Mass General Brigham

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator:	Dr. Jae Hyun Jung
Project Title:	Pilot study to understand visual confusion using stereoscopic displays
Version Date:	8/2021

For Intervention/Interaction studies, submit a Detailed Protocol that includes the following sections. If information in a particular section is not applicable, omit and include the other relevant information.

1. Background and Significance

- Summarize relevant literature, data, and historical background
    - Visual field loss is a common outcome of numerous eye diseases, neurological disorders, and injuries. Patients with field loss have difficulties avoiding obstacles and hazards (Yates et al., 2002; Bowers et al., 2014). The consequent loss of safe mobility; increased risk of collision with other pedestrians, falls due to tripping obstacles (Freeman et al., 2007), and unsafe driving (Bowers, 2016), are detrimental to patients' independence and quality of life (Papageorgiou et al., 2007; Chen et al., 2009; O'Neill et al., 2011). Effective field expansion devices to detect hazards and avoid collisions are needed for them.
    - Various devices using mirrors, prisms, and recently head-mounted displays (HMDs) have claimed to expand the visual field. However, if a device shifts part of the scene from the blind side into the seeing side, while the device itself blocks similar size of the field of view (FoV) on the seeing side (i.e., mirror blocking (Ihrig et al., 2007; Jung et al., 2018) or prism apical scotoma (Apfelbaum et al., 2013)), it only provides field substitution, which may not be as beneficial as true field expansion (Jung et al., 2019). To serve true field expansion, the field expansion device should present both the unseen (generally as form of shifted view from the blind side) and seen FoV (seeing view) together, using spatial vision multiplexing, seeing two different scenes superimposed on one another, with both in view simultaneously. It rarely occurs in the natural world (e.g., superposition of reflected and transmitted scenes on window) but is increasingly common in augmented vision devices (e.g., see-through displays, augmented or mixed reality). Spatial vision multiplexing may result in *diplopia* (seeing the same object in two different directions), and *visual confusion*, or both (Apfelbaum et al., 2013; Peli, 2017). Whereas diplopia is not helpful and should be avoided, visual confusion represents the essential and beneficial effect in field expansion.

- Describe previous pre-clinical or clinical studies leading up to and supporting the proposed research
    - Visual confusion, the appearance of two different objects in the same perceived direction, is the core approach for field expansion. We have developed field expansion using spatial multiplexing, specifically, binocular visual confusion (showing a normal view on one eye and an expanded view on the other eye). This approach has proven effective in collision detection in mobility when applied in the upper and lower

peripheral fields but is not optimal due to the binocular rivalry. We previously showed that the detection performance in the field expansion with the binocular visual confusion on motion background (mobility) is reduced.

- Describe rationale behind the proposed research and significance to patients, society, and/or science
    - Monocular visual confusion, which provides see-through and shifted views simultaneously with reduced contrast (about half) can be applied bilaterally to reduce the binocular rivalry in the field expansion. The bilateral monocular visual confusion provides monocular visual confusions of see-through and shifted views from both eyes. This provides stereoscopic depth cue in each and between see-through and shifted views and thus may help to detect the collision which is perceived as looming (approaching) at fixed bearing with two different background motions. However, the source of the binocular rivalry may be the incoherent motion flow between two views, which may still cause monocular rivalry in the same way and affect collision detection even in monocular visual confusion.
    - To study these effects rigorously, we will show various targets with unilateral/bilateral and monocular/binocular visual confusions on a motion background using a stereoscopic display (e.g., head-mounted display (HMD) and stereoscope). The contrast, motion, stereoscopic depth cues, and the location and the size of the targets will be controlled as well as visual confusion conditions to measure the rivalry rates.
    - The results of these experiments will inform the design of newer field expansion devices or help to modify the configuration of current existing devices. We may potentially help persons with visual field loss achieve better performance with field expansion devices that use the principle of visual confusion.

2. Specific Aims and Objectives

- Specify objectives and hypotheses to be tested in the research project
    - The objective of the study is to understand the mechanism of the visual confusion and determine the parameters that minimize the rivalry and thus improve detection performance in future field expansion devices for field loss patients.
    - We will iteratively measure visual rivalry with varying parameters(e.g., contrast, motion flow, stereoscopic depth cues) in the presence of binocular visual confusion (two eyes see two different images)/monocular visual confusion (one eye sees two different images) conditions for persons with normal binocular vision.

