

INFORMED CONSENT FOR WEIGHT LOSS PROGRAM

PATIENT NAME: _____

DOB: _____

We want you to know...The calorie deficit and portion-controlled diets are used with patients who are overweight. These methods of weight reduction have been described and evaluated in many professional medical journals since 1974.

Your role...Your success depends upon your commitment to fulfilling your obligations during treatment. You should be willing to:

- Provide honest and complete answers to questions about your health, medications, weight, eating, and lifestyle patterns.
- Devote the time needed to complete and comply with the course of treatment as prescribed.
- Attend your appointments regularly and follow your diet and exercise prescription.
- Obtain blood/diagnostic tests which your provider may deem necessary during your treatment.
- Advise the clinic staff of ANY concerns, problems, complaints, symptoms, or questions even if you may think it is not terribly important. This affords the best chance of intervening before a problem becomes serious.

Risks Associated with Being Overweight...People who are overfat, overweight or obese have greater tendencies toward:

- High blood pressure, Diabetes/Metabolic Syndrome, Hyperinsulinemia, High Cholesterol, Asthma, Esophageal Reflux, Fatigue, Heart Attack, Stroke, Peripheral Vascular Disease, Abnormal Cardiac Rhythms, Pulmonary Hypertension, Decreased sense of smell, Obstructive Sleep Apnea, Arthritis, Subfertility/Infertility, Polycystic Ovarian Syndrome and various types of cancer.

These risks/conditions can be reduced or eliminated with weight loss (starting around 5-10 percent of initial weight).

Medications...If you are taking medications for one or more of these conditions, dosages will be adjusted as your diet progresses.

Unknown Side Effects...The possibility always exists in medicine that the combination of any 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.

Common Side Effects...During a low calorie diet, common side effects can be: *a reduced metabolic rate, increased urination, dizziness, sensitivity to cold, a slower heart rate, dry skin, fatigue, diarrhea, constipation, bad breath, dry or brittle hair, hair loss, muscle cramps, or menstrual changes.* These responses are temporary and resolve when calories are increased after the period of weight loss. You will be given a drug monograph with more specific information for each medication added to your program.

Reduced Potassium Levels...It is important to consume all of the food that has been prescribed in your diet. Failure to do so may cause low blood potassium levels or deficiencies in other key nutrients. Low potassium levels can cause serious heart irregularities.

Gallstones...Overweight people develop gallstones at a rate higher than normal weight individuals. It is possible to have gallstones and not know it. 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 chance of developing stones or sludge and increase the size of existing stones within the gallbladder. Should symptoms develop (commonly fever, nausea and a cramping right upper abdominal pain) or if you know or suspect that you already have gallstones, let your provider know immediately. Gallbladder problems may need medication or surgery to remove the gallbladder, and less commonly, may be associated with more serious complications or even death.

Pancreatitis, or an inflammation/infection of the pancreas, 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 are 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 or even death.

Pregnancy...If you become pregnant, report this to your health care professional and physician immediately. Your calorie restricted diet and anorectic medications must be stopped promptly to avoid further weight loss and potential damage to 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 exercise, adherence to a healthy diet, and having a coping strategy for weight regain before it occurs. Successful treatment may take months or years.

Sudden Death...Patients with morbid obesity and serious health problems such as severe hypertension, heart disease, or diabetes, have a statistically higher chance of suffering sudden death when compared to normal weight people without these 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.** Other rare risks are primary pulmonary hypertension and valvular heart disease.

Your Rights and Responsibility...You may leave treatment at any time. You have a responsibility to notify the provider that you are discontinuing treatment and to find another provider who is able to assume medical care for you after you leave treatment.

No Guarantees...I understand that much of the success of the program will depend on my efforts and that there are no guarantees that the program will be successful. I also understand that I will have to continue watching my weight all of my life if I am to be successful.

Food Items...Food items purchased in the office are non-returnable once purchased.

Supplements...Dietary supplements may be added to your program and may include vitamins, minerals, and/or lipotropics (fat burners) given in oral or injection form. You will be given a drug monograph for each supplement added to your program. I understand that scientific literature supporting my provider's use of these supplements may be limited but feel the potential benefit of use of such supplements outweighs the risks discussed with me.

FDA Labeling...Appetite suppressants have labeling which recommends to use the medications for obese individuals, for time periods up to 12 weeks, and at the dosage indicated in the labeling.

ASBP Guidelines for Anorectic Usage: We adhere to the guidelines for anorectic usage as recommended by the American Society of Bariatric Physicians. Indications for *initiation* of anorectics include (staff to mark those which apply to patient):

- BMI > 30 in normal healthy individuals
- BMI > 27 in individuals with co-morbidities (DM, HTN, Insulin/Leptin resistance, vascular disease, hyperlipidemia, asthma, cancer, GERD, OSA, kidney disease, osteoarthritis, gall stones, PCOS, psoriasis, acrocordon, acanthosis nigricans, or other related conditions)
- Current weight > 120% of a long standing healthy weight maintained after the age of 18.
- Body fat >30% in females and >25% in males (Sarcopenic Obesity)
- Waist-hip ratio > 0.8 in women or > 0.95 in men
- Waist circumference > 35" in women and > 40" in men
- Any co-morbid condition that is aggravated by weight
- Prevention of weight regain in a person who has previously lost weight
- Weight loss for occupational needs
- Prevention of weight gain in a person who has a familial/genetic predisposition to obesity, cancer, or other obesity related conditions.

