PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: A decentralized study to assess the effects of a 30 day-wellness program on digestive health, weight and overall well-being

PROTOCOL NO: 2023-11-437-0003

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SPONSOR: Alticor Inc

CONCISE SUMMARY:

This study is evaluating the effects of a 30-day wellness program that includes two supplements and one functional food, a recommended diet, a physical activity plan, a hydration plan and mindfulness activities on digestive health, weight and overall well-being. Over 30 days, participants will follow the program protocol daily, provide feedback through questionnaires, collect data from the fitness tracker provided and take and report body measurements. The study seeks to understand the potential benefits, and overall impact of the program on participants' digestive health, weight, and overall well-being.

No immediate risks are expected with this study. However, introducing new products may cause some people to have adverse reactions. Participants might experience improvements in their digestive health, potential weight loss, some changes in their energy levels and stress management practices.

If you are interested in learning more about this study, please continue to read below.

INTRODUCTION

In a world where unhealthy dietary patterns and digestive complaints, weight gain, irregular energy levels and suboptimal quality of life are common, there's a growing interest in interventions that may promote general health and wellness, including gut health, metabolic health and other aspects of overall well-being. This study is evaluating the potential benefits of a 30-day wellness program by monitoring its effects on a group of participants over a defined period.

You are invited to take part in a research study. The decision to participate in this study is entirely voluntary. Your involvement will provide information that could help with the development of

programs to improve human health and well-being. This Informed Consent Form (ICF) provides details about the study so that you are well-informed before making a decision to participate.

Alticor Inc is sponsoring this research study.

Please read this form carefully. Take your time to ask the study investigator or study staff as many questions about the study as you would like. The study investigator or study staff can explain words or information that you do not understand. Reading this form and talking to the study investigator or study staff may help you decide whether to take part or not. The decision to participate in this study is entirely voluntary. If you decide to take part in this study, you must sign your name at the end of this form and date it.

ABOUT THE STUDY

You are being asked to participate in a study evaluating the effects of a 30-day wellness program on digestive health, weight and overall well-being. This program includes two supplements and a functional food product, a recommended diet, physical activity plan, a hydration plan and mindfulness activities.

The human digestive health and gut microbiome plays an important role in overall health, affecting not just nutrient absorption and regularity, but also metabolism and various other physiological processes. The supplement products and functional foods used in this study are made with a blend of natural plant-based ingredients, pre-, pro- and postbiotics believed to promote digestive health and overall wellness.

To ensure consistency and reliability of the data, participants will be provided instructions for the program components and will be asked to wear a fitness tracker, complete questionnaires and take body measurements at predetermined intervals.

This study is being sponsored by a consumer products company. The study investigator is being paid by the consumer products company to conduct this study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. Sterling Institutional Review Board (Sterling IRB) has reviewed the information in this consent document and has given approval for the study investigator to do the study. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Approximately 150 people aged 20 to 65, inclusive, will participate in this study. This study will use competitive enrollment. This means that when a target number of subjects begins the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be removed without your consent if the target number of subjects has already begun the study.

WHAT WILL WE ASK YOU TO DO?

If you decide to participate in this study, participation in this study will last approximately 30 days and will include 0 visits to the study center. The study test products and study materials will be shipped to your home.

You will be assigned by chance, like the flip of a coin, to **GROUP A** or **GROUP B**. You will have an equal chance of being in each group. You will be instructed on how to use the products daily, follow a recommended diet, physical activity, and hydration plan and complete daily mindfulness practices for the entire study duration as described in the following table.

Program Intervention	**GROUP A**	**GROUP B**
(1) Green powder supplement	1 serving 1x day before breakfast	
(2) Probiotic supplement	1 serving 1x before sleep	
(3) Plant-based Protein powder	1 serving as part of a meal or a snack	-
(4) All-in-one meal powder	-	1 serving to replace a lunch or a dinner
Recommended Diet	High fiber, plant-forward, Mediterranean-like diet	
Physical activity plan	7,000-10,000 steps per day + 75 minutes of exercise per week	
Hydration plan	At least 0.5 oz of water/per 1 lb of body weight of water or other non-caffeinated unsweetened beverages	
Mindfulness activities	At least one (1) activity per day of your choice (diaphragmic breathing, stretching/yoga, prayer, meditation, mindful eating)	

Each study product (three out of the four listed below) will be taken in the form of a powder.