3. General Description of Study Design

- Explain the basic study design, e.g., parallel group, randomized controlled trial, open-label single arm study, cross over, adaptive, etc.
    - We will conduct pilot studies to rigorously investigate the mechanisms and impact of visual confusion and rivalry. There will be no masking involved. Subjects who have normal binocular vision will be seated and observe stereoscopic images. We will show peripheral target images on a background motion in a stereoscopic display. For the binocular visual confusion condition, the target peripheral image will be displayed on only one eye. For unilateral and bilateral monocular visual confusion conditions, the half-transparent peripheral image will be displayed on only one eye and both eyes,

respectively. Because the peripheral image will be detected only under pre-dominance on that eye/image, the subjects will be asked to press a button when they see/detect the peripheral target images. Various contrast, motion, stereoscopic depth cues, and the location and the size of the targets will be tested. To determine test-retest repeatability, subjects may be asked to perform the detection test twice at the same visit with a break between, or two separate visits. The study will typically involve 1 or 2 visits (each 2 to 3 hours).

- Provide study schema as applicable (a schema is required for greater than minimal risk studies, and optional for minimal risk studies
    - N/A

4. Subject Selection

Describe sources of subjects and procedures for subject selection, including the following:

- Inclusion/Exclusion Criteria

    Inclusion criteria

    - Better than 20/40 visual acuity in the worse eye
    - No restrictions of the peripheral visual field: (at least 60 degrees vertically and 40 degrees horizontally)
    - At least 14 years of age (no upper age limit)
    - In sufficiently good health to be able to complete sessions lasting 2-3 hours
    - Able to give voluntary, informed consent
    - Able to understand English
    - Binocular vision parameters within normal limits (Stereopsis ≤ 100 arc sec on any stereo test)

    Exclusion criteria

    - Patients with any physical or mental disabilities, including cognitive dysfunction, balance problems, or other deficits that could impair their ability to respond to the stimuli presented in this study will be excluded
    - Any person with history (such as pacemaker use) or physical condition listed on the device manual of the Oculus / HMD system used for the experiment as a contraindication will be excluded
    - It is not necessary for subjects to participate in multiple visits, but those who are willing to make several visits can do so.

- Local Recruitment Procedures:
  Explain in detail the methods and procedures you will use to recruit participants. Describe in a step-by-step procedure below:
- How individuals are identified for recruitment including description of use of recruitment materials such as flyers, brochures, advertisements, letters, etc.
    - Sources: Participants will be recruited 1) from prior volunteers who have previously participated in studies in our lab, and have given their consent to be contacted about future studies and 2) from members of the lab or adjacent labs within the institute.
    - For subjects who participated in previous studies: (Telephone script attached)
    - For subjects from members of the lab or adjacent labs within the institute: We will place advertisements about the study within Schepens Eye Research Institute and interested volunteers can complete a permission-to-be contacted form and send it to the research assistant mentioned on the advertisement. Internal Lab members will not directly be

requested to participate but can choose to do so voluntarily in response to the advertisement.

- Who is responsible (role on research team) for identifying and recruiting individuals- All members of the research team can be involved in identifying potential subjects. Recruitment using the telephone script will be performed by the research assistant.
- When individuals are recruited
  - See above
- Where individuals are recruited
  - The recruitment process will be carried out at Schepens Eye Research Institute by the research assistant.
- How recruitment goals match the prevalence rates of the condition/disease being studied and the populations most impacted by the condition/disease being studied
  - Does not apply as this is a basic science study to understand visual mechanism.
- Methods to enhance enrollment of diverse individuals and under-represented populations
  - N/A
  - The selection of subjects will be affected neither by sex/gender nor by racial/ethnic group. We are not planning to test specific age/racial/ethnic groups in this pilot study.

