Informed Consent Form

Sponsor / Study Title:	**Complement Theory / "A Decentralized, Double-blinded, Randomized, 18 month, Parallel-group, Superiority Study to evaluate the impact of Complement Theory's Live 1:1 Exercise Coaching and Personalized Digital Application on Breast, Colorectal, Prostate and Lung Cancer Survivors' Cost of Care"**	
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Purpose of the Study
The purpose of this research study is to test the safety, tolerability, and effectiveness of Complement Theory's Lifestyle Modification Application, when used for Breast, Prostate, Lung and Colorectal Cancer.

You are being asked to participate in this study because you have been diagnosed with either of the 4 cancer types and may meet the study entry requirements.

Description of the Study
Complement Theory's Lifestyle Modification Application, is an investigational digital intervention, which means it has not been approved by the U.S. Food and Drug Administration (FDA). In this study, Complement Theory's Digital Application Program, will be compared to commonly-used expert guidelines on lifestyle modification for cancer patients.

Your participation in this study will last up to 18 months. Approximately 146 participants will participate in this study.

What will happen if I take part in this research study?
Upon submission of the screening form, you will undergo an initial eligibility assessment based on predefined inclusion and exclusion criteria. Once you are found to be eligible, you will then be randomized into either the treatment or control group. This randomization is performed after the completion of the screening process and is based solely on the cancer type, ensuring an equal distribution of participants across different cancer categories within both groups. We (Sponsors and investigators) don't have any choice in deciding which group you fall into.

If you are in group 1 (often called "Arm A") then you will be given Complement One Digital Application, focusing on Exercise and Meditation for 24 weeks. You will be expected to attend exercise and meditation sessions 3-5 days per week. Along with that, you will be given evidence-based information on Diet, Sleep, and other lifestyle practices - which you will be encouraged to follow. On a predefined basis, data will be collected from you on Quality of Life, Sleep, Medicine Adherence, Pain, Physical Activity, Work and Medical Expenses.

If you are in group 2 (often called "Arm B") then you'll be given access to expert guidelines on lifestyle modification focusing on exercise, meditation, as well as information on diet, sleep and other lifestyle practices through an App. You will receive instructions and guidance to complete exercise and meditation routines 3-5 times per week. You will be encouraged to follow them throughout 24 weeks and beyond. On a predefined basis, data will be collected from you on Quality of Life, Sleep, Medicine Adherence, Pain, Physical Activity, Work and Medical Expenses.

Before the study begins:
You will need to fill out the following forms:

1. Demographic Details
2. Morisky Medication Scale (MMAS-8) for Medicine Adherence Score
3. Functional Assessment of Cancer Therapy-General (FACT-G) for Quality of Life Score
4. Patient Reported Outcomes Measurement Information System (PROMIS) for measuring sleep quality
5. Godin Leisure-Time Exercise Questionnaire (GLTEQ) for physical function measurement
6. Brief Pain Inventory to report pain levels
7. Motivation to work
8. Employee Performance Review
9. Absenteeism Data
10. Medical Expenditure Form

<u>During the study: Main Intervention</u>
In addition to your regular cancer care, the Program involves doing these for 24 weeks:

- Practicing suggested exercises and meditation at least three times, up to five times a week.

- Implementing lifestyle modifications based on the program's advice.
- Periodically completing these forms to track your progress:
    - FACT-G for Quality of Life Score
    - MMAS-8 for Adherence Score
    - PROMIS for measuring sleep quality
    - GLTEQ for physical function measurement
    - Brief Pain Inventory to report pain levels
    - Motivation to work
    - Employee Performance Review
    - Medical Expenditure Form
    - Absenteeism Data
    - Cancer Progression Status

<u>During the study: After main intervention</u>
After 24 weeks of the main intervention program, you will be encouraged to continue with the exercise and meditation program. You will be given access to our Application for the entire duration of 18 months to help you continue on the path of lifestyle modification.

We will require all participants to regularly fill in these details to continuously track your progress till the end of the study at 18 months:

- FACT-G for Quality of Life Score
- MMAS-8 for Adherence Score
- PROMIS for measuring sleep quality
- GLTEQ for physical function measurement
- Brief Pain Inventory to report pain levels
- Motivation to work
- Employee Performance Review
- Medical Expenditure Form
- Absenteeism Data
- Cancer Progression Status

How long will I be in the study?
Since this is a lifestyle modification program, you will be encouraged to make positive changes for the entire duration of 18 months. However, particular emphasis will be given by the Complement Theory's Digital Application Program for 24 weeks of the main intervention.

