Study Title: Persistence of Glaucoma Patients With Web-Browser-Based Visual Field Test

Principal Investigator: Andrew Pouw, MD

NCT Number: NCT05690152

Unique Protocol ID: 202207403

IRB ID: 202207403

Date: 9/5/2025

Web Browser Visual Field Study

PI: Andrew Pouw
IRB ID #: 202207403

Project Details

I. Project Introduction

I.1 ***Project to be reviewed by:***
IRB-01

I.2 ***Project Title:***
Visual Field Telemedicine in Glaucoma Patients using a Web Browser-Based Test Strategy

I.3 ***Short Title (optional):***
Web Browser Visual Field Study

I.4 ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.***

- ***DO NOT include information on studies not proposed in this application.***
- ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
- ***DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.***

The purpose of this prospective study is to determine the reliability of and patient compliance with a testing strategy with a novel home, web-based visual field test, EyeSimplify (M&S Technologies, Niles, IL), for purposes of surveilling glaucomatous progression. In this study, EyeSimplify will be compared to the current accepted gold standard Standard Automated Perimeter, the Humphrey Visual Field Analyzer (Carl Zeiss Meditec Inc., Dublin, CA).

The proposed study will be conducted at the University of Iowa Hospitals and Clinics and via telemedicine encounters. We estimate 50 subjects will be recruited to participate in the study. Data collected will not include patient identifiers.

Research involves retrospective collection of data, documents, and records, as well as prospective collection of visual field testing performance. The source of data will be retrospective review of computerized or written medical record and testing conducted in clinic beginning upon IRB approval. Patients with suspected, mild, moderate, or severe glaucoma will be included. Clinical data including age, gender, ethnicity, visual acuity, intraocular pressure, severity of disease, Humphry Visual Field performance, EyeSimplify Visual Field performance, and satisfaction survey will be recorded.

Following study recruitment, subjects will be asked to take EyeSimplify visual field tests at home biweekly for six months. They will have no additional responsibilities between tests. Subjects will access the EyeSimplify web browser on their personal electronic devices using a link and login credentials provided to them by a research assistant. Upon logging into the EyeSimplify web browser, subjects will click the "Start Test" button found along the left side of the window and follow the prompts presented on screen to calibrate their screen. Screen calibration involves holding a driver's license/credit card/ID to the screen to ensure the test window is the appropriate dimensions. Following screen calibration, subjects will follow the test prompts presented on screen to complete their visual field test. Test results are automatically sent to the research assistant who issued the exam, so subjects may exit the browser after each test. Upon study completion, subjects will be asked to fill out a brief satisfaction survey.

M&S Technologies is the developer of the EyeSimplify web-based visual field test. Dr. Andrew Pouw, Mr. Wisam Najdawi, and Ms. Helen Servellon have no financial or intellectual relationship with M&S Technologies, aside from the current study and an additional study under IRB review investigating the Pico Virtual Reality Headset visual field test.

As the developers of the web-based visual field test, M&S Technologies maintains a secure, encrypted, HIPAA-compliant database of EyeSimplify users. This database includes patient profiles containing unique patient IDs (de-identified), birth year, and visual field testing results. Outside of this testing information, M&S Technologies does not have access to any additional patient information.

I.5 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***
Aim 1: Determine test reliability of the EyeSimplify (M&S Technologies, Niles, IL) home, web-based visual field test in glaucoma patients.
Aim 2: Determine the concordance of EyeSimplify to the Humphrey Visual Field Analyzer (Carl Zeiss Meditec Inc., Dublin, CA) in identifying visual field loss progression.
Aim 3: Determine patient compliance with and tolerance of biweekly EyeSimplify testing for a 6 month period, assessed by test recordkeeping and a patient experience survey.

Primary Hypothesis: The EyeSimplify visual field test will produce reliable visual field testing data.
Secondary Hypothesis: The EyeSimplify visual field test will be non-inferior to the Humphrey Visual Field Analyzer in identifying glaucomatous progression trends.