(1) Green Powder supplement containing:
Greens Blend (Fermented Glasses (Barley, oat, alfalfa, and wheatgrass), spirulina, matcha tea), Fruits and Vegetable concentrates blend (kale, amla fruit powder, apple powder, artichoke powder, asparagus powder, prune, cranberry fruit, goji juice powder, beet), Spices blend (ginger, fermented turmeric, fermented cinnamon, fermented cayenne, fermented fennel), Fiber and Prebiotics (partially hydrolyzed guar gum, apple fiber, slippery elm bark, citrus flavanoids), Digestive enzymes blend, heat-killed Bifidobacterium longum, Heat-killed Lactobacillus plantarum, Ascorbic acid, Thiamine Hydrochloride, Riboflavin, ZInc Gluconate. Other ingredients: Sweetener (Allulose, Monk fruit), Natural Flavor, Apple cider vinegar, and Sunflower lecithin powder
Allergens: none. Not tested for potential gluten content

(2) Probiotic Supplement containing:
Chicory root extract, maltodextrin, 6.3B CFU of lactic acid bacteria (*Bifidobacterium animalis ssp. lactis, Lactobacillus acidophilus,* and *Lactobacillus paracasei* strains), silicon dioxide
Allergens: none. Not tested for potential gluten content

(3) Plant Protein Powder (Chocolate or Vanilla) containing:
Organic Protein Blend (Organic Pea Protein, Organic Rice Protein, Organic Chia Seed Protein), Organic Dutched Cocoa, Organic Creamer Blend (Organic Coconut Oil, Organic Rice Syrup Solids, Organic Pea Protein, Sodium Citrate, Organic Sunflower Lecithin, Tricalcium Phosphate), Organic Steviol Glycosides (Reb-A), Organic Natural Flavors, Sea Salt, Xanthan Gum, and Organic Monk Fruit Extract.
Allergens: Treenut (coconut).

(4) All-In-One Meal Powder (Chocolate, Berry or Vanilla flavor) containing:
Organic Pea Protein, Organic Sunflower Oil, Organic Cocoa Powder, Organic Coconut Oil, Organic Cane Sugar, Organic Natural Flavors, Organic Rice Protein, Organic Coconut Nectar, Organic Green Banana Flour, Vitamin Blend (Tricalcium Phosphate, Magnesium Oxide, Ascorbic Acid, Vitamin E Acetate, Zinc Bisglycinate Chelate, Niacin, Vitamin A Palmitate, Manganese Sulphate, Calcium Pantothenate, Copper Sulphate, Sodium Selenite, Sodium Molybdate, Biotin, Folic Acid, Phylloquinone, Cyanocobalamin, Pyridoxine Hydrochloride, Thiamine Hydrochloride, Potassium Iodide, Chromium Chloride, Riboflavin), Organic Guar Gum, Organic Fruit Blend (Apple, Cranberry, Blueberry), Potassium Chloride,Organic Acacia Fiber, Organic Green Blend (Kale, Broccoli, Spinach), Salt, Organic Stevia Leaf Extract, Xanthan Gum, Organic Acerola Fruit Powder, Organic Mushroom Powder
Allergens: Treenut (coconut)

The study products should be kept out of the reach of children and stored as instructed.

In addition to following the program and taking the products, you will be required to wear a fitness tracker and provide daily feedback about your activities, sleep, stress and wellbeing. This will involve recording the fitness tracker data and completing online questionnaires at predetermined time intervals.

Over the course of the study, you will be asked to record the following tracking and health data and transfer it online at least once a week:

- Daily tracking of program activities completed, from Day 1 through 30
- Daily data from the fitness tracker for Day 1 through Day 30: total number of steps, active zone minutes (moderate, vigorous and peak), resting heart rate, nighttime-average heart rate variation, sleep score and stress management score.
- Body self-measurements (weight, height and waist circumference) need to be taken at Day 1,2, 16 and 30.
- Validated online questionnaires at Day 1, 16, 30

To ensure the study's results are as accurate as possible, you must take all three products as recommended and follow the program guide consistently.

You will be asked to avoid additional drastic changes to your lifestyle during the study period (extended travel, relocation, major life events). This helps ensure that any observed effects can be attributed primarily to the program and not external factors.

