



## Kaiser Permanente **InControl** Program

### INFORMED CONSENT

#### **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 are 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 long-term management 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.



Your signature below represents your permission, understanding and commitment to the above

***Potential benefits...***

Medically-significant weight loss (usually about 10% 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. The bariatrician will see you as needed to reassess your medications. Your bariatrician will share your results with your primary care physician, so the physician is informed about your progress.

Other benefits may also be obtained but cannot be guaranteed. 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 that other side effects could occur that 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.

**Pregnancy** If you become pregnant, report this to your healthcare professional and physician immediately. Your diet must be changed promptly to avoid further weight loss and your antiobesity medication discontinued because a restricted diet and/or antiobesity medication 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 many overweight individuals who lose weight may 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. Additionally, attendance at group sessions particularly during weight maintenance has been associated with better long-term weight maintenance.

Obesity is a chronic condition and successful treatment requires lifelong behavior and lifestyle change. Medical studies of calorie deficit/portioned controlled diets have shown varying results for percentage of patients who maintain weight loss. In one study, patients on a program similar to InControl were able to lose almost 9% of their initial body weight during their first year in the program and on average, maintained more than half (4.7%) of their initial weight loss after 8 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.

**Risk of Antiobesity Medication** Medications should be taken as prescribed by your bariatrician. There are side effects and risks associated with the anti-obesity medications. These side effects and risks will be dependent on the medication you are prescribed but may include (and are not limited to) insomnia, increased blood pressure, increased pulse rate or tremors. Headaches, palpitations, constipation, nervousness, sweating, fatigue, irritability, dizziness, memory impairment, anorexia, and altered taste, dry mouth are also possible side effects. Gastrointestinal effects may include constipation, diarrhea or bloating. Other potential cardiovascular effects may include but are not limited to heart irregularities, valvular heart disease, pulmonary hypertension, cardiac arrest, or stroke. These side effects may be serious, and on rare occasion even fatal. Your bariatrician will review these side effects with you at your intake visit.



Off label use of medications is common practice and may be used for weight loss in conjunction with lifestyle management. Most medications are contraindicated in pregnancy and can cause fetal abnormalities. Use of abstinence, contraception, or evidence of surgical inability to become pregnant is recommended during treatment. Medications are to be used only by the prescribed patient and should not be shared, dispersed, or sold to others. I understand that any such activity on my part constitutes a serious violation of this agreement and will result in my treatment being terminated. Any lost medication will not be replaced regardless of the reason for such loss.

***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 bariatrician knows you are discontinuing treatment and to verify your primary care 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. I give permission for data regarding my treatment to be entered into a national database, so that research, science and the weight management industry may learn and benefit from my treatment and the treatment of others. 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.

Please initial

- \_\_\_\_\_ I will commit to this one-year weight control program.
- \_\_\_\_\_ I will be on time for group meetings.
- \_\_\_\_\_ I will keep the confidentiality of the other patients in the program.
- \_\_\_\_\_ I will avoid alcohol consumption during the active weight loss phase of the program.
- \_\_\_\_\_ I understand that excessive eating of other foods outside of my plan, while on the **InControl** diet, may cause abdominal pain, bloating, and/or diarrhea.
- \_\_\_\_\_ I will not donate blood during the active weight loss phase of the program.
- \_\_\_\_\_ I will consume a minimum of 64 ounces of calorie-free fluids each day.
- \_\_\_\_\_ I understand that the program fee is non-refundable.
- \_\_\_\_\_ If I have entered into a payment plan with Kaiser, I agree to make my payments as scheduled or risk being terminated from the program.
- \_\_\_\_\_ I will not share or sell any medication prescribed to me by my bariatrician.



I, the undersigned, have reviewed this information with my healthcare 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

