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UPMC Department of Ophthalmology, University of Pittsburgh School of Medicine

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Visual Information Restoration and Rehabilitation via Sensory Substitution Technology in Children

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The aim of this research study is to evaluate a non-surgical visual prosthetic called the BrainPort vision device. This device enables participants who are blind to appreciate their immediate surroundings and determine the way the brain interprets information. Our main goal is to determine if the BrainPort can be used in a pediatric population. Please consider this form carefully since it gives you information about this research study, which will help you decide if you want your child to participate. The study staff will review the information in this form with you and your child and answer any questions. If you agree to have your child take part in this study, you will need to sign this form. Your signature means that you and your child have been told about the study and have been told what risks to expect. Your signature also means that you give your permission to have your child participate in this study.

Description of the BrainPort Device

The BrainPort vision device consists of a control box and device resembling a lollipop that is put on the tongue. The device on the tongue has an array consisting of 400 metal electrodes that are connected to a camera mounted on a pair of sunglasses. The video camera provides information about objects in its field to the control box. The box then gives this information back to the array on the tongue.

How many people will take part in this research study?

A total of 52 subjects between 4 and 17 years of age will be screened for this study in order to enroll a total of 26 subjects.

How long will my child be in this research study?

The duration of this study is 5 sessions (6 sessions if you agree to the optional MRI) over a two week period. Each study session will be limited to 90 minutes in length (30 minutes for the MRI). You and your child can elect to have up to two sessions per day, depending on your scheduling needs. We can schedule these visits to accommodate you and your child's schedule, work, and travel needs.

What will happen in this research study?

Following consent, your child's vision, medical history, and medication history will be reviewed. Next, your child will complete baseline vision assessments, which have been used in similar BrainPort studies. These assessments include computer-based tests of the ability to detect light, direction, motion, and letters. In addition, we may ask your child to sit at a table and recognize objects using the BrainPort. Each of these tests takes between 5 and 15 minutes to complete. Sighted patients will have both eyes blindfolded for all study procedures.

Following the baseline studies, we will teach your child how to use the BrainPort. Our lab has trained over 100 people to use the BrainPort device (the largest center worldwide). We are trying to give your child basic skills under the direction of a therapist who works in our laboratory. After the BrainPort training has been completed, the same assessment tests we gave your child at the beginning of the study will be repeated.

All of the procedures will occur at either the UPMC Eye Center or UPMC Eye Center at Children's Hospital and will be supervised by trained study staff at all times. The optional MRI portion of this study will occur at the Neuroimaging Science Center at McGowan Institute for Regenerative Medicine.

What procedures will be performed for research purposes?

Session 1

Informed consent: The consent form tells you information about this research study in order to help you decide if you want your child to participate. The study staff will review the information in this form with you and your child and answer any questions.

Review of inclusion & exclusion criteria: This is a review of procedures that determine if your child is eligible to take part in this research. This includes the confirmation of vision status, an oral exam, and the confirmation of whether your child is pregnant or breastfeeding, if they are of childbearing potential.

Pregnancy Test: If your child is of childbearing potential, they will undergo a pregnancy test. If the result is positive, they will not be allow to participant in this research study. Both you and your child will receive the results of the pregnancy test.

Medical history: This is a review of your child's medical history.

Medication history: This is a review of any medication your child has taken or is currently taking.

Oral exam: This consists of physically checking your child's tongue for piercings, visible open lesions, cold sores, abrasions, blisters, or rashes. The examiner will also ask your child how their tongue feels after use of the BrainPort device.

Baseline vision tests: In order to test your child's visual function, they will be asked to view various images on a computer screen or identify objects or words and respond either verbally or by pushing a button. It is possible that your child will not be able to detect the images without the BrainPort device. These assessments test the ability to detect light, direction, motion, and letters. We may also ask your child to sit in a chair and recognize objects.

BrainPort Vision Device Training: Your child will be asked to place in their mouth a thin, flat strip that has many small individual electric stimulators. This looks like a lollipop. Each of the stimulators will produce a vibrating or tingling sensation on the tongue when activated. Your child will be asked to wear special glasses with a camera mounted on top. Your child will then be taught how to interpret the pictures that form on their tongue. Each training session will last for approximately 90 minutes. Your child will be able to control the strength of the electrical signal on their tongue. There is also a safety circuit that prevents the electrical activity from being too strong.

