods of weight reduction have been utilized in hundreds of clinics in the United States. They have been described and evaluated in many professional medical journals since 1974.

## *Your role...*

Your success will depend upon your commitment to understanding and fulfilling your obligations in a course of treatment. It is important that you be willing to:

- ◆ Provide honest and complete answers to questions about your health, weight problem, eating activity and lifestyle patterns so your health care professional can better understand how to help you.
- ◆ Devote the time needed to complete and comply with the course of treatment your health professional has outlined for you, including assessment, treatment, and maintenance phases.
- ◆ Work with your health care professional and others who may participate in helping you manage your weight loss, including keeping a daily diary, attending your sessions regularly if appropriate, and following your diet and exercise prescription.
- ◆ Allow your health care professional to share information with your personal physician.
- ◆ Make and keep follow-up appointments with your physician and have any blood tests taken or any other diagnostic measures made which your physician may deem necessary during your course of treatment.
- ◆ Follow your exercise program within the guidelines given to you by your health care professional and your physician.
- ◆ It is vitally important for you to advise the clinic staff of ANY concerns, problems, complaints, symptoms, or questions even if you may think it is not terribly important, so the physician can determine if you should be seen more often. Keeping the clinic informed of any questions or symptoms you have, affords the best chance of intervening before a problem becomes serious.

If you do not have a personal physician, you must agree to find one before you and your health care professional begin working together. Your health care professional can assist you in this process if you like. Your signature below represents your permission, understanding and commitment to the above.

### ***Potential benefits...***

Medically-significant weight loss (usually about 10 percent of initial weight, or as an example, losing 20 pounds from 200 pounds starting weight) can:

- ◆ Lower blood pressure, reducing the risks of hypertension
- ◆ Lower cholesterol, reducing the risks of heart and vascular disease
- ◆ Lower blood sugar, reducing the risks of diabetes

If you are taking medications for one or more of these conditions, dosages may need to be adjusted as your overall health improves. You agree to see your physician as needed to have your need for these medications reassessed. Your health care professional will share your results with your physician on a regular basis so the physician is informed about your progress.

Other benefits may also be obtained. Increasing activity level can favorably affect the above conditions and has the additional benefit of helping you sustain weight loss. Weight loss and increased activity provide important psychological and social benefits, as well.

### ***Possible side effects...***

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, including death. Should one or more of these conditions occur, additional medical or surgical treatment may be necessary. In addition, it is conceivable other side effects could occur which have not been observed to date.

**Reduced Weight.** When you reduce the number of calories you eat to a level lower than the number of calories your body uses in a day, you lose weight. In addition, your body makes some other adjustments in physiology. Some of these are responsible, in some participants, for rapid improvements in blood pressure and blood sugar; other adjustments may be experienced as temporary side effects or discomforts. These may include an initial loss of body fluid through increased urination, momentary dizziness, a reduced metabolic rate or metabolism, sensitivity to cold, a slower heart rate, dry skin, fatigue, diarrhea or constipation, bad breath, muscle cramps, a change in menstrual pattern, dry and brittle hair or hair loss. These responses are temporary and resolve when calories are increased after the period of weight loss.

**Reduced Potassium Levels.** The calorie level you will be consuming is 800 or more calories per day and it is important that you consume the calories which have been prescribed in your diet to minimize side effects. Failure to consume all of the food and fluids and nutritional supplements or taking a diuretic medication (water pill) may cause low blood potassium levels or deficiencies in other key nutrients. Low potassium levels can cause serious heart irregularities. When someone has been on a reduced calorie diet, a rapid increase in calorie intake, especially overeating or binge-eating, can be associated with bloating, fluid retention, disturbances in salt and mineral balance, or gallbladder attacks and abdominal pain. For these reasons, following the diet carefully and following the gradual increase in calories after weight loss is essential.

**Gallstones.** Overweight people develop gallstones at a rate higher than normal weight individuals. The occurrence of symptomatic gallstones (pain, diagnosed stones and/or surgery) in individuals 30 percent or more over desirable body weight (50 pounds or more overweight) not undergoing current treatment for obesity is estimated to be 1 in 100 annually, and for individuals who are 20-30 percent overweight, about one-half that rate, or 1 in 200 annually. It is possible to have gallstones and not know it. One study of individuals entering a weight loss program showed that as many as 1 in 10 had "silent" gallstones at the onset. As body weight and age increase, so do the chances of developing gallstones. These chances double for women, women using

estrogen, and smokers. Losing weight--especially rapidly--may increase the chances of developing stones or sludge and/or increasing the size of existing stones within the gallbladder. Should any symptoms develop (the most common are fever, nausea and a cramping pain in the right upper abdomen or if you know or suspect that you may already have gallstones), let your physician and health care professional know immediately. Gallbladder problems may require medication or surgery to remove the gallbladder, and, less commonly, may be associated with more serious complications of inflammation of the pancreas or even death. A drug (Actigall®) is currently available which may help prevent gallstone formation during rapid weight loss. You may wish to discuss Actigall® with your primary care or weight management physician for more information.

