INFORMED CONSENT DOCUMENT AGREEMENT TO BE IN A RESEARCH STUDY

TITLE OF STUDY:

Safety and Efficacy of Microcurrent Level Bioelectric Signaling in the Treatment of Age-Related Macular Degeneration

Principal Study Investigator:

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Introduction

You are deciding if you would like to volunteer for a 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 and answer questions you may have. 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.

This is physician initiated independent research, supported, in part, by an unrestricted grant from Leonhardt Ventures LLC. All treatment technologies and micronutrient support will be provided to all subjects at no cost however, intermittent medical testing may be the responsibility of the subject or submitted to the subject's medical insurance providers.

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 aims to examine and validate the safety, efficacy and optimal sequencing for both previously studied and novel bioelectric signals in the treatment of dry age related macular degeneration (D-AMD). Simply put, this study will pass various electrical currents, which are typically too slight to sense, through the eyes to assist those who suffer from dry macular degeneration. Most of the currents have already been studied in the eyes. Subtleties, yet differences in terminologies and functions of the microcurrents are termed as: frequency specific microcurrent (FSM) and bioelectric signals (BES). All have been successfully used throughout the body and will now be similarly used for those with AMD.

In this document, you may see the terms "medication", "treatment", and "treatment period"; these are terms used in research studies as mentioned above and does not mean that you will be receiving medical treatment for any condition. These terms apply to the study device and parts of the study where you will receive the investigational product.

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

This study will recruit 40 participants. Each participant's involvement will be from 7 to 8 months.

- Two months of at-home medical food use (Ocufolin®)
- Three to four months (depending upon your group placement) of twice-a-week, approximately 1 hour of microcurrent exposure
- Two months of at-home medical food use (Ocufolin®)

TO BE IN THIS STUDY

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

This study is part home based and part clinic based.

If you are interested in participating in the study, before you join, we will ask you a series of questions about your physical health to see if you are eligible. At this time some screening ocular testing will be performed to assure you meet the criteria to be in the study. We will ask you some additional questions. If it is determined you are eligible to join this study, you will be randomly placed in an active or control group (a control, or placebo, contains no active ingredient(s) or frequencies).

Since those with D-AMD should at least be taking an AREDS 2 formulation supplement, while some may not, others may be taking any number of supplements, our study will normalize every subject to take the same "eye-supplement" for 2 months before the initiation of treatments, during the period of treatment or simulated treatment and for 2 months after the end of microcurrent treatments. The supplement which will be used, Ocufolin®, is actually in a special category called "medical foods". Ocufolin® is more beneficial for those with AMD than other AREDS 2 supplements. Publications supporting that statement can be provided. Ocufolin® will be provided to all subjects for their duration in the study (a $50.00 per month retail value).

Before the initial 2 months of at-home use of Ocufolin®, all patients will present to the office for a series of clinical tests (which will be retested throughout the following months of treatments). These tests include:

- Best corrected visual acuity (refraction as needed)
- Retinal imaging
- OCT or OCT-A retinal scans
- Microperimetry
- Intraocular pressure
- Contrast sensitivity
- Blood Pressure

Testing and treatment schedule:

1. Determination of eligibility
2. Initiation into the study; Randomized placement into the treatment of control groups
3. All subjects receive the clinical tests as listed above
4. Initiation of study arm #1:
    a. Subjects are initiated on Ocufolin® (3 at a time with the first meal of the day). Any inability to tolerate the Ocufolin® (upset stomach, loose bowels, etc.) will eliminate that subject from the study.
5. At the end of 2 months, the clinical tests are repeated
6. A blood draws is taken
7. Initiation of study arm #2:
    a. All subjects participate in twice-a-week in-office sessions, totaling 8 sessions of FSM exposure with damp felt applicators over the closed eyes and the back of the neck. The control group will be unaware they will not be receiving active FSM.

