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INTEGREVIEW IRB
DECEMBER 31, 2020

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF SPONSOR COMPANY:	Jose Antonio
PROTOCOL NUMBER AND TITLE OF STUDY:	102; "The effects of oral 5-hydroxytryptophan administration on body weight, energy intake, mood, and sleep patterns in healthy adult subjects"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Jose Antonio, Ph.D
TELEPHONE NUMBER(S), DAYTIME & AFTER HOURS:	561-239-1754

KEY INFORMATION

1. This is a research study and your participation is voluntary.
2. The main purpose of this research study is to determine if a dietary supplement that is comprised of 100 mg of 5-hydroxytryptophan (5-HTP) can affect energy intake, mood, and sleep patterns. You will be randomized into a placebo (maltodextrin) or treatment (5-HTP). You will consume one capsule per day for 60 days. You will be tested before and after the treatment for body composition, mood, energy intake, and sleep patterns.
3. The main risks you should be aware of are the following side effects: dizziness, nausea and diarrhea.
4. The main benefit to you (or others) for taking part in this study is: we will learn whether this particular supplement can improve body composition as well as enhance measures of mood and sleep.

INTRODUCTION

You are deciding if you would like to volunteer for a sports supplement research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. Do not sign this form if you have any questions that have not been answered.

The investigator is the sponsor, and is paying for this study.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

PURPOSE OF THE STUDY

This study is an investigation of the effects of an over-the-counter supplement (100 mg of organic 5-HTP, brand name CLEANMOOD®) on 1) body composition, 2) mood, and 3) sleep. The latter two measures are done via a questionnaire.

If you qualify for the study, you will be randomly assigned to one of two groups: placebo maltodextrin) or treatment (100 mg daily of 5-HTP in a capsule).

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HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The treatment duration is 60 days. You will consume one capsule daily during that period. You will come to the clinical site before and after the 60 days to assess changes (if any) in body composition, mood and sleep.

WHEN ARE YOU ELIGIBLE TO PARTICIPATE IN ANOTHER SPORTS NUTRITION STUDY?

Typically, you can participate in another study as soon as 7 days after the last dose of sports supplement received in the study you are enrolled in. Our goal is to keep you from doing anything that may be potentially harmful to you. Your safety while participating in these studies is our primary concern.

TO BE IN THIS STUDY

You cannot be in this study if you are in another research study or if you have been in any other research study in the last 30 days. You cannot be in this study if you are taking any drugs of abuse (illegal and/or prescription).

Subject Responsibilities:

While participating in this research study, you will need to:

- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems
- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study.

WHAT WILL HAPPEN DURING THE STUDY

Screening:

We will be seeking exercise-trained men and women between the ages of 18-60 to participate in this study. Subject participants must be exercise-trained; that is, they must participate in either aerobic and/or resistance training exercises three times per week for the last year. Before the study starts, you will be asked to sign this consent form, give your health history, and tell the study staff if you take any over-the-counter or prescription medicines, vitamins or herbs.

The investigator will do some tests to find out if you can be in the study. These tests include: vital signs (blood pressure, heart and rate), height and body composition.

Study Procedures:

While you are taking part in this research study, you will be asked to come to the Clinical Site. It is required that you come to the site after a 3-hour fast.

You will be randomized into one of two groups: placebo or treatment (5-HTP). Neither you nor the investigators will know which is placebo versus which is the actual product.

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What you will be doing when you come to the laboratory:

Your resting heart rate and blood pressure will be assessed prior to both laboratory visits.

In addition, your body composition will be measured pre and post. This will consist of using a BIA (bioelectrical impedance device). The BIA device measures percent body fat based on how quickly electricity is conducted through your body. That is, the less fat mass you possess, the quicker electricity flows through your body. For the InBody BIA, you will stand on the platform of the device barefoot with the soles of their feet on the electrodes. You'll grasp the handles of the unit with their thumb and fingers to maintain direct contact with the electrodes. You will stand still for 15 seconds while maintaining their elbows fully extended and their shoulder joint abducted to approximately a 30-degree angle. This electrical current is harmless and painless and these devices are widely used commercially and for home use.

In addition, we will collect data from 4 skinfolds as another method of assessing body composition. Those sites include: abdominal, thigh, tricep, and suprailiac.

We will get a pre and post assessment of your mood (i.e., Profile of Mood States online questionnaire) and sleep (i.e., online Pittsburgh Sleep Quality Index online questionnaire).

Furthermore, we will show you how to log your dietary intake into a mobile app (i.e., MyFitnessPal).

Collectively, all of these measures will take ~20 minutes.

You will then be provided with capsules that contain either the placebo or product. You will be instructed to take the capsules once daily with a meal.

Sixty days later, all of these measures will be repeated.

POSSIBLE SIDE EFFECTS AND RISKS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

Below is a list of the most common side effects associated with 5-HTP:

Below is a list of the most common side effects of 5-HTP:
Nausea

Below is a list of less common side effects of 5-HTP:
Heartburn, gas, feeling of fullness, diarrhea

Below is a list of rare side effects of 5-HTP:
Muscle spasms

Below is a list of very rare side effects of 5-HTP:
Confusion, anxiety, sweating, shivering

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ADDITIONAL RISKS OR DISCOMFORTS

Some may experience an allergic reaction (i.e., skin rash, shortness of breath etc)

POSSIBLE BENEFITS OF THE STUDY

You will get no medical benefit from this study, other than the benefit of free scientific tests.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator
- The Clinical Site
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other state or federal regulatory agencies
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. After the research, identifiers might be removed and your de-identified information or bio-specimens may be used for future research without additional informed consent. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

No other form of compensation is offered.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Principal Investigator:
Jose Antonio Ph.D – cell 561-239-1754

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

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If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview is a group of people that has reviewed this research study. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive a $50.00 voucher to purchase VPX products for participation in this study. If you choose to complete only part of the study after qualifying, you will receive a $25.00 voucher instead.

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment within 2 weeks of the final study visit, or if you choose to leave or are withdrawn from the study for any reason, you will receive payment within 4 weeks of the final study visit.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The investigator, the sponsor company, IntegReview, or the FDA, if applicable, may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

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If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will receive a signed and dated copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
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