Consent Form to Participate in a Research Study
University of Oklahoma Health Sciences Center (OUHSC)

Study Title: Targeted HD-tDCS for reducing post-stroke movement impairments

Sponsor: Oklahoma Shared Clinical and Translational Resources (NIH NIGMS U54GM104938)

Principal Investigator: Yuan Yang

Phone Number: 918-660-3290

KEY INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to participate in a research study. Research studies are voluntary and include only people who choose to take part. This consent form begins with a 'Key Information' section to provide important information to help you decide whether or not to participate in this study. More detailed information is provided after the key information. Please take your time, discuss this with family and friends, and ask the investigator and study team any questions you may have.

WHY HAVE I BEEN ASKED TO PARTICIPATE IN THIS STUDY?
You are being asked to participate in this research study because you are a survivor of a stroke.

WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?
The purpose of this study is to:

- Describe abnormal movement patterns in the impaired arm of stroke survivors
- Reveal the change in the central nervous system and nerves in your extremities after a stroke
- Test how non-invasive brain stimulations may change the way nerve signals travel and affect the movement functions after a stroke.

We think that you will be in the study for up to 7 weeks with 3 visits.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?
If you decide to participate in this study, you will be asked to visit the lab 3 separate times to participate in an exploratory clinical research study in the University of Oklahoma Health Sciences Center. Participation in this study, as defined below and will last up to 3 hours including preparation and resting time if necessary. You will receive clinical movement and sensory assessments, non-invasive muscle (EMG) and brain (EEG) activities measurement, and non-invasive brain stimulation.

WHY MIGHT I WANT TO PARTICIPATE IN THIS STUDY?
If you are a stroke survivor and you participate in this study, possible benefits include an improved ability to determine how to control your arms during movement tasks. Benefits may not continue after the research has ended. The possible benefits to others include an enhanced understanding and treatment of movement disturbances following a stroke.

WHY MIGHT I NOT WANT TO PARTICIPATE IN THIS STUDY?
This is a basic neuroscience study that aims to understand the changes in the brain after a stroke and how non-invasive brain stimulation may potentially facilitate motor recovery. It will not provide you with any healthcare you may need at this moment. If you're seeking a diagnosis or a treatment, you might not want to participate in this study. You may want to discuss your participation with your physician before enrolling in this study if you have any concerns.

The researchers do not know all of the side effects that could happen. For a complete description of known risks, refer to the Detailed Information section of the consent form.

WHAT OTHER OPTIONS ARE THERE?

- You may choose to only participate in one session of this study if you don't want to participate in a complete study.
- You may choose not to participate in this study.
- You may choose to be included in our database for a future study if you don't want to participate in the current study.

Feel free to discuss with us about these and other options.

HOW WILL PARTICIPATING IN THE STUDY AFFECT ME FINANCIALLY?

There is no cost to you if you participate in this study.

If you agree to take part in this research study, we will pay you $50 (cash or checks) per visit to compensate for your time and travel.

DETAILED INFORMATION ABOUT THE RESEARCH STUDY

The following pages of the consent form will provide you with more information about this study. Please take your time in reviewing this information and ask the investigator and study team any questions you may have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 50 people will take part in this study at the University of Oklahoma Health Science Center.

WHAT IS THE STATUS OF THE DEVICE USED IN THIS STUDY?

- *Transcranial Direct Current Stimulation (tDCS)* is approved by the US Food and Drug Administration for other treatments, but is not approved for the disease in this study, so it is considered investigational in this study.

WHAT IS INVOLVED IN THE STUDY?

You will be asked to come to the OU Physician Neurology Clinic 825 NE 10th Street Oklahoma City, OK 73104 or College of Allied Health located at 1200 N. Stonewall, Oklahoma City, OK 73117 based on the availability of the site.

This study has three visits and will include non-invasive brain stimulation and pre/post-stimulation assessment per visit. The total time per visit will last up to 3 hours including the preparation and resting breaks. In each visit, a standard clinical assessment (i.e., Fugl-Meyer Motor Assessment – Upper Extremity Portion Only, Modified Ashworth Scale, Nottingham Sensory Assessment, and its revised versions) will be performed before the start of the experiment. In this standard clinical screen, we may ask to do some simple movements such as touch your mouth, lift your arm, etc. We may also touch you with some items that are used daily, such as a pen, coin, etc. while you are required to keep your eyes closed and tell us what the item is. After that, your muscle (EMG) and brain activities (EEG) will be measured and followed by non-invasive brain stimulation. We will re-assess your movement ability via Fugl-Meyer Motor Assessment – Upper Extremity Portion Only, Modified Ashworth Scale, and EMG and EEG after the brain stimulation. The detailed information about movement assessments, EMG, EEG and non-invasive brain stimulation are provided below.

