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UNIVERSITY OF PITTSBURGH
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THIS STUDY

1.1 Study title: Clinical Trial to Evaluate Commercial Readiness for AAC-BCI IRB# STUDY24040169

1.2 Company or agency sponsoring the study:
National Institute on Deafness and Other Communication Disorders (NIDCD) NIH# 5SB1DC015142-05

1.3 Research Statement
You may be eligible to participate in a research study if you are currently receiving speech and language services from a licensed speech-language pathologist, using a speech-generating device (SGD) to meet daily communication needs, and want to trial a wearable brain-computer interface (BCI) device for communication. Initial training and evaluation sessions will be arranged. You will be asked to use the AAC-BCI device for ≥10 hours a week. Your opinions on the device, communication performance, and outcomes will be monitored each week, including a monthly home visit.

This form gives you important information about the research study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Please take time to review this information carefully. After you finish, you may use any method of communication to ask the researchers about the study. You may also want to have a conversation with your family or significant other about your interest in the study, and you may also wish to converse with others (for example, friends, or doctors) about your participation in this study. If you decide to take part in the study, you will be asked to give informed consent. Before a legally authorized representative or family member signs this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1.4 Research Summary

- The purpose of this study is to determine if a newly optimized augmentative and alternative communication (AAC) device with brain-computer interface (BCI) by Prentke Romich Company (PRC) - Saltillo is ready for commercial use. This clinical trial will evaluate the effectiveness of communication over time with PRC-Saltillo's AAC-BCI system and the peripheral electroencephalography (EEG) dry electrode headgear. In addition to the EEG and communication performance data being gathered, patient-reported outcome measures and user satisfaction data on usage, performance, reliability, and comfort will be collected.
- Duration: Up to six (6) months of in-home AAC-BCI device use for ≥10 hours a week. About twenty-four (24) weekly check-ins. Six (6) monthly monitoring sessions.
    - Initial interview and home visit to set up the AAC-BCI device
    - Up to three (3) training sessions to ensure the support person can set up and maintain the device, and access technical support
    - Weekly check-in sessions and completion of diary entries
    - Monthly monitoring visits by a PRC-Saltillo consultant with the option for the speech-language pathologist to attend
    - Completion of an exit survey and outcome surveys
    - You may withdraw from the study at any time

1.5 Reasonable, foreseeable risks or discomforts

- Risks and side effects related to the procedures include those which are:
    - Likely: fatigue, confusion, or frustration during the set-up of the device
    - Less likely: headache from watching computer screen or flashing lights
    - Rare but serious: possible seizure caused by flickering of computer screen

1.6 Reasonable, expected benefits

- There will be no direct benefit to you from participating in this study. However, this study may result in improvement to the standard of care for individuals with severe communication and significant movement impairments receiving AAC evaluations.

1.7 Alternative procedures to course of treatment

- If you decide not to participate in this research, your other choices may include:
    - Continuing AAC treatment and intervention without being in the study.
    - You receive no treatment.

2. INFORMATION ABOUT THE RESEARCHERS

2.1 Names, degrees, and affiliations of the researchers conducting the study:

Kendrea Garand, PhD, Associate Professor, School of Health and Rehabilitation Sciences, University of Pittsburgh
Jane Huggins, PhD, Research Associate Professor, Department of Physical Medicine and Rehabilitation and Department of Biomedical Engineering, University of Michigan, Ann Arbor

3. PURPOSE OF THIS STUDY

3.1 Study purpose: The purpose of this study is to determine if a newly optimized augmentative and alternative communication (AAC) device with brain-computer interface (BCI) by PRC-Saltillo is ready for commercial use. We are studying innovative clinical resources to improve the standard of clinical care for delivery of speech, language and AAC services available to individuals with minimal movement due to amyotrophic lateral sclerosis (ALS), brain stem strokes, severe cerebral palsy, and traumatic brain injury (TBI). We are asking anyone interested in alternative access methods who has severe speech and movement disorders who wants to use the AAC-BCI device to inquire about participation.

Anyone using the AAC-BCI device cannot set up the device or headgear and check that the device is reading brain activity correctly by themselves. They will need to appoint someone to act as the main system operator to ensure the device is functioning properly before starting to communicate, handle the maintenance after use, and follow the recommended troubleshooting procedures. You and the primary support person for the AAC-BCI device in the home will be involved in weekly check-ins and monthly visits to discuss how you are using the AAC-BCI and how you are meeting expected outcomes.

4. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

4.1 Who can take part in this study?

Individuals who:

- Have minimal to no natural speech which inhibits meeting daily communication needs requiring the use of a speech-generating device
- Are receiving speech therapy from a licensed speech-language pathologist
- Has been assessed for and is currently using a speech-generating device as a means of communication
- Has a diagnosis resulting in minimal movement interfering with direct selection to a keyboard or AAC display
- Has a support person who is comfortable with technology, is willing to learn a new technology system, and is available to set up the AAC-BCI daily at the user's request.
- In-home internet access
- Has access to an environment that is suitable for setting up the in-home AAC-BCI system
- You are age 14 years or older
- Primary language is English

People cannot take part in this study at all if:

- Do not own or use a speech-generating device
- Unable to participate during the scheduled time periods
- Has a history of photosensitive epilepsy
- Has a history of uncorrectable hearing loss
- Has a history of open scores on the scalp
- English is not their primary language

4.2 How many people (subjects) are expected to take part in this study?

We expect that 8 people will participate as users of an AAC-BCI device in the home.

5. INFORMATION ABOUT STUDY PARTICIPATION

5.1 What will happen to me at the in-home training part of this study?

Your support person and you will receive up to (3) training sessions on the AAC-BCI device that will last no more than 3 hours. A location will need to be arranged in your home to set up the AAC-BCI device and supplies; preferably a small table that is convenient for you to access prior to our arrival. During the training, your support person will learn how to fit you with the electrode headgear, confirm that the device is reading your brain activity and then you are independently able to use the AAC-BCI device to communicate. You will be trained on the basics of the communication software to start generating messages using the AAC-BCI. At the end of training, the researchers will compile a form to verify that your support person can set up the AAC-BCI device for you and knows the maintenance procedures and what to do, and with whom to talk to troubleshoot any problems. Your support person and you will be asked if you have any questions about training. The training visit will end by identifying the first in-home treatment visit.

When you use the AAC-BCI device, you will sit in a comfortable chair (or your wheelchair or bed) facing a computer screen. We will first put a dry electrode headgear on your head to pick up your brain activity (Figure 1). We will record your brain activity while you are using the AAC-BCI.

Figure 1: Dry Electrode Headgear

The study includes several different parts for trialing the AAC-BCI device:

Fitting of dry electrode headgear: Measurements of your head circumference will be taken to fit you with a dry electrode headgear. Once the headgear is in place, you will be asked about the fit and comfort. Adjustments to the headgear are possible if it feels too tight or too loose. After fitting the headgear, system calibration starts. At any time during testing, you may ask to have the headgear removed and the testing stopped.

System calibration (reading your brain activity): Everyone will be part of the system calibration part of the study. During system calibration, we will give you instructions about what to do. These instructions may ask you to do something like count the number of times that an item (e.g., a box or letter) on the computer screen flashes. If you have difficulty focusing both eyes together, we may cover one of your eyes with an eye-patch. We will record your brain activity while you follow these instructions. We will then calibrate the AAC-BCI so that it can be operated by your brain activity.

System Use: To use the AAC-BCI device for communication tasks, you will pay attention to the location of the item on the communication screen that you want to select. The AAC-BCI screen will "flash" the location in some way. For example, it may flash a box on top of the location or change the brightness of the location. When you pay attention to the flashes at one location and ignore those at other locations, the BCI can figure out which location you are paying attention to. It will then create a virtual mouse click at that location, operating the communication software. You will use the AAC-BCI device to perform several communication tasks, such as copying sentences or describing a picture.

If you **do want to trial** the AAC-BCI device in your home, then you will be asked to select a support person to sign the consent, and weekly check-ins and monthly home monitoring sessions will be arranged.

If you **do not want** to use the AAC-BCI device, then you will be referred back to standard speech-language and AAC clinical care services.

5.2 What will happen to me in the in home treatment part of this study?
We will ask you questions about how you have been using the AAC-BCI device and any SGD or AAC strategies you are using for communication. We will measure your performance by asking you to complete a copy spell and language sample task while video recording and collecting logfile data to analyze.

We will also ask you questions during check-ins regarding your perception on the level of effort to complete tasks, as well as your perspective on the level of burden, usability, comfort, satisfaction, and reliability of the system.

