Official Title: TRANScranial Direct Current Stimulation for POst-stroke Motor Recovery - a Phase II sTudy (TRANSPORT 2)

NCT: NCT03826030

IRB Document Date: 7/3/2023

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: TRANScranial direct current stimulation for POst-stroke motor Recovery - a phase II sTudy (TRANSPORT2)

Performance Site Principal Investigator: Dr. Jody Feld

Performance Site: Duke University

Participant Name(Print): _____

Telephone Number: _____

If applicable,
Legally Authorized Representative Name(Print):_____

Telephone Number: _____

INTRODUCTION

The study doctor wants to know if you would like to be part of a research study. This informed consent document contains important information about the research.

If you have any questions about or do not understand something in this document, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

If you are acting as a representative to give consent for another person to participate in this study, “you” throughout this consent document refers to that individual.

The obligation of a representative is to try to determine what the individual would do if competent, or if the subject's wishes cannot be determined, what the representative thinks is in the person's best interest. If possible, an attempt should be made to obtain permission from the individual. Some persons may resist participating in a research

protocol that has been approved by their representatives. Under no circumstances may individuals be forced to participate.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are 18 to 80 years old. You had an ischemic stroke between 1 and 6 months ago. An ischemic stroke is caused by a clot in a blood vessel that blocks blood flow to a part of the brain. You have arm weakness as a result of the stroke.

WHY IS THIS RESEARCH BEING DONE?

tDCS in combination with mCIMT is considered investigational for the treatment of your arm weakness. The effectiveness of this approach has not been established.

This research is being done to find out if brain stimulation combined with a rehabilitation therapy improves your arm weakness. The stimulation technique is called transcranial direct current stimulation (tDCS). The treatment uses direct electrical currents to stimulate specific parts of the brain. The rehabilitation therapy is called “modified Constraint Induced Movement Therapy” (mCIMT). During this therapy you will wear a mitt on the hand of your arm that was not affected by your stroke. It is designed to restrain the use of your good arm, while performing therapy with impaired one.

It is not known if brain stimulation combined with rehabilitation therapy will improve your arm weakness. You will receive rehabilitation therapy while on this study. You may or may not receive the brain stimulation therapy.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately 3.5 months.

The researcher may decide to take you off this research study at any time. The research team may end your participation in this study if you do not follow instructions and miss scheduled visits, if your safety and welfare are at risk, or if the study sponsor decides to stop the study.

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first so that stopping can be done safely. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

If you become ill during the research, you may need to stop study treatment, even if you would like to continue. The research team will determine if it is not possible for you to

continue. This decision would be made to protect your safety and welfare. You will still be able to continue with study visits to check on your progress.

If you withdraw or are removed from the study, the reasons for study exit will be discussed with you and all questions will be answered. You will not be required to undergo any procedures to exit the study.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is funded by the National Institute of Neurological Disorders and Stroke.

The local investigator for the study is: Dr. Jody Feld, Duke University

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 129 people will take part in this study at up to 15 sites. Up to 50 people may take part at our site, Duke University.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

You will have the following tests and procedures:

Screening/Baseline visits: (about 3 hours in duration):
If you provide informed consent to participate in this study, the researcher will determine if you are eligible to be in this study at this visit.

At this visit we will collect your demographic information and medical history. We will perform several tests to evaluate your brain function. Your vital signs (blood pressure, heart rate) will also be taken. You will also perform several activities to test your arm strength and function.

Randomization visit:
(up to 5 hours in duration, may be divided into several visits):

You will be asked to perform activities to test your arm strength and function. If some of these results do not match the results from your screening visit, you may be rescheduled for another visit about 2 weeks later to test this again. If the results are not the same, you will not be able to be in the study.

If the results match the results from your screening visit, you will undergo a Magnetic Resonance Imaging (MRI) scan of your brain. The MRI will either be done on the same day or on another visit. This will tell us the degree and extent of injury to your brain from

the stroke. If an MRI can not be obtained, a previous scan, from your medical record, maybe used.

You will also undergo Transcranial Magnetic Stimulation (TMS) to tell us how well your brain and arm talk to each other. The TMS will either be done on the same day or at another visit. During the procedure you might experience a clicking sound and a mild jolt-like sensation. There may be a muscle twitch in your hand/arm. Additional details on the procedure are described below.

If you are able to be in the study, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group completely by chance. It is like flipping a coin.