Sessions 2, 3, 4

BrainPort Vision Device Training: See Session 1 description.
Oral exam: See Session 1 description.

Session 5

BrainPort Vision Device Training: See Session 1 description.
Oral exam: See Session 1 description.
Baseline vision tests: See Session 1 description.

Session 6 (OPTIONAL)

Session 6, the MRI Scan, is completely optional. If your child does not participate in the optional MRI scanning, they will be able to continue with the reminder of the study.

MRI Safety Screening: Your child will be checked by our MRI technician for any implanted medical devices or metallic objects being worn that are not safe for the MRI scanner.

MRI Scanning: Your child will lie down and be moved to the center of the magnet, which is a relatively short but narrow tube. While acquiring images, the scanner will make a series of knocking noises. Anyone in the scanner room will be given earplugs to protect their hearing from these noises. We will collect a series of both structural and functional images. During most of these scans (all structural scans and resting state fMRI), your child will be asked to lie quietly and as still as possible. Two task-based fMRI scans will be pursued using auditory sensory substitution signals that are played through a set of MR-safe headphones. During these tasks, your child will be asked to either passively listen to a set of sounds or actively interpret the sounds as images, and then respond on a keypad with their answer. The volume of the headphones will be adjusted for comfort, and the headphones will further diminish scanner noise along with the provided ear plugs.

Four major steps will be taken to maximize comfort and reduce stress for your child. First, the total scan time will be significantly reduced compared to adult subjects, with the total scanning time targeted for 30 minutes. Second, we will not use the MR-safe version of the BrainPort in children for fMRI scanning. Using only auditory stimuli will simplify the setup, reducing the length of the session and leaving more space for the subjects in the scanner. Third, your child will be in contact with you via an intercom system, or if necessary, directly in the scanner room (as long as you pass the MRI safety screening). Fourth, a short break will be worked into the scanning session in order to describe the second auditory fMRI task.

Does the investigator stand to gain financially from the research?
The investigator does not expect to gain any benefit from the results of the study. The study is being supported by grant funds from the University of Pittsburgh. This project has been carefully reviewed to ensure that your child's well-being holds more importance than any study results. Any questions you or your child has about this study will be answered by Dr. Ellen Mitchell, who has no financial conflict of interest with this research, or by the Human Subject Protection Advocate of the University of Pittsburgh (866) 212-2668.

What are the possible risks, side effects, and discomforts of this research study?
As with any research study, there may be side effects that are not known and it is possible that certain of these unknown risks could be permanent, serious or life threatening. When using the device, the participant will be supervised. It is important that when using the device that participants do not take any additional physical risks that they would not ordinarily take.

Stimulus of the Tongue: It is rare, but possible, that the stimulus on the tongue may become too strong and produce discomfort. Subjects have complete control of the sensation strength, and can adjust it to their preference. They can also simply remove the electrical stimulator at any time or press a button to end the stimulus. We have not observed any tissue irritation on the tongue during eight years of studies similar to this one. No information is presently available on the effects of long-term electrical stimulation in the mouth. After the stimulus is turned on, it is common for subjects to report a mild buzzing sensation on the tongue, lasting from several minutes for up to 1

hour. While unusual, this sensation is not reported to be annoying and does not interfere with normal activities such as taste, talking, or swallowing. Subjects will be asked to report this sensation to the study staff.

Mouth or Tongue Irritation: It is rare that the materials used in the construction of the device may irritate the mouth or tongue, irritate the tongue from the electrodes on the component of the device that contacts your tongue, excessive electrical stimulation from the strength of the signal coming through the electrode array resulting in burns to the tongue.

Falling or Bumping into Objects: There is a rare risk of your child falling or bumping into objects; however, a research coordinator will always accompany your child. The research coordinator will maintain a high level of close supervision and will prevent your child from bumping into objects whenever your child is ambulatory. All travel while using the BrainPort Vision device will be on one level and will not involve ascending or descending steps.

