



eQUEST -- ESIGHT QUALITY OF LIFE AND EFFICACY STUDY¹

A multi-center, prospective cohort study to assess the impact of eSight Eyewear on functional vision improvement and quality of life in a low vision population

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Abbreviations & Definitions

Through this document, the following acronyms and terms are used. Terms, when capitalized, carry the specific meanings described below.

ADL:	Activities of Daily Living
AE:	An Adverse Event is defined as any untoward medical occurrence, including deterioration of a pre-existing medical condition in a patient or clinical investigation subject administered a pharmaceutical product/device and which does not necessarily have a causal relationship with this treatment.
AT:	Assistive Technology.
BCVA:	Best Corrected Visual Acuity
CRF:	Case Report Form
CCTV:	Closed-circuit television, which uses a video camera to project a magnified image onto a TV screen. For people with low vision, it can help with reading, viewing photos and other such tasks
CTA:	Clinical Trial Agreement. Legally binding document between the Sponsor and the Institution and the Investigator defining roles, responsibilities, payment, consideration, intellectual property ownership, liability, publication rights, etc.
DEVICE:	eSight Eyewear. A wearable, video based low vision AT device.
eSKILLS PROFICIENCY PROGRAM:	The eSkills program is a structured training program for eSight Eyewear users. It includes various tasks the improve the user's effectiveness with the device. Normally, eSkills is administered by eSight staff by telephone. For the eQUEST study, eSkills will be administered by Site staff.
ETDRS:	Early Treatment Diabetic Retinopathy Study – the worldwide standard for visual acuity testing.
EYECARE PHYSICIAN:	Optometrist or Ophthalmologist at the Study Site.
EXAMINER:	Any staff at the test site who, under the supervision and oversight of the INVESTIGATOR, will administer portions of the protocol and record results in the CRF.
INSTITUTION:	The Low Vision Clinic, Hospital or other location where Eyecare Physicians and low vision rehabilitation specialists are equipped to

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	conduct this study. The Institution shall have a CTA in place with the Study Sponsor.
INVESTIGATOR:	The eyecare physician responsible for oversight of Study activities at the Institution.
LV:	Low vision
MLVAI:	Melbourne Low-Vision ADL Index Test
MN Read Eye Charts:	A continuous text chart designed for normal and low vision at the Minnesota (MN) Laboratory for Low Vision Research
PD:	Pupil Distance. For the purposes of this study, PD means independent left and right pupil distances from nasal center. PD does <i>not</i> mean the distance between the two pupils.
QOL:	Quality of Life
RESEARCH ASSISTANT:	Site associate deemed qualified, and authorized by the Site PI, to carry out portions of the protocol and complete related sections of the CRF. Often the Research Assistant will be the same Site staff person as the Site Administrator.
SAE:	A Serious Adverse Event is defined as any untoward medical occurrence that: <ul style="list-style-type: none">• Results in death,• Is life-threatening,• Requires inpatient hospitalization or prolongation of existing hospitalization (visit to emergency department without admission to the hospital is not considered hospitalization),• Results in persistent or significant disability/incapacity or• Is a congenital anomaly/birth defect.
SITE ADMINISTRATOR:	Often the Site Administrator will be the same Site staff person as the Research Assistant.
SPONSOR:	eSight Corp.
STUDY:	The research protocol as defined herein.
SUBJECT ID:	A unique number used to identify a Study Subject. This facilitates the provision of study data if necessary amongst different Study Sites, and between the Study Site and the Sponsor, without disclosing breaching the confidentiality of the Subject.
STUDY MANAGER:	Person appointed by eSight to oversee the overall management of the Study, manage data integrity, and the overall Study schedule.

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STUDY SITE: Also, "Site". There are six Study Sites in the eQUEST Study. These are the locations at which the research is being conducted. In all cases, Study Sites have achieved ethics approval to conduct the Study, and informed consent from the Study Subject.

SUBJECT: An individual enlisted as a participant in the eQUEST Study.

THIRD PARTY SURVERYOR: A HIPAA-trained independent third party, trained to administer the VA LV VFQ-48 and eSight-8 Questionnaires by telephone.

VA LV VFQ-48: Visual function questionnaire designed to measure the difficulty a person has performing daily activities

1. Background

eSight Corp., Toronto, Canada (Sponsor), has developed a wearable, electronic low vision aid, “eSight Eyewear” (Device). eSight Eyewear deploys ophthalmic grade video camera and display components, and real-time video modification algorithms to significantly improve the functional visual performance of people with non-correctable, inoperable low vision caused by eye diseases such as but not limited to:

- Macular Degeneration
- Diabetic Retinopathy
- Stargardt’s Disease

Over 100 million people in the developed world have low vision, defined by the World Health Organization as best corrected visual acuity in the better eye of 20:60 or worse². Other factors can also contribute to low vision such as diminished field of view or impaired occipital/cognitive image processing.

In most cases of low vision, individuals will retain sufficient residual visual function that, with the help of Assistive Technology (AT) devices they can still perform various life tasks or Activities of Daily Living (ADLs). The eSight device can help people perform various ADLs such as:

- Reading
- Interacting with others
- Viewing a computer screen
- Orientation and Mobility
- Watching television
- Distance Viewing

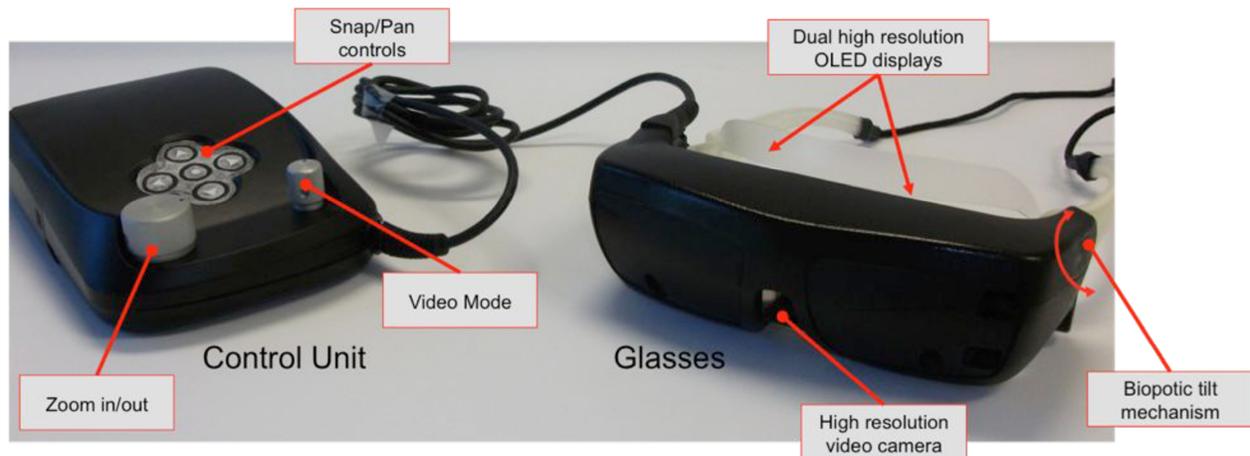
The mechanism of eSight Eyewear is to stimulate vestigial retinal function through existing retinal photoreceptors (rods and cones), thereby enabling more effective neurological (cortical/occipital) visual processing, helping the brain to extract more usable information from a visual scene. We do not believe eSight Eyewear affects disease progression, nor does it interact with the body’s metabolism or physiology in any way other than through the stimulus described above. eSight Eyewear is a Class-I medical device. The mechanism of

² “The Global Economic Cost of Visual Impairment”, AMD Alliance International, April 2010

physiological/neurological action with the body's natural processes is through visible light (non-harmful intensities and wavelengths) into the eye.