I.6 ***Background and significance and/or Preliminary studies related to this project.***
(do not indicate "see protocol")
Glaucoma is the leading cause of irreversible blindness worldwide (1-2). Standard Automated Perimetry is the current accepted standard for diagnosis and monitoring of glaucomatous visual field loss (3), and the Humphrey Visual Field Analyzer (HFA; Carl Zeiss Meditec Inc., Dublin, CA) is the automated perimeter that is most frequently used due to it currently having the largest market share. The HFA is a useful clinical tool; however, it is a large, expensive device. Testing takes approximately seven minutes per eye when using the Swedish Interactive Threshold Algorithm (SITA) Standard testing algorithm, and testing is typically only done at 6-12 month intervals. Recently, there has been interest in the development of alternative methods to monitor visual field progression outside of the clinic setting (4). EyeSimplify (M&S Technologies, Niles, IL) is a web-based visual field test that aims to increase the frequency at which patients can test their visual fields, improve accessibility to visual field testing, and potentially identify visual field loss progression more quickly.

I.7 ***Literature cited / references (if attaching a grant or protocol enter N/A).***
1. Quigley HA. Number of people with glaucoma worldwide. Br J Ophthalmol. May 1996;80(5):389-93. doi:10.1136/bjo.80.5.389
2. Quigley HA, Broman AT. The number of people with glaucoma worldwide in 2010 and 2020. Br J Ophthalmol. Mar 2006;90(3):262-7.

doi:10.1136/bjo.2005.081224
3. Beck RW, Bergstrom TJ, Lichter PR. A clinical comparison of visual field testing with a new automated perimeter, the Humphrey Field Analyzer, and the Goldmann perimeter. Ophthalmology. Jan 1985;92(1):77-82. doi:10.1016/s0161-6420(85)34065-4
4. Prager AJ, Kang JM, Tanna AP. Advances in perimetry for glaucoma. Curr Opin Ophthalmol. Mar 1 2021;32(2):92-97. doi:10.1097/ICU.0000000000000735

II. Research Team

II.1 ***Principal Investigator***

Name	E-mail	College
Andrew Pouw	andrew-pouw@uiowa.edu	Carver College of Medicine

II.2 ***Team Members***

UI Team Members

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Andrew Pouw, MD	andrew-pouw@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
Helen Acevedo, AA, BA	helen-gomez@uiowa.edu	Carver College of Medicine	No	No	No		Yes	No
Wisam Najdawi, BA	wisam-najdawi@uiowa.edu	Carver College of Medicine	No	Yes	No		No	No
Aditya Somisetty, BA	aditya-somisetty@uiowa.edu	Carver College of Medicine	No	No	No		No	No

Non-UI Team Members

Name	Institution Location	FWA	Role	DHHS Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Email
Nothing found to display.									

II.3 ***The Principal Investigator of this study is:***

Faculty

II.5 ***Select research team member who is the primary contact for study participants.***

Wisam Najdawi

II.6 ***Identify the key personnel. The system will automatically designate the PI and all faculty members on the project as "key personnel." For information about other team members who should be designated as "key personnel" please click on the help information.***

Name	Is Key Personnel
Andrew Pouw, MD	Yes
Helen Acevedo, AA, BA	No
Wisam Najdawi, BA	Yes
Aditya Somisetty, BA	No

III. Funding/Other Support

III.1 ***Select all sources of funding and/or support that will be applied to this research (select all that apply):***

- ☐ The funding award (contract/grant) has been routed through the Division of Sponsored Programs (DSP)
- ☐ University of Iowa Center for Advancement (UICA)
- ☐ Howard Hughes Medical Institute (private foundation)
- ☐ Fellowship Award
- ☐ In Kind Donations
- ☐ PI Discretionary
- ☑ Departmental
- ☐ UI Institutional Grant/Award
- ☐ PI Personal Funds (students only)
- ☐ No Funding (students only)

III.2 ***Funding Sources***

Source Entered as Text	DSP Link	Type	Source	Project Title	Name of PI on Grant	Status
Source is entered as text	no	Private Foundation/Association	American Glaucoma Society	A novel perimetry platform	Andrew Pouw	Awarded/Approved

Source Entered as Text DSP Link	Type	Source	Project Title Name of PI on Grant	Status
			with virtual reality and tablet testing	

* new source name

III.3 ***Does any member of the research team have a financial conflict of interest related to this project according to the Conflict of Interest in Research policy? If yes, please indicate which members below.***

Name	Has Conflict of Interest
Andrew Pouw, MD	No
Helen Acevedo, AA, BA	No
Wisam Najdawi, BA	No
Aditya Somisetty, BA	No

IV. Project Type

IV.1 ***Do you want the IRB to give this project***
Regular (expedited or full board) review