Movement Assessments: Your arm(s) either will be moved by a researcher(s) to assess your movement function or impairments. You will be asked to lift your arm up to reach a specified amount of

force production. Simultaneously, you may receive oral instructions or instructions on the screen to encourage the performance of desired movements. Upon completion of the movement, you may be asked to respond with how you perceived the movement (e.g., How difficult it was). A minimum of three movements will be collected for both arms. The non-invasive electrical muscle activity (electromyography, EMG) may be recorded during the movement to assess muscle function.

EMG: surface electrodes (i.e., non-invasive electrodes applied to the skin) will be placed on up to eight-arm muscles in your upper arm to assess your muscle functions. Markers may be placed at several locations along your arm to allow for tracking of your arm's location.

EEG: Your brain electrical activity (EEG) will be measured from your scalp via gel-based non-invasive electrodes. After you are familiarized with the equipment, a cap consisting of multiple EEG electrodes with gel in them will be placed on your scalp and a few electrodes with gel in them will be placed on your back. The electrodes will be connected to a data collection system and EEG signals will be collected and stored onto a computer. Two EEG sessions per visit for pre- and post-stimulation assessments. EEG will be recorded when you're at rest and you're doing some movement tasks such as moving your arm as directed by the investigator. There will be between 16-64 leads placed on your scalp.

Non-invasive brain stimulation. You will receive non-invasive brain stimulation via transcranial direct current stimulation (tDCS), which applies a small electric current to selected regions of the brain through electrodes placed directly on the scalp. The transcranial magnetic stimulation (TMS) may be used to find the locations in your scalp for placing tDCS electrodes and will be used as a diagnostic tool to assess your neural function.

To ensure that the tDCS/TMS procedure in this session will be safe, you will first be asked to fill out a screening form prior to participation. It is important that you tell the researcher(s) in this study if you have any history of:

- Metal fragments in your head
- Implantation of any electronic devices such as (but not limited to) cardiac pacemakers, cardiac defibrillators, cochlea implants, or nerve stimulators
- Migraines or ongoing severe headache with unknown reasons
- Scalp or skin conditions (e.g., psoriasis or eczema)
- Epilepsy or seizures
- Any adverse effects to previous tDCS, TMS or any other types of brain stimulation.

During tDCS, your brain will be stimulated via non-invasive electrodes. tDCS is a minimal-risk technique that passes a small electric current across your scalp to stimulate your brain and temporarily affect the activity of specific muscles. During testing, small sponges that have been soaked in saline (saltwater) or gel-based electrodes will be placed at specific locations on your scalp. During the stimulation, you may feel a slight tingling sensation or a sensation of warmth on your scalp which often fades during the session and will rapidly disappear once stimulation has stopped. The tDCS session may be done during a movement exercise or while recording electrical activity from your head via a gel-based electrode or your hand, wrist, elbow, and shoulder muscles with surface electrodes.

We may ask you to participate in future research as a result of your participation in this study. You do not have to agree to participate in future studies in order to participate in this study.

WHAT ARE THE RISKS OF THE STUDY?

In addition to the risks described in the Key Information section, you may also be at risk for the following side effects.

Surface electrodes: The self-adhesive surface of the EMG electrodes and stimulator electrodes may produce minor irritation of the skin; there is also the possibility of an allergic reaction to the electrode

paste. The possibility of irritation will be minimized by cleaning the skin with alcohol before and after the application of the electrodes.

EEG Cap: To hold the EEG electrodes on your scalp, a cap with a strap around the chin will be used. You may find the cap uncomfortable when having it on your head. We will place cotton or foam underneath the cap to minimize this side effect. There is no known risk in performing an EEG recording on human subjects.

Reaching movements: Although the movements of your arm will not meet or exceed your elbow's normal range of motion, repeated motions may cause minimal temporary discomfort in your arm by the end of the study session. We may do the stretching or massaging of your arm prior to and following the experiment to eliminate this potential discomfort.

Transcranial Direct Current Stimulation (tDCS): It is expected that you will experience a slight tingling sensation or a sensation of warmth during the stimulation. Additionally, it is possible that you may experience a mild, brief headache, redness of the skin under the sponges, fatigue, dizziness, or nausea after participating in the experiment, but all sensations will fade soon after completing the experiment. You are free to withdraw at any time during the tDCS procedure.