Limited experiments have demonstrated the benefits of eSight Eyewear to certain subjects, and helped to refine inclusion/exclusion criteria in this study. These preliminary results are presented herein.

This study seeks to generate further evidence-based conclusions about the efficacy of eSight Eyewear for various ADLs in the low vision population. Specifically, the study seeks to understand how eSight Eyewear can be used to improve employee productivity and satisfaction in vocational, educational, and home settings.



An initial assessment was performed by the CNIB where 33 individuals of various age, vision and eye pathologies showed improved visual function for both distance and near vision using traditional visual assessment tests (distance acuity and contrast performance) using various image processing algorithms including variable magnification, adjustable contrast, and colour remapping techniques. The CNIB test did not include assessment of the Activities of Daily Living (ADLs) or seek to measure improved functional vision. To date there are ~400 “early-adopter” individuals with low-vision that wear the glasses in their day-to-day lives. Most users self-report high satisfaction with the device however, the technology has not been subject to rigorous scientific study to determine which users would most benefit from using this technology and how the glasses improve their functional visual performance and quality of life. Considering the high cost of this technology (\$15,000) this Clinical Study will guide patients and physicians on the expected benefits and indications for the large population affected with untreatable vision disorders.

1.1. Prior Research

There have been previous attempt to develop and commercialize a head-borne video based low vision aid. The original design from the 90's was called the Low Vision Enhancement System

(LVES), developed by researchers at John Hopkins University³. The LVES device was the subject of various studies and notably, was evaluated extensively by the U.S. Department of Veterans Affairs as an aid suitable for visually impaired veterans.⁴

More recently, the “Joint Optical Reflective Display (Jordy) system was developed by Enhanced Vision Systems, Huntington CA, in collaboration with scientists from the National Aeronautics and Space Administration. The Jordy enjoyed margin commercial success, but has been discontinued⁵.

The use of head worn video as opposed to optical magnification does present exciting possibilities for the partially sighted. Various researchers have sought to understand how video enhancements such as contrast, edge enhancement, overlays, and various other techniques not possible through simple optical magnification or filtering, can be used to enhance functional vision^{6, 7, 8, 9}.

There have been other attempts at head-borne video devices for low vision. Historically, all have suffered from the same drawbacks, largely due to technological implementation at that time. These units were large and cumbersome, with limited field of view, poor camera performance, and unacceptable latency¹⁰. eSight Eyewear, by far the most commercially successful such device to date, overcomes these historical shortcomings through leading edge technology choices and various proprietary design elements.

³ Massof, Rickman, “*Obstacles encountered in the development of the low vision enhancement system*”, Optometry and Vision Science. 1992 Jan;69(1):32-41

⁴ Ballinger, Lalle, Maino, Stelmack, Tallman, Wacker, “*Veterans Affairs Multicenter Low Vision Enhancement System (LVES) study: clinical results. Report 1: effects of manual-focus LVES on visual acuity and contrast sensitivity*”. Optometry. 2000 Dec;71(12):764-74.

⁵ Chang, “*Sleek New Devices Help Low-Vision Patients See*”, NY Times, April 2004

⁶ Peli *et al.*, “*Applications of Augmented Vision Head-Mounted Systems in Vision Rehabilitation*”, Journal of the Society for Information Displays. 2007 Dec; 15(12): 1037–1045.

⁷ Arici, Dikbas, Altunbasak, “*A Histogram Modification Framework and Its Application for Image Contrast Enhancement*”. IEEE Transactions on Image Processing, Vol. 18, No. 9, 2009.

⁸ Peli, “*Augmented Vision for Central Scotoma and Peripheral Field Loss*”, 1999

⁹ Moshtael, Aslam, Underwood, Dhillon, “*High Tech Aids Low Vision: A Review of Image Processing for the Visually Impaired*”, Translational Vision Science and Technology. 2015 Aug; 4(4): 6.

¹⁰ Culham, Chabra, Ruben, “*Clinical performance of electronic, head-mounted, low-vision devices*”, Ophthalmic and Physiological Optics. 2004 Jul;24(4):281-90.

2. Study Objectives

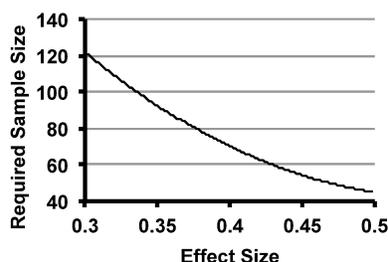
The purpose of this study is as follows:

- To assess the impact of eSight Eyewear on the functional visual performance¹¹ of subjects with various low vision conditions.
- To assess the impact of eSight Eyewear on standard QOL assessments.
- To determine which ADLs are most profoundly impacted by eSight Eyewear
- To learn more about the mechanism of physiological/neurological action of eSight Eyewear
- To assess various subjective aspects of eSight Eyewear such as usability, comfort, learning curve, aesthetics and social interaction
- To further assess the diseases and visual performance criteria for which subjects appear to be well positioned to benefit from eSight Eyewear and conversely, to understand and characterize the visual performance and diagnosis of subjects for whom eSight Eyewear provides little or no functional visual improvement.

3. Study Sample

3.1. Sample Size

Subjects will undergo an initial screen and device demonstration (screening arm) to determine their suitability for an extended trial of the device (extended arm). The target number of subjects for the extended arm is 60 subjects.



Power analysis indicates that in a single tailed test with an alpha level of .05 and a power of .95, the relationship between anticipated effect size and the required sample size is shown in the chart at left. As indicated if we assume an effect size in the range 0.40 – 0.45¹², an appropriate n=60 (ten Study subjects per site).

¹¹ The term “functional visual performance” describes the wearer’s ability to perform various Activities of Daily Living (ADL) with better efficacy and speed than using habitual assistive technology devices. In some cases, because of the hands-free, variable distance, and portable attributes of eSight Eyewear, it is hypothesized that certain ADLs may be possible which were previously impossible or very difficult for certain subjects.

¹² This higher than typical anticipated effect size is an appropriate assumption for this Study design, because of prescriptive inclusion criterion (i.e.: not random population).

About $\frac{1}{3}$ to $\frac{1}{2}$ of subjects who fall into the acuity and visual field inclusion criterion described in Section 3.2 below, demonstrate acute objective improvement and an immediate aptitude with the device. Therefore, we anticipate a total of 150-200 to be enrolled in screening arm of the study, from which 60 will be selected to participate in the extended arm, a three month take-home trial of the device. We expect attrition to be low due to the rigorous screening process for participation.¹³

In addition to a clinician's unit, which incorporates trial lens frames and other unique features for fitting and demonstration, each Site will receive devices for Subjects as they are required. The Site and eSight can, at any time, agree to deploy additional devices to accelerate the collection of data.