- Group 1: inactive tDCS + mCIMT
- Group 2: tDCS (low dose) + mCIMT
- Group 3: tDCS (high dose) + mCIMT

Neither you nor the researcher conducting this study will know or choose what group you will be in. You will have a 1 out of 3 chance of being placed in any group.

Intervention visits (10 visits over 14 days, about 3 hours per visit):

At these visits you will undergo the investigational study interventions.

If you were randomized to the active tDCS treatments, you will receive 30 (± 6) minutes of active tDCS at certain dose level.

If you were randomized to the inactive tDCS, you will undergo 30 (± 6) minutes of inactive tDCS.

Two pads will be put on your head, they will be connected to a device to provide very low electric current, you may not feel or you may feel itching or tingling with your scalp. This constant low electric current may stimulate the brain.

You will receive 120 (± 24) minutes of mCIMT therapy.

The details of these procedures are described below.

We will also monitor your blood pressure and heart rate.

You will be asked to complete a questionnaire about your experience with tDCS.

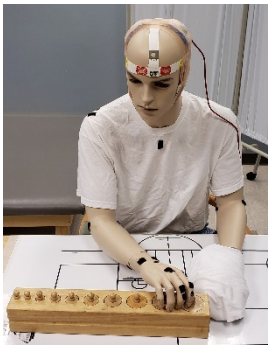
On the last intervention visit, you will be asked to guess to which study group you were assigned.

You will be videotaped for the first couple of sessions for the quality control purposes.

Follow-up visits (3 visits, about 2 hours per visit):

Study staff will ask you to perform various activities to assess your arm strength and function. There will be 3 follow-up visits; the first visit will happen several days after the intervention ended, on this visit, you will get another MRI scan and TMS assessment; the second visit will happen approximately 30 days after the intervention ended; and the last visit will happen approximately 90 days after the end of intervention. You will be videotaped during this assessment for quality control purposes.

DESCRIPTION OF PROCEDURES



Transcranial direct current stimulation (tDCS)

tDCS is a non-invasive, painless brain stimulation treatment that uses direct electrical currents to stimulate specific parts of the brain. A constant, low intensity current at 3 different levels is passed through two electrodes placed over the head which modulates neuronal activity. The picture on the right shows an example of a tDCS set-up. The local specific set-up may slightly vary from this picture.

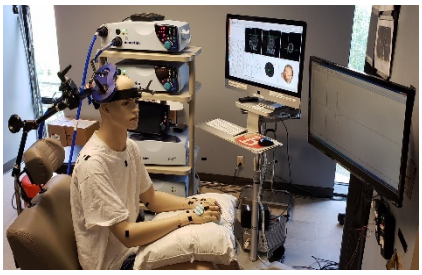
Magnetic Resonance Imaging (MRI)

MRI uses a strong magnet to make images of the brain and the blood vessels. MRI does not involve x-rays. The MRI scanner is a large machine with a hole, or tunnel, in the center. You will lie on a table that slides into and out of this tunnel. You will hear tapping noises from the MR scanner. To protect your hearing, you will be provided with earplugs or headphones to wear.

If you experience any other discomfort, you can tell your research team member or the scanner operator (via the intercom) and the scans will be stopped. A little microphone and a loudspeaker are placed inside the MR scanner so that you can talk to the operator at any time. Also the operator will inform you during the examination about the progress of study. The MRI scan will take about 20 minutes. The picture on the right shows an example of an MRI scan.

Transcranial magnetic stimulation (TMS)

TMS is a noninvasive procedure that uses magnetic fields to stimulate cells in the brain. During the TMS session, an electromagnetic coil is placed against your scalp near your forehead. The electromagnet painlessly delivers a magnetic pulse that stimulates cells in your brain. The picture on the right shows an example of a TMS set-up. The local specific set-up may slightly vary from this picture.



modified Constraint Induced Motor Therapy (mCIMT)

mCIMT involves intensive training of the weaker arm while restricting the use of the good arm. Specifically, the use of the stronger arm is restricted by the use of a mitten. The mitten is worn to encourage you to use your weaker arm and hand to do everyday tasks. In addition, the therapist will do exercises with you and give you exercises to do on your own or with a family member or friend. In addition to wearing the mitt at the intervention visits, you will also be asked to wear the mitten on your good hand for at least 6 hours a day at home and perform various tasks. The idea is to encourage you to use your weaker hand to do daily activities.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Principal Investigator and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Principal Investigator or research study staff to reschedule as soon as you know you will miss the appointment.
- If we are unable to reschedule your study appointments, we will continue to contact you by telephone to determine if you are willing to continue in the study.
- Tell the Principal Investigator or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Ask questions as you think of them.
- Tell the Principal Investigator or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the Principal Investigator of each study. This is to protect you from possible injury arising.

