



THE hCG WEIGHT LOSS PROGRAM INFORMED CONSENT

Date: ____/____/____

(Month/Day/Year)

Purpose

This informed consent form is intended to 1) give fair notice of the requirements of patients seeking to participate in the hCG Weight Loss Program at Ultimate Weight Loss Solution (UWLS), 2) fully disclose any risks associated with participation in the hCG Weight Loss Program, and 3) obtain written "Informed Consent" from the patient to undergo treatment by healthcare professionals associated with UWLS.

Clinical Applications

The hCG hormone was used in the treatment of obesity disorders by British doctor and PhD, A.T.W. Simeons. Dr. Simeons concluded that the hCG hormone, or Human Chorionic Gonadotropin hormone, when used for weight reduction, along with a strict 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. Dr. Simeons theorized that by injecting small doses of hCG into the body, and pairing this with a diet high in protein, the hCG would be able to mobilize the fat into the blood stream, where protein and enzymes could break down fats for energy. A number of medical authorities have since supported the theories advanced by Dr. Simeons. Nevertheless, in spite of 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."

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.

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Risks and Discomforts

On this page is a list of risks and discomforts that may be experienced, especially in patients already predisposed to allergies caused by a hyper-stimulation of the hormone heparin within the body. The patient shall inform UWLS if any of the following conditions occur:

Risks and Discomforts

Allergic Responses

A. 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). The following are signs of an allergic reaction:

• *hives • difficulty breathing • swelling of face, lips, tongue, or throat*

B. Before administering hCG, tell your doctor if you are allergic to any drugs.

C. Before administering hCG, tell your doctor if you have any of the following diseases. It is necessary to tell your doctor about these in order to rule out any symptoms that may be related to the disease and not a reaction to using hCG:

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

D. In allergic responses, the body overproduces fibrin, which induces blood clotting, a potentially life-threatening situation. Call your doctor at once if you have any of these signs of a blood clot:

• *localized pain, warmth, redness, or numbness • tingling in arm or leg • extreme dizziness • severe headache • nausea or vomiting • confusion • urinating less than normal*

Less Serious Side Effects

Less serious side effects may occur from the change in dietary patterns associated with the weight-loss program. Many of these symptoms are related to changing blood-sugar levels and will stabilize and eventually disappear with high protein intake: • *headache (diet related) • restlessness or irritability • mild swelling or water weight gain • a feeling of depression • pain, swelling, or irritation where the injection is given • breast tenderness or swelling*

Breast Feeding

It is not known whether hCG as a weight loss aid passes into breast milk. Do not use hCG without telling your doctor if you are breast feeding a baby.

Other drugs may affect hCG

Tell your doctor about all prescriptions and over-the-counter medications you use. This includes vitamins, minerals, herbal products, and prescription drugs. Do not start a new medication while on the hCG Weight Loss Program without first consulting 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.

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TO THE PATIENT OR LEGAL GUARDIAN:

INITIAL TO INDICATE THAT YOU UNDERSTAND AND AGREE WITH THESE STATEMENTS.

I, _____, request and consent to injections of hCG and strict dietary restrictions for the purpose of
(Patient Initials)
losing weight.

I, _____, understand that as part of the program, I will be given a limited physical exam, an
(Patient Initials)
orientation to the program, and instruction on how to self-administer hCG injections (or make arrangements
for someone else to administer the injections to me).

I, _____, understand that initial blood tests will be performed to rule out any conditions
(Patient Initials)
that would disqualify me from the program or require treatment before starting the weight-loss program.

I, _____, agree to immediately report any problems to UWLS that arise while on the
(Patient Initials)
weight-loss program.

I, _____, understand that if I choose not to comply with the dosage recommendations
(Patient Initials)
and dietary restrictions, I am reducing my chances of successfully losing the unwanted weight.

I, _____, understand that at this time hCG is not yet FDA approved for weight loss.
(Patient Initials)

I, _____, understand and agree that all services rendered to me are charged directly to
(Patient Initials)
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.

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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.

I have read and understand all of the above. I fully understand what I am signing and hereby request and consent to weight-loss treatment using injections of hCG and strict dietary restrictions.

Patient Signature

Date

UWLS Representative Sig

Date