3.2. Inclusion Criteria

1. Male or female subjects between the ages of 13-75. The goal for the extended arm is that 50% of subjects will be 65 years of age or younger, and 50% will be older than 65¹⁴.
2. Subject must have distance BCVA measured with ETDRS of between 20:60 and 20:400 in the better eye.
3. Subjects have been diagnosed with a condition that presents as one or all of the following: Central scotomata, geographic atrophy, or scattered scotomata. These are typically symptoms attributed to conditions such as: Diabetic Retinopathy, Stargardt's Disease, Age Related Macular Degeneration, Leber's Disease, Retinopathy of Prematurity, Cone Rod Dystrophy, or Ocular Albinism¹⁵.
4. Subject must have an estimated functional field of view of at least 20 degrees (bilateral or monocular).¹⁶
5. If the subject is employed, they must be prepared to use eSight Eyewear in their workplace environment, have informed their employer of their involvement in the study, and received permission from their employer to bring eSight Eyewear into the workplace. If the subject is self-employed, they must be prepared to use eSight Eyewear in their

¹³ "Sample size estimation and power analysis for clinical research studies", Suresh & Chandrashekar, J Hum Reprod Sci. 2012 Jan-Apr; 5(1): 7-13. "G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences", Erdfelder, Faul, & Buchner, Behav Res Methods. 2007 May;39(2):175-91.

¹⁴ The intention of this stratification of the cohort is to understand age effects related to the eSight Eyewear device. This stratification does not impact the statistical analysis in Section 3.1

¹⁵ These have been demonstrated by current eSight users to be conditions for which eSight Eyewear can provide significant benefit. For other conditions, especially those which present as peripheral degeneration encroaching inwardly ultimately towards the central vision, eSight Eyewear's effectiveness has not yet been convincingly demonstrated (e.g.: early stage Retinitis Pigmentosa, early stage Glaucoma).

¹⁶ Acuity and field criteria, while firm requirements here, are inflection points in the real world population. Evidence indicates that eSight users outside of the 20/60 – 20/400 BCVA and 20° field can still have success with the eSight device, but results are less consistent.

workplace environment. Similarly if the subject is a student, they must be prepared to use eSight Eyewear in their educational environment.

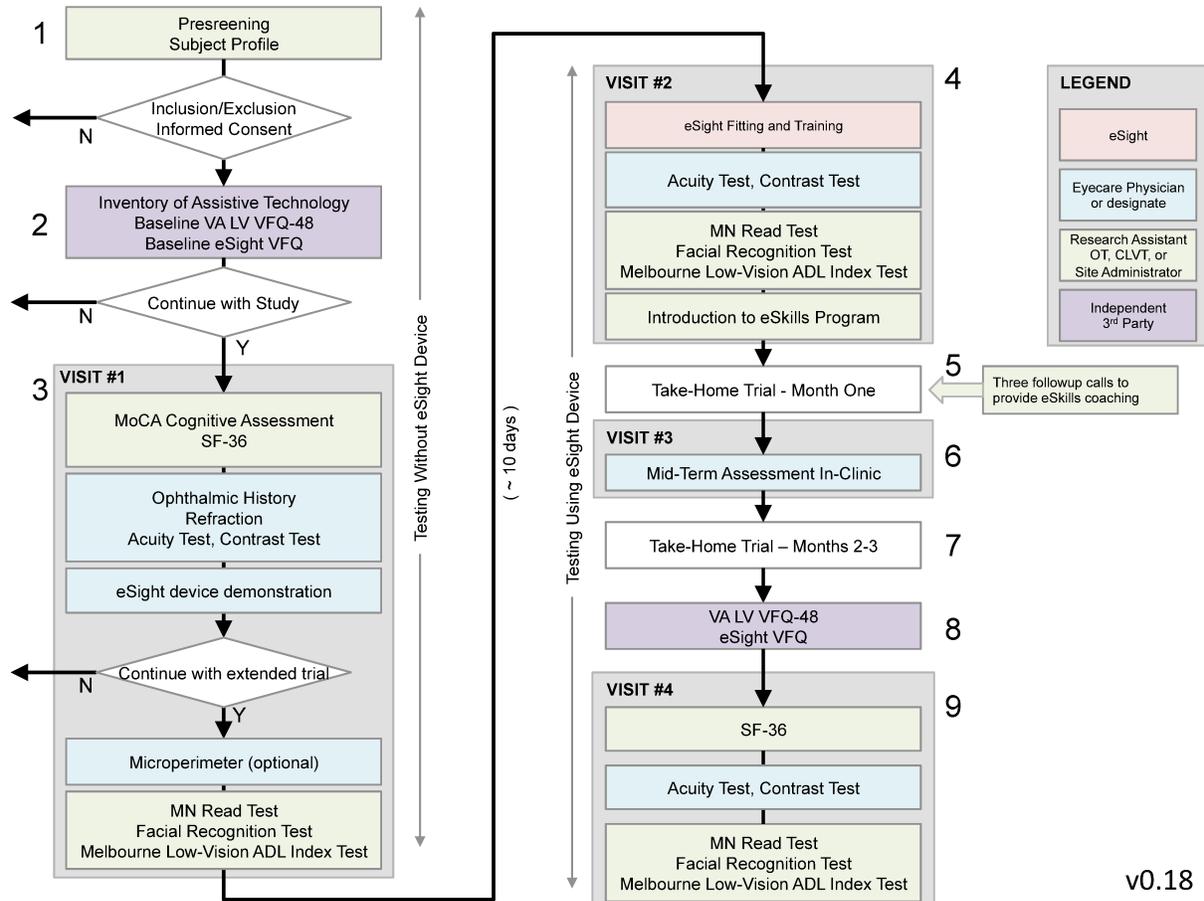
6. Subject must be, in the opinion of the examiner, highly motivated, alert, articulate, mentally competent and able to understand and comply with the requirements of the study (defined herein).
7. Subject must provide informed consent. Subjects under the age of majority must have a legal guardian present during the informed consent process, who must sign the Informed Consent form on their behalf.
8. Subject must agree to use eSight Eyewear only under conditions that will not jeopardize the safety of either the user or the device.

3.3. Exclusion Criteria

1. Subject must not be currently undergoing any medical or surgical procedures resulting in unstable vision.
2. Subjects for whom their vision, for whatever reason, can be considered unstable.
3. Subjects who have undergone cataract, refractive, or other surgical procedures related to vision in the six month period prior to the study.
4. Subjects who have undergone any eyesight-related injections (e.g. anti-VEGF) in the six month period prior to the study.
5. Subjects unable or unwilling to adhere to the examination schedules as they are described in the study protocol. This may also include Subjects already enrolled who, for whatever reason become unable or unwilling to continue the study. This may also include subjects for whom the travel time to/from the study site is unacceptable.
6. Subjects who self report a history of alcoholism or use of illegal drugs, Subjects who exhibit clinical evidence of depression, poor motivation, emotional or intellectual problems, who are deemed unsuitable psychologically or physiologically for study participation by the investigator.
7. Subjects who may have a conflict of interest with eSight Corp, which could reasonably influence their participation in the study.