5. Subject Enrollment

- Describe any pre-screening procedures as applicable. Indicate whether subjects will be prescreened over the phone and/or will be asked to provide separate informed consent specific to screening procedures.
  - Subjects will not be pre-screened before provision of consent on-site.
- Describe in a step-by-step procedure the consent process including:?
- When and where informed consent will be obtained (including description of any electronic consenting procedures)
  - The person scheduling the visit will offer to send them an electronic copy of the consent form if they would like to review it before coming into the lab. When the subject comes into the lab to participate in the study, an interview will be carried out where the experimenter explains what the study will involve and the subject will be encouraged to ask any questions they may have. Then the subject will be given the consent form to read. If desired or necessary, the subject may have friends or family with them to help to read the consent form. The subject will be asked if they have questions about any part of the consent form before they sign, and the experimenter will always be careful to stress that signing the form is required for the subject to participate, but does not represent any obligation on the part of the subject. The subject is allowed to retain a copy of the signed consent form, while the original is kept in a locked file cabinet at SERI.
  - It is usual for the subjects (in similar studies we have conducted) to sign the consent form as soon it has been administered. However, they may choose to go back home or take their time to decide on their participation in the study. There is no fixed timeline imposed on the subject within which the decision has to be made other than the meaningful duration for the study to be active.

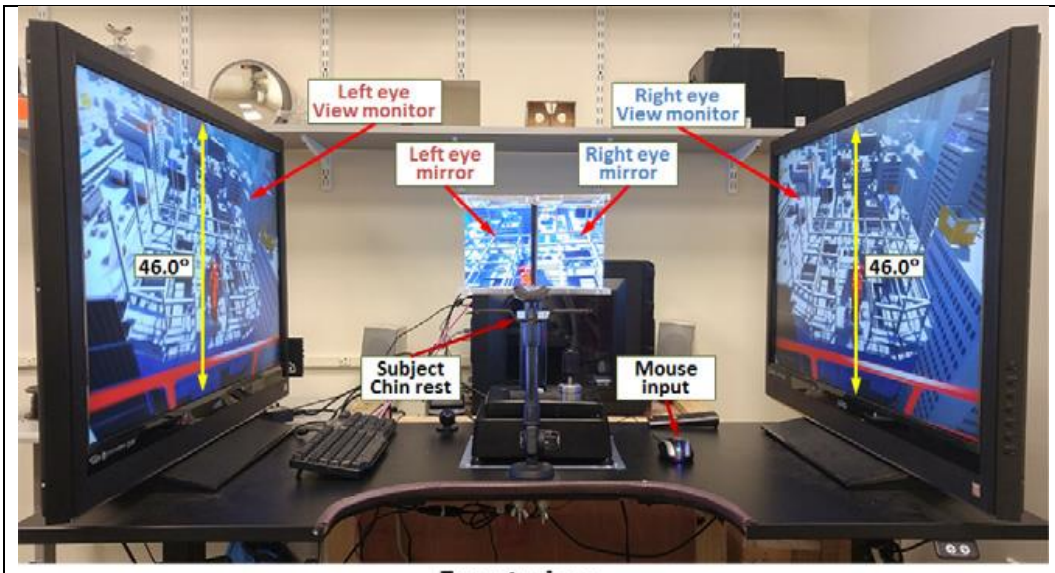
- A separate description for adults and children if applicable – We have a separate section in the same consent form for the children and their parents/guardians to sign
- The process for obtaining consent from non-English speakers if applicable -NA
- The process to determine capacity to consent and use surrogate decision makers if applicable
- Procedures to minimize undue influence to enroll, particularly if recruiting the investigators' own patients
    - For participants who are among the internal lab members, risk of coercion is minimized by having one of the study coordinators (rather than the investigator) contact them about the study upon receiving a permission-to-be-contacted form and conduct the informed consent procedures within the lab. They will be reassured about privacy protection and de-identification of data. Informed consent procedures include a full explanation about the study, including the fact that participation is voluntary; that the participant can withdraw at any time without consequence, and that declining to participate in spite of providing a permission to contact slip or choosing to discontinue the study in the middle of a visit will have no impact on their role within the lab or in Schepens. As much as possible the principal investigator will be masked to internal lab members identity or participation as calendar appointments will only hold de-identified subject IDs
- Describe post-consent intervention assignment and randomization method if applicable
    - After the informed consent process is completed, subjects will complete a series of screening tests to ensure that they meet the study criteria:
        - **SCREENING PROCEDURES**
        - After the informed consent process is completed, subjects will complete a series of screening tests to ensure that they meet the study criteria including visual acuity (logMAR chart), visual field screening, stereopsis checked with standard clinical tests, including computer-based tests.

