Study Title: **Restoring Functional Stereopsis in Age Related Maculopathy using Virtual Dichoptic Training.**

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The Institutional Review Board at The Smith-Kettlewell Eye Research Institute would like to advise you that any person who is asked to participate, or consent on behalf of another, as a subject in a research study 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 experiment, as well as any drug to be used in the experiment.
3. Be given a description of any attendant discomforts and risks that might be expected from the experiment.
4. Be given an explanation of any benefits to the subject that might be expected from the experiment.
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 questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the experiment may be withdrawn at any time, and the subject may choose to discontinue participation in the experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to an experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

If you have questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may seek information from the Institutional Review Board--established for the protection of volunteers in research projects--by calling (415) 345-2075 Monday through Friday, between 9:00 a.m. and 4:00 p.m. PST.

_____
Participant's Name

_____ _____
Participant's Signature or legal representative if appropriate Date

Study Title: **Restoring Functional Stereopsis in Age Related Maculopathy using Virtual Dichoptic Training.**

Investigator: Dr. Tony Succar, Ph. D. tony.succar@envisionus.com, Research Fellow Envision Research Institute (316) 440-1533

Mentor: Dr. Laura Walker, Ph.D. Associate Scientist, Smith Kettlewell Eye Research Institute (415) 345-2097 and Executive Director – Envision Research Institute (316) 440-1506.

Research Team: Dr. Donald Fletcher, MD; Karen Kendrick, OT; Andra Meis, OTA

You are invited to participate in this research study conducted by Dr Laura Walker and Dr Tony Succar, from The Smith-Kettlewell Eye Research Institute and Envision Research Institute. You are eligible to participate because you are over the age of 18, have been diagnosed with a vision impairment and have visual acuity better than 20/200 in each eye.

Purpose

The purpose of this research study is to evaluate the effectiveness of virtual training on restoring functional 3D vision.

Duration and procedures

If you decide to participate, this study will take 5 sessions. Each session will consist of 2 hours per visit. You will be asked to play a visual training game:

Each session you will play 2 hours, consisting of:

15 minutes Game Play
3 minutes break
15 minutes Game Play
3 minutes break
15 minutes Game Play

Then take 15 minute break and repeat session.

Risks or Discomforts

There is a chance that mild fatigue and/or mild eyestrain may occur during gameplay and a slight risk of developing diplopia. In order to minimize the likelihood of these risks

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there will be careful monitoring at each session and regular contact during training period outside of sessions. Regular breaks will be taken and total testing time will not exceed 120 minutes each session. It is possible that your score on the cognitive screening test may indicate the presence of cognitive impairment. If this is the case, we will provide you with a letter informing you of this result that you can share with your doctor, if you choose.

Benefits to you or others

You will not directly benefit from this research study, however, you will be making a contribution to the advancement of science in the field of rehabilitation.

Confidentiality

Any information that is obtained in connection with this study that can be identified with you will remain confidential and will be disclosed only with your permission. Subject identities will be kept confidential by masking names and coding them with numbers.

The research team, authorized members of the Institutional Review Board (a committee that reviews and approves the involvement of humans in research), and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law.

Publications and/or presentations that result from this study will not include identifiable information about you.

An authorization describing how health information about you may be used and to whom it will be disclosed by the principal investigator and the research team will be provided to you. Federal and state law requires that patients must give authorization for use of their protected health information in order to participate in this research study.

Compensation

As compensation for your time you will be given $50 for completing each research session (not to exceed 120 minutes) for a total of 5 sessions (Total $250). If you should chose to withdraw before completion of the research session you will be given a pro-rated amount based on the amount of time that you participated.

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IF YOU HAVE QUESTIONS

If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form.

If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact Smith-Kettlewell's Human Subject Coordinator by phone, (415) 345-2075 or by e-mail at **margaret@ski.org** or in person at 2318 Fillmore Street, San Francisco, CA.

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VOLUNTARY PARTICIPATION STATEMENT

Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with Smith-Kettlewell, Envision or your doctor. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the study.

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this consent form and the Experimental Subject's Bill of Rights.

I agree to participate in the study.

Participant's Name	Date
Participant's Signature	Date
Name and Signature of Legally Authorized Representative (if appropriate)	Date
Name and Signature of Person Conducting Consent Discussion	Date

Study Title: **Restoring Functional Stereopsis in Age Related Maculopathy using Virtual Dichoptic Training.**

Participant's Name: _____

Principal Investigator: Dr Laura Walker, PhD _____

Phone: (415) 345-2097 or (316) 440-1506 _____

Address of Principal Investigator: 2318 Fillmore Street, San Francisco, CA 94115
or 600 N Main Street, Wichita, KS 67203

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Protected health information (PHI) is any health information including medical records, mental health records, billing records, survey data, and demographic data that is identified to you. By signing below, you are authorizing the principal investigator and the staff of The Smith-Kettlewell Eye Research Institute participating in the research to collect, store, use and disclose the PHI described below. You are also authorizing the principal investigator and the research team to request copies of your previous medical and/or billing records from the providers listed.

The main reason to share this information is to be able to conduct the research as described earlier in the research consent form. Information is also shared to report adverse events or situations that may help prevent other individuals at risk. Other reasons include treatment, payment, or health care operations.

Your authorization is required for participation in the research study. You may revoke your authorization at any time. This request must be in writing and must be signed by you or your legal representative, and mailed or delivered to the principal investigator at the address above. When your request is received, the principal investigator will stop collecting your information except as required to maintain the integrity for the research study or as required by law. For example, we may need to use your information to document why you have withdrawn from the study or to report adverse events.

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During the research study, your research team will look at the following information:

ALL HEALTH INFORMATION pertaining to your medical history, mental or physical condition and treatment received. These records may include (check all that apply):

☐ Billing records for healthcare services
☒ Medical records
☐ Lab, pathology and/or radiology results
☐ Mental health records
☒ Previous research records
☒ Questionnaires or interviews
☐ Other (please specify):

_____

_____

The research team may disclose your PHI to the following individuals or organizations:

☐ The Smith-Kettlewell Institutional Review Board for oversight purposes
☐ Study Sponsor: The Smith-Kettlewell Eye Research Institute
☒ Office of Human Research Protections (OHRP) in the US Department of Health and Human Services (DHHS) for safety, efficacy, and compliance reports
☐ Food and Drug Administration
☐ National Institutes of Health
☒ Other federal or state agencies that have authority over the research project or other governmental offices as required by law
☐ A data safety monitoring board, if applicable
☐ A statistician for data analysis
☐ Outside lab for specimen processing
☐ Other (please specify):

_____

_____

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During the research study, we may request copies of your PHI from the following sources (list all that apply):

Name: Dr. Donald Fletcher, MD

Address: Frank Stein & Paul S May Center for Low Vision, CPMC, San Francisco
Envision Vision Rehabilitation Center

Name: _____

Address: _____

You have the right to choose not to sign this form. However, if you decide not to sign, you cannot participate in the research study. Refusing to sign will not prejudice your future relationship with this institution.

Participant's Statement:

I acknowledge that my right to access my health information pertaining to the research study will be suspended until the study is concluded.

I hereby authorize the Principal Investigator listed above and the research team to use and disclose my protected health information as described herein.

Participant's Name: _____

Participant's Signature: _____

Date: _____

Signature of Legally Authorized Representative: _____
(if appropriate)