e-Consent and HIPAA

NCT02743728

Title of Research Study: Perinatal Stroke: Understanding Brain Reorganization through Infant Neuroimaging and Neuromodulation

Investigator Team Contact Information:
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?
Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study. The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because your child is 5 years old or younger and has a history of stroke or brain bleed, and your child has previously participated in research study assessments in the Gillick Lab.

What should I know about a research study?

Someone will explain this research study to you. Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you. You can ask all the questions you want before you decide.

Why is this research being done?

Stroke in infants occurs in 1 in 2,300 births. Some babies with stroke or bleeding in the brain are at risk of developing limits in movement and activity. To provide early therapies for these infants at a time when the brain is still developing, we first need to understand changes to the brain after a stroke and the long-term outcomes of these changes. This research is being done to learn about how the brain develops after a stroke or bleeding in the brain in order to promote earlier detection of cerebral palsy and to develop early interventions to improve outcomes for children with this diagnosis.

How long will the research last?
We expect that you will be in this research study for one day, with one virtual visit lasting less than one hour.

What will I need to do to participate?
You will be asked to respond to several questionnaires about your child's development and to give permission for the research team to access your child's medical records. The research team member will guide you through the questionnaires on a video call using the Zoom platform. The Zoom call will take less than one hour.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?"

Is there any way that being in this study could be bad for me?

We will be collecting Protected Health Information about your child as part of this study. There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, we hope that your participation will help us to better understand early brain changes in infants with perinatal stroke, and also help develop future interventions to improve brain function.

What happens if I do not want to be in this research?

Your participation in this study is voluntary. There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?
We expect about 10 people will be in this research study.

What happens if I say "Yes, I want to be in this research"?

We will ask you to sign a form that allows us to access your child's medical records. For this study, we would like to access the following information, as applicable to your child. We will only access information that you give us permission to access.

Diagnosis of any medical conditions, such as cerebral palsy Recent movement or developmental assessments Types and amounts of rehabilitation therapies received Speech, cognition, or sensory assessments Surgeries or major medical procedures Recent imaging We will also ask you (the parent/legal guardian) to participate in a virtual visit using the secure video conferencing platform Zoom. Your child will not need to be present during this call. The Zoom call will not be video recorded. The virtual visit will last less than one hour. During the virtual visit, the research team member will answer any questions you have about the consent form. The researcher will also ask you questions from three different questionnaires. These include:

A questionnaire to assess your child's participation in roles and activities appropriate to their development A questionnaire about your child's mobility A questionnaire about your child's fine motor skills

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP).

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records

☐ My HIV/AIDS testing records

☐ My genetic testing records

☐ My mental health diagnosis/treatment records

☐ My sickle cell anemia records

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

The University of Minnesota research team and any institutions or individuals collaborating on the research with us Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others) The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research Organizations who provide accreditation and oversight for research and the research team and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity) and Organizations that process any payments that may be made to you for participating in this study, and any other

individuals or organizations specifically identified in this Consent Form. Additional sharing of your information for mandatory reporting.

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

Current or ongoing child or vulnerable adult abuse or neglect; Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule; Certain wounds or conditions required to be reported under other state or federal law; or Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy. How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Will I receive research test results?

Most tests done in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

What will be done with my data when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Will anyone besides the study team be at my consent meeting?

Only the study team will be present at your consent meeting.

Whom do I contact if I have questions, concerns or feedback about my experience?
This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

Your questions, concerns, or complaints are not being answered by the research team. You cannot reach the research team. You want to talk to someone besides the research team. You have questions about your rights as a research participant. You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you $50 for your time and effort at completion of your participation.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will mail you a debit card and the money will be added to the card after the completed virtual visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given the participant's name, date of birth, and address. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

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.

	Yes, I agree	No, I disagree
The investigator may contact me in the future to see whether I am interested in participating in other research studies by Bernadette Gillick, PhD	◯	◯

Enter your initials here to verify that you selected the correct option(s) above.

_____

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of participant:

_____
(Please click the green "add signature" button, sign, and save)

Typed Name of Participant

_____
(First Last)

If the participant is physically unable to sign the consent form. Please describe

_____

Typed Name of Participant (Child)

_____
(First Last)

Signature of Parent/Guardian

_____
(Please click the green "add signature" button, sign, and save)

Printed Name of Parent/Guardian

_____
(First Last)

Date:

_____

Signature of 2nd Parent/Guardian

_____
(Please click the green "add signature" button, sign, and save)

Signature Block for Person Obtaining Consent:

Printed Name of 2nd Parent/Guardian

_____
(First Last)

Signature of Person Obtaining Consent

_____
(Please click the green "add signature" button, sign, and save)

Typed Name of Person Obtaining Consent

_____
(First Last)

Date

_____
(Click on Now)