

### **Informed Consent for Medically Management Weight Loss Therapy**

I acknowledge that I am voluntarily entering into a medically managed weight loss program with Stronger with... Dr. Elizabeth Donathan, LLC. I fully realize that entering any program involving weight reduction, which includes moderate calorie restriction, exercise, and medications, involves potential risks and side effects. The risks include, but may not be limited to the following:

- 1. Cardiovascular (heart or blood pressure):** These problems may include heart palpitations, irregular beats, or rapid heartbeat. These effects are usually mild but can result in serious problems including heart attack or stroke. Also, these medications may increase blood pressure, which if left untreated can lead to heart attack or stroke. If you discontinue the weight loss medication, the elevated blood pressure usually resolves. For this reason, if you are on blood pressure medications you are required to monitor your blood pressure daily and discontinue medications if blood pressure rise, your heart rate increases, or you feel palpitations. (Please initial) \_\_\_\_\_
- 2. 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. (Please initial) \_\_\_\_\_
- 3. 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, 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. (Please initial) \_\_\_\_\_
- 4. Gall Bladder Disease:** Any program resulting in rapid weight loss may precipitate the formation of gallstones, which could lead to cholecystitis (inflammation of your gallbladder), which is a medical urgency or emergency and could require surgery. This is typically because of the rapid weight loss, not the medications you are taking. Symptoms include right upper abdominal pain, abdominal just below your ribs, nausea, and vomiting. (Please initial) \_\_\_\_\_

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5. **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. (Please initial) \_\_\_\_\_
6. **Psychiatric:** There are reported cases of “hysterical or psychotic reactions” associated with the use or discontinuation of some of the drugs utilized for weight loss purposes. These reactions are extremely rare. (Please initial) \_\_\_\_\_
7. Men over 40 and post-menopausal women in general, and patients with risk factors for cardiovascular disease should have a cardiovascular evaluation before entering a medically managed weight loss program. This may include an ECG, a stress test, or other testing procedures, as per the discretion of a cardiologist. If you are over the age of 40, post-menopausal (female), smoke, have a history of high blood pressure, high cholesterol or you are diabetic, you acknowledge that you have had a cardiac evaluation and that you have been cleared medically prior to starting this weight loss program. (Please initial) \_\_\_\_\_
8. Common, but troublesome side effects may include but not be limited to dry mouth, palpitations, “speedy” feeling, headaches, sleeplessness., Rash, fever, nausea, vomiting, allergic reactions, decreased insulin sensitivity, flushing, headache, fatigue, lightheadedness, abdominal cramping, joint pain, fluid retention, and additional side effects not listed that will be discussed during your evaluation with Stronger with... Dr. Elizabeth Donathan, LLC. These side effects are generally rare, and most patients tolerate treatment without an issue. Please initial) \_\_\_\_\_
9. Drug interactions may occur if other medications are taken. Therefore, I will check with my prescribing medical provider before starting the program if I am taking other medications. (Please initial) \_\_\_\_\_
10. Certain medical conditions may be worsened if on this program, including glaucoma, hypertension, and heart disease. (Please initial) \_\_\_\_\_
11. Pregnancy (Females Only). 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. (Please initial) \_\_\_\_\_
12. The use of medications for weight management is indicated for those patients who have a BMI of 30 or higher or a BMI of 27 or higher with other medical conditions such as high blood pressure, diabetes, or high cholesterol. Prescribing medications for patients not fitting these criteria, is considered “off label” and not “FDA approved.” Therefore, the

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potential risks vs. benefits may be great. For patients not fitting the BMI criteria for use of appetite suppression medication, you are acknowledging that:

- a. You have put forth a true effort to lose weight through diet and exercise over the past 6 months and have still not achieved your weight loss goals.
  - b. That your inability to lose weight is causing significant emotional distress
  - c. You are choosing to enter this medically managed weight loss program voluntary and hold harmless Stronger with... Dr. Elizabeth Donathan, LLC and Elizabeth Donathan, DNP, MS, APRN, FNP-BC for use of such medications.
  - d. (Please initial) \_\_\_\_\_
13. You acknowledge that alcohol and illicit drug use is prohibited in the program. Drugs like cocaine and amphetamines when used in conjunction with appetite suppressants and other medications prescribed could cause in serious injury or death. The use of alcohol will also affect your results. (Please initial) \_\_\_\_\_
14. I understand that the physician and I will determine what my daily caloric intake will be at my initial visit. (Please initial) \_\_\_\_\_
15. I acknowledge that I understand that the amount of weight loss varies from patient to patient, and is, to a large extent dependent on each patient's personal motivation and commitment to their diet and exercise plan. No claims as to efficacy or specific amount of weight loss is either expressed or implied. I understand the importance of routinely following up with (LLC NAME) to monitor my progress during treatment. I understand this is vital to the safety of the treatment program and certify that I will be returning monthly as prescribed. (Please initial) \_\_\_\_\_
16. I hereby authorize Stronger with... Dr. Elizabeth Donathan, LLC and Elizabeth Donathan, DNP, MS, APRN, FNP-BC and additional staff of Stronger with... Dr. Elizabeth Donathan, LLC to evaluate me for admission into Stronger with... Dr. Elizabeth Donathan, weight management program and treat me accordingly. I consent to obtaining blood work before treatment if deemed necessary. I certify that I am signing this under my free will and am competent to make my own medical decisions. (Please initial) \_\_\_\_\_
17. I have reviewed the mentioned risks and have determined the benefits outweigh the possible risks associated with medically managed weight loss therapy with Stronger with... Dr. Elizabeth Donathan, LLC and Elizabeth Donathan, DNP, MS, APRN, FNP-BC. I release any claim in court or any type of complaint that could result from treatment with Stronger with... Dr. Elizabeth Donathan, LLC and Elizabeth Donathan, DNP, MS, APRN, FNP-BC and any other staff associated with Stronger with... Dr. Elizabeth Donathan, LLC and Elizabeth Donathan, DNP, MS, APRN, FNP-BC and will not hold liable any provider or staff of Stronger with... Dr. Elizabeth Donathan, LLC. (Please initial) \_\_\_\_\_
18. I understand that treatment modalities utilized by Stronger with... Dr. Elizabeth Donathan, LLC might not be supported by scientific/medical literature and could be seen as

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experimental or based off anecdotal claims. Many medical providers, including endocrinologists, surgeons, family practice doctors, etc., might see these types of treatments as not medically necessary. I also understand that many of the medications being utilized within Stronger with... Dr. Elizabeth Donathan, LLC and Elizabeth Donathan, DNP, MS, APRN, FNP-BC medically managed weight loss program are considered to be used "off label" and might not be FDA approved for weight loss purposes. (Please initial)

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By signing below, I acknowledge that I have had an opportunity any concerns and the above information with Stronger with... Dr. Elizabeth Donathan, LLC and Elizabeth Donathan, DNP, MS, APRN, FNP-BC, either in person or by telephone conversation. I consent to the treatment being offered to me by Stronger with... Dr. Elizabeth Donathan, LLC and Elizabeth Donathan, DNP, MS, APRN, FNP-BC and I am satisfied with the explanation. I acknowledge that I have read or have had read to me the above consent and understand the information presented.

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Signature of patient

Date

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Printed Name of patient

### **Risks and Benefits Acknowledgement**

I recognize the potential risks of this treatment program, and I also understand the potential benefits of weight loss, which may include:

1. Decreased risk of heart attack.
2. Decreased risk of adult onset diabetes mellitus.
3. Decrease risk to developing arthritis or developing musculoskeletal conditions that are caused by excessive weight.
4. Increased emotional and psychological well-being.
5. Decreased risk of developing certain types of cancer.

I acknowledge that the medically managed weight loss program recommended to me by Stronger with... Dr. Elizabeth Donathan, LLC and Elizabeth Donathan, DNP, MS, APRN, FNP-BC is just one of multiple strategies to reduce weight. Alternative treatment options include:

1. Diet and exercise alone without medications.
2. The use of other kinds of medications to achieve appetite suppression.
3. Non-medical weight loss programs like Weight Watchers.



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exercising. Additionally, if you have had fluctuations in your weight in the past, it may be more difficult to maintain the weight you lose.

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Signature of patient

Date

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Printed Name of patient