APPROVED
AS MODIFIED
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WIRB®

Informed Consent Form

TITLE: Beta Pilots: Assessing the Efficacy of Netra-G

PROTOCOL NO.: None
WIRB® Protocol #20132130

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SUB-INVESTIGATOR(S): Vitor Pamplona, PhD

STUDY COORDINATOR(S): Rahul Modi, B.S. Biomedical Engineering

Participant's Name: _____

In this consent form, "you" always refers to the subject. If you are a parent or guardian, please remember that "you" refers to the study subject.

BACKGROUND:

NETRA-G is a novel value-driven solution aimed at improving access to vision care and eliminating barriers. Empowering people to drive their own care experience from anywhere, anytime, will dramatically reduce costs and inspire wiser-informed decisions. Over 4B (billion) people worldwide require refractive correction of which more than half are still uncorrected. Some countries lack both the infrastructure and manpower to offer sufficient care. The remaining 1.7B who are fortunate to receive corrective aid (e.g. glasses, contact lenses, etc.) still have little insight and understanding of their refraction

history, the meaning of their prescription numbers, and the status of their general eye health. Vision loss carries significant societal stigma and inhibits equal opportunity.

Furthermore, the global cost of vision loss in 2010 was nearly $3 trillion. Eyeglass manufacturers are currently achieving average production costs of $3/unit. However, today's diagnostic tools (no matter how optically advanced) are expensive, cumbersome, require clinical training to operate, and fail to leverage modern-day mobile computing. Furthermore, lengthy and inconvenient subjective eye exams using a phoropter require highly trained professionals in a clinical setting. In India (population of over 1.2 billion), there are roughly only 9,000 practicing optometrists. The ratio of ophthalmologists to people is 1:1 million in Africa. Also, consider the fact that nearly 3 billion people survive on less than $2/day. Even in in the United States where care is more accessible (albeit not always convenient and affordable), 60% of the so called "problem learners" in schools are thought to be undetected cases of poor vision. Such bottlenecks are pro-longing treatment, hindering fulfillment, and simply fail to instill patient awareness.

PURPOSE:

The aim of this research proposal is to assess the performance, usability, and value of NETRA-G across multiple outlets in a real-world setting. Refractive error testing will take place using NETRA-G. Habitual Rx (the subject's previous prescription) will be measured using a lensometer and Snellen visual acuity will help validate the results. 10,000 subjects with an unrestricted range of refractive errors will participate across 30 sites consisting of organized public events, shopping malls, corporate campuses, pharmacies, big box retail, and clinical practices.

These studies will take place at the following site(s):

- Practice of Dr. Neil Schafran: 87 Nassau Street, New York, NY.
- Practice of Dr. Jordan Kassalow: 30th E 60th Street, Suite 201, New York, NY.
- Practice of Dr. Roy Cohen: 2nd W 47th Street, New York, NY.
- Practice of Dr. Yvonne Tsai: 16 Route 111 Suite 9, Derry, NH.
- Practice of Dr. Adam Deutscher: 82 Christopher Street, New York, NY.
- Practice of Dr. Judith Mei: 79 East Street, New York, NY.
- Pride Optical: 150 William Street, New York, NY.
- Long Island Opticians: 3844 Sunrise Hwy, Seaford, NY.

- EyeNetra Office: 35 Medford Street, Somerville, MA.
- Athenaeum Center: 215 First Street, Cambridge, MA.
- The Davenport Building: 25 First Street, Cambridge, MA.
- Nassau Futton Optical: 87 Nassau Street, New York, NY.
- Third Square Apartments: 285 Third St., Cambridge, MA.
- Digital LBI: 33 Arch Street, Boston, MA.
- MassChallenge, Inc: One Marina Park Drive, Boston, MA.
- The West End Apartments, 72 Staniford St, Boston, MA.
- Museum of Science, 1 Science Park, Boston, MA.
- Reservoir Place, 1601 Trapelo Road, Waltham, MA.
- Archstone Cambridge Park Apartments, 30 Cambridge Park Dr., Cambridge, MA.
- Droga5, 120 Wall St, 11th Floor, New York, NY.
- CityView at Longwood Apartments, 75 St. Alphonsus Street, Roxbury Crossing, MA.