IN CASE OF PREGNANCY:
Due to the known effect of tDCS on pregnant women we will not include pregnant women in the current study. If you could become pregnant during this study, you must talk to the study doctor about the birth control you will use to avoid getting pregnant during the study or withdraw from this study. It is your responsibility, and for your safety, to check it and disclose this information to us if necessary. We will perform a pregnancy test on you for your safety if you request or if the study doctor thinks this is necessary.

Acceptable methods of birth control (continuing throughout the study) include:

- An approved oral contraceptive (birth control pill)
- Intra-uterine device (IUD)
- Hormone implants
- Contraceptive injection (Depo-Provera)
- Barrier methods (diaphragm with spermicidal gel or condoms)
- Transdermal contraceptives (birth control patch)
- Vaginal contraception ring (birth control ring)
- Sterilization (tubal ligation, hysterectomy, or vasectomy)

For more information about risks and side effects, ask the researcher.

TO WHAT EXTENT WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for the use or sharing of your protected health information if necessary.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations may include the listed study sites, the US Food & Drug Administration (FDA), and other regulatory agencies, such as the National Institutes of Health (NIH) and the American Heart Association (AHA). The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, OUHSC Office of Compliance, and other

University administrative offices may also inspect and/or copy your research records for these purposes.

Certificate of Confidentiality:
To help protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. government that is used for checking or evaluating federally-funded projects or for information that must be disclosed in order to meet the requirements of the US Food and Drug Administration.

The protection offered by the Certificate of Confidentiality does not prevent us from being required by applicable state law to report information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The Certificate, however, does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. This means that you and your family should actively protect your own privacy.

If you are enrolled in the study after the expiration or termination of the Certificate, the protection afforded by the Certificate as described above will not apply unless the study is funded by NIH.

Storing and Sharing Your Information:
The data collected from you may be used for future studies without your additional consent. We will remove direct identifiers from your data and assign a code. The key to this code will be kept separately and only the researcher for this study will have access to the code. If your data is shared with another investigator for research purposes, they will not have access to the key code and will not be able to re-identify you.

CAN I WITHDRAW FROM THE STUDY?

You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your referring doctor first.

There may be circumstances under which your participation may be terminated by the investigator without your consent. The examples may include but are not limited to:

- The investigator feels that it is in your medical best interest.
- Your condition worsens or your new condition makes you no longer qualified for this study.
- New information becomes available.
- You fail to follow the study requirements.
- The study is stopped by the sponsor.

WHAT IF I AM INJURED OR BECOME ILL WHILE PARTICIPATING IN THIS STUDY?

In the case of injury or illness results from this study, you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

You or your insurance may be charged for this treatment.

Complications arising as a result of the natural progression of an underlying or pre-existing condition will be billed to you or your insurance. Please check with the investigator or with your insurance company if you have questions.

No other funds have been set aside by the University of Oklahoma Health Sciences Center, University of Oklahoma, and Laureate Institute for Brain Research, to compensate you in the event of injury, illness, or for other damages related to your event of injury or illness.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time. You may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

We will provide you with any significant new findings developed during the course of the research that may affect your health, welfare, or willingness to continue your participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

If you have questions, concerns, or complaints about the study or have a research-related injury, contact Dr. Yuan Yang (Principal Investigator) at 918-660-3290 (call only) M-F 9:00 am to 5 pm or 312-721-3622 (text only) after the working hours. You can also contact Dr. Evgeny Sidorov (Co-Principal Investigator and chief study doctor) at his research office: 405-271-4658 (M-F 9:00 am to 5 pm). Alternatively, in case of emergency, you can have Dr. Sidorov paged at 405-271-5656 after working hours. If you're seeking a diagnosis or treatment, please contact your physician. If this is a medical emergency, please dial 911 without a delay.

If you cannot reach the Investigator or wish to speak to someone other than the investigator and for questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection, at 405-271-2045.

Others:

There may be security camera monitoring and/or recording in buildings and/or labs in our study sites for security and safety purposes. Please understand that these recordings are not managed by our research team and these recordings will not be used in our research. Research-related recordings are explained in optional elements and will need your agreement to conduct them.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may audio or video record me (which is different than the security camera monitoring/recording mentioned above) to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although all videos will be de-identified by adding a face cover to the subject's image. I understand the risks associated with such identification.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies as a result of my participation in the current study.

SIGNATURE:

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18)	**Printed Name**	**Date**
_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**