**Pancreatitis.** Pancreatitis, or an infection in the bile ducts, may be associated with the presence of gallstones and the development of sludge or obstruction in the bile ducts. The symptoms of pancreatitis include pain in the left upper abdominal area, nausea, and fever. Pancreatitis may be precipitated by binge-eating or consuming a large meal after a period of dieting. Also associated with pancreatitis is long-term abuse of alcohol and the use of certain medications and increased age. Pancreatitis may require surgery and may be associated with more serious complications and death.

**Pregnancy.** If you become pregnant, report this to your health care professional and physician immediately. Your diet must be changed promptly to avoid further weight loss because a restricted diet could be damaging for a developing fetus. You must take precautions to avoid becoming pregnant during the course of weight loss.

**Binge Eating Disorders.** Binge eating disorder is defined as the habitual, uncontrolled consumption of a large amount of food in a short period of time. Participation in a calorically restricted diet has been shown in one study to increase binge eating episodes temporarily. Several other studies demonstrated reduced episodes of binge eating following a calorie deficit and portion-controlled diet. Extended binge eating episodes are associated with weight gain.

### *The risk of weight regain...*

Obesity is a chronic condition, and the majority of overweight individuals who lose weight have a tendency to regain all or some of it over time. Factors which favor maintaining a reduced body weight include regular physical activity, adherence to a restricted calorie, low fat diet, and planning a strategy for coping with weight regain before it occurs. Successful treatment may take months or even years. Medical studies of calorie deficit/portioned-controlled diets (including modified fasting) have shown varying results for percentage of patients who maintain weight loss. In some studies, the percentage has been fewer than 5% of the patients after five years. A group of patients who have been followed for 3 years show that patients have maintained about one half of initial weight loss. Additionally, if you have had fluctuations in your weight in the past, it may be more difficult to maintain the weight you lose during and after this program. A recently published medical study indicated people whose body weight fluctuates greatly or often have a higher risk of heart disease and death compared with persons of relatively stable body weight, and such weight fluctuations may play a role in the development of other chronic diseases.

**Sudden Death.** Patients with morbid obesity, particularly those with serious hypertension, coronary artery disease, or diabetes mellitus, have a statistically higher chance of suffering sudden death when compared to normal weight people without such medical problems. Rare instances of sudden death have occurred while obese patients were undergoing medically supervised weight reduction, though no cause and effect relationship with the diet has been established. The possibility cannot be excluded that some undefined or unknown factor in the treatment program could increase this risk in an already medically vulnerable patient.

***Your rights and confidentiality...***

You have a right to leave treatment at any time without penalty, although you do have a responsibility to make sure the physician knows you are discontinuing treatment and to verify your physician is able to assume medical care for you after you leave treatment.

By signing this Informed Consent, you state: I understand the information about my treatment in the weight management program offered by the clinic identified below is shared, from time to time, with obesity researchers, medical scientists, and developers of weight management treatment. So research, science and the weight management industry may learn and benefit from my treatment and the treatment of others, I give permission for data regarding my treatment to be entered into a national database. I understand that strict confidentiality for the identities and individual records of patients in the database will be maintained. I also give local and national program staff permission to contact me by mail or telephone after my initial period of treatment to obtain information about my health and weight status. Should the results of my treatment or any aspect of it be published, all reasonable precautions will be taken to protect my anonymity.

***Resale of Products...***

The Novartis Nutrition products purchased through this weight management program, including OPTIFAST<sup>®</sup>, OPTITRIM<sup>®</sup>, etc, are intended to be sold through medically supervised weight management programs. By signing this Informed Consent, you agree that you will not resell any Novartis Nutrition products purchased through this weight management program.

***I, the undersigned, have reviewed this information with my health care professional or my physician, and have had an opportunity to ask questions and have them answered to my satisfaction.***

\_\_\_\_\_  
**Participant Signature**

\_\_\_\_\_  
**Date**

***I hereby certify that I have explained the nature, purpose, benefits, risks of, and alternatives to, the proposed program and have answered any questions posed by the patient. I believe the patient/relative/guardian fully understands what I have explained and answered.***

\_\_\_\_\_  
**Physician/Signature**

\_\_\_\_\_  
**Date**

***I have received a copy of this signed consent form.***

\_\_\_\_\_  
**Participants Initials**

\_\_\_\_\_  
**Date**