



## Informed Consent for Medical Weight Management with Meal Replacement

**PLEASE READ THE FOLLOWING PAGES CAREFULLY  
AND INITIAL AND SIGN WHERE INDICATED.  
PLEASE DO NOT SIGN ANY SECTION  
THAT YOU HAVE NOT READ OR DO NOT UNDERSTAND.**

### **SECTION 1: INTRODUCTION**

It is our hope to fully inform you of the side effects, limitations and complications of the KP Medical Weight Management with Meal Replacement Program ("KP Program"). We continually balance the benefits of treatment with the known and unknown risks. It is important to understand that you must accept a certain degree of risk and responsibility for undergoing rapid weight loss. This consent form, in combination with educational materials and consultation, is designed to enhance your understanding of potential difficulties during the weight loss phase.

Calorie-deficit and portion-controlled diets (including liquid formula) were developed over 25 years ago for weight reduction. The KP Program is medically supervised and designed to treat individuals with a greater than 30 BMI or a BMI of 27 with 2 comorbidities, such as high blood pressure, coronary heart disease, diabetes, gallbladder disease, lung disease, joint, or bone disease.

It is not our intention to frighten or dissuade anyone from pursuing the KP Program. We intend to accurately outline the associated risks so you may either elect not to accept the associated risks or be better prepared to deal with unexpected complications or side effects. This is a purely elective program, and you may decide not to participate at all.

### **SECTION 2: POTENTIAL BENEFITS**

***Medically-significant weight loss (usually 5-10% percent of initial weight, or as an example, losing 10-20 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.

**SECTION 2: ALTERNATIVES TO WEIGHT MANAGEMENT WITH MEAL REPLACEMENT**

Non-surgical and surgical alternatives to the KP Program exist:

- **Non-Surgical Alternatives.** There are other ways and programs to assist in decreasing body weight. In particular, behavior modification classes, interactive on-line programs, balanced calorie counting, support systems, and self-dieting will likely prove successful if followed.
- **Surgical Alternatives.** Bariatric surgery is available for qualified individuals with a BMI over 40.

**SECTION 3: POTENTIAL SIDE EFFECTS AND RISKS**

Rapid weight loss - losing more than 1½ pounds per week - may cause serious health problems and require that you see a program physician at least bi-weekly during the first 16 weeks. Such problems could, on occasion, be serious or fatal for obese individuals, particularly those with serious hypertension (high blood pressure), coronary artery disease (poor circulation to the heart), and diabetes mellitus (sugar diabetes). The possibility cannot be excluded that some undefined or unknown factor in the treatment program could increase this risk in a medically vulnerable individual. Some of the risks and side effects include, but are not limited to:

- **Temporary symptoms.** These include sensitivity to cold, dry skin, rash, fatigue, diarrhea or constipation, muscle cramps, bad breath, change in menstrual patterns, hair loss that regrows after dieting, and heart irregularities.
- **Dizziness.** During the active weight loss phase, individuals may become momentarily dizzy. You should avoid activities that might accentuate dizziness or cause danger if you become momentarily dizzy, including hot steaming baths, whirlpool baths, scuba diving, swimming alone, diving off boards, piloting a plane, horseback riding, motorcycle riding, hang gliding, etc.
- **Gallstones.** You may experience the clinical appearance of previously undiagnosed gallstones with or without acute inflammation of the gallbladder if you deviate from the recommended protocol, particularly sudden ingestion of rich foods but a causal connection has not yet been conclusively demonstrated. Gallstone problems may require surgical removal of the gallbladder.
- **Pancreatitis.** The presence of gallstones and the development of sludge or obstruction in the bile ducts could result in pancreatitis, or infection of the bile ducts. The symptoms of pancreatitis include pain in the left upper abdominal area, nausea, and fever. It may be caused by binge eating or consuming a large meal after a period of dieting. It may require surgery and may be associated with more serious complications and death.
- **Pregnancy.** You should consult with your primary care physician if you become pregnant. You will need to change your diet immediately to avoid damage for a developing fetus from a calorically restricted diet.
- **Physical activity.** Physical injury can result from such things as increased exercise and activity.
- **Allergies.** Meal replacement products (i.e. shakes and bars), similar to all commercially prepared food products, may contain ingredients (including but not limited to nuts and milk products) that produce an allergic reaction in some individuals. You should check the label before consuming the products.

**SECTION 4: WEIGHT REGAIN**

Weight loss may be only temporary for many dieters. You can enhance your chances of maintaining lost weight in the long term with permanent lifestyle changes such as making healthful food choices and increasing physical activity. Individuals who participate actively in the maintenance phase of the KP

Program are more likely to maintain their weight loss as compared to those who do not complete treatment. Significant health benefits accrue from reducing your body weight. However, these benefits may diminish if weight loss is not sustained.

**SECTION 5: NO GUARANTEES**

You understand that much of the success of the program will depend on your efforts and that there are no guarantees or assurances that the program will be successful. You also understand that you will have to continue watching your weight all of your life if you are to be successful in the long term.

**SECTION 6: VOLUNTARY CONSENT**

Please sign below that you have carefully reviewed this Informed Consent document and that you have had an opportunity to have any questions that you may have had answered. By signing below you also indicate that you are voluntarily enrolling in the KP Program and authorizing the program to provide you with medical care to assist in your weight reduction efforts. You understand that such care may include but is not limited to physical examination, laboratory screening, EKG testing, intense follow-ups, direct phone calls, instruction in behavior modification techniques, nutritional counseling, fitness counseling and vitamin supplementation. You further understand that you may be requested to discontinue the KP Program before completing the active weight loss phase if:

- You are losing too much weight or lean body mass;
- You are not following the KP Program as prescribed;
- You are away from the KP Program for more than 2 consecutive weeks;
- You suspect pregnancy (if female); or
- The Program medical staff deems it necessary for medical or psychological reasons.

Patient Full Name (print)	
Patient Signature	
Witness Full Name (print)	
Witness Signature	
Date / Time	