6. Study Procedures

Provide detailed description of all study visits, procedures, and data collections, including:

- Description of each study visit and procedures at each visit (include a schedule/table of study procedures)
    - If the subject meets the enrollment criteria, and agrees to participate in this study, the subject will be asked to participate in any of the following studies. All subjects will be informed that participation in these tests is voluntary and they may choose to participate in some of the tests only.

      Experiment with stereoscopic display:
    - This will involve looking at monocular/binocular targets of varying contrast or motion direction/flow presented on a television display placed at a specified distance from the subjects. The subject may view a reflection of the screen on an angled mirror placed at a distance from them used to induce a stereoscopic effect. A chinrest will be used to maintain a constant viewing distance. The subjects will be requested to make specific responses to the target/targets shown on the display by making a button press on a keyboard or similar input device.



Sample front view of a Wheatstone stereoscope setup used to display stereoscopic moving or stationary images to viewers

Experiment with HMD:

- This will involve looking at monocular/binocular targets of varying contrast or motion direction/flow presented on the Oculus Quest 2 HMD headset (or similar commercialized stereoscopic HMDs) to induce a stereoscopic effect.
- The subjects will be seated while participating in the experiment
- The subjects will be requested to make specific responses to the target/targets shown on the display by pressing a key on the Oculus Quest 2 controllers.

	
Subject wearing the Oculus headset	The controller used by the subject to make button press responses to the target shown on the screen

  - Study participants will participate in a practice session before continuing with the actual experiment. The experiments will be broken into sessions of 10-15 minutes each. They will be allowed to take frequent breaks to rest between these sessions. A study visit will typically consist of 6-8 sessions. Participants may choose to complete these on the same day or over multiple days according to their convenience.
  - Each subject will require only 1 or 2 sessions to complete these procedures
- Description of study drugs, devices, or other interventions/exposures administered, including:
    - We will use the Oculus Quest 2, or a similar commercially available head mounted display to show images or videos that the subjects will respond to.
    - Alternatively, the images may be displayed on a stereoscopic television display.
    - Both of these systems do not come under FDA oversight as medical devices or therapeutic intervention. This is not a study exploring therapeutic intervention. There is no dose/time of intervention applicable to the participant interaction with the display system.
    - The Unity 3D game design software will be used to generate the visual targets that are presented on the stereoscopic display.

  - Dose, method of administration, schedule of administration, dose modifications: N/A
  - Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications (“off-label”): How are doses, routes of administration, or participant populations different from FDA approved indicated use? N/A

- Description of specific data variables to be collected, including data collection methods, assessments, data collection sheets, and/or schedule of assessments (A schedule/table of study assessments is preferred)
  - The data collected may typically involve response time measures to specific targets shown on the head mounted display or stereoscopic display

  - Data collection will be through a button or keypress on a keyboard/similar input device and logged by a computer.
  - Demographic data and the name of the experiment may be documented on a separate data collection sheet.
- Description of planned genetic research as applicable (e.g., specific description of whole genome sequencing, creation of immortalized cell lines or induced pluripotent stems cells, and sharing of genetic material with collaborators and central repositories as applicable, etc.)
  - N/A
- Description of plans for return of research results as applicable (e.g., specific description of, rationale for, and process by which research results will be returned, including to whom, by whom, and when, etc.). Include plans for managing incidental findings as applicable.
  - We do not plan to provide results of the research to the subject and state this in the informed consent form.
- Definition of primary and secondary outcomes/endpoints. Note that outcome measures should be quantifiable and measurable.
  - Duration of the target detected (primary), Number of targets detected (after disappearance of the target)
- Definition of study termination criteria, e.g., objective criteria for clinical worsening, lack of improvement, and/or unacceptable adverse events
  - N/A
- Local site restrictions or site-specific procedures as applicable, including:
  - Description of how study procedures (e.g. intervention or diagnosis) compare to standard of care, including description of alternative treatments, procedures, or methods of diagnosis
    - N/A
  - Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
    - N/A
- Remuneration as applicable. Indicate if payments to subjects are made upon completion of study visits/certain procedures and how remuneration is pro-rated, particularly for non-completers
  - We will offer compensation of $20 for every visit the subject has participated in the study. We will reimburse up to $50 every visit towards the subject's travel charges.
  - Internal Lab members will not be reimbursed for time or travel if they choose to participate as they are already on site. Members from adjacent labs will not be reimbursed for travel if they have traveled to the site for purposes other than the study but will be reimbursed for their time.
- Description of plans for sending and/or receiving specimens or data with research collaborators outside Mass General Brigham or with NIH (e.g., dbGaP) or other tissue/data repositories (include details of identified versus de-identified sharing, how data or specimens are labeled/coded, secure transfer method, external IRB approval as applicable, storage for future use, secure transfer method, etc.)
  - N/A

