

# Virginia Weight & Wellness

4439 Cox Road | Glen Allen, Virginia 23060

804-726-1500 | Fax: 804-726-1501 | [www.VirginiaWeightLoss.com](http://www.VirginiaWeightLoss.com)

## THE OPTIFAST® PROGRAM OVERVIEW

### INTRODUCTION

Weight gain and obesity is one of the most critical health conditions we face today. It is a chronic medical condition that affects millions of Americans, and causes or contributes to the development of an array of life-threatening diseases, including hypertension, heart disease, and type 2 diabetes.

Unfortunately, there is no simple solution because the root causes of weight gain and obesity are a complex interaction of genetic, social, cultural, and emotional factors. Unless all aspects of the problem are addressed, it is extremely difficult for most people to achieve sustained weight loss.

The OPTIFAST Program is a medically based obesity treatment program that helps obese patients lose weight safely and maintain their weight loss. Developed by Sandoz Nutrition (now Nestlé HealthCare Nutrition), the OPTIFAST Program is based on the belief that a problem as complex as obesity requires a complex solution—one that deals effectively with the physical, social, and emotional aspects of being overweight. OPTIFAST has evolved to be a multidisciplinary approach to obesity treatment that combines a high quality, calorie controlled full meal replacement diet with behavior modification, nutrition education, exercise, psychological support, and medical monitoring of the patient's conditions.

### HISTORY OF THE OPTIFAST PROGRAM

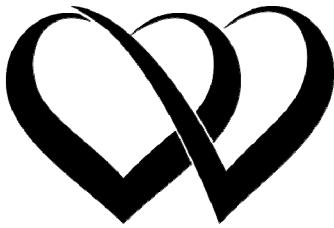
In the early 1970's, Dr. Victor Vertes, Director of the Department of Medicine at Mt. Sinai Hospital in Cleveland, OH, evolved the concept of stimuli narrowing, or using very controlled liquid nutritional formulas as a means of helping obese patients lose weight. Dr. Vertes' work grew out of studies on the physiological effects of this approach conducted in the late 1960's by Dr. Saul Genuth, Director of Mt. Sinai's Saltzman Institute for Clinical Investigation.

In working with obese patients, Drs. Vertes and Genuth discovered that limiting food intake by using a liquid formula diet instead effectively promoted rapid weight loss, but that patients tended to regain the weight once they left the program. It was clear that another element of treatment was needed to help patients sustain their weight loss.

In 1974, Sandoz Nutrition developed The OPTIFAST Program with the assistance of Vertes, Genuth, and other experts in the treatment of obesity. In addition to the liquid formula diet, Sandoz Nutrition worked with Dr. Vertes to develop a weight maintenance program, and with behavior modification experts from around the country to create the behavioral system that forms the framework of the present OPTIFAST Program.

### THE OPTIFAST FORMULA

The OPTIFAST products are manufactured by Nestlé HealthCare Nutrition. This includes a series of nutritional products useful in the treatment of obesity. Foremost among them is the OPTIFAST 800 full meal replacement products which can be used by patients in a complete meal replacement program. The OPTIFAST Formula contains balanced nutrition, including high quality protein, carbohydrates, minerals, and vitamins. It contains no amphetamines, laxatives, or water pills, and is available only through physicians who have received training in the OPTIFAST Program.



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## Informed Consent for the Optifast Program

Patient Name: \_\_\_\_\_

### 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 complete answers to questions about your health, weight condition, 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.
- ◆ Keep follow-up appointments with your physician and have any blood tests or any other diagnostic measures made which may be deemed necessary during your course of treatment.
- ◆ Follow your exercise program within the guidelines given to you by your health care professional.
- ◆ 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.

## Potential Benefits of Weight Loss...

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

Other benefits may also be obtained including improved energy, reduced joint pains, improved mobility, and improved fertility amongst others. 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 of Weight Loss Include...

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 any 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.

**Lowering of Blood Pressure and Blood Sugars and other General Symptoms.** When you lose weight, you may see rapid improvements in blood pressure and blood sugar. If you are on medications for blood pressure or diabetes, these may need to be adjusted over time. You may also have side effects of reduced fluid retention through increased urination, momentary dizziness, a reduced 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 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 electrolytes, 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) is estimated to occur in approximately 1 in 100 individuals (1%) per year who are 50 pounds or more overweight. 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 weight management physician for more information.

**Pancreatitis.** Pancreatitis, or an infection in the bile ducts, may be caused by gallstones or 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, inform your 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.

**Sudden Death.** Patients with morbid obesity, particularly those with hypertension, heart disease, or diabetes, 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.

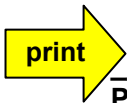
### **There is a Risk of Regaining the Weight you have lost...**

Obesity is a chronic condition, and the majority of overweight individuals who lose weight have a tendency to regain all or some over time. Factors which favor maintaining weight loss include exercise, adherence to a low calorie 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 have shown varying results for percentage of patients who maintain 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.