Every month we will be in touch to assess your progress. We would like to do this by asking you to fill out digital forms and giving us access to your electronic health records (EHR). Keeping in touch with you and checking on your condition helps us look at the long-term effects of the study.

Can I stop being in the study?
Yes. You can decide to stop at any time. Tell the Principal Investigators if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

The Principal Investigators or the sponsor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?
Even though exercises and lifestyle modifications are considered safe for cancer patients, there is still a possibility that you may experience side effects or discomfort while participating in the study. Please ensure that you have no prohibitions on physical exercise based on instructions from your physician or oncologist. There is a risk that certain adverse changes can happen during exercise such as abnormal blood pressure, fainting and nausea. Everyone taking part in the study will be monitored carefully for any side effects or adverse reactions, and measures will be taken to manage any adverse events.

Your study team may offer guidance or adjustments to the intervention to help manage or mitigate any discomfort.

You are encouraged to communicate openly with the Principal Investigators about any discomfort or side effects that you experience during the study.

It is crucial to follow all guidance provided by the Digital Application Program and to report any issues or concerns immediately to ensure your safety and well-being throughout the study.

Reproductive risks: There are no known reproductive risks associated with participating in this study.

There may be risks which are currently unforeseeable. For more information about risks and side effects, ask your Principal Investigators.

Are there benefits to taking part in the study?
Participation in this study may offer potential benefits to your health, although improvements are not guaranteed. There is a substantial body of research indicating that regular exercise, meditation, and dietary adjustments can positively affect overall health and well-being, particularly for individuals diagnosed with cancer. For instance, the program is expected to increase quality of life, reduce fatigue, reduce pain, improve sleep, improve medicine adherence, decrease hospitalizations and clinic visits in the short-medium term and even improve cancer outcomes, such as reduced recurrence in the medium-long term.

While it is our hope that the Complement Theory's Digital Application Program will demonstrate effectiveness in supporting cancer care beyond the current standard of care, conclusive

evidence on our Program is not yet available. Your participation is valuable as it will contribute to a deeper understanding of the program's impact on cancer care. The insights gained from this study have the potential to advance treatment approaches and benefit future cancer patients.

What other choices do I have if I do not take part in this study?
Your other choices may include:

- Continue with your current lifestyle along with treatment or care for your cancer, based on your physician's advice
- Taking part in another study involving lifestyle modification including exercise, meditation and nutrition
- Getting no lifestyle modification

Talk to your doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private?
We will do our best to make sure that the personal information in your medical record will be kept private. Your privacy and confidentiality will be strictly maintained throughout the study, but absolute confidentiality cannot be guaranteed. All data you share through your hospital Electronic Health Records and through the surveys will be stored securely in a HIPAA-compliant system and will only be accessible to authorized personnel involved in the research or to the review board. However, your personal information may be given out if required by law.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The data will never be sold (e.g. third party entities) and will be used only for the purposes related to this research study.

Your information will be assigned a code number. The list connecting your name to this code will be kept in a locked file. When the study is completed and the data have been analyzed, this list will be destroyed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the costs of taking part in this study?
You will not need to pay anything to be a part of this study.

Are there any incentives for taking part in this study?

Yes, there are incentives for taking part in this study. At the beginning, you will receive $50 for providing initial baseline data. Furthermore, each month you will receive $25 for

your active participation and for submitting the necessary data needed to track your progress (like medical expenditure, FACT G, GLTEQ and so on mentioned above).

Payments will be issued monthly, once the necessary data for that month has been provided. If you are unable to complete the study for any reason, you will still receive compensation for each month during which you successfully provide the required data.

If you have any questions about your compensation or any other aspects of your participation, please feel free to contact the study staff. We're here to help and ensure your experience is as smooth as possible

What happens if I am injured because I took part in this study?
If you think you have been injured by being in this study, contact the Principal Investigators listed on the first page of this form right away. Complement Theory shall cover the reasonable costs of treatment for a research injury that are not covered by your insurance or a government program.

However, a number of factors will influence whether the sponsor will or will not pay for the injury, such as: if the injury is a result of normal progression of your disease rather than the research; if you do something that contributes to the injury; or if you do not follow the instructions of the investigators or the protocol. A research injury is any injury or illness directly caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. Payment for such things as lost wages, expenses other than medical care, or pain and suffering is not routinely available. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). 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.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

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 such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Investigators 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.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00077693.

Consent Signature

I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant _____

Date _____