4. Study Design

The Quality of Life and Functional Visual Improvement Study Using eSight Wearable Video Eyewear is a prospective multi-site study. The main elements of the study are shown in the flowchart below. Decision points are shown as diamonds. Note that the flowchart below only shows activity for the extended arm (n=60), not the larger screening arm.



As indicated on the chart, the red boxes are activities conducted by eSight. The green and blue boxes are conducted at the study site, by a research assistant, Occupational Therapist, Certified Low Vision Therapist or Eyecare Physician respectively (or supervised and trained designate). Over the course of the study there are four visits by the subject to the study site as indicated by the larger grey boxes. Tests conducted during the first visit are without the eSight device. Subsequent tests deploy the eSight device. Tests within each visit (grey boxes), do not necessarily need to be in the order presented above.

Note that the Case Report Form (CRF) that will be used for the eQUEST Study will be Microsoft Excel spreadsheet with appropriate constraints (restricted cells, validated data entry, drop down choices, help text, etc.). Each site will be provided with a tablet computer with the CRF pre-installed. This will help to ensure data completeness and integrity. Each section of the CRF will identify the level of staff (eSight or Study Site) that is required to conduct that portion of the protocol. Information provided to the Study sponsor will be de-identified.

The components of the study are described in greater detail in Section 4.1 below:

4.1. Schedule of Events

This section indicates data that will be collected for each subject. Subjects will be screened for enrollment prior to their initial visit. At the initial visit, subjects will provide informed consent and the investigator will obtain medical and ophthalmic history information as described in the CRF, and conduct a complete low vision assessment.

At various points through the protocol, decision points are identified as red boxes below.

STEP 1: Pre-Screen, Subject Profile, and Informed Consent

The Eyecare Physician at the Study Site will select potential candidates from the Site's regular flow of patients. In some cases, eSight may direct interested persons to the Site, who have contacted eSight directly.

Steps 1.01 through 1.03 may be administered by a Research Assistant or a similarly suitable staff person at the clinic (e.g.: CLVT, OT, etc.).

Step 1.01 Subject ID: When a potential Study Subject has been identified, the Site Administrator will assign a unique subject identification number from the site-specific list of numbers provided by eSight.

Step 1.02 Demographic Data: The Site Administrator will contact prospective study participants and obtain demographic data.

Step 1.03 Inclusion/Exclusion, and Informed Consent: The Site Administrator will work through the inclusion/exclusion criteria to verify the subject is qualified for the study, and then work with the subject through the informed consent process, obtaining their written approval to proceed. An IRB approved informed consent form will be used.

The site administrator will then provide to the Third Party Surveyor, contact information for the study subject in order to proceed with Step 2 below. The Third Party Surveyor will complete Step 2 and send that information back to the Site Manager for inclusion in the Subject's CRF.

STEP 2: Pre-Study LV Inventory Assessment & VA LV VFQ-48

Steps 2.01 through 2.03 will be administered by telephone using a Third Party Surveyor¹⁷.

Step 2.01 AT Inventory: The Third Party Surveyor will conduct a telephone interview with each subject. The purpose of this phone interview is to inventory the subject's current assistive devices and usage habits. This background information will be used by the study examiner to determine which visual aids will be used during benchmarking activities.

Step 2.02 Baseline VA LV VFQ-48 Questionnaire: Third Party Surveyor will work with the subject to complete the VA LV VFQ-48¹⁸ questionnaire.

Step 2.03 Baseline eSight-8 Questionnaire: Third Party Surveyor will work with the subject to complete seven QoL type questions which will provide predictive insights regarding their affinity with the eSight device.

Step 2.04 Advancement Decision: Based on the Subject's responses to 2.02 and 2.03 above the Eyecare Physician will determine whether or not the Subject ought to proceed through the Protocol.

Note: While not an explicit inclusion criterion, there are seven questions on the VA LV VFQ-48 items identified in red (2, 3, 5, 12, 14, 19, 45) for which the eSight Eyewear device has been shown to be particularly effective. If a subject scores four or more of these items as "moderately difficult" or "extremely difficult", they will be considered a strong candidate.

STEP 3: Clinic Visit – LV Assessment & eSight Demonstration

Subjects will also be asked to complete a series of supervised activities to establish a baseline of their visual function and functional visual performance *without* eSight Eyewear¹⁹.

Duration: 2-3 hours.

Steps 3.01 through 3.04 may be administered by a Research Assistant or a similarly suitable staff person at the clinic (e.g.: CLVT, OT, etc.).

Step 3.01 Low Vision Rehabilitation Goals: The CRF form identifies five ADLs, prioritized by the subject, which they wish do (or do better). It also asks how satisfied they are currently with their ability to perform this task, and how important this task is to their day-to-day quality of life. The purpose of this step is provide the subject with specific goals that they can work to achieve (or improve) using eSight Eyewear over the course of the study.

¹⁷ In the case of Johns Hopkins University Wilmer Eye Institute, research assistants from the institute will conduct Step 2. These research assistants will be dis-associated from the PI and other researchers who have face-to-face interaction with the subject.

¹⁸ Using the VA LV VFQ-48 and LV VFQ-20 in Low Vision Rehabilitation, Stelmack, Massof, Optom Vis Sci. 2007 Aug;84(8):705-9.

¹⁹ Because we intend to deploy standardized ADL measures, it may be possible to compare our findings directly to some other interventions (e.g.: Haymes, Johnston, & Heyes, 2001).

Note: If, in the estimation of the researcher, the Subject identifies goals which are too abstract (e.g. “I want to do more”, “I want to be happier”), or not suitable uses for eSight Eyewear (e.g. “I want to swim”, “I want to drive”, “I want to go downhill skiing”), they will be encouraged to elaborate or identify a different goal that can be considered applicable to the Study/Device.

Step 3.02 Cognitive Assessment: To determine the cognitive capability of the subject to continue with the remainder of the study protocol, an assessment using the Montreal Cognitive Assessment – BLIND (MoCA)²⁰ test will be conducted. Psychometric properties of the MoCA in its full version include a test-retest correlation of $r = .92$, while internal consistency was evaluated with a Cronbach’s alpha of $.83$.²¹

While the cognitive suitability of the Subject for the test protocol is ultimately the decision of the researcher, a MoCA score of less than 20 indicates that careful consideration is necessary²². If the researcher determines that the subject is cognitively unsuited for the study, the remaining steps below are unnecessary (skip to 3.10).

Step 3.03 36-item short-form health survey (RAND SF-36)²³: The SF-36 is a brief questionnaire that provides a validated indication of the subject’s broad general health. It was chosen in part because of its excellent psychometric properties, which include a minimum of $.70$ for reliability statistics. Content, concurrent, construct, criterion, and predictive validity have been shown to be satisfactory (Ware & Gandek, 1998)²⁴

Steps 3.05 through 3.11 are administered by the Eyecare Physician or suitably trained and supervised clinical staff. These tests benchmark the subject’s visual performance with their habitual low vision aids where possible²⁵. As a minimum for these tests, the subject should wear their corrective lenses (distance or reading) as applicable. NOTE: if the lens prescription as

²⁰ “Sensitivity and Specificity of the Montreal Cognitive Assessment Modified for Individuals Who Are Visually Impaired”, Wittich, Phillips, Nasreddine, Chertkow, JVIB 06/2010; 104(6):360-368. See also: <http://www.mocatest.org>.

