RESEARCH PARTICIPANT INFORMED CONSENT FORM
SUBJECT INFORMATION

NAME OF SPONSOR COMPANY: Zenchi, Inc.

PROTOCOL NUMBER AND TITLE OF STUDY: #20219 Study to evaluate the efficacy of Elix's Cycle Balance and its impact on PMS and menstrual symptoms

NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (PRINCIPAL INVESTIGATOR): Susanne Mitschke, BSc., MSc.

TELEPHONE NUMBER(S), DAYTIME: 424-248-9151
AFTER-HOURS: 424-248-915

CONCISE SUMMARY

The purpose of this research study is to determine the effectiveness of an herbal supplement to alleviate common PMS and menstrual symptoms. Participation will be entirely virtual and there won't be any in-person visits. Participants will be given the test product, which they start taking at the study start date and continue taking it until study completion, for approximately 3 months. Participants will be asked to complete a menstrual wellbeing survey after every menstruation until the study period is complete.

There are no major risks to this study except an allergic reaction (rare) or sensitivity to the ingredients. Participants may benefit from less menstrual discomfort and improved well-being.

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

INTRODUCTION

You are invited to participate in a research study that examines a dietary supplement which potentially reduces the discomfort and improves well-being during menstruation. The test product contains all-natural ingredients which have been combined into a liquid that shall be taken with water, tea, smoothies, or any other liquid (except alcohol) for one week (monthly) before your period starts for the duration of the study. All participants will receive the test product as part of their participation in the study.

This form is called an informed consent form and it contains information regarding the purpose of the study, participation requirements, potential risks, potential benefits, and how your protected health information (PHI) will be managed. Please read every section in this consent form carefully and take as much time as you need to review the material and make an informed decision.

A company called Zenchi Inc. (also known as "Elix") is sponsoring (paying for) this research study.

About 65 individuals who are at least 18 years of age will be enrolled in the study.

Participation in this study is completely voluntary. It is your choice if you want to be in the study. No one can force you to be in the study. Before you decide to participate, please read this form carefully and ask the study staff for further information or clarification as necessary. Ask as many questions as required to fully understand what your participation will involve. Please do not sign and date this form unless you are fully satisfied with the answers you have received. You may also stop participating at any time and you can do this without penalty or loss of benefits to which you are otherwise entitled. Not participating does not affect your relationship with any stakeholder involved in this study.

Please take as much time as you need to review the material and make an informed decision.

ABOUT THE STUDY

Discomfort from menstruation is one of the most common symptoms reported and can affect not just personal wellbeing but also social interactions and work performance. Because many consumers are increasingly reluctant to use hormonal contraception or to use pharmacological treatments, they are left with few options to help with menstruation cramps or discomfort. Prior to menstruation, the most common complaints and symptoms of premenstrual syndrome (PMS) are mood swings, bloating, and breast tenderness.

Options for mild to moderate discomfort as a result of these menstruation and PMS symptoms are primarily either hormonal contraception or non-steroidal anti-inflammatory drugs (NSAIDs). Increasingly, however, consumers are interested in non-hormonal treatment options as well as the potential for more plant-based or dietary options.

The purpose of the study is to find out if the test product is capable of supporting the body as it responds to the natural fluctuations in hormone levels associated with menstruation, and alleviates the symptoms of PMS and pelvic cramps.

WHAT WILL WE ASK YOU TO DO?

After providing informed consent, we will ask you to fill out a short survey on your medical history. We will need this to get a better understanding of your health journey and how menstrual cramps and PMS symptoms affect you.

In the week leading up to your period, we ask you to take Elix Cycle Balance as follows:

- in the morning take 6 drops of Elix Cycle Balance with tea, water, smoothies, or any liquid of your choosing (not alcoholic);
- in the afternoon, with dinner OR before bedtime, repeat the process and take 6 drops of Elix Cycle Balance with tea, water, smoothies, or any liquid of your choosing (not alcoholic).

If you have a sensitive stomach, we advise that you take the drops in combination with a meal.

Each participant will receive 3 bottles of the test product. Each week prior to your scheduled period (approximately once per month), 12 drops of Elix Cycle Balance will be consumed per day: first, 6 drops in the morning, and then 6 drops in the evening, with dinner OR before bedtime. You will take Elix Cycle Balance until your period starts and then stop taking it until you expect your period again, then you take it again one week prior to your period. In total, you will take Elix Cycle Balance for approximately one week per month for the total study period (3 months).

HOW LONG IS THE STUDY?

The study period will be 3 months.

WHAT HAPPENS WHEN I DECIDE TO PARTICIPATE?