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WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

You will not change your regular medical care for this study. Participation in this research involves the following risks:

- **Risk of tDCS:** Many research studies on animals and humans have shown that the currently used tDCS protocols are likely safe, tolerable and involve minimal risk, although data is limited for the high dose group. Commonly reported side effects are: local skin irritation (itching, tingling, and a warming sensation) and skin redness under the electrode. They typically go away within minutes. Skin injury is a very rare side effect (1 out of 1000). Theoretical risks at high dose group might involve second degree skin burns or clinical seizures, but these risks were not observed in the Phase 1 safety study.
- **Risk of MRI:** There are no known major risks with an MRI scan. But, it is possible that harmful effects could be found out in the future.

  Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan.

  The MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

  It is very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator.

  You may experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful.
- **Risks of TMS:** The hand or facial twitching you may experience with TMS therapy is not expected to be painful. You may experience a mild headache but it does not last long. If you have pacemakers, medication pumps, cochlear prostheses or ear implants or other implantable devices, you will not be allowed in this study as there could be a risk of injury to you. Magnetic media, such as credit cards, and watches near the coil may also be damaged. You will be asked to remove these items before TMS is applied.
- **Risks of mCIMT:** The common side effects are muscle fatigue or achiness or discomfort which is a normal response of exercise, and they usually disappear

overnight with rest. You are allowed to have small breaks within the 120 minute therapy session.

- **Risks of assessments:** Assessments may occasionally cause fatigue; however; the investigators have the option to adjust the pace of their assessments and give you small breaks as needed to complete the tests.

Because some visits might last for 2 hours or more, study participation also carries the potential risk of general fatigue. We will always try to be sensitive to this possibility, and offer a short break, a light snack, water or a bathroom break as needed. Of course, you can request any of these at any time.

As part of study participation, information about you (such as video recordings of some sessions) will be collected and retained on paper and/or stored in computer files. Great care will be taken to safeguard all forms of such information, for example using locks for files with paperwork and using passwords for computer files on secured servers. However, the possibility remains that a determined thief might try to steal information. Thus, one risk of study participation is that information about you could be stolen. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Research study staff will closely monitor you during the therapy sessions and help to prevent or minimize any side effects. If at any point you feel too uncomfortable, please inform the research study staff about this and they will determine how to proceed. They may consult with the Principal Investigator for further directions.

There may be unknown or unforeseen risks associated with study participation.

WHAT ARE THE REPRODUCTION RISKS?

Potential effect of MRI, TMS and tDCS and on pregnancy is unknown. If you are a woman capable of becoming pregnant, you must agree to use adequate birth control, see list below. All women of child bearing potential will be given a urine pregnancy test to verify that you are not pregnant before receiving MRI or TMS or tDCS.

Use of acceptable birth control includes one of the following: oral hormonal contraceptives; implanted hormonal contraceptives (intramuscular progesterone injections); diaphragm with spermicide; condoms; intra-uterine device; and abstinence.

If you are currently pregnant or become pregnant while you are part of this study, let your study team know as soon as possible so that no additional interventions are performed.

Oral hormonal contraceptives that contain estrogen are not safe for women who have had an ischemic stroke. Only hormonal method that contain only progesterone (progestin-only pills, implants, or injections) are considered safe.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there may be a direct benefit to you because you will receive the mCIMT by participating in this study. Potential benefits to you may include improvement in arm strength and function. There may or may not be an added medical benefit to you from the use of tDCS.

We hope the information learned from this research study will benefit other patients with arm weakness as a result of a stroke in the future.

WHAT OTHER CHOICES FOR CARE ARE THERE?

The alternative to participating in this research trial would be to receive standard of care.

WHAT IS THE CLINICAL TRIALS REGISTRY?

A description of this clinical trial will be available on http://www.clinicaltrials.gov , as required by U.S. Law. ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide not to participate, you do not lose any benefits to which you would otherwise be entitled. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

You will be told of any important new information that is learned during the course of this research study, which might affect your health, welfare or your willingness to continue participation in this study.

