Title: Comparison of a Novel Head-Mounted Perimeter versus the Humphrey Field Analyzer

Principal Investigator: Andrew Pouw, MD

NCT #: NCT05674890

Date: July 10, 2024

VR Headset vs HVF

PI: Andrew Pouw
IRB ID #: 202206347

Project Details

I. Project Introduction

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

I.2 ***Project Title:***
Comparison of a Novel Head-Mounted Perimeter versus the Humphrey Field Analyzer

I.3 ***Short Title (optional):***
VR Headset vs HVF

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 compare the novel Smart System VR Headset (M&S Technologies, Niles, IL) to the current accepted gold standard Standard Automated Perimeter, the Humphrey Field Analyzer (Carl Zeiss Meditec Inc., Dublin, CA). Use of the Humphrey Field Analyzer is the standard of care and would be completed regardless of study participation if clinically indicated.

The proposed study will be conducted at the University of Iowa Hospitals and Clinics. 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, Pico VR Visual Field performance, and satisfaction survey will be recorded.

Subjects will undergo regular clinical examination, including measurement of visual acuity, intraocular pressure, slit lamp examination by their physician, and visual field testing as indicated. When it comes time to perform visual field testing, subjects will be randomized to complete either the Pico VR Headset visual field test first followed by the Humphrey Field Analyzer visual field test, or vice versa. Visual field tests will be separated by a rest period of one hour to minimize testing fatigue.

The Smart System VR Headset is fit to subjects' head using an adjustable head strap. Once the headset it fit to the subject, a research assistant will send a test to the headset from a bluetooth-connected electronic device using M&S Technologies' secured application platform. Subjects will follow prompts from the Smart System VR Headset to complete their visual field test, responding using a handheld "trigger" device. Testing is expected to take approximately 5-10 minutes, depending on the subjects' severity of visual field loss. Following visual field testing using both the Smart System VR Headset and Humphrey Field Analyzer, subjects will complete a 13-question satisfaction survey. The total expected time commitment of this study is an additional 1.5-2 hours to the subjects' regular clinical appointment.

M&S Technologies is the developer of the Smart System VR Headset 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 EyeSimplify visual field test.

As the developers of the Smart System VR Headset visual field test, M&S Technologies maintains a secure, encrypted, HIPAA-compliant database of Smart System VR Headset users. This database includes patient profiles containing unique subject 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: Compare the performance of the Smart System VR Headset to the Humphrey Visual Field Analyzer
Aim 2: Determine the subjective perception of ease of use of the Smart System VR Headset

Primary Hypothesis: The Smart System VR Headset (M&S Technologies, Niles, IL) will perform as well as or better than the Humphrey Visual Field Analyzer (Carl Zeiss Meditec Inc., Dublin, CA) in identifying glaucomatous visual field changes.

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 with the Humphrey Visual Field Analyzer (HFA; Carl Zeiss Meditec Inc., Dublin, CA) is the current accepted clinical standard for diagnosis and monitoring of glaucomatous visual field loss (3). Despite ubiquitous use, the HFA has several disadvantages that limit its utility. The HFA is a large, expensive device that requires dedicated clinic space. It is immobile, so bedside examination and home monitoring are not possible. Additionally, it is difficult for patients with limited mobility or large body habitus to comfortably position themselves for the duration of the exam. Recently, there has been interest in development of a head-mounted virtual reality perimeter to address these limitations (4-6).

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. Hollander DA, Volpe NJ, Moster ML, et al. Use of a portable head mounted perimetry system to assess bedside visual fields. Br J Ophthalmol. Oct 2000;84(10):1185-90. doi:10.1136/bjo.84.10.1185
5. Mees L, Upadhyaya S, Kumar P, et al. Validation of a Head-mounted Virtual Reality Visual Field Screening Device. J Glaucoma. Feb 2020;29(2):86-91. doi:10.1097/IJG.0000000000001415
6. Nakai Y, Bessho K, Shono Y, Taoka K, Nakai Y. Comparison of imo and Humphrey field analyzer perimeters in glaucomatous eyes. Int J Ophthalmol. 2021;14(12):1882-1887. doi:10.18240/ijo.2021.12.11

II. Research Team

II.1 ***Principal Investigator***

Name	E-mail	College
Andrew Pouw		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		Carver College of Medicine	Yes	Yes	No		Yes	No
		Carver College of Medicine	No	No	No		Yes	No
		Carver College of Medicine	Yes	Yes	No		Yes	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.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
	No
	Yes

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

III. Funding/Other Support

III.1 ***Funding Sources***

Source Entered as Text	DSP Link	Type	Source	Project Title	Name of PI on Grant	Status
* Source is entered as text	yes		Corporate/Industry	M&S Technologies		
* new source name						

III.2 ***What type of funding agreement would be completed?***
Corporate/Industry Funded

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
	No
	No

III.5 ***What is the current status of this funding source?***

Source	Status	Other Status Description
M&S Technologies	Other	In kind support

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 <u>any</u> 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?***
52

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 (including best corrected visual acuity less than 20/80), 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)***
250

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 participate 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

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)
  - ☐ **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.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.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.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:***
The Department of Ophthalmology already owns a Smart System VR Headset, so no additional device will need to be ordered/shipped/received.

VII.B.20 ***Who will be responsible for maintaining these shipment and receipt records?***
The Department of Ophthalmology already owns a Smart System VR Headset, so no additional device will need to be ordered/shipped/received.