TECHNOLOGY:

In contrast to today's cumbersome autorefractors, which employ sophisticated hardware, NETRA-G leverages the powerful processing capability and high resolution display of today's smartphones. The portable device consists of a plastic-molded binocular housing, basic optical components (e.g. lenses), mechanical parts (e.g. scroll wheel), and a mobile application loaded onto a smartphone. To operate NETRA-G, the subject simply looks through the binocular-like device and aligns red/green lines at various angles. By best-fitting the measurements from eight angles per eye, the device automatically outputs the patient's refractive error: defined as spherical power, cylindrical power, axis of astigmatism, and inter-pupillary distance.

Incorporating a subjective element to an otherwise purely objective measurement (the latter being typical of commercially available autorefractors) introduces a potential benefit: an easy self-test experience that allows the user to precisely fine-tune their refraction and therefore reduce discomfort without the need for expensive optical sensors. The accuracy and repeatability of EyeNetra's patented technology also stems from intelligent algorithms embedded in the mobile application such as outlier removal procedures, data fitting metrics, and machine learning.

NETRA-G's output (displayed on a Bluetooth connected tablet) is therefore equivalent to that of a traditional refractometer. Thus, NETRA-G and a traditional refractometer both assess myopia, hyperopia, and astigmatism. NETRA-G's core technology is scientifically accepted as Inverse Shack-Hartmann theory in which a smartphone's display captures user feedback to quantify line displacement on the eye's naturally occurring wavefront. This device is as safe as traditional refractometers since NETRA-G does not emit any laser radiation and is non-invasive. Moreover, NETRA-G's ingenuity does not require any integrated electronics. This device is not approved by the U.S. Food and Drug Administration (FDA).

METHODS:

After the subject signs this consent form, the entire procedure will take no more than 30 minutes to complete per subject:

- 2-5 minutes for intro and intake form
- 5-10 minutes with the NETRA-G
- 5-10 minutes for visual acuity
- 1 minute for the lensometer (if applicable)
- 5 minutes concluding debrief

First, the subject will receive a brief introduction to EyeNetra and an overview of the protocol. Next, the subject will be requested to complete an intake form if they haven't already done so (can also be completed electronically in advance). The participant will then be given a tutorial of the NETRA-G experience using an integrated simulation that explains the device controls and instructs proper intended use. A supplemental audio prompt will also help guide the subject through the test's entirety.

Once seated in the recommended testing position, the subject is instructed to look through the NETRA-G binocular with the device resting comfortably on the nose and flush against the forehead. The next step is to discover an on-screen circle using the scroll wheel found on the top right-hand side of the device. The circle will slowly dim once found and 2 lines (one green and one red) will appear in view. The subject then proceeds to make both lines completely overlap (i.e. two lines become a single line). For this step, the subject utilizes a second scroll wheel found on the top left-hand side of the device. Once the lines are overlapped to the subject's best ability, he/she is instructed to press the OK button (the third of three buttons found on top of the device). This action serves

two purposes: register the subject's diopter reading at that particular instance and proceed to the next angle.

This task of overlapping lines is repeated 8 times per eye (i.e. 16 angles in total). Testing with NETRA-G is expected to take under 5 minutes for 75% of users and less than 10 minutes for 95% of users. Once finished, the subject is instructed to put the NETRA-G device down. On a separate tablet screen (connected via Bluetooth), the test results are instantaneously displayed: spherical error, cylindrical error, axis of astigmatism, and pupillary distance.

After the NETRA-G test is finished, the operator will use a lensometer to measure the refractive power of the subjects' existing glasses (if applicable). Visual acuities for both the NETRA-G measurements and habitual Rx are collected thereafter (both monocular and binocular). To gauge usability and human factors criteria, a host of supplemental qualitative data may also be collected (e.g. subject survey or operator notes). With permission, the subject's test results will finally be sent to an off-site licensed optometrist for independent review to determine prescription eligibility. All patient data will be securely managed.

RISKS AND DISCOMFORTS:

There are no known significant risks associated with the proposed protocol, and any minimal discomforts are the same as in a subjective refraction. In this study, NETRA-G serves as an ancillary measurement tool to be used in conjunction with a licensed optometrist operating under standard practices.

CONFIDENTIALITY:

Your medical records will be kept as confidential as possible within the limitations of state and federal law. Clinical, technical, and demographic information will be collected if you agree to participate in this study.

