Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Interhemispheric communication and compensation

Principal Investigator: Benjamin Philip, Ph.D.

Research Team Contact: Summer Fletcher
314-747-7724

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION

This is a research study conducted by Dr. Philip having to do with how your brain controls movements of your left hand. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to spend about 4-5 hours. You will need to come to the East Building (4525 Scott Avenue) at Washington University School of Medicine. During that time you will be asked to complete surveys, movement tests, and MRI brain scans. The main risks to you if you participate are boredom, exhaustion, and muscle cramps from lying still in the MRI scanner.

We don't expect this study to benefit you directly, but it will help us understand how to help people who lose the use of their dominant right hand. By volunteering you may help someone else in the future. There is no cost to you, and you will be paid $110 for being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have a nerve injury that affects your dominant right hand.

The purpose of this research study is to help us understand how the brain controls movements of the left hand, and how this changes after injury. Ultimately, these results may help us improve rehabilitation for people who are forced to use their left hand after injuries to their right hand.

WHAT WILL HAPPEN DURING THIS STUDY?

During the course of this study, you will be asked to do the following things at Washington University in St. Louis School of Medicine:

1. Initial Surveys and Assessments. You will be asked to complete a few surveys and movement tasks. You will be free to skip any survey questions you would prefer not to answer.

- **1a.** You will complete a MRI screening to make sure it is safe for you to have an MRI.
- **1b.** You will complete surveys on your hand dominance and preference.
- **1c.** You will complete demographic and payment paperwork, for our records.
- **1d.** You will complete a survey on your injury affects your ability to live your life.
- **1e.** You will complete a brief interview about your nerve injury.
- **1f.** You will complete a movement task that involves picking up small objects.

2. Training. Inside and outside a simulated MRI machine, you will practice a drawing task on a tablet. This will help you get familiar with the task, and what it will feel like to be in a MRI scanner.

3. MRI. You will have a series of MRI scans. You will complete a task while inside the MRI machine.

- **3a.** Drawing Task. During some of the MRI scans, you will complete a drawing task on a tablet.

An MRI scanner takes pictures of the inside of your body by sending out a magnetic field and radio waves. Because the MRI scanner contains a very strong magnet, you may not be able to have the MRI if you have certain kinds of metal in your body (for example, from medical devices or a metal plate). Someone will ask you questions about this before you have the MRI.

The MRI scanner is a large machine that contains a hollow tube. You will be asked to lie on your back on a special table that slides into the tube. The sides of the tube will be fairly close to your body and the scanner makes a loud hammering noise while you are inside.

Although the research MRI exam is limited as compared to a clinical MRI, a radiologist will review your scan and inform you if there are any incidental findings.

4. Tests and Surveys. After the MRI, you will complete a few last tasks and surveys. You will be free to skip any survey questions you would prefer not to answer.

- **4a.** You will complete a Lego-building task.
- **4b.** You may complete a survey on the activities you enjoy.
- **4c.** You may complete surveys on your mood, pain, quality of life, and sleep.
- **4d.** You may complete an interview on how you use your hands in your daily life.

Research results obtained in this study will not be available to you or your doctor, or be put in your medical record.

Will you save my research information to use in future research studies?

We would like to use the movement, survey, and brain image data we are obtaining in this study ("research data") for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding nerve injuries, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your research data you give up any property rights you may have in the data.

We might remove identifiers from your private information and your research data and then use the information and your research data for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information or research data.

We will share your research data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

Your data will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

Please place your initials in the blank next to Yes or No for the questions below:

My data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**

Identifiers may be removed from your private information and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

Audio Recording/Video Recording/Photographs

This study involves making recordings of your movements and your voice. These recordings will allow us to review your movements in the future for careful study and measurement, and to take notes on your answers to interview questions. The recordings may be retained indefinitely. Video recording is necessary for us to evaluate your movements. A printed photo of your brain may be available at the end of your MRI scan. While this image is a real excerpt from your scan, it is not intended for medical use, diagnosis, or treatment

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 147 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately four or five hours. This normally happens in a single visit, though we may be able to split it into multiple visits if necessary for scheduling.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

MRI Scan

Common risks:

- discomfort inside the MRI scanner if you do not like to be in closed spaces ("claustrophobia")
- muscle stiffness from lying still
- muscle cramping caused by nerve stimulation
- tissue heating which may cause you to feel very warm

Rare risks:

- hearing loss due to the loud hammering noise from the MRI scanner
- sensation of flashing lights while in the MRI scanner
- burns that could be serious

During the procedure, you will be able to talk with the MRI staff through a speaker system. You will be given earplugs to reduce the risk of hearing loss. If you experience any of these symptoms and do not wish to continue, you can ask that the scan be stopped immediately.

Devices

If you have a device such as a pacemaker, bone hardware, cardiac stent, or device placed in your uterus there may be additional risks. We will review what device you have and inform you of

these risks. In general, these risks could be:

- heating or movement of the device
- device malfunction
- damage to the tissue that surrounds the device.

Exhaustion and Boredom

You may experience frustration and boredom completing the surveys and tasks. You may therefore decline to answer any questions that make you uncomfortable. Rest breaks will be provided and you can conclude your participation at any time.

Negative Feelings

It is possible that by asking you questions about how you're feeling, we may accidentally increase any negative or frightening feelings you may be having. If you appear to be at risk of depression or self-harm, we will provide resources to help you handle these feelings.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because will contribute new information that may be useful for improving the rehabilitation of people who lose the use of their right hand.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. Payment will be in gift cards or by check. Checks will be sent by mail and take approximately 4-6 weeks to arrive. The research team will provide information about any fees associated with the gift cards. In order to issue your gift card, we will ask for your name, address, phone number, and social security number (SSN). Your SSN will not be retained for research purposes. You may refuse to provide your SSN.

Payment will be $110. Additional travel reimbursement may be available if you do not have a car. If you withdraw from the study before entering the MRI scanner, you will receive $20 instead. Also, your compensation may be reduced if you split the study across multiple visits but fail to show up for later visits.

WHO IS FUNDING THIS STUDY?

The National Institute of Neurological Disorders and Stroke (NINDS) is funding this research study. This means that Washington University is receiving payments from NINDS to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NINDS for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Institute of Neurological Disorders and Stroke
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives, to complete Hospital or University responsibilities
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will assign a unique ID code for you. Confidentiality will be maintained through the use of password-protected computer files on a secure network. To help protect your confidentiality, all testing will occur in a private room. All paper documents will be kept in a locked cabinet in a locked office. Only members of the study team will have access to subject identifiers.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

CAN WE CONTACT YOU BY EMAIL?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- To provide a copy of this signed consent form for your records
- Appointment scheduling and study information
- Links to study surveys
- Follow-up to a question or adverse event

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at

https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Summer Fletcher, 314-747-7724, ot-neurolab@wustl.edu. If you experience a research-related injury, please contact: Summer Fletcher, 314-747-7724, ot-neurolab@wustl.edu.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

_____	_____
(Signature of Participant)	(Date)
_____	
(Participant's name – printed)	

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)