

**OPTIFAST INFORMED CONSENT**  
Genesis Center for Weight Management  
Genesis Medical Center - Davenport, Iowa

***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.
- ◆ Make and keep follow-up appointments with your physician and have any blood tests or other diagnostic measures recommended by your physician during your course of treatment.
- ◆ Follow your exercise program within the guidelines given to you by your health care professional and your physician.
- ◆ During the full formula phase, you are to avoid all alcohol consumption.
- ◆ Eating raw fruits or vegetables during the full formula phase will cause abdominal pain, bloating and diarrhea.
- ◆ No more than three missed group sessions, regardless of reason, for the duration of the program or you will automatically be discharged from the program. (No refunds given)
- ◆ Two consecutive absences with no communication from you will automatically discharged you from the program. (No refunds given)
- ◆ Understand that the Optifast products and supplies are not likely to be reimbursed by insurance.
- ◆ As part of a medically supervised program, Optifast products must be purchased from the Genesis Medical Center Pharmacy.
- ◆ It is vitally important for you to advise the clinic staff of ANY concerns, problems, complaints, symptoms, or questions. Keeping the clinic informed of any questions or symptoms you have.

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 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

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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 these medications reassessed.

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...***

**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. In some participants, improvements in blood pressure and blood sugar. 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. Consult your physician if these occur.

**Reduced Potassium Levels.** The calorie level you will be consuming is 1200 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. 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. Should any symptoms develop (the most common are fever, nausea and a cramping pain in the right upper abdomen, let your physician and health care professional know immediately.

**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.

***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.

**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.

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By signing this Informed Consent, you state: I understand the information about my treatment in the weight management program offered by Genesis Center for Weight Management

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

The Nestlé HealthCare 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 buy from outside sources or resell any Nestlé HealthCare 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.***

\_\_\_\_\_  
Care Provider Signature and Title

\_\_\_\_\_  
Date

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

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

\_\_\_\_\_  
Date

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