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INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

PROTOCOL NUMBER AND TITLE OF STUDY: 2518: "Neurostimulation & Depression Study"

NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR): Kyle Lapidus, M.D., Ph.D.

TELEPHONE NUMBER(S), DAYTIME & AFTER HOURS: 323-284-4626

INTRODUCTION

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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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.

The investigator is being paid by the sponsor (the company paying for this study) to conduct this research study.

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 the efficacy of the Fisher Wallace device on mild to moderate Major Depressive Disorder using two 20-minute per day treatment sessions over eight weeks. The Fisher Wallace Device is a cranial electrotherapy stimulation (CES) device which sends very mild electric current to your brain. The Fisher Wallace device has been on the market for several years and is now part of a controlled clinical study.

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 175 participants. Each participant’s involvement will be for a little more than 8 weeks after the Fisher Wallace device arrives at your home.

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 completely home based. You do not need to go anywhere to participate.

If you are interested, before you join, we will ask you a series of questions about your physical and mental health on ProofPilot to see if you are eligible. You will meet with licensed physicians via telemedicine to review your information. At this time they will ask you some additional questions and confirm your identity with a photograph you provided of a government issued ID. If they determine you are eligible to join this study, an active or sham (a placebo or sham contains no active ingredient) device will automatically be shipped to you within a couple of business days.
Once the device arrives, you will carefully review written and video instructions. You will then begin treatment with the device, which involves using it once for 20 minutes in the morning after you wake up,

and once again in the evening for 20 minutes before you try to go to sleep. You will receive a reminder via ProofPilot to use your device at 6:45AM in the morning and 7:15PM in the evening. In addition, every morning we will send you a treatment diary to fill along with a treatment reminder.

Your only other requirement is to answer a series of questions about how you feel, your physical and mental health, how you slept and how you are responding to the Fisher Wallace device at the beginning of the study and at the end of week 2. At the end of week 4, you'll answer those same questions again, and then speak with a physician again via remote video conference. You will then continue in the study for another four weeks, answering a series of questions again at the end of the study (at week 8).

If you had a sham device, at the end of week 4, we will send you an active device to use for weeks 5-8 of the study.

At the end of the week 8, you will need to send back your device(s).

Your Privacy and Security.

This study collects some sensitive data, including a photograph of your government issued ID, which along with responses to questions about your mental health will be assessed by a licensed physician in your state to ensure you are a good match for this study. The study will also collect your shipping information.

Dr. Kyle Lapidus has partnered with ProofPilot to run this study. He will serve as the Principal Investigator. Together, we have done everything we can think of to protect your privacy and earn your trust. At no point will your photo, your shipping information or any other data you share be shared outside the study without your specific and expressed permission. Your shipping address is never presented together with your answers about your mental health even to study staff.

Possible Side Effects and Risks:

As part of participating in this study, you may find some of the written questions asked during the study to be distressing to answer fully and honestly.

The risks associated with the Fisher Wallace Device are low. Many patients do not feel the stimulation at all, while some may feel a mild tingling at the sponge contact sites.

Less than 1% of patients report a temporary headache or dizziness upon using the device.

When using the device, you may or may not feel a mild, brief tingling sensation beneath the electrodes when the device's yellow lights initially turn on and stimulation begins. This sensation, should you experience it (not all patients do), ends quickly - typically within a couple of seconds.

Although not a side effect, improper use of the device may result in minor electrode irritation to your skin - this can occur if the sponges are not thoroughly wet before use. Please watch the instructional video and read the instruction manual provided when you receive your study device thoroughly before using the device. People with very sensitive skin may find that the sponge electrodes, even when wet, 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

You may benefit from being formally diagnosed, learning about yourself via the study questionnaires, and through the use of the Fisher Wallace device.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only 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 electronically sign this document with your password below.

What to do in a medical emergency.

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

If you feel significant discomfort beyond normal everyday stress, for mental health issues you can call 1-800-273-8255 or Text HOME to 741741 from anywhere in the US, and get help from the National Suicide Prevention Hotline. In medical emergencies dial 911.

How to Leave the Study

You may contact crew@proofpilot.com 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. Your data will be encrypted and stored in a secure facility thousands of miles away.

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 physicians in your state in addition to Dr. Kyle Lapidus will review such information and contact you if necessary.

The shipping staff who are fulfilling your orders will never see any data submitted by you (including your photographs) beyond your address for shipping purposes.

Who Will Have Access to Your Data?

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Your data will be stored on secure servers held by ProofPilot under the strictest standards. ProofPilot will share your shipping and order details with Fisher Wallace for fulfillment so you can receive your device. ProofPilot will share your photographs and eligibility data via a secure web system without any other contact or identifying details with licensed physicians in your state. The psychiatrists may not copy or otherwise download your photo or any of your data. It must stay on the ProofPilot assessment application.

If any study staff feels you are a risk to yourself or others, at the discretion of a licensed physician who will meet with you via video conference, we may share your information with local authorities and providers so you can get immediate help.

Statistical and management staff at ProofPilot, Fisher Wallace and our statistical partner NAMSA 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 support and conduct analysis.

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
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- Other state or federal regulatory agencies
- 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 looking at how you stuck with the interventional regimen and whether you liked it.

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

As part of participating in this study, you will receive notifications via e-mail, SMS, or push notification when new study tasks like questionnaires and reminders are ready for you. You can adjust your communication preferences in the ProofPilot application 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.

To ensure others don't see these alerts, you should make sure your phone or desktop computer and your e-mail accounts are protected by a password, pin, or other form of "access control." You should also avoid sharing your accounts with others or sharing your account passwords.

As this study is hosted in ProofPilot, it is governed by a set of privacy and confidentiality standards that put you, as a participant, in control. You can learn more about Your Privacy and Security rights on ProofPilot by pressing "Me" and clicking Your Privacy and Security.

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For more information

If you have further questions about this study, contact Dr. Kyle Lapidus at crew@proofpilot.com.

CONTACT INFORMATION

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

Dr. Kyle Lapidus
Daytime and After hours number: 323-284-4626

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.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview is a group of people that have reviewed this research study. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	**OR**	**Email Address:**
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

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

PAYMENT FOR BEING IN THE STUDY

As a token of our appreciation in the study, participants may earn up to $100.00 for participation payable on the following criteria:

- $10.00 Visa Gift Card for Baseline through completing first Fisher Wallace Treatment (aka 'Start Task').
- $90.00 presented within 2 weeks of study completion (as defined by return of devices - both sham and active - at Week 8) based on the following:
    - $20.00 for each 2 week check in (up to $60.00)

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- Up to $30.00 as calculated by percentage of daily diaries completed over the 8 weeks (you should complete the daily diaries even if you did not use the device as directed).

You will be compensated for the portions of the study you complete.

VOLUNTEERING TO BE IN THE STUDY

The investigator, the sponsor company, or IntegReview, 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 more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

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

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

IntegReview approves the use of electronic signatures.

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS INFORMED CONSENT DOCUMENT.

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

Acceptance On-Line:

☐ I AGREE

☐ I DECLINE

You will receive a signed and dated copy of this consent form to keep.