²¹ Nasreddine ZS, Phillips NA, Bedirian V, Charbonneau S, Whitehead V, Collin I, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. J Am Geriatr Soc. 2005;53(4):695-9.]

²² The MoCA scoring tool does not provide regarding pass/fail criterion. Ultimately, a subject’s performance in the test is meant to provide clues to the researcher about cognitive deficiencies.

²³ Ware, Sherbourne. “The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection”. Med Care. 1992 Jun;30(6):473-83.

²⁴ Ware JE, Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. J Clin Epidemiol. nov 1998;51(11):903-12.

²⁵ References: The forms provided with this study are a subset of LV rehabilitation practice guidelines from the following sources:

- a) Ontario Practice Template - Low Vision Assessment.
- b) New York Lighthouse for the Blind LV Intake Exam (Dr. Bruce Rosenthal) <http://www.lighthouse.org/professionals/practice-management/structured-low-vision-exam>.
- c) VisionAware: <http://www.visionaware.org/info/your-eye-condition/eye-health/low-vision/low-vision-examination/1235>

determined in step 1.04 is substantially different from the subject's habitual glasses, this portion of the protocol may be conducted with a trial lens frame.

Step 3.04 Medical and Ophthalmic History: The clinician and/or site administrator will record the following information on the CRF:

- OD and OS disease type(s), and approximate number of years, if possible.²⁶
- Free-form field: other eye-health related history (e.g.: laser photocoagulation, Lucentis, etc.), considered by the examiner to be relevant.
- subject's verbal description of visual scotoma if present

Step 3.05 Refractive Prescription: The clinician will perform a refraction to determine the prescription lenses required by the subject for best distance and near vision. Note: No prism element may be included in the refraction prescription.

Step 3.06 Acuity Test: Choose ONE OF ETDRS or Snellen

ETDRS²⁷: Using the subject's habitual corrective lenses (if applicable). For each eye independently, and then binocularly, determine the ETDRS acuity.

- Determine the last row where the subject can correctly identify all 5 letters on that row.
- Determine the log score for that row (these scores are shown in the margin of the ETDRS test, e.g. the 20/25 line has a log score of 0.1)
- subtract 0.02 log units for every letter that is correctly identified beyond the last row where all of the letters are correctly identified.

For example: if the subject reads all of the letters correctly on the 20/32 row and then 3 letters correctly on the 20/25 row, the Log Score would be calculated as follows:

$$\begin{aligned} \text{ETDRS Acuity Log Score} &= 20/32 \text{ Row} = 0.20, \text{ plus } 3 \text{ letters on } 20/25 \text{ row} \\ &= 0.20 - (3 \times 0.02) \\ &= 0.14 \end{aligned}$$

Snellen: Using the Subject's habitual corrective lenses (if applicable). For each eye independently, and then binocularly, determine the Snellen acuity²⁸.

Step 3.07 Mars Contrast Sensitivity Test: Test Contrast Sensitivity using the Mars chart. Mars test score sheet to be provided²⁹.

²⁶ On the CRF this will be a date range, because subjects will not recall with accuracy. E.g.: <6mos, 6-12mos, 1-2yrs, 2-5yrs, 5-10yrs, >10yrs.

²⁷ <https://www.good-lite.com/Details.cfm?ProdID=639>

²⁸ In some cases (e.g. dense scotoma) the test Subject may have difficulty reading ALL 5 letters on any line of the ETDRS chart, which limits the precise ETDRS scoring algorithm above. Adding Snellen allows greater flexibility in participant inclusion and data analysis.

²⁹ © 2003-2004 The Mars Perceptrix Corporation. <https://www.good-lite.com/Details.cfm?ProdID=549&category=26&Secondary=71>

Step 3.08 eSight Demonstration: eSight Eyewear will be demonstrated using a clinician's version of the device³⁰. The subject will be provided basic instruction on its use (zoom in/out, contrast adjust). The researcher will observe the Subject's performance in tests of, acuity (ETDRS) contrast performance, facial recognition, and reading (MNRead). These above tests are observational only, and are not recorded to provide a baseline performance measure with the eSight Device.

Step 3.09 Advancement Decision: At this point in the protocol the Subject and the Eyecare Physician will come to an agreement about whether to continue with the extended portion of the protocol evaluating eSight Eyewear. The decision will be based on a minimum 4-line ETDRS improvement using the device, the subject's performance of the various tasks above, their impressions of the eSight Eyewear demonstration, and the continued compliance with inclusion/exclusion criteria as defined in Sections 3.2 and 3.3 respectively. There is a subjective and personal aspect to this decision, not unlike a patient's decision about whether or not to purchase the device.

Should the subject and/or the examiner decide not to proceed with the remainder of the study, this should be noted on the CRF, along with their reason for withdrawal.

Step 3.10 Microperimter Test (without eSight): This test is optional. Bilateral. The intent is to understand how field performance correlates with efficacy results. Because this diagnostic test requires a significant time commitment, the subject will be asked for consent, as indicated on the CRF. Ideal candidates for this test are <60 years old, with a central scotoma in both eyes. A 10-2 pattern is preferred. Indicate on the Case Report Form which test was conducted.

Steps 3.11 through 3.13 may be administered by a Research Assistant, or a similarly suitable staff person at the clinic (e.g.: CLVT, OT, etc.).

Step 3.11 Minnesota Low Vision Reading Test (MN READ): Under normal "office" lighting conditions, using the hand held MNREAD charts, record the subject's score. Score sheets to be provided³¹. This test will be conducted without eSight Eyewear, using the Subject's habitual spectacle correction if applicable.

Step 3.12 Cohn-Kanade Facial Recognition Test: The subject will complete a task of recognizing the sex and facial expressions on a randomized selection of faces from the University of Pittsburgh Cohn-Kanade Facial Images Database. These will be displayed on a

³⁰ The clinician's version of eSight Eyewear is more adjustable (e.g. trial lenses, pupil distance, etc.), but compromises on weight, comfort and aesthetics. Subjects who receive eSight Eyewear for the trial will be provided a consumer version of the product, appropriately sized, incorporating their prescription lenses and correct pupil spacing.

³¹ Scoresheets will follow Lighthouse Low Vision Products format.

computer screen simulating faces at a distance of five feet and ten feet³². This test will be conducted without eSight Eyewear, using the Subject's habitual spectacle correction if applicable.

Step 3.13 Melbourne Low-Vision ADL Index Test (MLVAI)³³: The MLVAI is a series of standardized ADLs appropriate for the low vision population. The test has been modified for eQUEST to remove certain dated or impractical items. The intention of this test is to establish a benchmark performance for the various activities identified. This test will be conducted without eSight Eyewear, using the Subject's habitual spectacle correction if applicable.

STEP 4: Clinic Visit – Fitting & Baseline Testing with eSight Eyewear

Within a period of 25-30 days following the first visit³⁴, subjects will be required to return to the clinic to receive their eSight Eyewear device and training. Subjects will also be asked to complete a series of supervised activities to establish a baseline of their functional visual performance *with* eSight Eyewear³⁵.