The primary analyses will carefully study the refractive measurements, visual acuities, and lensometer readings collected for each eye. Simple correlations, plots, tables, and statistical calculations will help EyeNetra better understand the aggregate data. All data will be securely managed by EyeNetra's server (on a safeguarded cloud platform). Any paper documentation will be locked in file-cabinets found at the EyeNetra

office in Somerville, MA. Only the listed PI, coordinator, and sub-investigators will have access to this data. The security of sensitive health information will be prioritized with the utmost importance. All captured information will uniquely serve to meet the aims of this proposal (which may include scientific publications or product validation reports). A regulatory authority or the Institutional Review Board might additionally inspect the investigator's records pertaining to you as a subject.

Only the list PI, coordinator, sub-investigators, and select optometrists who are independent from your test site (but who are an approved point of contact at a different site) will have access to this data.

PERSONAL HEALTH INFORMATION:

Your personal health information (PHI), as related to this study, is described in the "Confidentiality" section above. If you sign this informed consent form, it grants EyeNetra the permission to use your PHI as specifically discussed. This permission does not have an expiration date, but you can cancel at any time.

If you cancel your permission to use your PHI after the study has started but before your study participation would normally cease, you will not be allowed to continue in the study and the investigators will stop collecting data. Nevertheless, they retain the right to use the information they have already collected to evaluate the study's results.

PRIVACY PRACTICES AND YOUR RIGHTS:

Health care providers are required by law to keep private any health information that identifies people. Federal Privacy Regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or inspect all of the health information generated or collected about you during this study includes the study doctor(s), the study staff, the Institution, any study Sponsor (or the authorized agents of the sponsor), the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) agencies, and the Institutional Review Board. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. Once your personal health information is released it may be re-disclosed, at which point the health information may no longer be protected by federal privacy regulations.

You may ask the study investigator to see a copy of your PHI related to the study. You may also request the study investigator to correct any information that you feel is incorrect. However, you may have to wait until the end of the study to see your records so that the study can be organized and conducted scientifically. You must be given notice of your investigator's privacy policies. The Confidentiality, Personal Health Information, and Privacy Practices and Your Rights sections of this form fulfill this requirement. Unless you authorize the use and disclosure of your personal health information, you cannot participate in this research study. If you refuse to give your authorization, your medical care will not be affected.

ALTERNATIVES:

Your alternative is to not participate.

VOLUNTARY PARTICIPATION OR WITHDRAWAL:

Being part of this project is voluntary. You may choose not to take part or to quit at any time without penalty or loss of any benefits to which you are otherwise entitled. Whether or not you chose to take part in the project will have no bearing on any care you may be receiving via EyeNetra, Inc. or your own practitioner(s). You may take yourself out of this project at any time. Taking yourself out of this project will not affect your right to health care. The Institutional Review Board, the sponsor or the investigator may terminate your participation in the study (at any time with or without your consent for any reason) if it is believed to be in your best interest or if you fail to keep appointments or follow study instructions.

COMPENSATION:

If you need to receive follow-up care from another doctor after this study, the cost of obtaining this follow-up care will not be covered. Moreover, you will not receive a stipend or any compensation for participating in this study.

CONSENT:

If you have any questions about your participation in this study, questions, concerns, or complaints about this project, or if you feel you have a research-related injury you may contact David Schafran, BA at 617-629-5803 or 973-229-3341.

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

EyeNetra, Inc. and Western Institutional Review Board approved the informed consent form of this IRB study. Furthermore, I have been satisfactorily informed of the above-described procedure with its possible risks and benefits. I have chosen to participate in this study on my own will. I know that David Schafran, BA or his associates will be available to answer any questions that I may have. I understand that I am free to withdraw this consent and discontinue my participation in this project at any time, even after signing this form, and it will not affect my care. All information will remain confidential.

Upon request, you will be given a copy of this form.

Consent/ Assent Instructions

Consent is provided by the subjects if they are over 18 years of age.
Consent is provided by a Parent/Guardian for subjects 10 to 17 years of age.
Assent is required for subjects 10 to 17 years of age, as determined by the investigator.

_____

Name of Subject

_____

Subject's Signature with Date

_____

Parent/Guardian Signature and Date (if applicable)

_____

Name of Person Conducting Informed Consent Discussion

_____

Signature of Person Conducting Informed Consent Discussion with Date

_____

Signature of EyeNetra, Inc. Representative