Long Term Use...Additionally, an anorectic medication may be used for individuals that have shown previous benefit and not had adverse reactions (beneficial risk-to-benefit ratio) for the purpose of restarting a weight loss program, to lose weight that has been recently gained following a therapeutic loss of weight, or to maintain weight loss on a chronic basis even if the above criteria are no longer met.

Off Label Prescribing... A provider is not required to use the medication as the labeling suggests. This is called off label prescribing and is specifically provided for by the FDA. We have found appetite suppressants and other non-anorectic type medications to be helpful for periods exceeding 12 weeks and at doses larger than those suggested in the labeling. The indications for these usages are based on our experience, the experience of our colleagues, and guidelines from the ASBP. Such usage has not been as systematically studied as that suggested in the labeling and it is possible, as with most other medications, that there could be serious side effects. We believe the probability of such side effects is outweighed by the benefit of the appetite suppressant for the given dose and indication. However, you must decide if you are willing to accept the risks of side effects, even if they might be serious, for the possible help the medication(s) may give.

Dispensing and Furnishing...In general, weight loss related medication(s) will be prescribed and dispensed within this office. I will be given an opportunity to count my pills to ensure accuracy at the time of dispensing. I understand that I have a choice in where I may obtain my prescription and that I may obtain a prescription appetite suppressant or other weight related medication at any pharmacy of my choice. Dispensed prescriptions may not be refunded or exchanged after leaving the office

_____ - By initialing here I agree to have my prescription dispensed at this office. I may change my mind and request to have the prescription filled at a pharmacy of my choice at any time.

Responsibility...It is my responsibility to follow dosing instructions carefully and to report promptly any medical problem(s) that may be related to my weight control program. In general, medications will not be prescribed without an office visit. One time, short term exceptions can be decided on a case by case basis. We reserve the right to refuse such an exception to anyone. Abuse of this policy can result in dismissal from the clinic. I must be re-evaluated by the provider within 30 days of starting any new medication. ***If I am prescribed a controlled medication from this clinic, I agree to only obtain that medication from providers of this clinic.*** Obtaining controlled medications from multiple providers is illegal and will be reported to law enforcement as required. Diversion of medications to other individuals is grounds for dismissal. Random urine drug testing may be done and if refused, is grounds for dismissal.

Refunds...I understand that no refunds will be given after services are performed.

Purpose...I understand the purpose of this treatment is to assist me in my desire to decrease my body weight and to maintain this weight loss. My continuing to receive weight loss treatment will be dependent on my progress in weight reduction and weight maintenance.

Drug Testing...If you are drug tested as part of your employment or for another purpose, you may test positive for amphetamines or their derivatives. If needed, you may be given a doctor's note to state you are taking a medication to aid in weight loss.

Alternatives...I understand there are multiple ways to decrease my body weight and to maintain a healthy weight. In particular, a reduced calorie diet or protein sparing modified fast and regular exercise without the use of appetite suppressants or other medications or supplements could help if followed, even though I may be hungrier, fatigued, or the weight loss may not be as great without these adjunctives.

Risk of Proposed Treatment...The use of weight loss related medications, involves some risk. Risks are higher still for dosages that exceed the recommended labeling. Common side effects of stimulant type appetite suppressants include: **insomnia, palpitations, dry mouth, headaches, psychological problems, medication allergies, short term high blood pressure, and dependence** (exceedingly rare). Blood pressure can become more elevated when taken with pseudoephedrine, an over the counter cold medicine. Rare, but serious risks include **primary pulmonary hypertension and valvular heart disease**. These side effects were observed rarely with Fenfluramine and have a very rare occurrence with other appetite suppressants and have not been found to have a direct association. These risks could be slightly higher with Belviq (Lorcaserin), a weight loss medication that is mechanistically similar to Fenfluramine. Medications containing naltrexone will cause opiates to be less effective. Medications containing topiramate (Qsymia) have been found to have an increased rate of cleft palate formation in a developing fetus. Monthly pregnancy tests may be required. Women of childbearing age need to take care not to become pregnant while taking medications to aid in weight loss. These and other possible risks could, on rare occasion, be serious or fatal.

Patient's Consent – Low Calorie Diet...I, the undersigned, have reviewed the above information with my health care professional, regarding low calorie diets and understand/agree that the potential benefits of weight loss outweigh the risks of the proposed therapy. I have had an opportunity to ask questions and have them answered to my satisfaction.

Patient's Consent – Pharmacotherapy...I, the undersigned, have reviewed the above information with my health care provider, regarding the use of supplements/ medications for the purpose of weight loss and understand/agree that the potential benefits of weight loss outweigh the risks of the proposed therapy. I have had an opportunity to ask questions and have them answered to my satisfaction.

Participant Signature

Date

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.

Medical Provider Signature

Date