Electrical Shock: There is a rare risk of electrical shock. These risks may be minimized through the assessment and education of your child in the orientation phase of the study, instructions to limit the electrical stimulation and signal strength to a safe level, training subjects to set the electrical stimulation level according to their preferred level of strength, using only device materials that have been previously tested to be sure the materials of the device are suitable for contact with and use in the mouth and close guarding by the clinician during the Training Phase. Wicab, Inc. has not observed any significant adverse events during prior clinical studies of the first generation BrainPort vision devices. Nor has the company observed adverse events during studies of a similar device used for balance rehabilitation. Your child will be told to report to the researcher and/or their medical doctor about any side effects.

Injury to Teeth: If the device becomes displaced in your child's mouth, there is a chance that they may bite down on it and injure their teeth.

Pregnancy: There is not enough medical information to know what the risks might be to a breast-fed infant or to an unborn child carried by a woman who takes part in this study. Therefore, women who are pregnant or breast-feeding will not be able to take part in the study.

Embarrassment: Since we are administering a pregnancy test to childbearing potential participants who are minors, it is common that both you and your child may become uncomfortable or embarrassed when this situation arises. Should the pregnancy test come back positive, the research coordinator will discuss the situation with both you and your child privately.

MRI: The MRI exam involves ***no*** exposure to x-rays or radioactivity.

Risks of the Magnetic Field: There is a potential risk of the strong magnetic field of the scanner attracting metallic objects toward the magnet. There are certain conditions that would exclude your child from having an MRI. These conditions include the presence or suspected presence of a heart pacemaker, aneurysm clip, ear implant, IUD, shrapnel or metallic fragments in or on the body or eyes, neuro-stimulators, or other metal devices. Dental fillings do not present a problem with MRI. No other serious effects have been reported from being in the 3 Tesla magnet in this study, although vertigo (e.g., dizziness and nausea) has been reported at higher field strengths. To

minimize these risks, your child will be carefully screened for metallic objects in your possession before entering the magnet room. All such metallic objects will be collected and placed in a locker outside of the magnet room.

Risks of the Confined Space: Individuals with claustrophobia or fear of confined spaces, excessive anxiety, and a body weight over 250 lbs. may not be able to enter or remain inside the MRI magnet. If your child experiences a fear of the confined space while in the magnet, your child should immediately notify the operator (by voice communications or the squeeze bulb) and the exam will be terminated.

Risks from Switched Magnetic Field Gradients: During the exam, the magnet will make intermittent, loud, knocking noises that could cause ear discomfort in some people. Even though this noise is within safety levels, your child will be asked to wear headphones, which will not interfere with their ability to communicate with the magnet operator.

Nerve Stimulation: The rapidly switched magnetic fields used during imaging may cause nerve stimulation in subjects (e.g., an uncontrolled twitch or tickle near the waist). Individual responses to these fields may vary from no sensation to intolerable pain. If your child feels pain or cannot tolerate the level of nerve stimulation, your child should immediately notify the operator (by voice communications or the squeeze bulb) and the exam will be terminated.

Risks to Pregnant Women: Although there are no known risks of MRI for pregnant women, pregnant women will not be permitted in this study. If you are not certain about your pregnancy, your child will receive a urine test to rule out pregnancy. Your child will not be able to participate in this study if their pregnancy test proves to be positive.

Risks of Radiofrequency (RF) Pulse: Individual responses from the RF pulses may vary. In the event your child feels uncomfortable from excess heating and sweating, your child should immediately notify the operator (by voice communications or the squeeze bulb), and the exam will be terminated. This situation will unlikely happen, because there are measures built into the scanner to prevent such heating and to ensure that the RF pulses stays within the FDA guidelines.

Risks of Breach of Confidentiality (MRI specific): To protect your child's privacy and maintain the confidentiality of information we obtain from you and from your medical records, we will maintain all information about your child in a secure location. All paper records that could identify them will be stored in a locked room, while all electronic records will be stored in password-protected files. Although we will do everything in our power to protect your child's privacy and the confidentiality of your records, just as with the use of your medical information for health care purposes, we cannot guarantee the confidentiality of your child's research records.

Risks of Breach of Confidentiality (IUD): If it is revealed in the MRI pre-screening that your adolescent child is using an IUD for birth control reasons, it is possible that investigators will reveal this fact to you.