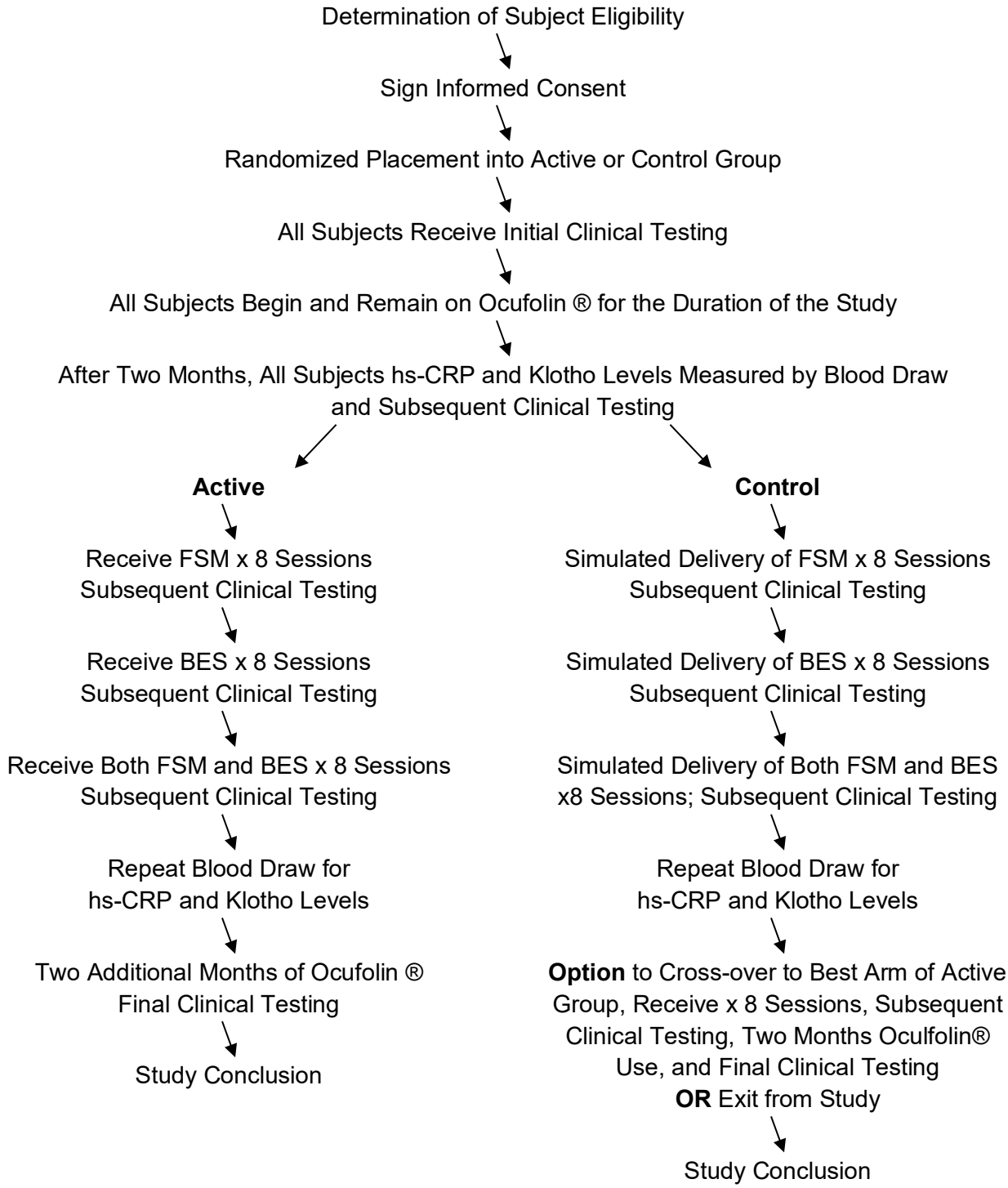
    b. After the 8 sessions are concluded, the clinical tests will be repeated.
8. Initiation of study arm #3:
    a. All subjects participate in twice-a-week in-office sessions, totaling 8 sessions of BES exposure with damp felt applicators over the closed eyes and the back of the neck. The control group will be unaware they will not be receiving active BES.
    b. After the 8 sessions are concluded, the clinical tests will be repeated.
9. Initiation of study arm #4:
    a. All subjects participate in twice-a-week in-office sessions, totaling 8 sessions of FSM and BES exposure with damp felt applicators over the closed eyes and the back of the neck. The control group will be unaware they will not be receiving active FSM and BES.
    b. After the 8 sessions are concluded, the clinical tests will be repeated.
10. The Blood draw is repeated
11. The subjects who were assigned to the control group will be offered to either exit the study or receive 8 sessions of the best arm (2, 3, or 4). Those who were in the treatment arm will progress to arm #5.
12. Initiation of arm #5
    a. Continue taking Ocufolin® for 2 months then return for the final round of clinical tests
13. Those who were in the control group and who elected to receive the additional 8 sessions of the most efficacious treatment arm will have the clinical tests repeated after those 8 sessions, then continue the use of Ocufolin® for 2 months, then return for the final round of clinical tests.