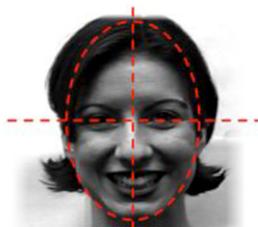
Duration: 2-3 hours.

³² "eSight Facial Recognition Test Description", July 28, 2015.

50th percentile head size is about 22.5cm x 15cm. This is an average of male and female anthropometric data. Females are typically about a cm smaller than males in both directions (ref: pp72-75 of Poston, Alan. April 2000, Department of Defense Human Factors Engineering Technical Advisory Group (DOD HFE TAG).

On a 22" monitor, PowerPoint in "Slide Show" mode shows a 4:3 image letterboxed on the left and right sides. A 22.5cm high Monitor is 29.5cm high. Slide height is 19.5cm. Therefore, a face that is 14.9cm high in Powerpoint will appear 22.5cm high on a 22" monitor in Slide Show mode.

Four sets of fifty randomized facial images have been selected. Faces are centered as show below. Expressions are "neutral", "joy", "sadness", "fear", "anger", "disgust", "surprise".



³³ Haymes, Johnston, Heyes, Investigative Ophthalmology & Visual Science, May 2001, Vol. 42, No. 6. The ADLs included in the MLVAI include: Reading Headlines, Packet Labels, Digital Clock, Accounting, Wall clock, Cheque, Wrist watch, Faces, Pouring, Telephone, Newsprint, Telephone book, Medicine label, Typed letter, Needle threading.

³⁴ This time requirement ensures that benchmark tests performed in Step 3 remain valid.

³⁵ Because we intend to deploy standardized ADL measures, it may be possible to compare our findings directly to some other interventions (e.g.: Haymes, Johnston, & Heyes, 2001).

Steps 4.01 through 4.04 are administered by the eyecare physician (Optometrist or Ophthalmologist), or suitably trained and supervised clinical staff. eSight staff will be in attendance throughout this visit to provide guidance and support.

Step 4.01a Fitting subject's eSight Eyewear: The subject's personalized eSight Eyewear will have their ophthalmic lens prescription incorporated into the prescription frames, and the left and right PD set internally. The device will be properly fitted to the subject by adjusting the nose bridge, forehead strap, and headband.

Step 4.01b Training on eSight Eyewear Controls: The subject will receive complete training on the features and controls of eSight Eyewear. This will include a demonstration of

1. Using the HDMI input for computer use and television viewing, including using the motion sensors in the device to control panning across the scene.
2. Using the various binary colour modes to improve reading capability.
3. Various other features such as saving images, etc.

Tests 4.02 through 4.07 below are repeats of previous tests, but using eSight Eyewear.

Step 4.02 Acuity Test – with eSight Eyewear (ETDRS or Snellen)

Step 4.03 Mars Contrast Sensitivity Test – with eSight Eyewear

Step 4.04 n/a

Steps 4.05 through 4.08 may be administered by a Research Assistant or a similarly suitable staff person at the clinic (e.g.: CLVT, OT, etc.).

Step 4.05 Minnesota Low Vision Reading Test (MN READ) – with eSight Eyewear

Step 4.06 Cohn-Kanade Facial Recognition Test – with eSight Eyewear

Step 4.07 Melbourne Low-Vision ADL Index Test (MLVAI) – with eSight Eyewear

Step 4.08 Introduction to eSkills Program³⁶: The subject will be introduced to eSight's "eSkills Program". This is a program which guides the individual through various activities, helping them to understand how to use the eSight controls to optimize their functional visual performance for various activities. While in clinic, Site staff will guide the Subject through session one of the eSkills program.

STEP 5: Take-Home Trial, Month One

The subject will now take the eSight Eyewear with them for a period of about four weeks, during which they will be encouraged to use eSight Eyewear for as many of their ADLs as possible.

³⁶ "eSkills Proficiency Program", Oct 30, 2014.

The subject will be trained that there are certain ADLs that are not permitted, such as driving or operating any sort of dangerous machinery (e.g.: power tools), and walking or performing other mobility tasks while using the device in “immersive” mode. Other ADLs will be prescribed, using eSight to purchase a coffee, using eSight to attend an event where distance viewing is required (e.g. church, theatre, wedding, conference, classroom, etc.), watching television, using a computer, social event, etc.

Site staff will contact the subject by telephone in accordance with the “eSkills Proficiency Program” as follows:

- **Day 9:** verify Session One steps are satisfactory, confirm commitment to proceed with session Two steps. This interaction can occur within a window of ± 2 days of Step 4.
- **Day 16:** Verify Session Two steps are satisfactory, confirm commitment to proceed with Session Three steps. This interaction can occur within a window of ± 2 days of Step 4.
- **Day 23:** Verify Session Three steps are satisfactory, confirm commitment to proceed with Session Four steps, and confirm one-month check in appointment. This interaction can occur within a window of ± 2 days of Step 4.

STEP 6: Subject Visit – Midterm Assessment

Step 6 must occur within 26-34 days of Step 4.

Step 6.01 The purpose of this visit is to assess the subject’s progress with the eSight device, and provide additional guidance and training as required. Part of this visit will be to assess the Subject’s self reported progress with the goals identified in Step 3.01 above, and to work with the Subject to improve their achievement of these goals through further device training. If necessary, the researcher may contact eSight to learn goal-specific ways that eSight Eyewear can be used. This visit may be conducted in-clinic.

Step 6.02 Also in this visit, the Subject will complete Session Four, the final part of the eSkills program.

STEP 7: Take-Home Trial, Months Two & Three

The subject will again take the eSight Eyewear home with them, this time for a period of two more months.

STEP 8: Telephone Survey

Within 86-94 days of Step 4 (total of three months), subjects will be contacted by the Third Party Surveyor to revisit the VFQ-48, and RAND SF-36 questionnaires³⁷.

³⁷ In the case of Johns Hopkins University Wilmer Eye Institute, research assistants from the institute will conduct Step 2. These research assistants will be dis-associated from the PI and other researchers who have face-to-face interaction with the subject.

Step 8.01 Final VA LV VFQ-48 Questionnaire

Step 8.02 Final eSight-8 Questionnaire

SETP 9: Final Assessment

Within 86-94 days of Step 4, subjects will be required to come to the clinic for a two hour assessment. Subjects will again repeat various supervised tasks and a VA LV VFQ-48 questionnaire to assess improvements in their functional visual performance compared to baseline.

Duration 2-3 hours

Step 9.01 through 9.03 may be administered by a Research Assistant or a similarly suitable staff person at the clinic (e.g.: CLVT, OT, etc.).

Step 9.01 Re-Assessment of Goals Established in Step 3.01: The Research Assistant or Site Administrator will reassess the Subject's satisfaction with their performance of the personal goals as reported in Step 3.01.

Step 9.02 Re-administration of RAND SF-36 Questionnaire

Tests 9.03 through 9.09 below are repeats of previous tests, intended to assess changes in visual function and functional visual performance over time using eSight Eyewear.

Steps 9.03 through 9.05 are administered by the eyecare physician (Optometrist or Ophthalmologist), or suitably trained and supervised clinical staff.