We will take a photo of your current seating, positioning and mounting preferences and make suggestions to improve your comfort if notable.

The monthly in-home visit also is a time to enhance your skills using more features of the communication software on the AAC-BCI device. You may ask about vocabulary features, taking photos, using the internet, using email, printing notes, and changing/modifying speech output.

5.3 What is the location for the study?

The monthly visits are in the home. However, video conference calls are possible upon request. At least four (4) of the six (6) sessions should be in-person.

5.4 How much of my time will be needed to take part in this study?

The AAC-BCI in home trainings are no more than 3 hours. In home visits will take no more than 2 hours. Weekly visits may be video conference calls.

The AAC-BCI device is recommended to be used for ≥10 hours a week.

5.5 When will my participation in the study be over?

After you have participated in six (6) months of in-home AAC-BCI device use for ≥10 hours a week, including the twenty-four (24) weekly check-ins and six (6) monthly monitoring sessions. The study will then conclude with an exit interview and outcome surveys.

At any point in time, you may decide to withdraw from the in-home training and treatment.

6. INFORMATION ABOUT RISKS AND BENEFITS

6.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks and what we will do about them are:

- *Risk*: There are no significant risks associated with recording of brain activity (called electroencephalography or EEG). EEG is used daily in hospitals and clinics all over the world including monitoring over days and weeks. EEG relies on electrodes set on the scalp that record changes in brain activity. The brain activity is recorded only. You should not feel anything unusual during the recording. The BCI system uses clinical-grade equipment. Thus, the study risk is no greater than the extremely small risk associated with routine clinical EEG recording.
    - *What we will do*: Our EEG recording equipment is tested on a regular basis in accordance with the safety policies of the University of Pittsburgh Health System.
- *Risk*: The electrode headgear holds the electrodes close to your head and may feel tight or cause a headache.
    - *What we will do*: We will readjust the Velcro straps for a more comfortable fit.
- *Risk*: Some people can get a headache or feel sick to their stomach from watching a computer screen or flashing lights.
    - *What we will do*: If this bothers you, we can adjust the color, brightness and speed of the flashing to make it less bothersome.

- *Risk:* Possible seizure caused by the flickering of the computer screen. Some people have seizures when they see lights or patterns flashing at certain speeds. However, the risk of having a seizure because of this experiment is no greater than the risk when you are watching television.
    - *What we will do*: If you have ever had a seizure caused by something you saw (a condition called photo-sensitive epilepsy), you should not be part of our study.
- *Risk*: You may experience fatigue, confusion, or frustration during the data collection process of the monthly monitoring sessions.
    - *What we will do*: You are permitted to take breaks during the sessions as needed. You are allowed to ask as many questions as needed for clarification to make the process as salient as possible.

As with any research study, breach of confidentiality is always an associated risk with data collection, and there may be additional risks that are unknown or unexpected.

6.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell Dr. Garand (listed in Section 11) about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your 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 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. You do not waive any rights by signing this form.

6.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

6.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study.

This study may result in improvement to the standard of care for individuals with severe communication and significant movement impairments receiving AAC evaluations, training to individuals and family support persons, and treatment monitoring. Also, the study may result in improvement to the features and functions of an AAC-BCI device**.** This study will also help us understand more about electrode headgear preferences and hardware options and how to make BCI access more efficient and effective. AAC-BCI devices may help people perform many activities using only brain activity beyond communication such as using a computer or controlling lights and the TV.

6.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

7. OTHER OPTIONS

7.1 If I decide not to take part in this study, what other options do I have?

Participation in this study is voluntary. You do not have to be part of this study if you do not want to. As an AAC-user, your family member or significant other will receive the standard of care for AAC treatment from a speech-language pathologist whether you decide to be part of this study or not.

8. ENDING THE STUDY

8.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell Dr. Garand listed in Section 11 "Contact Information" (below).

8.2 Could there be any harm to me if I decide to leave the study before it is finished?

No.

8.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are several reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

9. FINANCIAL INFORMATION

9.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There is no cost or direct billing to you for participation on this study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

9.2 Will I be paid or given anything for taking part in this study?

You will be compensated for your participation in this study. You will receive a payout of $250 upon completion of training sessions 1-3. You will receive another payout of $250 after the completion of the study.

Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or outside agencies may receive.