If you decide to participate in this research, you will sign this Informed Consent Form (ICF) and be screened for eligibility. If eligible, you will be enrolled in the study, and a member of our research team will contact you to onboard you onto our software program.

Following that, you will complete a baseline survey which will mark the start of your participation in the study.

In the week (5-7 days) prior to your scheduled period, we are asking you to start taking Elix Cycle Balance. You will take the test product until your period starts (approximately one week) and will then stop taking it until the **week prior to your next menstrual cycle**. You will take Elix Cycle Balance approximately for one week per month, for a total of 3 months (approximately 12 weeks total of Elix Cycle Balance).

The herbs are meant to be taken in the 5-7 days leading up to your cycle, twice per day, 6 drops. If your cycle starts without warning, you can still take the herbs! They are most effective when you are able to get ahead of the symptoms, but they still work when you are already experiencing pain/PMS - you just may need to increase your dosage frequency to 3-4x/ day. It is important to finish the entire bottle with each cycle in order to see the most impactful and long-lasting results.

In the week prior to your period, you will take 6 drops of Elix Cycle Balance in the morning, and 6 drops of Elix Cycle Balance in the evening, with dinner OR before bedtime.

Each month, after your period ended, you will also fill out progress surveys to track how your PMS and menstrual symptoms behaved.

We will send you a separate message when it is time to fill out the surveys - so don't worry about remembering the timing.

ARE THERE ANY POTENTIAL RISKS?

Minimal risk is foreseen for participants through their participation in the study. The dietary supplements selected for this study are well tolerated, and the daily doses are within the FDA tolerated upper limits. The most common side effect of dietary supplementation is gastrointestinal distress (such as diarrhea) as a result of very high doses, particularly if a study participant has a previously unrecognized allergy. In rare cases, it is also possible that you experience rashes, hives, or a headache, especially if there is an unrecognized allergy.

WHAT ARE THE POTENTIAL BENEFITS?

Participants may benefit from the test product by improved well-being as a result of reduced discomfort during menstruation and premenstrual syndrome (PMS), such as fewer cramps and improved mood. However, there is no guarantee that you will benefit from your participation in this study.

Participants are also contributing to the development and improvement of PMS and menstrual cycle discomfort treatments, which some consider a benefit.

COMPENSATION & COSTS

If you complete the study, which includes all of the surveys and study forms, you will receive an Amazon gift card of $75.00 sent to your email, at the end of your participation in the study. Plus, you will receive 3 additional months of Elix Cycle Balance after the study is complete. You will not receive any other compensation.

There will be no charge to you for your participation in this study. The test product will be sent to each participant without any cost. Any leftover test product will not need to be returned.

HOW WILL MY INFORMATION BE PROTECTED?

The Health Insurance Portability and Accountability Act (HIPAA) describes how your Protected Health Information (PHI) may be used, disclosed, and made accessible. You will be asked to log in to a secured software (patient portal), accessed via the internet, using a login code and a password. The patient portal used for the data collection is HIPAA compliant, meaning your private information is protected by law. In order to confirm your identity, communicate with you, and determine your eligibility, we will collect your name, address, phone number, email address, and date of birth. Through the surveys, we will be collecting personal health information related to the study.

The information we collect will be kept confidential and will be used only for the purpose of this study. Only the study staff involved in this study and the people overseeing the study including Argus IRB will have access to your study records and PHI. All reports and communications released from this study will identify participants by an identification number only and will not contain identifying information. The overall results of the study may be published; however, the identity of participants will not be included. Your right to access your PHI 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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

During the study, if you have any questions, concerns, or complaints about the study, please contact **Susanne Mitschke and team at 424-248-9151**.

An Institutional Review Board (IRB) is an independent committee (group of people) established to help protect the rights and well-being of research subjects participating in research studies. The IRB reviews those studies. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, or if you do not want to talk to the investigator or study staff contact Argus IRB at argusirb@juno.com or call 520-298-7494.

Argus IRB has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean Argus IRB 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.

You will not lose any of your legal rights by agreeing to participate in this study.

You also understand that Zenchi Inc. (Elix), Citruslabs, and Argus IRB will keep your data confidential and that your name and other identifying information (such as email address) will never be used in any presentations, reports, or public documents related to this research study. You understand that your data and information will be analyzed as part of a group and that all study results will be presented in aggregate format.

My return of this form implies my consent to participate in this research and I have been given a second copy of this form to keep for my records.

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**

Person Obtaining Consent	**Signature**	**Date**

Keep a copy of this consent form for your records.

Bill of Rights for Human Subjects in Medical Research

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's

Keep a copy of this BOR form for your records.