Nothing in this consent document waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent document.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

There will be no cost to you to be in this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be paid $75 for each visit for your time and travel costs (including parking) related to taking part in this study. If the cost of travel is greater than $75 for each visit, there may be additional assistance available for participants that travel 100 miles round trip or an excessive amount of travel time to get to their visits. This amount will not exceed $500 additional reimbursement for the duration of your study involvement.

Reimbursement will be made by debit card. Please note that it may take up to two weeks after each visit for the payment to be loaded onto the debit card and become available for use. Do not discard or toss out the debit card over the course of the study. The same card will be used to reimburse you for the duration of the study visits.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual exceeds $600 in any one

calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator. Your hospital or physician's office will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance. If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs.

You do not waive any liability rights for personal injury by signing this form.

Duke University has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier outside of NIH StrokeNet. Your research records may be disclosed outside of Duke University, but in this case, you will be identified by a unique code number. This information will be kept in a secure location and access limited to research study personnel. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authorization to Use Your Health Information for Research Purposes

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. Researchers covered by this

regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you.

If you sign this informed consent document, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this document. However, if you do not sign this document, you will not be able to participate in the study.

Who Will Use and Disclose My Health Information? The study doctor and research staff (the study team) may use your health information to conduct, review, and determine the results of the study. The study team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication without your permission.

What Health Information will be Used and Disclosed? The study team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study on study forms. The study team will send the completed study forms to the study sponsor. Representatives from the groups identified below may need to look at your medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Your medical records may include other health information about you and may include documents that directly identify you. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

Who Will Receive My Health Information? Your study information or medical records (as described above) or both may be shared with the following people or groups:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services.
- The funder of this research, National Institute of Neurological Disorders and Stroke.
- The representative of companies/Institutions working on the study on behalf of the Sponsor may have access to, inspect and review your information during and after the study for verification of clinical and scientific research procedures and/or data.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study.
- Other collaborating institutions.

- The results of imaging studies may be disclosed to outside institutions, not directly involved in this research study, as part of a collaborative imaging project. Your name and other identifying information will not be disclosed.
- Department of Health and Human Services (DHHS) agencies.
- The StrokeNet Central Institutional Review Board and any other committees responsible for overseeing the research.
- StrokeNet Central Institutional Review Board Human Research Protection Program staff.
- The StrokeNet National Data Management Center (NDMC), housed in the Data Coordination Unit (DCU) in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC).

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others? Duke University is required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. The goal of any such research would be to learn more about drugs, devices or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services.

What Happens if I Leave the Study Early? If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

Will My Authorization Ever Expire? This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

May I Take Back My Authorization? You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose information is listed on the front of this document. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected

information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

May I Look At My Study Information? You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make medical or billing decision about you (e.g., if included in your official medical record).

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study. Please initial your selection below.

____I **want** the researcher to inform my primary care physician/specialist of my participation in this study.
____I **do not want** the researcher to inform my primary care physician/specialist of my participation in this study.
____I do not have a primary care physician/specialist.
____The researcher is my primary care physician/specialist.

Who Can Answer Your Questions?

If you have questions, concerns, complaints and or suggestions about this research study or to report a research-related injury, please contact the Principal Investigator: Dr. Jody Feld (919) 681-1979 (office) or (919) 802-3053 (cell).

You can also call the StrokeNet CIRB at 513-558-5259, Monday-Friday 8AM--5PM EST if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research, cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

Investigator Information:

Duke University
Local Site Name

Dr. Jody Feld (317) 217-0337
Local Principal Investigator Name Telephone Number 24 hr Emergency Contact

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated document for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

I give my consent to participate.

_____
Signature of participant Date

_____
Print Name

Or

_____
Signature of legally authorized representative Date

_____ _____
Print Name Relationship to Participant

Person Obtaining Consent
I attest that the requirements for informed consent for the medical research project described in this document have been satisfied – that the participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent document, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____
Signature of Person Obtaining Consent Date

_____
Print Name

WITNESS STATEMENT:

The participant was unable to read or sign this consent document because of the following reason:
___The participant is illiterate
___The participant is visually impaired
___The participant is physically unable to sign the consent document. Please describe:

_____

___Other (please specify):

_____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____ _____
(Date) (Printed Name of Witness)

_____
(Signature of Witness)

_____ _____
(Date) (Printed Name of Individual Obtaining Consent)

_____
(Signature of Individual Obtaining Consent)