IV.2 ***Enter the date you will be ready to begin screening subjects/collecting data for this project. (If you do not have a specified date, add "upon IRB approval")***
Upon IRB approval

IV.3 ***Are you requesting a waiver of informed consent/authorization (subjects will not be given any oral or written information about the study)?***
No

V. Other Committee Review

V.1 ***Does this project involve any substance ingested, injected, or applied to the body?***

- ***Do not answer yes, if the involvement includes a device, wire, or instrument***

No

V.2 ***Are any contrast agents used for any purpose in this study?***
No

V.9 ***Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?***
No

V.14 ***Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?***
No

V.20 ***Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?***
No

V.21 ***Will any portion of this project be conducted in the CRU, or does it use any CRU resources?***
No

V.22 ***Will this project use:***

- ***any resource/patients of the Holden Comprehensive Cancer Center***
- ***involve treatment, detection, supportive care, or prevention of cancer***

No

V.25.a ***Will the study involve any of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?***

- ***Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or***
- ***Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)***

Yes

V.25.b ***Will there be any procedures or services that may happen as part of a subject's regular medical care and as part of the study?***
Yes

V.25.c ***Will any study equipment or devices be supplied by a study sponsor?***
No

V.25.e ***Is there or will there be an internal budget for this study?***
No

V.25.f ***Is there or will there be an external budget for this study?***

No

V.26 ***The study involves Department of Nursing Services and Patient Care nursing, nursing resources or evaluates nursing practices at UI Health Care.***
No

V.27 ***Will the study involve the use of the I-CTMS (OnCore) for clinical trial data management? Select yes if any or all of the following apply:***

- ***Any study required to register subjects in EPIC are encouraged to use the I-CTMS***
- ***Best practice is to use the I-CTMS for any new study that involves subject tracking or sponsor invoicing***

Note: This question is for non-oncology studies only. For oncology studies use existing HCCC OnCore processes by selecting V.22
No

VI. Subjects

VI.1 ***How many adult subjects do you expect to consent or enroll for this project?***
50

VI.2 ***What is the age of the youngest adult subject?***
18.0

VI.3 ***What is the age of the oldest adult subject?***
100.0

VI.4 ***What is the percentage of adult male subjects?***
50

VI.5 ***What is the percentage of adult female subjects?***
50

VI.6 ***How many minor subjects do you expect to consent or enroll for this project?***
0

VI.13 ***Describe EACH of your subject populations***

- ***Include description of any control group(s)***
- ***Specify the Inclusion/Exclusion criteria for EACH group***

Inclusion criteria: Patients older than 18 years of age with suspected, mild, moderate, or severe glaucoma

Exclusion criteria: Non-English speakers, patients with systemic or ocular disease affecting central vision, neurocognitive or psychiatric patients that are unable to perform testing, astigmatism >+2.00/-2.00 diopters

VI.14 ***Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)***
450

VI.15 ***Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.***
Patients at the University of Iowa Hospitals and Clinics' Glaucoma clinic will be approached at the time of their scheduled appointments to determine if they are interested in participating in this research study.

VI.16 ***Do you plan to recruit/enroll non-English speaking people?***
No

VI.18 ***Do you propose to enroll any of the following in this study as subjects?***

- ***Employee of the PI or employee of a research team member***
- ***Individual supervised by PI or supervised by member of research team***
- ***Individual subordinate to the PI or subordinate to any member of the research team***
- ***Student or trainee under the direction of the PI or under the direction of a member of the research team***

No

VI.20 ***Will subjects provide any information about their relatives?***
No

VI.23 ***Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?***
No

VI.26 ***Is this project about pregnant women?***
No

VI.27 ***Will this project involve fetuses?***
No

VI.28 ***Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?***
No

VI.32 ***Does this project involve subjects whose capacity to consent may change over the course of the study?***
No

VI.37 ***Does this project involve prisoners as subjects?***
No

VII.A. Project Description (A)

VII.A.1 ***Where will project procedures take place (check all that apply)?***
- UIHC - Glaucoma clinic
- U.S. off-campus - Patients' homes via telemedicine

VII.A.2 ***Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?***
No

VII.B. Project Description (B)

VII.B.1. ***Does this project involve any of the following (Check all that apply):***