7. Risks and Discomforts

Provide detailed description of potential risks of each study-related procedure/intervention, including: This study is not intended for treatment or diagnostic purposes.

- Complications of surgical and non-surgical procedures: N/A
- Drug side effects and toxicities : N/A
- Device complications/malfunctions : N/A
- Psychosocial risks : N/A
- Privacy/confidentiality risks
    - Every individual will undergo testing in a confidential setup and only research assistants or investigators from the study involved in data collection will have direct contact with the subject. Persons involved in these interactions will have undergone GCP training.
    - All information will be de-identified and the risk related to privacy or confidentiality will be minimal.
- Genetic research risks: N/A
- Radiation risks: N/A
- Include description of steps taken to decrease relevant risks, including the following: (How procedures used are consistent with sound research design and do not expose unnecessary risks)
    - All procedures in this study are minimal risk and are otherwise regularly performed in the clinic or a task of daily living that study participants would otherwise perform anyway.
    - Screening is composed of standard clinical procedures (visual acuity, visual field, and stereo tests), which will be carried out in a stationary sitting or standing position and pose a minimum risk for patients.
    - During the experiment, the participants will see stereoscopic 3D images on given stereoscopic display settings (HMD or stereoscopic TV). This may cause subjects fatigue and visual discomfort including motion sickness, but the risks associated with participating in the test are not bigger than the risks normally associated with watching a 3D movie or playing a 3D video game on the commercialized HMD at home (the device we will use). Subjects will be in a sitting position during the experiment. These kinds of risks are considered minimal by most people.
    - There is minor discomfort for being seated or paying attention for prolonged periods. However, each procedure will be split into sub-components to allow the subject to take frequent breaks and study visits will be flexible so that subjects may choose to come back to complete the study.
    - Discomfort is possible due to temporary motion sickness from viewing video backgrounds with simulated motion. The discomforts induced during the study are expected to be naturally dissipated quickly. The fact that study participants can choose to stop and exit the study at any point without any obligation will be re-emphasized. In our other driving simulator study, we have seen subjects who stopped due to motion sickness symptoms but many of them requested to continue on another day, and as is expected, they had a lower level of discomfort on second or third exposures.
- When appropriate, researchers use procedures already being performed on subjects for diagnostic or treatment purposes
    - N/A

8. Benefits

Provide detailed description of potential benefits of study participation, including:

- Either describe potential benefits to participating individuals or clearly state that there is no direct benefit to individuals
    - There are no direct benefits for an individual subject from participation in this study.

- If multiple subject populations are to be enrolled, describe any differences between groups with regard to potential benefit (e.g. potential for benefit to an affected subject population versus no potential benefit for healthy controls, etc) -NA
- Potential benefits to society (e.g., increased understanding of disease process, etc.)
    - The knowledge gained from the study will provide an important understanding of binocular/monocular visual confusion or rivalry and how the visual system processes information. We hope that this will in turn be useful to design better field expansion devices for persons with visual field loss in future studies.

9. Statistical Analysis

Describe plans for statistical analysis, including:

- Statistical methods/data analysis plan
    - The study coordinator and the investigator performing the statistical analyses will be masked (blinded for the conditions). Interventions will be identified by a code (devised by a person external to the study) that will not be broken until after data analyses are completed.
    - We plan to use ANOVA to compare within-subject data for various modifications to the images or videos presented.
- Power analysis (e.g., sample size, evaluable subjects, etc.)