VII.B.21 ***Describe in detail procedures in place for tracking use and disposition of devices described in this study:***
The Smart System VR Headset is stored in a locked office in the University of Iowa Hospitals and Clinics' Department of Ophthalmology. The device will only be accessed by key personnel of the study. Device usage is automatically recorded upon test completion, so no additional physical record will be maintained.

VII.B.22 ***Who will be responsible for maintaining these use and disposition tracking records?***
Key personnel of the study, including the PI and research assistants, will be responsible for the testing data and, therefore, the "disposition tracking record".

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)***
The Smart System VR Headset will be stored in a locked office in the University of Iowa Hospitals and Clinics' Department of Ophthalmology. Only study personnel authorize to use the device will have access to this office.

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 Smart System VR Headset 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 Smart System VR Headset 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 studies investigating the Smart System VR Headset.

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 - No additional subjects are being recruited for this 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***

No

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
	Yes
	Yes

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 needed to consider participation; however, the Smart System Headset will be stored in the UIHC Department of Ophthalmology and must be used during a patients' appointment. As a result, if a patient requires additional time beyond their appointment to consider participation, they may be approached at future visits to participate in the study if this falls within the study period. They will be free to discuss the study with family/friends before consenting.

VII.D.28 ***How long after the subject agrees to participate do study procedures begin?***
Testing will begin approximately 5-10 minutes after the patient consents 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?***
Yes

VII.E.1.a ***Will any subjects be blinded to which study arm they have been assigned?***
No

VII.E.2 ***Describe randomization scheme/assignment including ratio such as 1:1, 2:1 etc.***
Patients will be randomized in a 1:1 ratio to either perform Humphrey Visual Field testing followed by Smart System VR Headset testing or vice versa.

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)***
Smart System VR Headset 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 routine clinical examination including measurement of visual acuity, tonometry, and slit lamp examination, subjects will undergo perimetry with both the Smart System VR Headset (SSVR) and the Humphrey Field Analyzer (HFA). If the subject requires pupillary dilation during their appointment, visual field testing (VF) will be conducted prior to dilation. Subjects will be randomized to perform either the SSVR VF followed by the HFA VF or vice versa. Both VF will occur on the same day with a 15-20 minute break between tests at the University of Iowa Hospitals and Clinics' Glaucoma clinic. The total additional time commitment of study participation is expected to be 1-2 hours.

The SSVR Headset 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 Goldmann size III stimulus. The research assistant will administer the SSVR VF. The SSVR VF will be deemed unreliable if FP >25%. The HFA uses a 24-2 examination protocol with a SITA standard testing algorithm. A clinical technician will administer the HFA VF. The HFA VF will be deemed unreliable if FP >15%. After completing both VF tests, subjects will complete a satisfaction survey regarding the SSVR.

VII.E.7 ***Will you attempt to recontact subjects who are lost to follow-up?***
No - those lost to followup will not be recontacted

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 (expected study commitment is 1-2 hours)
-Loss of confidentiality
-Minor risk of physical discomfort due to experimental headset weight and security strap

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.

M&S Technologies receives subject demographic and testing data upon completion of testing using the Smart System VR Headset. This data is stored in a secure, encrypted, HIPAA-compliant database. Subject names are not stored. Instead, Subjects receive encrypted ID codes. Subject data is only shared with M&S-affiliated consultants and service providers, healthcare providers using the Smart System VR Headset, and for law enforcement and judicial proceedings are permitted by law.

The study utilizes data generated as a consequence of routine clinical practice, as well as an additional in-clinic visual field test. 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 head-mounted perimeter for the diagnosis and monitoring of glaucoma. Society may benefit from this study by validation of such a novel head-mounted perimeter. This device 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.

M&S Technologies receives subject demographic and testing data upon completion of testing using the Smart System VR Headset. This data is stored in a secure, encrypted, HIPAA-compliant database. Subject names are not stored. Instead, Subjects receive encrypted ID codes. Subject data is only shared with M&S-affiliated consultants and service providers, healthcare providers using the Smart System VR Headset, and for law enforcement and judicial proceedings are permitted by law.

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):***

- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Any paper documents will be transported directly from the University of Iowa Hospitals and Clinics' Glaucoma clinic to the principal investigator's office by a research team member where they will be stored in a locked file cabinet until the conclusion of the study.
- 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. M&S Technologies receives subject demographic and testing data upon completion of testing using the Smart System VR Headset. This data is stored in a secure, encrypted, HIPAA-compliant database. Subject names are not stored. Instead, Subjects receive encrypted ID codes.
  - Name -
  - Title - Senior IT Support Consultant
  - University Job Classification - Faculty/Staff

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 Smart System VR Headset 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, visual acuity, intraocular pressure, Humphry Visual Field performance, Smart System VR Visual Field performance, and satisfaction survey will be collected and analyzed.

Data analysis: Humphrey Visual Field and Smart System VR Visual Field performance will be analyzed using pointwise comparisons grouped according to the Garway-Heath structure-function map.

XI.2 ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.***

Power analysis calculation summary:
Sample sizes of 80 on device one (Smart System VR Headset) and 80 on device two (Humphrey Field Analyzer), which were obtained by sampling 40 clusters for device one and 40 clusters for device two with an average of 2 subjects per cluster, achieve 87% power to detect a difference between the device means of at least 0. The standard deviation of subjects is 0.25. The intracluster correlation coefficient is 0.500. A test based on a mixed-model analysis is anticipated at a significance level of 0.050. Here we view cluster one as testing using device one before device two and cluster two as testing on device two before device one.

A full version of the power analysis calculation has been attached as an additional document to the IRB - there was some difficulty with formatting when transferring this calculation from our statistician's text document to the IRB form.

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 for future use is mandatory for participation in the study