- ☑ **Interventional** – Includes **Clinical (or Treatment) trial**, **Physiology intervention/study**, **Behavioral intervention/study**, **Diagnostic Trial**.
  - ☑ **Clinical (or Treatment) trial** – A prospective biomedical or behavioral research study of new treatments, new drug or combinations of drugs, new devices, or new approaches to surgery or radiation therapy. (NIH and ClinicalTrials.gov & FDA) The University of Iowa requires a freestanding protocol.
  - ☐ **Physiology intervention/study** – A pharmacologic or measurement study aimed at understanding basic mechanisms of disease and/or of normal human physiology, often without any therapeutic intent (though a clinical trial could include such components, often labeled as "translational" or "basic science" aims.) Measurements in such studies could include, but are not limited to, a blood draw, EKG, EEG, MRI, auditory or sensory testing, checking vital signs, DEXA scans, eye tracking, specimen collection, exercise, fasting, special diets, etc.
  - ☐ **Behavioral intervention/study** – May be used to refer to studies of individual or group behavior. This option does not include drugs, biologics, or devices but could include psychotherapy, lifestyle counseling, behavior modification, etc.
  - ☐ **Diagnostic trial** – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition (ClinicalTrials.gov & FDA)
- ☐ **Observational**
- ☐ **Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track (ClinicalTrials.gov & FDA).
- ☐ **Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project.(UI Guide)
- ☑ **Repository** – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from OHRP)
- ☐ **Other**

VII.B.1.a ***Does this project involve any of the following (Check all that apply):***

- ☐ **Phase I trials** – include initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients (ClinicalTrials.gov & FDA)
- ☐ **Phase II trials** – include controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks(ClinicalTrials.gov & FDA)
- ☐ **Phase III trials** – include expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling(ClinicalTrials.gov & FDA)
- ☐ **Phase IV trials** – studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use(ClinicalTrials.gov & FDA)

VII.B.11 ***Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)***

No

VII.B.2 ***Does this project involve a drug washout (asking subject to stop taking any drugs s/he is currently taking)?***
No

VII.B.6 ***Will any subjects receive a placebo in this study when, if they were not participating, they could be receiving an FDA-approved treatment for their condition?***
No

VII.B.18 ***Does this project involve the evaluation, or testing, of the safety and/or efficacy of a medical device?***
Yes

VII.B.19 ***Describe in detail procedures in place for maintaining device shipment and receipt records:***
EyeSimplify is a web browser-based visual field test and, therefore, will not require shipment or receipt records.

VII.B.20 ***Who will be responsible for maintaining these shipment and receipt records?***
EyeSimplify is a web browser-based visual field test and, therefore, will not require shipment or receipt records.

VII.B.21 ***Describe in detail procedures in place for tracking use and disposition of devices described in this study:***
The EyeSimplify web browser automatically tracks when subjects complete a visual field test and no additional physical record will be kept to minimize risk of loss of confidentiality.

VII.B.22 ***Who will be responsible for maintaining these use and disposition tracking records?***
The EyeSimplify web browser automatically tracks when subjects complete a visual field test and no additional physical record will be kept to minimize risk of loss of confidentiality. The PI and key research personnel will have access to the EyeSimplify web platform; however, M&S Technologies maintains this secure, encrypted, HIPAA-compliant database.

VII.B.23 ***Describe in detail procedures in place to limit access to authorized study personnel for the storage, control, and dispensing of the investigational devices. (For example, investigational devices are kept in a locked area away from approved devices or have a keyed interlock, and only study personnel authorized to dispense the device have the keys)***
EyeSimplify is a web-based visual field testing platform. Access requires subject-specific login credentials (created by a research assistant upon study recruitment) and to be granted tests (subjects will be unable to take an EyeSimplify visual field test if they do not have a test sent to them by a research team member, even if they have login credentials).

VII.B.24 ***Is the device FDA-approved for the way it will be used in this study?***
No

VII.B.25 ***Is there an IDE (Investigational Device Exemption) for this device in this research project?***
No

VII.B.29 ***Indicate the appropriate FDA status you and/or the sponsor are requesting for the use of this device in this study.***
Non-Significant Risk (NSR) device/software

VII.B.31 ***Provide a detailed rationale for why this device meets the FDA definition of a Non-Significant Risk Device (NSR)***
Per M&S, the EyeSimplify web browser-based visual field is "Class I" and doesn't need FDA Approval (highest-risk like neurostimulators) or FDA Clearance (medium-risk devices / 510(k)). They include it in their device listings on the FDA Establishment Registration (screen prints attached to additional documents section).