If you experience significant life events, sickness or changes during the study, please inform the study team.

HOW LONG IS THE STUDY?

You will participate in the program for 30 days.

ANY POTENTIAL RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

There are no known risks or side effects anticipated from following this program. However, as with any new food or dietary supplement, or life-style intervention there's always a potential for individual reactions. While the program is intended to support gastrointestinal health, help with weight management, metabolic health, stress management and other aspects of well-being, you might experience initial discomfort as your body adjusts to the new products and life-style regiment. The study products are formulated with natural plant-based ingredients and contain no known allergens, except coconut. It's essential to note that while the products are believed to be gluten-free, the specific products used for this study have not been tested for gluten. If you have a gluten sensitivity or other known allergies, please tell the study staff. Some symptoms of allergic reactions are:

- Rash.
- Wheezing and difficulty breathing.
- Dizziness and fainting.
- Swelling around the mouth, throat or eyes.
- A fast pulse or sweating.

Please seek treatment immediately and tell the study investigator and study staff if you have any of these symptoms, or any other side effects, during the study. Any other adverse events from the time of study product consumption until 24 hours following final day of consumption should be reported.

You will be provided with a telephone number for the study site and instructions to contact the study site if they experience an adverse event requiring medical care.

ALTERNATIVES TO PARTICIPATION

This study is for research purposes only. The only alternative is to not participate in this study.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

POTENTIAL BENEFITS

This study is for research purposes. You might experience improvements in your digestive health, weight and overall well-being, however this cannot be guaranteed. You may not experience any

benefit from being in this study. There are no other known benefits to participants for participating in this study.

Information learned from this study may help in the development of a program for improving digestive health and overall well-being.

COMPENSATION FOR PARTICIPATION

For your participation in this study, you will be compensated up to a total of $500.00 and be able to keep the fitness tracker provide for the study. If you do not complete this study for any reason, you will be compensated for the part of the study you do complete. You will be paid at the end of your participation in the research study once all study-related tasks, including data records, daily tracking and questionnaire submissions have been satisfactorily completed.

If you have any questions regarding your compensation for participation, please contact the study staff or study investigator at the telephone number listed on page one of this document.

CONFIDENTIALITY

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent form. The study investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. The Sponsor, P&K Research and IRB will keep your data confidential.

The study's overall results may be published; however, the identity of participants will not be included. Your name and other identifying information (such as date of birth) will never be used in any presentations, reports, or public documents related to this research study. Your data and information will be analyzed as part of a group and that all study results will be presented as a group.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care you need.

If you are injured as a result of taking the study product or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third party coverage. You will not lose any of your legal rights or release the sponsor, the study investigator, the study staff, or study site from liability for mistakes by signing and dating this consent document. To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

You do not waive any of your legal rights by signing this form.

COSTS

There will be no charge to you for your participation in this study. The study products and study-related materials will be provided at no charge to you or your insurance company.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free) or info@sterlingirb.com.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

Your decision to withdraw will bring no negative consequences to you.

The study investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you.
- If you fail to follow directions for participating in the study.
- If it is discovered that you do not or no longer meet the study requirements.
- If the study is canceled.
- For administrative reasons.

If you leave the study for any reason, the study investigator may ask you to have some end-of-study tests for your safety.

CONSENT

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing, and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

Your signature will be electronically captured if you agree to participate.

Participant Name	**Signature**	**Date**

Signature of Person Explaining Consent	Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, to confirm your identity, communicate with you, determine your eligibility, and send you the product, we will collect your name, address, phone number, email address, and date of birth. Through the surveys, we will collect personal health information related to the study. As a result, the study investigator and research team may collect the following personal and health data about you:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study records, measurements and responses

Health data may come from your study records or from existing records kept by your investigator or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of Alticor Inc
- Representatives of P&K Research.
- Representatives of Sterling IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Other companies, research investigators and medical centers, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study or evaluate the study resutls.
- A data safety monitoring board which oversees this research, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study products and program work and are safe.
- For other research activities related to the products and program.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study investigator at the address listed on the first page of this form. If you do

this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a copy of this form for my records. I am not giving up any of my legal rights by agreeing to participate.

Your signature will be electronically captured if you agree to participate.

Participant Name	**Signature**	**Date**