### **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.

***I 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 Name (printed)



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

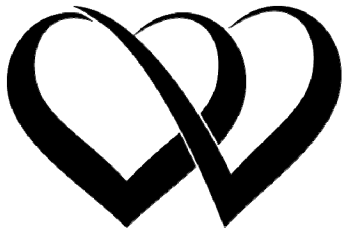
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Date

***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 Name (printed)

\_\_\_\_\_  
Physician Signature

\_\_\_\_\_  
Date



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## OPTIFAST<sup>®</sup> Commitment Agreement

### For our part of this agreement, we commit to:

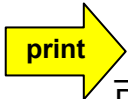
1. Provide you with the best professional and medical services we can.
2. Maintain patient confidentiality.
3. Call you if you are absent and we have not heard from you.
4. Send periodic progress reports to your primary care physician.

### For your part of this agreement, you commit to:

1. Arrive on time.
2. Attend regularly.
3. Call the office or the group leader **in advance** if you are unable to attend a meeting. If you are in the active weight loss phase, call the office to make arrangements to come in during the week to see a program physician for a medical check and to pick up more OPTIFAST products.
4. Be especially careful not to miss meetings while in active weight loss.
5. Complete all “homework” assignments. These are critical to reversing habits that contribute to your weight problem and creating a healthier lifestyle.
6. Let us know if there is something that bothers you about the program or the staff.
7. Notify a program physician regarding any changes in medications or your health.
8. See a program physician and have all lab tests and EKG’s as scheduled.
9. Pay weekly for the current week’s fees, and/or abide by your payment plan. It may be necessary to purchase additional products if the program physician believes that you are losing weight too quickly and it is necessary to slow weight loss through extra calories, or, if with the physician’s permission, you are extending your active weight loss or modifying your program.

10. Understand that the OPTIFAST® products and supplies are not likely to be reimbursed by insurance.

**I acknowledge that I have read the OPTIFAST Commitment Agreement and have had ample opportunity to discuss any and all of my questions.**



\_\_\_\_\_

Patient Name Printed

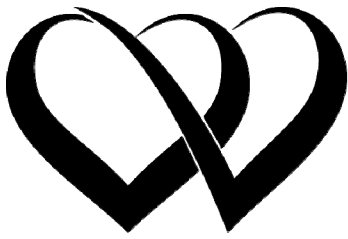


\_\_\_\_\_ Date \_\_\_\_\_

Signature of Patient

\_\_\_\_\_ Date \_\_\_\_\_

Signature of Health Care Provider



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## Optifast Small Group Rules

### 1. Participation

- ✓ Be on time for your group session – no one will be allowed to enter the group after fifteen minutes into the session.
- ✓ Actively participate by paying close attention, engaging in discussions and providing group members with feedback or suggestions.
- ✓ Stay for the duration of group time.

### 2. Behavior toward others

- ✓ Be respectful and supportive of group members.
- ✓ Share group time with others so they can have the opportunity to express their feelings/concerns.

### 3. Confidentiality

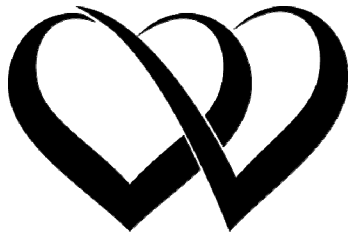
- ✓ What is said in the group stays in the group. Do not discuss other's problems and personal matters with outsiders. (Trust is vital to the success of the group; therefore, confidentiality is extremely important.)

### 4. Children

- ✓ Children will not be allowed in the group or left unattended in the clinic waiting area.

### 5. Cell phone usage

- ✓ Please turn off cell phones or put on vibrate during class.



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## Instructions for Optifast Weekly Clinic Flow

### For Wednesday Group Class Attendees

#### Note: Group Class is Highly Recommended but not Required

1. Optifast Clinic hours are from 4:00 – 5:15 pm on Wednesday evenings and then the Group Class starts at 5:15pm. Class times are subject to change as we try to flex to patients' work schedules.
2. Upon arriving for your weekly class & office visit, please check in with the receptionist.
3. You will be given a "Weekly Questionnaire" and a "Products Order" form.
4. Once you complete them, please return both of the forms to the receptionist.
5. Payment will be due at the time of check-in.
6. You can then have a seat in the waiting room.
7. The staff will call you in to obtain your weight, blood pressure, and pulse.
8. If you are due for lab testing (every 2-4 weeks), our staff will draw your blood then.
9. Please bring your canvas bag with you every week (provided at your initial visit) so that you can transport your food products home. Please write your name on the bag.
10. If you are due for a medical visit, the staff will take you to an exam room.
11. Once you have completed the above steps, you may have a seat in the group meeting room until the small group class begins.
12. After class, your food products will be waiting for you for pickup in the waiting room.

**Remember that if you are due for a medical visit, you should arrive at the office at least 30 minutes before class begins ideally at 4:30pm or earlier to ensure you can make it to class on time.**