Under 21 CFR 812.3(m), a "serious risk" device means an investigational device that:
1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2. Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
3. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

The EyeSimplify web browser-based visual field test does not meet any of these criteria, qualifying it as a nonsignificant risk medical device.

VII.B.32 ***Provide a summary of prior investigations with this device.***
There are no prior research studies investigating the EyeSimplify visual field test.

VII.B.33 ***Have there been any prior IRB reviews (at UI or elsewhere) and/or determinations made with regard to this device?***
No

VII.B.35 ***Has the FDA made an assessment of risk with regard to this device?***
No

VII.B.36 ***Has this device/software been approved by the FDA for another indication or in another form from its use in this project?***
No

VII.C. Project Description (C)

VII.C.1 ***Does this project involve any research on genes or genetic testing/research?***
No

VII.D. Project Description (D)

VII.D.1 ***Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):***

- Other - Patients at the University of Iowa Hospitals and Clinics' Glaucoma clinic will be approached at the time of their scheduled appointments to determine if they are interested in participating in this research study.

VII.D.1.a ***Will any of the materials/methods below be used by researchers (or their colleagues) to recruit subjects into this study?***

- ***the potential subject is a patient OR***
- ***use of any information considered to be Protected Health Information (PHI) OR***
- ***review of patient/clinic records be used in recruiting subjects***

Yes

VII.D.1.b ***Describe source of records***

Patients at the University of Iowa Hospitals and Clinics' Glaucoma clinic will be approached at the time of their regularly scheduled appointments to participate in this research study.

VII.D.1.c ***Select all Private Identifiable Information (PII) or Protected Health Information (PHI) accessed and used for this study (select all that apply)***

Identify types of PHI accessed

Type of PHI	Data source
Name	☑
Street address	☐
City	☐
County	☐
Precinct	☐
Zip code	☐
Geocodes smaller than state	☐
Date of birth, ages > 89 years of age	☑
Diagnosis dates	☑
Procedure dates	☑
Admission or discharge dates	☐
Telephone numbers	☐
Fax numbers	☐
E-mail addresses	☐
Social Security number	☐
Medical record number	☑
Health plan beneficiary or account numbers	☐
Certificate/license numbers	☐
Vehicle identifiers and serial numbers or license numbers	☐
Device identifiers or serial numbers	☐
Web URLs	☐
Internet Protocol (IP) address numbers	☐
Biometric identifiers including finger/voice prints	☐
Full face photographic images or any comparable images	☐
None of the above	☐

VII.D.2.a ***List ALL of the variables, including any identifiers not previously entered or links to identifiers you plan to obtain/use for purposes of this study. (The information accessed should be the minimum data variables necessary for performing the desired analysis.)***

Data elements to be collected will include name, MRN, age, and glaucoma diagnosis/severity.

VII.D.3 ***Describe why you could not practicably recruit subjects without access to and use of the information described above***

Without the above, there would be many patients who would not meet inclusion or exclusion criteria after initial assessment. Using the above data will allow for a better patient experience while enrolling in this study, as well as better specificity in identifying the population we intend to recruit.

VII.D.4 ***Describe why you could not practicably obtain authorization from potential subjects to review their patient or clinic records for recruitment purposes.***

This study intends to review patients from a physician's practice panel to identify recruits. To request written authorization from all patients prior to identification for study inclusion or exclusion would require contacting all of the physician's patients prior to identification, for authorization to review records that the physician is already reviewing for their clinical care. This would require an inordinate amount of time, administrative labor and solicitation of thousands of patients.

VII.D.5 ***Describe plans to protect the identifiers from improper use or disclosure***

Only a “de-identified” aggregate data record will be kept in a central electronic database. The link between the subject, the medical record number, and the patient’s project identifier will be maintained exclusively by the principal investigator and designated key research team members. The data record will be kept in an encrypted UIHC network drive specifically for protected research data, while the linking file will be kept in a similarly encrypted UIHC network drive in a separate file location. The files will also be password-protected.

Additionally, M&S maintains patient demographic and testing data in a secure, HIPAA-compliant, encrypted database. Patient names are encrypted when they are stored in the database. M&S only shares the information it collects with M&S-affiliated consultants and service providers, healthcare professionals using the product, and for law enforcement or judicial proceedings as permitted by law. Aggregate de-identified data may be used by M&S to improve their web-based testing software.