Step 9.03 Acuity Test – with and without eSight Eyewear (ETDRS or Snellen)

Step 9.04 Mars Contrast Sensitivity Test – with eSight Eyewear

Step 9.05 n/a

Steps 9.06 through 9.09 may be administered by a Research Assistant or a similarly suitable staff person at the clinic (e.g.: CLVT, OT, etc.).

Step 9.06 Minnesota Low Vision Reading Test (MN READ) – with eSight Eyewear

Step 9.07 Cohn-Kanade Facial Recognition Test – with eSight Eyewear

Step 9.08 Melbourne Low-Vision ADL Index Test (MLVAI)

Step 9.09 Final comments, opportunity for freeform feedback, relinquishment of the device.

5. Withdrawal from the Study

A subject may withdraw or be removed from the study at any time without prejudice for any of the following reasons:

- The subject wishes to withdraw
- Occurrence of any serious or adverse device-related effect that is considered by the investigator to represent an unacceptable risk to the subject's physical or mental well-being.
- Occurrence of any physical or mental illness that affects the subject's further participation.
- The subject fails to comply with the requirements of the study.

Time permitting, subjects that withdraw from the study will be replaced by other candidates. Every effort will be made to have withdrawn subjects complete the follow-up procedures (Part 4).

6. eSight Support for Clinical Sites

At each site, before the Study commences, eSight staff will visit the Study location to provide one full day of training with the eSight Eyewear device. This will include the following:

- Training on device demonstration and fitting (trial lenses, adjustment of forehead strap and headband, P.D. adjustment, etc.).
- Explanation of device controls (zoom, video modes, OS/OD displays on/off, saving images).
- Training on various ADLs (bioptic and immersive activities).
- Using direct video feed for television and computer use.
- Facial Recognition test training.
- Training on the eSkills program.
- Training on study management, data collection, and CRF administration.

In addition, eSight will visit site locations for clinical visit number two, during which fitting and training of the subject is provided. To control costs, sites will attempt to consolidate multiple subjects in a single day for this step in the process. This means that each study site will have two or three visits by eSight staff over the course of the study, assuming 8-12 subjects per study site.

7. Adverse Events

An adverse event (AE) is defined as any untoward medical occurrence, including deterioration of a pre-existing medical condition in a patient or clinical investigation subject which may or may

not have a causal relationship with the investigational product (i.e. eSight Eyewear). An AE can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of an investigational product, whether or not considered related to the investigational product.

The Principal Investigator/Sub-Investigator will assess the relationship of all adverse reactions to the investigational product, using the following scale:

Probable	A clinical event, including laboratory test abnormality, with a reasonable time sequence to device usage, unlikely to be attributed to concurrent disease or other drugs or chemicals, and which follows a clinically reasonable response on withdrawal.
Possible	A clinical event, including laboratory test abnormality, with a reasonable time sequence to device usage, but which could also be explained by concurrent disease or other drugs or chemicals. Information on device withdrawal may be lacking or unclear.
Unlikely	A clinical event, including laboratory test abnormality, with a temporal relationship to device usage which makes a causal relationship improbable, and which other drugs, chemicals or underlying disease provide plausible explanation.
Unrelated	This category is applicable to Aes which are judged to be clearly and incontrovertibly due to extraneous causes (diseases, environment, etc.) and do not meet the criteria for device relationship listed for the above mentioned conditions.

The incidence, severity and duration of all adverse events will be recorded according to the following scale:

Mild	Adverse event resulting in discomfort, but not sufficient to cause interference in normal daily activities.
Moderate	Adverse event resulting in discomfort that is sufficient to cause interference in daily activities.
Severe	Adverse event resulting in discomfort causing an inability to carry out normal daily activities.

All severe Aes, whether or not the event is deemed device-related, will be reported to the Sponsor by telephone within twenty-four hours of being aware of a severe AE, followed by a written report within five business days.

Practically speaking, the risk of adverse events with eSight Eyewear is extremely low. The most significant risk is injury resulting from disorientation or poor psycho-spatial hand-eye performance related to using the device to perform any task where injury may be possible. Some examples include: Falling or tripping while wearing the eSight device in an immersive mode while walking; risk of burns while cooking or drinking hot beverages; participating in specifically prohibited activities such as riding a bicycle or driving.

8. Stopping Criteria

Should any AE necessitate that a specific Subject must terminate their participation in the Study, the Site Administrator will, within their best judgement, inform his/her counterparts at the other Study Sites so that they are prepared for similar circumstances at their respective Study Sites.

9. Study Materials

If the study site does not already own any of the materials below, they will be provided by eSight at the beginning of the study:

- **Case Report Form (CRF):** This form is used to record and track the subject's progress through the course of the study. For each unique CRF, Subject identifying information appears on the first page of the form only. Subsequent pages show only a unique identification number provided by the Study Sponsor. CRFs returned to eSight for

analysis will be “de-identified”, referenced by this identification number only. The first page will be removed.

- **ETDRS Acuity Chart**
- **Mars Contrast Chart**
- **MN READ Test Charts**
- **Clinical Unit:** This unit is identical to the subject’s configured unit except that it incorporates provision for trial lenses so that it may be used on multiple subjects.
- **eSight Facial Recognition Test:** Materials required to conduct this test and record results³⁸.
- **MLVAI Materials**
- **Subject’s Unit:** If the subject is deemed a suitable candidate for an extended evaluation period, they will receive a unit with the user interface customized for them, along with their prescription lenses incorporated, if applicable.
- **Materials for In-Clinic ADL Testing:** Telephone book, kitchen ingredients, etc.

10. Analysis

Some of the data gathered through the course of this study is subjective, and will be used by eSight to prioritize ongoing improvements to the device.

The minimum objective data that will be reported is acuity, contrast, reading speed, without eSight Eyewear at the beginning of the trial, and with eSight Eyewear at its conclusion.

Further objective data is the comparison between the initial VFQ, and RAND SF-36 scores, and the change, if any, in score at the conclusion of the study.

Data analysis will be conducted using IBM SPSS Statistics version 22. The data will be pooled from all testing sites by the Study Manager. Before merging of the data, any systematic differences among testing sites will be assessed. Should such differences exist, they will be considered in subsequent analyses.

Repeated measures Analysis of Variance (ANOVA) and t-tests will be used to compare the effect of the eSight devices on all dependent variables that adhere to the assumptions of parametric data analysis (continuous variables, normal distribution etc.). Categorical variables or those who do not adhere to parametric assumptions will be compared using repeated-measures non-parametric techniques (e.g. Friedman Test). Qualitative data will be analyzed using qualitative description (Sandelowski, 2000).

³⁸ Requires 22” monitor with HDMI input. To be provided by eSight in the event that the study location does not have one available.

The eSight device contains an electronic logging capability, wherein daily on-time hours, and user commands (e.g.: zoom in/out, focus distance, increase/decrease contrast, etc.) are saved to an SD card. No images or video or other information that may personally identify the subject is recorded. These electronic logs may be used to validate user reported usage data³⁹.