Risks for Young Children Undergoing the MRI: Your child may have trouble keeping still while in the MRI or feel stressed that they are separated from you. To reduce the stress of your child, we will shorten the total scan time to approximately 30 minutes. Furthermore, a short break will be worked into the scanning session in order to

describe the second auditory fMRI task. Your child will be in contact with you via an intercom system, or if necessary, directly in the scanner room (as long as you pass the MRI safety screening).
Other than the above-mentioned problems, there are no known risks or side effects to you when the MRI study is performed under the guidelines that will be used for your exam.

Are there benefits to taking part in this research study?
Your child may not directly benefit from their participation in this study. The information learned from this study may help investigators provide better care for those who are blind in the future.

The device will be given to your child during the study, but must be returned at the end of the study. The device is not available for sale nor can we ever guarantee that it will be. There are no plans to sell you or your child a device or make a device available to you.

What treatments or procedures are available if I decide not to have my child take part in this research study?
Other than mobility training for those who are blind, we are not aware of any non-invasive alternatives to this device. Your child has the alternative to pursue blind mobility training programs. You and your child also have the right to not participate in this study.

Will you need to pay for the tests and procedures?
You will not need to pay for the investigational device or procedures used during the study. All procedures related to the study will be paid for by study funds.

Will you be paid for your participation?
You and your child will be compensated $100 when all study visits are completed. There will be no partial compensation. There is no additional payment for the optional MRI portion of this study. Out-of-State and international participants may be reimbursed for travel expenses in upwards to $1,000 at the completion of the study. Only airfare, car rental, and hotel expenses are eligible for reimbursement. These expenses will be reimbursed with proper receipts and an itemized statement from you.

Who do I contact if I have questions about the study?
You may contact Dr. Ellen Mitchell at (412) 692-8940.

What happens if my child is injured because they took part in this research study?
If you believe that the research procedures have resulted in an injury to your child, immediately contact the Dr. Ellen Mitchell at (412) 692-8940. Emergency medical treatment for injuries solely and directly related to your child's participation in this research study will be provided to them by the hospitals of UPMC. Your child's insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your child's research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

If you seek emergency care, or if you are hospitalized, please alert the doctor who is treating you and tell them that you are enrolled in a research study being conducted by Dr. Ellen Mitchell at the UPMC Eye Center – Children's Hospital.

What are my child's rights if they take part in this research study?
Taking part in this research study does not take away any other rights or benefits your child might have if they did not take part in the study. Taking part in this study does not give your child any special privileges. Your child will not be punished in any way if you or your child decides not to take part or if your child stops the study. Specifically, your child does not have to be in this study to receive or continue to receive medical care. If you stop the study, your child will still receive medical care for their condition.

Will I or my child be informed of any new findings?
You and your child will be told of any new findings or any changes in the study that may affect you or your child's willingness to continue in the study.

How will my child's information be protected in this research study?
Computer-based files will be accessed using passwords residing within the UPMC firewall and that whenever feasible, identifiers will be removed from study-related information for consistency with the protocol. Any information about your child obtained from this research will be kept as private as possible. All records related to your child's involvement will be stored in a locked file cabinet. Your child's identity on these records will be indicated by a number rather than by their name, and the information linking these numbers with their identity will be kept separate from the research records. Your child will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

Will this research study involve the use or disclosure of my child's identifiable medical information?
If your child is a patient, we may review their past, current, and future Ophthalmology medical record information, which includes their doctor's visit and any imaging or testing procedures. This will allow us to obtain information concerning their diagnosis, family history, what therapies they are being treated with, earlier eye testing, and previous surgeries. We will use this information to determine whether they meet the conditions for participation in this study and will keep this information for an indefinite period of time. Research records may be kept indefinitely but it is the University of Pittsburgh's policy to maintain the research records for seven years following final publication or completion of this study. We may continue to review their medical record information until you withdraw your permission or until your child turns 18 years old, at which time, they will be re-consented. We may use the information obtained from this study in other research studies examining new imaging devices. This information may also be shared with other researchers here, and at other research centers, but they will never be provided with any personal identifiers that would allow them to learn of your child's identity. We will protect your child's privacy and confidentiality as described below.

Who will have access to identifiable information related to my child's participation in this research study?
In addition to the investigators listed on the first page of this form and their research staff, the following individuals will or may have access to identifiable information (which may include your child's identifiable medical information) related to their participation in this research study.