VII.D.6 ***Describe plans to destroy identifiers at the earliest opportunity consistent with conduct of the research***

Subjects will be identified in order to collect data for protocol-specific research, but the subjects' data will be de-identified immediately after the completion of data collection per HIPAA regulations. The identifiers will be electronically stored (as per the above-described encrypted, password-protected manner) and will be destroyed as soon as identifiers are no longer needed for protocol-specific research.

VII.D.7 ***Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule***
Yes

VII.D.8 ***Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?***
Yes

VII.D.9 ***Describe the physical location where the consent process will take place:***
The University of Iowa Hospitals and Clinics' Glaucoma clinic

VII.D.10 ***Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?***
No

VII.D.12 ***Who will be involved in the consent process (including review of consent document, answering subjects' questions)?***

Name	Consent Process Involvement
Andrew Pouw, MD	Yes
Helen Acevedo, AA, BA	Yes
Wisam Najdawi, BA	No
Aditya Somisetty, BA	No

VII.D.15 ***Check all materials that will be used to obtain/document informed consent:***
- Consent Document

VII.D.16 ***Are you requesting a waiver of documentation of consent (either no subject signature or no written document)?***
No

VII.D.19 ***Before the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?***
No

VII.D.25 ***After the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?***
No

VII.D.27 ***Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.***
Patients will have as much time as they need to consider participation in this study - there will be no time constraint. They will be free to discuss the study with family/friends before consenting to participate.

VII.D.28 ***How long after the subject agrees to participate do study procedures begin?***
Testing will begin within one week of the subject's agreeing to participate in the study.

VII.D.29 ***Provide a description of the enrollment and consent process for adult subjects***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use 3rd person active voice "The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc..."***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

The Principal Investigator will identify subjects that meet inclusion criteria based on chart review prior to potential subjects' upcoming glaucoma clinic appointments. Potential subjects will be approached at the time of their scheduled appointment to participate in the study. The Principal Investigator and/or research assistant will describe the purpose of the study, study procedure, and risks/benefits of participation prior to obtaining informed consent from the subject. Additionally, the Principal Investigator and/or research assistant will reassure potential subjects that their participation in the study is completely voluntary, they are free to withdraw from the study at any point without consequences, and their decision to participate/not participate will not affect their regular care.

VII.D.37 ***Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?***

Examples:

- ***Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.***
- ***Participants will be provided with false information regarding the particular behaviors of interest in the research.***
- ***Procedures include a confederate pretending to be another participant in the study.***
- ***Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.***
- ***Study is designed to introduce a new procedure (or task) that participants are not initially told about.***
- ***If yes, a waiver of informed consent must be requested under question IV.3.***

No

VII.E. Project Description (E)

VII.E.1 ***Will subjects be randomized?***
No

VII.E.3 ***Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?***
Yes

VII.E.4 ***List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)***
EyeSimplify Visual Field Satisfaction Survey

VII.E.5 ***Does this project involve creating any audiotapes, videotapes, or photographs?***
No

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

Potential subjects will be approached at the time of their regularly scheduled appointment to participate in this research study. The research assistant will answer any questions potential subjects may have regarding the purpose, procedure, and risks of the study. If they agree to participate, subjects will sign an informed consent.

In addition to routinely scheduled clinical examination, including visual field testing (VF) with the Humphrey Field Analyzer (HFA), subjects will be asked to complete biweekly VF for six months using EyeSimplify, a novel, web-based VF, at home. Subjects will be instructed to complete the EyeSimplify VF in a quiet, dark room free of distractions. The research assistant will be available via email or telephone to troubleshoot any issues that may arise.

The EyeSimplify uses a 24-2 examination protocol with a Neighborhood-Zippy Estimation by Sequential Testing (ZEST) testing algorithm. Background brightness will be set to 15.8 ASB. The test will use a scaled white stimulus. Subjects will self-administer the EyeSimplify VF at home. The EyeSimplify VF will be deemed unreliable if FP >15%. The HFA uses a 24-2 examination protocol with a SITA standard testing algorithm. A clinical technician will administer the HFA VF at the University of Iowa Hospitals and Clinics' Glaucoma clinic. The HFA VF will be deemed unreliable if FP >15%. At the conclusion of the study, subjects will complete a satisfaction survey regarding testing using the EyeSimplify VF.