Methodological Limitations: Given the multi-site nature of the study, it is possible that inter-site differences may occur, based on recruitment possibilities or slight differences in procedural or testing administration differences. The research teams will closely work together with eSight during the preparation phase, in order to minimize such differences. In addition, before data are pooled across sites, statistical comparison will be conducted in order to detection and possibly compensate statistically for such site differences.

As for the limited follow-up time of 3 months, the current study may be limited in its ability to show long-term benefits (or device abandonment). However, follow-up and continuation possibilities are currently being discussed, in order to eventually examine the long-term variables involved in the eSight device use.

11. Ethical and Regulatory Requirements

The following must be observed to comply with Health Canada and U.S. Food and Drug Administration regulations for conduct and monitoring of clinical investigations. These requirements also represent sound research practices.

11.1. Institutional Review

The Institutional Review Board (IRB) must review this Protocol, the Informed Consent Form, and the Case Report Form in accordance with Health Canada and U.S. Food and Drug Administration regulations.

A status report must be submitted to the IRB upon conclusion of the study. The lead investigator must maintain an accurate and complete record of all reports and documents submitted to and received from the IRB.

Each subject withdrawal from the study is to be reported to the IRB in writing within three (3) days.

³⁹ The use of electronic logging has been added to the Johns Hopkins University Wilmer Eye Institute ICF. Because no PHI is being collected, other IRBs have not required that this information be added.

11.2. Informed Consent

The informed consent document used for the study must have been approved by the IRB for each site involved in the study. The Principal Investigator or one of his/her associates must explain verbally and in writing the nature of the study and the actions of the device in a manner such that all subjects are aware of the potential benefits and risks. After subjects have been informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice, they must sign the approved consent form in the presence of a witness. The subject must be provided with a signed copy of the ICF.

12. General Information

12.1. Study Record Retention

All records of device disposition, CRFs, test results, signed consent forms, IRB correspondence and documentation, and other documents pertaining to the study shall be retained by the investigator for a minimum of five years after the experiment ends.

12.2. Protocol Changes

Changes in the protocol may be made only by written amendment agreed upon by the Sponsor and the Investigator. The Institutional Review Board must be advised and the amendments attached to the protocol. The amendment must be approved by the IRB prior to instituting the change.

12.3. Deviations From Protocol

If a deviation is deemed necessary for an individual subject, it must be recorded. The decision and the reason for any deviation must be documented in writing.

12.4. Team Member Expertise

Gislin Dagnelie, PhD, is an Associate Professor of Ophthalmology in the Johns Hopkins University School of Medicine and the associate director of the Lions Vision Research and Rehabilitation Center, a division of the Wilmer Eye Institute. His work over the last 20 years has been supported by grants from the National Institutes of Health, National Science Foundation, Foundation Fighting Blindness, and several companies developing ophthalmic devices and visual prosthetics.

Scott Gartner, O.D., has been practicing low vision rehabilitation for over thirty years, and has had clinical directorship at various renowned low vision rehabilitation institutions including the Bascom Palmer Eye Institute, and the Miami Lighthouse for the Blind. Dr. Gartner has held professorships at New England College of Optometry, Pennsylvania College of Optometry, Southern CA College of Optometry, and University of Miami, and has been involved in numerous device and treatment clinical trials.

Judith Goldstein, OD, is low vision optometrist and researcher. She is an assistant professor of ophthalmology and rehabilitative medicine at the Wilmer Eye Institute and chief of the Low Vision and Vision Rehabilitation Service. She directs clinical and teaching activities, provides low vision rehabilitative care to patients and participates in clinical research.

Kanishka Jayasundera, MD, is an Assistant Professor, Ophthalmology and Visual Sciences, a Fellow of the American College of Surgeons, Fellow of the Royal College of Surgeons of Canada, and Fellow of the Royal Australia and New Zealand College of Ophthalmologists. His expertise includes diseases of the retina and vitreous including retinal detachment, diabetic retinopathy, retinal vascular diseases, macular diseases, age-related macular degeneration, surgical management of complex retinal detachments, anti-angiogenic therapy and photodynamic therapy. Dr. Jayasundera's areas of research focus include genotype-phenotype correlations of inherited retinal diseases, predictors of disease progression, and outcome measures for therapeutic clinical trials.

Samuel Markowitz, MD, is an ophthalmologist who specializes in low vision and is one of Canada's most renowned specialists in low-vision rehabilitation. He is Director, Low Vision Rehabilitation, Department of Ophthalmology and Vision Sciences, University of Toronto, the Toronto Western Hospital, and the University Health Network, and a world renowned leader in the field of low vision research. Dr. Markowitz has presented his work at numerous professional meetings and in many peer reviewed scientific papers nationally and internationally. In 2006 he was awarded the Distinguished Service Award from the Low Vision Rehabilitation Section of the American Optometric Association. Also in 2006 he was awarded the Secretariat Award from the American Academy of Ophthalmology for service and leadership in development of scientific and continuous education programs in Low Vision Rehabilitation.

Michael Tolentino, MD, is a retinal surgeon, specializing in macular disease. He is currently the director and founder of the clinical research program at the Center for Retina and Macular Disease. The center is now one of the largest retinal clinical trial centers in the world with over 100 retinal clinical trials in the last 7 years. Dr. Tolentino helped develop several treatments for wet macular degeneration and diabetic retinopathy, including Avastin, Lucentis, Macugen and Verteporfin. He has more than 80 peer reviewed publications and 5 issued patents.

Walter Wittich, Ph.D, is an Assistant Professor at the School of Optometry at the University of Montreal, in Montreal, Quebec, who currently holds a Junior Career Award from the *Fonds de recherche du Québec – Santé (chercheur boursier junior 1)*, with specific focus on the rehabilitation of older adults with combined vision and hearing loss. He is a resident researcher

at both the MAB-Mackay Rehabilitation Centre and the Institut Nazareth et Louis-Braille. Coming from a background in age-related vision loss, he now conducts research in dual sensory impairment and acquired deaf-blindness. His research domains include basic sensory science, as well as medical, psychosocial, and rehabilitation approaches to sensory loss. He is a Fellow of the American Academy of Optometry and is Quebec’s first Certified Low Vision Therapist.

12.5. Record of Revisions to this Document

Revision	Description of Change
v1.0	Initial Release: November 9, 2015
V1.1	November 10, 2015 Minor edit to flowchart – removed reference to “Geriatric Depression Scale”
V1.2	December 14, 2015 Added footnote to Step #2 and Step #8, indicating that JHU will use in-house research assistants to conduct telephone interviews. Added in section 10, “Analysis”, that electronic logging of non patient-identifiable information will be conducted.
V1.3	January 20, 2015 Removed all Humphreys 10-2 and eSight 10-2 requirements from the protocol. Added an optional baseline C24-2 Microperimeter test at Step 3.
V1.4	January 21, 2015 Changed Microperimeter description to be more generic. C24-2 is no longer prescribed, and 10-2 test is preferred. Researcher will indicate which specific microperimeter test was conducted.

13. References

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Wittich, W., Phillips, N., Nasreddine, Z. S., & Chertkow, H. (2010). Sensitivity and Specificity of the Montreal Cognitive Assessment Modified for Individuals Who Are Visually Impaired. *Journal of Visual Impairment & Blindness*, 104(6), 360–368. ([LINK](#))