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office and the Food and Drug Administration (FDA) are authorized to review research records (which may include your child's identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

These entities may review research records for the purpose of (1) fulfilling orders made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

In unusual cases, the investigators may be required to release identifiable information (which may include your child's identifiable medical information) related to their participation in this research study in response to an order from a court of law. If the investigators learn that your child or someone with whom they are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my child's participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, information (which may include your child's identifiable medical information) related to your participation in this research study for a minimum of seven years after final reporting or publication of the project.

May I have access to my child's medical information that results from my participation in this research study?
You are permitted access to information (including information resulting from your child's participation in this research study) contained within their medical records filed with your health care provider.

Is my child's participation in this research study voluntary?
Your child's participation in this research study is completely voluntary. If you do not provide your consent for the use and disclosure of your child's identifiable information for the purposes described above, your child will not be allowed to participate in this research study. Whether or not you provide your consent for their participation in this research study will have no effect on you or your child's current or future medical care at a UPMC hospital, affiliated health care provider, or with future health care insurance providers.

The investigator for this study is also an eye care provider at the UPMC Eye Center. It is possible that the investigator also treats your child as their patient. As both a medical doctor and a research investigator, Dr. Mitchell is interested both in your child's medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your child's study participation, you may discuss your child's care with another doctor who is not associated with this research study. Neither you nor your child is under any obligation to participate in any research study offered by their eye care provider.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study. Note, that if you withdraw your consent for the use and disclosure of your child's identifiable medical record information for the purposes described above, your child will also be withdrawn from further participation in this research study. Any identifiable research or medical information recorded for, or resulting from, your child's participation in this research study prior to the date that you formally withdrew your consent may continue to be used by the investigators for the purposes described above.

To formally withdraw your consent for your child's participation in this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first

page of this form. Your decision to withdraw your child from participating in this research study will have no effect on you or your child's current or future relationship with the University of Pittsburgh, UPMC hospital, or affiliated health care provider or health care insurance provider.

Are there reasons my child might leave this research study early?
Having your child take part in this research study is your decision. You may decide to stop their participation at any time. You should tell the researcher if you decide to stop and you will be advised whether any additional tests may need to be done for your child's safety.

If I agree to have my child take part in this research study, can they be removed from the study without my consent?
It is possible that your child may be removed from the research study by the researchers if, for example, they are unable to perform tests needed as part of our experiments, if your child does not follow the study rules, or if the study is stopped. Any identifiable research or medical information recorded for, or resulting from, your child's participation in this research study prior to the date that your child was withdrawn from participation may continue to be used and disclosed by the investigators for the purposes described above. In addition, the researchers at UPMC or the University of Pittsburgh Institutional Review Board may stop your child from taking part in this study at any time if it is in their best interest.

Voluntary Consent

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my child's rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form, I agree to have my child participate in this research study. Your signature also allows the use and disclosure of your child's medical information for participation. A copy of this consent form will be given to me.

_____

Participant's (Child's) Name (Print)

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____

Parent's or Guardian's Name (Print) Relationship to Participant (Child)

_____ _____

Parent's or Guardian's Signature Date & Time

Certification of Informed Consent:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date & Time

Assent

This research has been explained to me, and I agree to participate (for children 14-17 years of age or younger who may developmentally able to provide assent).

_____

Participant's (Child's) Name (Print)

_____ _____

Participant's (Child's) Signature Date & Time

Verification of Explanation

I certify that I have carefully explained the purpose and nature of this research study to the child subject in age appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e. assent) to participate in this study.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date & Time

Consent for Continued Participation

I am currently participating in a research study titled *Visual Information Restoration and Rehabilitation via Sensory Substitution Technology in Children*. Consent for my participation in this research study was initially obtained from my parent/guardian. I have now reached the age of 18 years and am able to provide direct consent for continued participation in this research study. I have had a chance to review the original consent document that my parent/guardian signed on my behalf and understand the research procedures that I am being asked to participate in during the remainder of the study.

I understand that I have the right to withdraw from the study at any time and that my decision to do so will not affect my care at UPMC Eye Center.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form I agree to continue my participation in this research study.

_____ _____

Participant's Signature Date & Time

Certification of Informed Consent

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of continued study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date & Time