Blood draws:

Blood samples for laboratory analysis will be taken twice, on all subjects, during the study (at the end of arm #1 and at the end of arm #4). These samples will be taken either at the study center or at a local laboratory. The samples will be evaluated for:

1. Hs-CRP (high sensitivity C-reactive protein)
    a. A protein made by the liver which is elevated when inflammation or infection are present
2. KL (Klotho)
    a. A functional membrane protein encoded by the klotho gene
    b. Mainly located in the liver, kidney, gut, spleen, brain and the highly metabolic retinal pigment epithelium
    c. Associated with wellness benefits including:
        i. Powerful antioxidant
        ii. Anti-senescence (anti-aging)
        iii. Anti-apoptotic (anti-cell death)
        iv. Increased longevity
        v. Protection of the vascular system
        vi. Improving vision
        vii. Improved exercise performance
        viii. More

Testing and Treatment Schedule



Your Privacy and Security.

This study collects sensitive data which, along with responses to questions about your health, will be protected.

Dr. Peter E. Wilcox, in Hayes, VA, as the principal investigator, and Dr. Brenden White in Sandy, Utah as the sub-investigator of this study, will have done everything they can to protect your privacy and maintain your trust. At no point will your photo, or any other data you share be shared outside the study without your specific and expressed permission.

Possible Side Effects and Risks:

Dr. L. Chakin's proven and published as eye-safe signals (arm #2) are similar in strength and power to the 'novel" frequencies which also have been proven as safe when used throughout the body. Regardless, our study will validate safety of the novel signals (arm #3) by performing immediate post-initial-procedure monitoring for 30 minutes followed by phone calls to the subjects at 24 and 48 hours.

There are no reported significant risk factors associated with the use of the battery operated microcurrent units which deliver sub-threshold, low micro-amperage, low phase strength frequencies to the eyes and adnexa by transpalpebral or transorbital approaches.

All subjects must accept the risk of loss of vision from related or unrelated etiologies during the term of the study.

Although not a side effect, people with very sensitive skin may find that the sponge electrodes, even when wet, may cause a slight irritation to the skin - but this is very rare.

IN CASE OF STUDY RELATED INJURY

Please take a moment and consider whether this study is right for you by reviewing the following information. As always, if you are at all unsure, consult with a medical professional before joining this study. Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

LEGAL RIGHTS

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

POSSIBLE BENEFITS OF THE STUDY

No benefits are guaranteed from being a subject in this study. You may benefit by having improved AMD at both a subthreshold and threshold level.

