Mass General Brigham

Research Consent Form
Certificate of Confidentiality Template
Version Date: February 2021

Subject Identification

Protocol Title: Pilot study to understand visual confusion using stereoscopic displays

Principal Investigator: Dr. JaeHyun Jung

Site Principal Investigator:

Description of Subject Population: Persons with normal binocular vision

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to test how people understand a visual scene when the same image is presented to both the eyes, but portions of these images are altered in terms of contrast, depth or in some cases motion.

How long will you take part in this research study?

If you decide to join this research study, it can take you a single visit to several months to complete the study. During this time, we will ask you to make at least one study visit to Schepens Eye Research Institute which is located at 20, Staniford Street, Boston MA 02114. A visit will last between 2 to 4 hours. We might invite you to make more visits, but you can decline if you do not want to make further visits.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen. We will take some measurements of your vision, similar to some of the vision tests when you visit the eye doctor (but we will not dilate your pupils). We might also ask you to watch some stationary or moving images on a head mounted or stereoscopic display such as the Oculus Quest 2.0 or similar commercially available device and press a button whenever you see a particular feature.

Why might you choose to take part in this study?

You will not benefit from taking part in this study. However, people with visual field loss may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Possible visual discomforts to know about include potential fatigue since the study visit will be at least 2 hours (though we will take breaks), and there is a slight possibility of experiencing some visual discomfort when watching motion videos, viewing stereoscopic displays or wearing head mounted displays.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called “What are the risks and possible discomforts from being in this research study?”

Other things to consider are a time commitment of 2 to 4 hours per visit for typically 2 visits, and the travel to Schepens Eye Research Institute located at 20, Staniford Street.

What other treatments or procedures are available for your condition?

Other things to consider are a time commitment of 2 to 4 hours per visit for typically 2 visits, and the travel to Schepens Eye Research Institute located at 20, Staniford Street.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. JaeHyun Jung, Ph D is the person in charge of this research study. You can call him/her at 617-912-2525 [Monday – Friday, 9-5 pm]. You can also call the research assistant at 617-912-2522 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, the research assistant at 617-912-2522 or the front desk at Schepens at 617-912-0100 [Monday-Friday, 9-5 pm]

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

In this research study, we want to learn more about the difference between binocular visual confusion (separate views presented to either eye when both the eyes are open) and monocular visual confusion (two different images within the view for one eye). These two display conditions are promising display methods for field expansion of field loss patients such as hemianopia, loss of half of the visual field on the same side in both eyes, caused from brain injury, stroke, or tumor.

We would like to design a test that can evaluate the ability of individuals to get information from a visual scene in the presence of visual confusion due to difference in contrast, stereo or motion flow differences in portions of the images. We are inviting people with normal binocular vision (as well as people with visual field loss who has normal binocular vision) to participate in this study.

Who will take part in this research?

We are asking you to take part in this research study because you have normal binocular vision (or being able to comfortably merge images seen with both eyes at the same time). We expect to enroll up to 30 people in this study. The National Eye Institute of the National Institutes of Health is paying for this research study to be done.

What will happen in this research study?

The first thing that will happen in this research study is that you will be asked to visit Schepens Eye Research Institute for a screening visit. If you qualify during the screening visit, we may ask you to come back for one or more subsequent visits with each visit typically lasting two to four hours. The number of visits and the timing between visits may also vary. We will tell you the approximate timings between visits. The duration of time between these visits can be flexible and you may choose not to participate or come back for a visit. It is possible that the duration between visits will be longer than anticipated due to COVID-19 related delays scheduling visits for multiple participants. We will contact you to confirm appointments.

Screening

Screening at the first visit includes measurements of your vision (described below). In addition, we might ask you some questions about your ocular and general medical history. (These questions might be asked via a telephone interview.)

Vision measures
You may have your visual acuity (ability to see fine detail) measured using a computer-based system or a chart. You may also have your visual fields (extent of vision) measured using a conventional clinical instrument, or a computer-based system. For the visual field measurements, you will sit with your chin in a chin rest and press a response button when you see targets appear on a screen in front of you. Your binocular vision (coordination between the two eyes) may also be measured with standard clinical tests.

Experiments with head mounted or stereoscopic displays:
This will involve looking at targets of varying contrast or motion direction/flow presented on a television display or head mounted display such as the Oculus Quest or similar commercially available device. You will be requested to make specific responses to the target/targets shown on the display by pressing a key on the keyboard, pressing a button on a gamepad or using a joystick to provide a response.

We will request you to participate in a practice session before continuing with the actual experiment. The actual experiments will be broken into sessions of 10-15 minutes each. You can take frequent breaks to rest between these sessions. A study visit will typically consist of 6-8 sessions. You may choose to complete these on the same day or over multiple days according to their convenience. If you are not comfortable with the experiment during the practice or any time during the actual experiment, you may choose not to participate in the experiment or exit the study. At the end of the experiment, we may ask you for general feedback related to the targets you were shown and requested to respond to.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use the de-identified data in other research related to visual field loss. It won't be possible to link the information back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding binocular vision. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

What are the risks and possible discomforts from being in this research study?

Vision testing:
The vision testing includes standard clinical tests carried out in an eye doctor's office. There may be some slight discomfort from sitting with your chin in a chin rest.

Using the head mounted or stereoscopic display:
There is a chance that you might experience some temporary discomfort when viewing motion video backgrounds. We will have crackers available should you feel discomfort, and you may take breaks whenever you need to, or stop the test altogether.

What are the possible benefits from being in this research study?

We expect that people with visual field loss may benefit in the future from what we learn in this study. The results of the study will assist us in understanding how the eyes and brain interact to provide an awareness of potential hazards, and possibly enable us to test the use of any special glasses or mobility solutions that may be designed to help persons with visual field loss in mobility. You may not expect to benefit directly from the study.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be offered reimbursement for your travel expenses, of up to a maximum of $50.00 per visit, for travel specifically for the study to the Schepens Eye Research Institute. You will be reimbursed at $20.00 per visit for your time while at Schepens participating in the study.

If you are an employee of Schepens Eye Research Institute, we may not reimburse you for your travel or time, unless you are visiting the institute exclusively to participate in the study.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose

What will you have to pay for if you take part in this research study?

Study funds will pay for the technology used in the study and for other study-related items. Partners may bill your health insurer for, among other things, routine items and services you would have received for care at a Partners institution even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and

foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records

- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Mass General Brigham, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her identifiable information to be used and shared as described above.

Parent(s)/Guardian for Child	Date	Time (optional)

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Child:

I agree to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

Child, Ages 14-17	Date	Time (optional)

Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Adult	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Subjects Who Cannot Read or Write or are Physically Unable to Talk or Write

The consent form was presented orally to the subject in the subject's own language, the subject was given the opportunity to ask questions, and the subject has indicated his/her consent and authorization for participation by (check one box as applicable):

☐ Making his/her mark above

☐ Other means _____
(fill in above)

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