Informed Consent Form

Consent to Participate in a Research Study

Study Title: A Pilot Randomized Controlled Study of Combinatorial Gerotherapeutics for Healthspan Improvement

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Site: This is a decentralized trial. Participants can be located in any of the 50 states of the USA. All participation will be via telemedicine using the AgelessRx website (agelessrx.com) and services.

Key Information

What should I know about a research study?

- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you have shown interest in improving at-risk healthspan indicators for decline on measures of cognitive, immune, and muscle function or reduced overall health functioning as determined by a physician. The purpose of this study is to evaluate combinations of known gerotherapeutics to identify a minimum regimen that substantially improves cognitive, muscle, and immune functions. These combinational modalities are investigational (experimental). The interventions are approved by the Food and Drug Administration (FDA) separately; however, they are not approved as combinatorial

modalities which this study aims to explore.

You will be assigned to one of the interventional or control arms for 90 days. Once assigned, you will follow a titration (increase per week) regimen for that arm, instructed by the research team, for the first 30 days. After the first 30 days, you will remain with a steady regimen for 60 days thereafter. You will be asked to complete questionnaires, cognitive testing, blood samples, a digital guided meditation program, imaging and attend two longevity consults personalized to your needs. You will also be asked to provide wearable health data to track healthspan measures.

Your participation in the research will last about 90 days.

Why might you choose not to participate in this research study?

The study may involve risks, including but not limited to gastrointestinal discomfort, changes in mood, and other side effects associated with the alternative therapies. See Risks for more details.

What are my other choices if I do not take part in this study?

The alternative to being in this study is to not take part.

Do the researchers or institution have any conflicts of interest relating to this study?

One or more of the Investigators conducting this study serve as consultants or employees for the company that makes products used in this study. These financial interests are within permissible limits established by the local institutional Conflict of Interest Policy. If you have any questions regarding conflicts of interest, please ask your study doctor.

Detailed Information

How Many People Will Take Part in this Study?

Approximately 20 people will take part in this study.

What is involved if you decide to take part in this research study?

Study Terms:

- Randomization: a process will be used to assign you, by chance, to one of the study groups. Neither you nor your doctor can choose which group you are in.
- Low-dose Rapamycin (LDR): This is a treatment using a very small amount of rapamycin, a drug that helps slow down the aging process by blocking certain pathways in the body that contribute to inflammation and cell damage. LDR may improve health, extend lifespan, and support tissue repair.
- Low-dose Naltrexone (LDN): This involves taking a small dose of naltrexone, a drug that normally treats addiction. At low doses, it may help boost the immune system, reduce inflammation, and relieve symptoms of autoimmune diseases, chronic pain, and other conditions.
- B12: Recent research has indicated that methylcobalamin provides an enhanced ability to support neurological function. Methylcobalamin helps maintain healthy glutamate activity in the brain, providing support for healthy brain cell activity. Methylcobalamin may also promote protein synthesis for healthy nerve cell maintenance. As a result,

methylcobalamin has been shown to encourage healthy cognitive, memory, emotional, and nerve function. Methylcobalamin offers advanced support for a healthy nervous system..

- Metformin: Metformin is a medication used to help people with type 2 diabetes to manage their blood sugar levels. Metformin lowers blood sugar levels primarily by blocking the production of glucose by the liver, a process called gluconeogenesis. Metformin may also work by increasing the ability of skeletal muscle to remove glucose from the bloodstream and use it for energy.
- Nicotinamide Adenine Dinucleotide (NAD+): NAD+ is a molecule found in every cell that plays a key role in energy production, DNA repair, and maintaining healthy brain function. Increasing NAD+ levels, often through supplements or other interventions, may help slow aging, improve energy, and promote overall health.
- Glutathione (GSH): Glutathione is an antioxidant that helps protect cells from oxidative stress and damage. It also plays a key role in detoxifying the body, supporting the immune system, and reducing inflammation. Boosting glutathione levels is often used for improving overall health and longevity.
- Infinite Premium Longevity Support: a nutraceutical formulation designed to enhance cellular health and mitigate age-related physiological decline. The ingredients include Calcium Alpha-Ketoglutarate, Quercetin, Glucosamine, Carnosine, Pterostilbene, Astaxanthin, and Curcumin.
- Placebo: pill(s) that contains no real medicine that looks the same as the study drug(s).