- You may see better but your retina may not "look better"
- Your retinal may "look better" but you will not see better, or
- Your retina will "look better" and you will see better

ALTERNATIVES TO PARTICIPATING IN THE STUDY

The current and typical standards of care for AMD are: (1) monitoring, (2) supplementation along with dietary and lifestyle changes, and (3) intraocular injections for those with the various forms of retinal bleeding or related complications. The other choice would be not to be in the study. If you understand the information in this document, and agree to adhere to the requirements, and do not have any questions, and you feel this study is right for you, please sign this document with your password below.

What to do in a medical emergency.

In medical emergencies dial 911. Do not contact the study or study staff if you have a medical emergency. This study does not provide emergency medical services.

That being said, many of you may already be our active patients, some may not, as such we will manage any evolving ocular needs if they arise.

How to Leave the Study

You may contact your site doctor or his staff at any time if you wish to leave the study. We'll ask you a couple of questions about why you want to leave which you may decline to answer and then immediately stop your participation.

Your Participation & Data is Completely Confidential.

Your participation in this study, and any data you contribute is strictly confidential. All individuals will be assigned a secure coded number. All data will be stored in a HIPPA compliant fashion on secured, password protected computers located in secure offices.

Other than when your information is presented to ensure your eligibility, your name, e-mail or telephone number will only be presented along with your data if we believe you have had a side effect that requires follow up. Licensed eye doctors and researchers involved in the data and image analysis in addition to Dr. Peter Wilcox and Dr. Brenden White will review such information and contact you if necessary.

Who Will Have Access to Your Data?

Statistic and management staff will have access to data stripped of any information that connects you personally to that data. We will use this data to provide better customer care and conduct analysis. It is likely that positive outcomes learned in the treatment of AMD will be published and shared in the eye care and greater scientific community. Your records of being in this study will be kept private except when ordered by law. In extremely rare cases (and in those cases we will take every step to prevent it), we may be required to share data with law enforcement in the case we receive a court issued subpoena.

The following people may have access to your study records:

- The investigator(s)
- Company or research institution (including monitor(s) and auditor(s))
- Other state or federal regulatory agencies
- Leonhardt Ventures LLC
- 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. If the study results are presented at meetings or printed in publications, your name will not be used.

What Will We Do with Data?

Your data will be stripped of any identifiers and pooled with other study participants and summarized for the study analysis. We will conduct an analysis on the data to determine how the interventional device affected your health. We'll also be evaluating your commitment to the study and any unique thoughts or experiences you care to share.

What You Can Do to Further Ensure Your Privacy and Security?

As part of participating in this study, you may receive notifications via email, short message service (SMS), or push notification when/if this study generates questionnaires and/or reminders for you. You can adjust your communication preferences at any time. If you do not want to receive notifications from this study, do not press the "Accept" button. You can decide not to join this study, and will not receive notifications.

For more information

If you have further questions about this study, contact Dr. Peter E. Wilcox at doc@wilcoxeye.com or Dr. Brenden White at Brenden@invisioneye.com.

CONTACT INFORMATION

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

Dr. Peter E. Wilcox

W: 804-642-9800

C: 757-871-3083

or

Brenden White, OD

W: 801-495-2020

C: 801-558-7997

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.

Alternative, Impartial Third Party

If you wish to contact an impartial third party not associated with this study, you may contact a representative of the ethical review board: James P. Farber of the Institute of Regenerative and Cellular Medicine: ipfarber@ircm.org (786) 271-2156

PAYMENT FOR BEING IN THE STUDY

- The medical food, Ocufolin® will be provided at no expense (an approximately $50.00 per month value)
- As physician initiated medical research of a current incurable disease, your participation is deeply valued by all of those, including yourself, who will benefit from your significant time contribution.

VOLUNTEERING TO BE IN THE STUDY

The investigator(s) 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

If you leave the study, no additional personal information will be collected, however, information collected prior to your removal will still be used.

NEW FINDINGS

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

Subject Name: _____

Address: _____

_____

_____

Date: _____

Witness: _____

Date: _____