VII.E.7 ***Will you attempt to recontact subjects who are lost to follow-up?***
Yes

VII.E.8 ***Describe - any procedures need to be included in the consent:***
If a subject fails to complete a scheduled home visual field test, the PI or research assistant will reach out to the patient via email and/or telephone to determine the cause of the missed test. If the patient can be contacted and wishes to continue participating in the study, the PI or research assistant will prompt the subject to complete the exam. If a patient misses a second scheduled test, the patient will be considered lost to follow-up and will not be contacted again.

VII.E.9 ***Will subjects be provided any compensation for participating in this study?***
No

VIII. Risks

VIII.1 ***What are the risks to subjects including***
- emotional or psychological
- financial
- legal or social
- physical?
Loss of time and confidentiality

VIII.2 ***What have you done to minimize the risks?***

- ***If applicable to this study ALSO include:***
  - ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
  - ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

Patient privacy will be protected by separating patient identifiers from the data and storing the data on a password-protected computer in a locked office within the Ophthalmology Department. To prevent a loss of confidentiality from occurring, all data will be located on a UIHC encrypted, password-protected Department of Ophthalmology server. Only designated research team members and PI will have access to the drive. Any paper documents will be kept in a locked file cabinet in the principal investigator's office.

All data collected by M&S Technologies will be stored in a secure, encrypted, HIPAA-compliant database. De-identified subject data is ultimately aggregated for quality improvement purposes by M&S Technologies.

The study utilizes data generated as a consequence of routine clinical practice, as well as additional home, web-based visual field tests. The study poses no therapeutic questions and no interventions; no treatment is directed by the study. Therefore, the study poses no substantive risk to the patient other than loss of time and confidentiality. It does not impose any significant burden on the patient.

VIII.3 ***Does this study have a plan to have an individual or committee review combined data from all subjects on a periodic basis (such as summary or aggregate safety and/or efficacy data)?***
No

IX. Benefits

IX.1 ***What are the direct benefits to the subject (do not include compensation or hypothesized results)?***
None

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***
To date, there is no universally accepted method for monitoring glaucoma at home. Society may benefit from this study by validation of a novel home, web-based visual field test that may decrease cost and discomfort of visual field testing and increase its accessibility.

X. Privacy & Confidentiality

X.1 ***What are you doing to protect the privacy interests of the subjects?***
All data collected into the research database will only be accessed by the principal investigator (PI) and/or designated key research team members. Patient identifiers and/or data (i.e., name, medical record number) will be collected but will be replaced by study numbers in the analytical file. Subjects' data will be de-identified immediately after completion of the data collection per HIPAA regulations. Subject identifiers will not be viewed by non-study members and will not be published. Subject number identifiers will be used rather than patient names. No other identifiable information will be recorded. All efforts will be made to protect subject's rights to privacy by collecting only the minimum information necessary to meet the aims of this study. Information collected is similar to that which the clinician would encounter for the subject's clinical care.

Subject demographic and testing data will be collected and stored by M&S Technologies in a secure, encrypted, HIPAA-compliant database. Subject identifiers are encrypted upon storage. Subject data is only shared with M&S-affiliated consultants and service providers, healthcare providers using EyeSimplify, and for law enforcement or judicial proceedings as permitted by law. De-identified subject data is ultimately aggregated for quality improvement by M&S Technologies.

X.2 ***Are you collecting the Social Security Number of any subjects for any purpose?***
No

X.4 ***How will information/data be collected and stored for this study (check all that apply):***

- Electronic records (computer files, electronic databases, etc.) - All electronic files will be kept as files on an encrypted, password-protected UIHC Department of Ophthalmology network server. There will be no identifiers or link available on any transferred data; therefore, there will be no way to compromise patients' privacy or confidentiality.
  - Name - Dustin McGranahan
  - Title - Senior IT Support Consultant
  - University Job Classification - Faculty/Staff
- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Informed consent documents will be transported directly from the UIHC Glaucoma clinic to a locked file cabinet in the PI's office within the Department of Ophthalmology and Visual Sciences immediately following the study recruitment clinical encounter by the PI or research assistant. These documents will remain in this locked cabinet for the duration of the study.

X.5 ***Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?***
No

X.6 ***Describe***
M&S Technologies, the developers of the EyeSimplify web-based visual field test, maintain a secure, encrypted, HIPAA-compliant database of patient testing information. This database includes study ID (de-identified), birth year, and experimental visual field testing data. M&S Technologies does not have access to any additional patient information.