Interventions:

You will be randomized into one of the following arms:

- Arm 1 Multi-Therapy: B12, LDN, NAD+, and Metformin
- Arm 2 - Comprehensive Therapy: LDR, LDN, B12, Metformin, NAD+, GSH, and Infinite Premium Longevity Support
- Control: Placebo

Specimen Collection:

- Commercially-available mail-based kits for advanced longevity biomarkers (Edifice Health's iAge test and iollo) will be completed at-home and returned by mail. The study staff will be available for assistance.
- Bloodwork will be completed for all participants at the Quest Diagnostics or LabCorp facility nearest to them (identified with the assistance of study staff).

Questionnaires/Assessments:

- Immune Status Questionnaire (ISQ)
- SF-36 Quality of Life (SF-36 QoL)
- Rapid Assessment of Physical Activity (RAPA) questionnaire
- Sleep Quality Survey (SQS)
- Creyos Cognitive Testing

Imaging:

- DXA Scan

Wearables:

- Oura Ring

Additional:

- Longevity consults personalised to the individual needs
- A digital guided meditation program
- A guided at-home exercise program

Risks

What are the risks of participating in the research study?

- Interventions: The potential risks of these interventions vary but may include common side effects like nausea, headaches, and digestive issues. Some, like low-dose rapamycin can increase the risk of infections or cause skin discoloration and dizziness. Others, such as metformin, may lead to GI discomfort, such as stomach cramps, diarrhea, nausea, bloating or constipation. Glutathione and NAD+ supplements can cause mild discomfort like bloating or fatigue. In some cases, these treatments may interact with other medications or have more serious effects. These risks have been deemed minimal and will be monitored closely by the research team.You will be instructed to notify the research team of side-effects and adverse events.
- Blood draw: The insertion of the needle to draw blood can be painful; however, the discomfort is brief. For most people, needle punctures to get blood samples do not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.
- Questionnaire/Survey Research: Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.
- Unknown Risks: There may be risks or side effects related to the study interventions that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

How will my data/specimens be used?

Your data/samples/images may be sent outside of the AgelessRx for research purposes only. We will allow data access, use, and material transfers to XPRIZE as needed for judging and future analyses. Any personal information that could identify you will be removed before they are shared.

Collection of biospecimens by third-party testing vendors will be treated in accordance with the procedures set up by vendors for maintaining and storing samples and sample data. While no genetic information is intended to be collected in this study, best efforts will be made to minimize exposure of any identifying biological information in perpetuity. A sample containing the participant's DNA may be archived and it could be analyzed by Whole Genome Sequencing, so the participant's DNA gene sequence may be known.

Additional information on the specific sample handling practices of each third-party vendor used for testing in this study is available upon request from the AgelessRx research staff.

Confidentiality Risks

There is a small, but non-zero potential risk of loss of confidentiality of your data. Every effort

will be made to keep your information confidential as it will be stored in a secure database and only accessible to the research study team. Personal information will be closely protected, and you will not be identifiable in any publication resulting from this study.

Your medical information is unique to you. There is a small, but non-zero risk that someone outside of the research study could get access to your study records or trace information in a database back to you. While the chance that someone could access and misuse your information is believed to currently be very small, it is possible that the risk may increase in the future as people find new ways to access information.

What are possible benefits of participating in the research?

Participation in this study may help to improve your healthspan and longevity, but it is also possible that your health may worsen. There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help others improve their healthspan and lifespan in the future.

Are there any costs to you if you participate in this study?

There is no cost to you to be in this research study.

Authorization to Use/Disclose Protected Health Information

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

AgelessRx has rules and procedures to protect information about you. Federal and State laws also protect your privacy. The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at AgelessRx may have access to your information on a need-to-know basis. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other AgelessRx staff.

People outside AgelessRx may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. AgelessRx will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside AgelessRx.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.
You may cancel your permission to use and disclose your information at any time in writing. If you do cancel your permission to use and disclose your information, your participation in this

study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Clinical Trials Language

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

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact the research team directly at research@agelessrx.com or (650) 503-1889, press 1 to leave a voicemail. If you have questions about your rights as a research participant, you should contact the Institutional Review Board.

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, AgelessRx may use your health information that has already been collected in accordance with the processes outlined above if the information is needed for this study or any follow-up activities.

Signatures

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. I understand that a copy of this consent will be provided to me.

Should I wish to contact an impartial third party not associated with this study, I may contact James P. Faber, secretary of the Institutional Review Board (IRB) of the Institute of Regenerative and Cellular Medicine (IRCM), which reviewed this study for ethical compliance: jpfaber@ircm.org or (786) 271-2156.

By signing below, I confirm that I have read and understood the information provided, have had the opportunity to ask questions, and agree to participate in this study.

Participant Name:_____

Participant Signature: _____ Date: _____

Principal Investigator Signature:_____Date :_____