  Sample size estimate:

  As this is pilot study, we currently aim to collect data from 30 subjects to understand performance differences and inform sample size calculation.

  As we do not yet have preliminary data for the proposed study, we have based our sample size calculation on the performance of 9 subjects in computerized target detection task on motion background with binocular and monocular viewing of unilateral peripheral prisms (Shen et al., 2015). The mean and standard deviation of detection rate for the monocular (no rivalry) and binocular (rivalry) were 58%±14% and 16%±10%, respectively. Assuming a similar standard deviation will occur in the proposed studies, 5 subjects will be needed (alpha 0.01 and power 0.9, 2 tailed test). We assume the magnitude of performance difference within the monocular visual confusion conditions is smaller than the magnitude of difference between binocular visual confusion and no visual confusion conditions. To detect a minimum difference of detection rate of 21% (half of the previous study) between conditions, we will need at least 9 subjects (alpha 0.01 and power 0.9, 2 tailed test). We were able to find significant effects in most of our driving studies with 12 subjects or less (Bowers et al., 2014; Bowers, 2016; Houston et al., 2018), and thus we will target to recruit 12 subjects. Allowing for attrition, we aim total 30 subjects.

10. Monitoring and Quality Assurance

Describe the plans that will be followed by study staff for monitoring and quality assurance, including:

The PI will have overall responsibility for monitoring the integrity of the data. The research assistant will be responsible for ensuring accuracy and completeness of data records and informed consents. Research staff will enter data into study spreadsheets in a timely fashion. Summaries of data for each subject will be reviewed and discussed by the study team at weekly project meetings.

- Adverse event criteria and reporting procedures

  - All guidelines of the Partners Human Research Committee for Adverse Event Reporting will be followed. Any adverse events will be reported immediately to the PI for review. Expected adverse events will be reported annually at the time of the continuing renewal. Any unexpected or serious adverse events will be reported to the IRB immediately.

- Planned safety monitoring (e.g., data safety monitoring board, independent monitor, PI-monitored, etc.), including planned frequency of review.
  - After each subject has completed study participation, a brief report summarizing the data and findings for that subject will be prepared by the research assistant and will be reviewed by the PI and may be presented and discussed with the rest of the project team at a weekly project meeting. Data reviewed will include the participant's informal feedback about the experiment and the experimenter's notes about the study visit. The PI will be responsible for determining whether the research should be altered or stopped.
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- Outcomes monitoring, including planned frequency of review.: N/A
- Study stopping rules as applicable - N/A
- Internal monitoring of source data, protocol adherence, and recordkeeping, including which staff will be responsible and planned frequency of review: See section above on Planned safety monitoring
- Independent monitoring of source data as applicable: N/A
- Description of data management methods
  - Research data will be coded using a subject identification number that does not include the subject's initials and is not derived from the subject's identifiable information. The document linking the code to personal information will be stored on a secure password-protected database of the local MEEI network that only authorized study staff will be able to access. Any paper files with subject-identifiable information (such as the consent form) will be kept in locked file cabinets at SERI accessible only to laboratory personnel in a locked office. Any paper data collection sheets that do not contain subject-identifiable information will be physically stored in a binder in the lab at SERI in a locked office that only authorized staff can access. Electronic data will be stored on secure password-protected computers and network drives. All study staff will complete all training required by Partners IRB and Mass Eye and Ear related to confidentiality of data.

11. Select the Privacy and Confidentiality measures that apply to this research:

☒ Study procedures will be conducted in a private setting
☒ Only data and/or specimens necessary for the conduct of the study will be collected
☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
☒ Data will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol

- ☐ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☐ Additional privacy and/or confidentiality protections

Describe below:

12. References

Apfelbaum, H.L., Ross, N.C., Bowers, A.R., & Peli, E. (2013). Considering apical scotomas, confusion, and diplopia when prescribing prisms for homonymous hemianopia. *Translational Vision Science & Technology,* 2, Article 2, PMCID: PMC3763894 DOI:http://dx.doi.org/10.1167/tvst.2.4.2.
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