# “Correlation of Several Formulas to Evaluate Insulin Sensitivity With the Predicted M Index (PREDIM) in Healthy Individuals”

**NCT 04010370**

**May 17, 2018**

# LETTER OF CONSENT UNDER INFORMATION

## " Correlation of Several Formulas to Evaluate Insulin Sensitivity With the Predicted M Index (PREDIM) in Healthy Individuals."

*The format may contain words or terms that you do not understand; please ask the doctor in charge of the study in your interview to explain in case this situation exists. Sign this informed consent form until all your doubts are satisfactorily clarified, and you are convinced that you want to participate in the study.*

**Purpose of the study**

The study aims correlation are several ways to assess insulin sensitivity index with Predicted M (PREDIM) in healthy individuals. Insulin resistance is a significant problem. It represents a threat to public health since it is an important mechanism of diseases such as Diabetes Mellitus, arterial hypertension, and central obesity. In addition to being present in glucose-intolerant individuals or even in 25% of lean, apparently healthy subjects with standard glucose tolerance. Early diagnosis of insulin resistance along with early intervention, can prevent the appearance of these conditions in subjects with or without risk.

The study will last for 3 hours, including two visits s and the participation of 25 people who will be operated to perform an oral glucose tolerance, for which they receive:

1. A 75 g dose of anhydrous glucose dissolved in water orally. After ingesting the glucose solution, venous blood will be taken at times 0, 30, 60, 90, 120, 150, and 180 minutes.

So we think you could be an excellent candidate to participate in this project.

**Procedures**

If you agree to participate, the following will take place:

**Procedures that are routine in the care of patients in this service:**

You will come here with us fasting from at least 8 a.m. to 8:00 a.m.

a. Clinical procedures: You will have a medical history that includes a complete physical exam measuring your blood pressure, weight, height, waist, and heart rate.
b. Laboratory procedures: take a sample of venous blood (about two teaspoons of blood), of one arm for some tests are done laboratory subsequently be given a drink containing 75 grams of glucose diluted in 300 mL of water, to measure your blood glucose after an oral glucose load and thus determine if you have glucose intolerance and insulin resistance. The laboratory studies that we will perform include measurement of your creatinine level, and a lipid or fat profile. For safety and hygiene, all the material used in the study is sterile and disposable. At the end of the planned analyzes, the rest of the sample will be destroyed.

The purpose of conducting clinical and laboratory studies is to learn more about your general health conditions and glucose levels, both fasting and 3 hours after a 75g glucose load. It will take us approximately 3 hours to perform these clinical and laboratory tests. We will give you the results of your lab studies within three days.

The knowledge that results from this research will help understand and improve the early diagnosis schemes of insulin resistance. In this case, it will allow to recommend to the medical community the use of the PREDIM index for its use in the general population for the evaluation of the state insulin resistance.

**Possible risks and annoyances**

*Discomforts or risks associated with clinical evaluation procedures:*

Measurement of weight, height, blood pressure, waist, and heart rate are non-invasive clinical measurements that do not cause pain, discomfort, or risk.

*Discomforts or risks associated with laboratory procedures:*

Discomfort during blood sampling is minimal. On some occasions, the procedure for taking a blood sample may cause mild pain or slight discomfort, and it is possible that a bruise may form.

**Possible benefits you will receive from participating in the study.**

The procedure will be performed as a prophylactic objective of metabolic diseases since it allows us to have a timely diagnosis of insulin resistance. Therefore, the results of the present study will contribute to the advance in the knowledge about the beneficial effects of knowing and improving the schemes of an early diagnosis of insulin resistance. By the above, will provide results and clinical summary of what was done in the study.

Your participation in this study is entirely voluntary. You will not receive payment for your participation in this study, nor does it incur any expense to you. For this research, we will only use the information that you have provided us from the time you agreed to participate until the time you let us know that you no longer wish to participate.

**Privacy and confidentiality**

The information that you provide us that could be used to identify you (such as your name, telephone number, and address), the responses to the questionnaires, and the results of your clinical tests will be kept confidential to guarantee your privacy.

The team of researchers, people involved in your health care, and your regular doctor will know that you are a participant in this study. However, no one else will have access to the information you provide to us during your participation in this study, unless you choose to do so. We will provide your data only if it is necessary to protect your rights or well-being (for example, if you suffer physical harm or need emergency care), or if required by law.

When the results of this study are published or presented at conferences, for example, no information that could reveal your identity will be released. Your identity will be protected and hidden. To protect your identity, we will assign you a password that we will use to identify your data, and we will use that password instead of your name in our electronic databases.

**Financing**

The financing will be with own resources of the University of Guadalajara.

**Declaration of informed consent**

By signing this consent, I acknowledge that I have been informed about the methods and routes of administration of study drugs, the procedures, and tests to which I will be subjected, and the inconveniences, benefits, and inconveniences that may arise.

I certify that I have read (or someone has read to me) the content of this consent form. I have had sufficient time to understand that all technical language used in the description of this research study has been satisfactorily explained to me. I received an adequate and understandable answer to all my questions that I have received a copy of this document, which I will keep in safe custody for future consultations. I'm free to withdraw from the study at any time without losing any benefit or suffer any penalty. I give my consent to be included in this study.

**Participant name:** _____

**Participant signature:** _____

**Participant's address:** _____
**Phone:** _____ **Date: _____ / _____ / ____**

**WITNESSES**

**Name:** _____

**Relationship:** _____ **Signature:** _____

**Address:** _____ **Date:_____ / _____ / _____**

**Name:** _____

**Relationship:** _____ **Signature:** _____

**Address:** _____ **Date:_____ / _____ / _____**

**Investigator statement**

I have explained the nature and purpose of this study to you and the possible risks and benefits of your participation. I have cleared all your doubts by answering all your questions. I believe that you understand the information described in this document and freely consent to participate in this research study.

_____ _____

**Investigator's name and signature** **Date**