9.3 Who could profit or financially benefit from the study results?

The results of this study may help to improve the standard of AAC assessment, training and treatment care and benefit various AAC stakeholders providing SGD and alternative access methods along with individuals who benefit from AAC and family members.

10. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

10.1 How will the researchers protect my privacy?

The information collected about you during the study will be put into a research record. This research record will not show your name. Identifying information will be removed and coded. The only place your name will appear is on these signed consent forms and in a confidential list of coded identifiers that allow the information to be linked to you. This list will be kept either at the University of Pittsburgh (for those participating in Pittsburgh) or the University of Michigan (for those participating in Michigan or near PRC-Saltillo). However, this research record will be confidential, to the extent provided by federal, state, and local law. Information will be kept private. Brain activity data will be analyzed at the University of Michigan. Communication data will be analyzed at the University of Pittsburgh. Data transferred between sites will be labeled with the coded identifier. Data will be transferred using an encryption software. You will not be identified by name in any reports on this study.

10.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- Some of the data will be analyzed at the University of Pittsburgh. There are no identifiers shared with other researchers.
- Data (identified by code) may also be shared with our colleagues at PRC-Saltillo and University of Michigan since they are co-primary investigators in the study
- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.

- University, Food and Drug Administration (FDA), and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Pittsburgh accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

10.3 Clinically relevant research results

You will be notified of any results that might affect your personal health or decisions.

10.4 What happens to information about me after the study is over or if I cancel my permission?

Your permission will not expire unless you cancel it. The information collected will be added to our database of recorded EEG activity for use in future BCI development experiments. The communication tasks completed with the BCI will be added to our database of communication tasks with various access methods for use in future studies. These databases may be used for future, unspecified research.

Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Pittsburgh Health System, it is protected by the Health System's privacy policies. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

At some point, your identifiers might be removed from the private information and/or biospecimens. This de-identified information and/or biospecimens may be used by other researchers for future research studies. If this happens, we will not contact you for additional consent.

10.5 When does my permission expire?
Your permission will not expire unless you cancel it. You may cancel your permission at any time by writing to the researcher listed in Section 11 "Contact Information" (below).

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

11. CONTACT INFORMATION

11.1 Who can I contact about this study?
Please contact the researchers listed below if you want to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express concern about the study

Principal Investigator: Kendrea Garand
Mailing Address: 6017 Forbes Tower, Pittsburgh, PA 15260
Telephone: 412-383-6659

You may also express a concern about a study by contacting the Institutional Review Board listed below.
University of Pittsburgh Institutional Review Board
3500 Fifth Avenue
Hieber Building
Main Office, Suite 106
Pittsburgh, PA 15213
Main Phone: (412) 383-1480
Main Fax: (412) 383-1508

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Pittsburgh Conduct and Compliance Hotline at 1-866-858-4456 or www.pitt.alertline.com.

When you call or write about a concern, please provide as much information as possible, including the name of the Pitt researcher, the IRB number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

12. RECORD OF INFORMATION PROVIDED

12.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document.

13. SIGNATURES

FOR PARTICICANTS OVER 18

If you agree to participate, you must be given a signed copy of this document and a written summary of the research. You may contact Dr. Kendrea at 412-383-6545 any time you have questions about the research. You may also contact the Human Subjects Protection Advocate at the University of Pittsburgh Institutional Review Board at 1-866-212-2668 if you have questions about your rights as a research subject. Your participation in this research study is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop. By signing this document, it means that the research study has been described to you orally, and that you voluntarily agree to participate.

_____
Participant Name (Print)

The above-named individual is unable to provide direct consent for study participation because of the nature of their limited mobility and verbal communication skills. Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____
Representative's Name (Print) Representative's Relationship to Participant

_____ _____
Representative's Signature Date

_____ _____
Witness Signature Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the abovenamed 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, concerns, or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

PARENTAL PERMISSION FOR PARTICICANTS UNDER 18

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 about any part of this research study at any time. Any future questions will be answered by a qualified person or by an investigator 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 answered 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. A copy of this consent form will be given to me/my child.

_____

Printed Name of Child-Subject

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 and authorization. Therefore, by signing this form, I give my consent for his/her participation in this research study and provide my authorization for the use of his/her medical records.

Parent's or Guardian's Name (Print)_____

Relationship to Participant (Child): _____

Parent or Guardian Signature _____ Date:_____

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.

_____ _____

Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date