

**Bridlewood Family Healthcare, P.A.**  
**HCG Diet Informed Consent to Treat**

**Purpose**

This Informed Consent Form is intended to give fair notice of the requirements of patients seeking to participate in the HCG Diet Program at Healthy Habits Wellness Clinic, Inc., to fully disclose any risks associated with participation in the HCG Diet program, and to obtain written "Informed Consent" from the patient to undergo treatment by health care professionals associated with the above stated clinics.

**Clinical Applications**

HCG was used in the treatment of obesity disorders by a British Doctor and PHD, A.T.W. Simeons. Dr. Simeons concluded that HCG ("Human Chorionic Gonadotrophic" Hormone) when used for weight reduction and concurrent with a regimented protein diet, not only resulted in significant weight loss from targeted areas where fat deposits were likely to collect, but also improved the lipolytic functions of the body when co-utilized with dietary protein sources. Dr. Simeons theorized that by giving daily injections of small amounts of HCG concurrent with a high protein diet, that the HCG would mobilize the fat into the blood stream where protein and various enzymes could exercise their lipolytic functions (lipolytic means to break down fats usually for the consumption of energy). Dr. Simeons' clinic had a 97% success ratio. A number of medical authorities have since supported the theories advanced by Dr. Simeons. In "Medicine and Science in Sports and Exercise" (19:5, sec. 179-190, 1986), Dr Layman, M.D. affirmed that the intake of high dietary protein: (1) aided in the metabolism of the free floating fat; (2) enhanced increased muscle mass; (3) preserved protein composition in the organs; (4) stabilized the blood glucose levels, and (5) enhanced the production of human growth hormone from the pituitary gland. Accord in J Am. Coll. Nutr. 2004 Dec; 23 (6:Suppl): 631S-636S. Nevertheless in spite of these findings by specialized experts in the field of Preventative Health Care, the American FDA requires the following disclaimer:

"This weight reduction treatment includes the use of HCG, a drug which has not been approved by the Food and Drug Administration as safe and effective in the treatment of obesity or weight control. There is no substantial evidence that HCG increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or "normal" distribution of fat, or that it decreases the hunger and discomfort associated with calorie restricted diets."

**Risks and Discomforts**

Below is a list of risks and discomforts that may be experienced by a small part of the population, in particular, those patients that are already predisposed to allergies; the latter condition caused by a hyperstimulation of the hormone heparin within the body. The patient shall inform the primary health care provider if any of the following conditions occur:

**Allergic responses**

If you experience allergic reactions to other substrates, you may have a sensitivity to HCG. It is required that you stop using HCG and report your allergic response to your physician immediately (emphasis added). The following are signs of an allergic reaction:

- hives
- difficulty breathing
- swelling of your face, lips, tongue, or throat

Before receiving HCG tell your doctor if you are allergic to any drugs or if you have:

- a thyroid or adrenal gland disorder;
- an ovarian cyst;
- cancer or a tumor of the breast, ovary, uterus, prostate, hypothalamus, or pituitary gland;
- undiagnosed uterine bleeding;
- heart disease;
- kidney disease;
- epilepsy;
- migraines; or asthma

It is necessary for the doctor to know these predisposed pathologies in order to rule out any symptomatology that may not be related to the HCG.

Also in allergic responses, the body overproduces fibrin which induces blood clotting, a potentially lethal situation. Call your doctor at once if you have any of these **signs of a blood clot**:

- pain
- warmth
- redness
- numbness
- tingling in your arm or leg
- confusion
- extreme dizziness
- severe headache
- nausea or vomiting; or
- urinating less than normal.

### **Less Serious Side Effects May Include**

Less serious side effects may occur from the change in dietary patterns, until the blood sugar levels stabilize over a period of time with high protein intake. These less serious side effects include:

- headache (diet related )
- feeling restless or irritable;
- mild swelling or water weight gain;
- depression;
- breast tenderness or swelling; or
- pain, swelling, or irritation where the injection is given.

### **Breast Feeding**

It is not known whether HCG passes into breast milk. Do not use HCG without telling your doctor if you are breast-feeding a baby.

### **Other drugs may affect HCG**

There may be other drugs that can interact with HCG. Tell your doctor about all the prescription and over-the-counter medications you use. This includes vitamins, minerals, herbal products, and drugs prescribed by other doctors. Do not start using a new medication without telling your doctor.

### **Mandatory Adherence to Diet Protocol**

To experience success on the clinic's HCG diet program, it is mandatory that you follow the diet protocol explicitly. We do not warrant the results of its diet program due largely to off-site administration and patient imposed application of the diet program.

### **Government Regulation**

In 1976, the FTC ordered the Simeon Management Corporation, Simeon Weight Clinics Foundation, Bariatrics Management Corporation, C.M. Norcal, Inc., and HCG Weight Clinics Foundation and their officers to stop claiming that their HCG-based programs were safe, effective, and/or approved by the FDA for weight-control. Although the order did not stop the clinics from using HCG, it required that patients who contract for the treatment be informed in writing that:

THESE WEIGHT REDUCTION TREATMENTS INCLUDE THE INJECTION OF HCG, A DRUG WHICH HAS NOT BEEN APPROVED BY THE FOOD AND DRUG ADMINISTRATION AS SAFE AND EFFECTIVE IN THE TREATMENT OF OBESITY OR WEIGHT CONTROL. THERE IS NO SUBSTANTIAL EVIDENCE THAT HCG INCREASES WEIGHT LOSS BEYOND THAT RESULTING FROM CALORIC RESTRICTION, THAT IT CAUSES A MORE ATTRACTIVE OR "NORMAL" DISTRIBUTION OF FAT, OR THAT IT DECREASES THE HUNGER AND DISCOMFORT ASSOCIATED WITH CALORIE-RESTRICTIVE DIETS [15].

Since 1975, the FDA has required labeling and advertising of HCG to state:

HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or "normal" distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets.

I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and/or Court cost and reasonable legal fees, should this be required.

By signing below, I acknowledge that I have read the foregoing informed consent and agree to the weight loss treatment that includes the use of Human Chorionic Gonadotrophin (HCG) along with diet and other therapies with its associated risks. I have disclosed my full medical history and have been physically examined by my health care practitioner. I am aware the significant or common risks, benefits, side effects and adverse reactions of HCG, and I have had full opportunity to ask any questions. I understand that HCG has not been approved by the United States Food and Drug Administration (FDA) for adjunctive therapy in the treatment of obesity and states that there is no substantial evidence that HCG increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or "normal" distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets. I hereby give consent to perform this and all subsequent Human Chorionic Gonadotrophin (HCG) treatments with the above understood. I hereby release the doctor, the person injecting HCG and the facility from liability associated with this procedure.

**Signature of Patient**

\_\_\_\_\_  
Signature of Patient

\_\_\_\_\_  
Date

**Witness to Signature:**

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date