X.7 ***Does your study meet the NIH criteria for a Certificate of Confidentiality or will you be applying for Certificate of Confidentiality?***
No

XI. Data Analysis

XI.1 ***Describe the analysis methods you will use, including, if applicable, the variables you will analyze***
Variables: Clinical data including age, gender, ethnicity, Humphry Visual Field performance, EyeSimplify Visual Field performance, and satisfaction survey will be collected and analyzed.

Data analysis: Humphrey Visual Field Guided Progression Analysis (GPA) and EyeSimplify Visual Field mean deviation linear trending will be compared using Bland-Altman analysis.

XI.2 ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.***
A similar study investigating home visual field testing using the Melbourne Rapid Fields iPad application (Glance Optical Pty., Ltd., Melbourne, Australia) recruited 47 subject, of which 43% (n = 20) were analyzed (Prea SM, Vingrys AJ, Kong GYX. Test Reliability and Compliance to a Twelve-Month Visual Field Telemedicine Study in Glaucoma Patients. J Clin Med. Jul 25 2022;11(15)doi:10.3390/jcm11154317).

XII. Future Research

XII.1 ***Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?***
No

XII.2 ***Do you wish to keep any information about subjects involved with this research project so that other researchers may contact them for future research?***
No

XII.4 ***Does this project involve storing any data, tissues or specimens for future research?***
Yes – contribution(s) for future use is mandatory for participation in the study

THE UNIVERSITY OF IOWA

Human Subjects Office/
Institutional Review Board (IRB)
105 Hardin Library for the Health Sciences
600 Newton Road
Iowa City, Iowa 52242-1098
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

IRB ID #: 202207403

To: Andrew Pouw

From: IRB-01 Univ of Iowa, DHHS Registration # IRB00000099, DHHS Federalwide Assurance # FWA00003007

Re: Visual Field Telemedicine in Glaucoma Patients using a Web Browser-Based Test Strategy

Protocol Number:

Closure Date: 09/05/25

Source of Support: American Glaucoma Society

Investigational New Drug/Biologic Name:
Investigational New Drug/Biologic Number:
Name of Sponsor who holds IND:

Investigational Device Name:
Investigational Device Number:
Sponsor who holds IDE:

The following documents have been submitted with the closure notification:
No new attachments.

This closure is acknowledged and has been electronically filed. IRB approval is no longer valid for the above-named project.

Study Closure: Closing a study with the IRB is a permanent action and cannot be undone. The PI is required to notify all research team members and participating research sites (as applicable) of the closure. Closing a project means:

- **The research is permanently closed to accrual/enrollment**
- **All subjects have completed all research related activities**
- **Collection and use of private identifiable information is complete**
- **Analysis of private identifiable information is complete**

The following applies to this research even after study closure:

Audits: Your research records may be audited at any time during or after the implementation of your project. Audits may also occur after the study has been formally closed with the IRB.

ClinicalTrials.gov reporting: If Clinicaltrials.gov results reporting is required based on FDA regulations (e.g.,

Applicable Clinical Trial) or federal funding (e.g., NIH clinical trials), then the results must have been submitted on the ClinicalTrials.gov website prior to the study's closure.

University of Iowa Research Data: In accordance with the University of Iowa's copyright policy (Operations Manual Section V(30.4)), research data generated as part of a University of Iowa research study is owned by the University. All research data policies remain in effect even after the research has ended. For additional information regarding the research data policy and any requirements for data leaving the University of Iowa, visit the Division of Sponsored Programs website under Data Use Agreements.

Record-Keeping/Retention Requirements: Federal and University policies require that all research records be maintained fora period of three (3) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application. For research that involves Protected Health Information(PHI) under HIPAA, the research records must be kept for a period of six (6) years following the close of the research project.

Special Note: The above-named project details can be accessed via HawkIRB by updating the project status filter from "open" to "any."

Additional Information: Complete information regarding research involving human subjects at The University of Iowa is available in the "Investigator's Guide to Human Subjects Research." Research investigators are expected to comply with these policies and procedures, and to be familiar with the University's Federalwide Assurance, the Belmont Report, 45CFR46, 21CFR50/52, and other applicable regulations prior to conducting the research. These documents and IRB application and related forms are available on the Human Subjects Office website or are available by calling (319) 335-6564.