NOVEL NOninVasive intracranial prEssure from transcranial doppLer ultrasound Development of a Comprehensive Database of Multimodality Monitoring Signals for Brain-Injured Patients

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STUDY00004039

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EMORY UNIVERSITY CONSENT TO PARTICIPATE IN A RESEARCH STUDY

(Subjects consenting prior to procedure)

Study Title: NOVEL NOninVasive intracranial prEssure from transcranial doppLer ultrasound Development of a Comprehensive Database of Multimodality Monitoring Signals for Brain-Injured Patients.

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Study Coordinator	[redacted] Research Specialist E-mail: [redacted]

IRB #: 00004039
Funding Source: National Institute of Neurological Disorders and Stroke

This is a medical research study. Your study doctors, [redacted] PhD, [redacted], MD, PhD, or other member of the study staff from Emory University will explain the study to you.

Medical research studies only include people who choose to take part in the research. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have been diagnosed with a brain injury or have a suspected elevation of pressure in the brain and have a catheter in your brain to monitor the pressure inside your skull.

If you are the Legally Authorized Representative, the person you are representing (hereafter referred to as the 'subject') is being asked to participate in a research study but is unable to consider whether to give consent to participate because of their medical condition. You, as the subject's legally accepted representative, are being asked to consider whether to give consent for the subject to participate in this study.

Why is this study being done?

The purpose of this study is to collect brain pressure recordings and measure of brain blood flow to determine if we can predict brain pressures from what we see in blood flow. Blood flow will be measured using an ultrasound device, called a Transcranial Doppler (TCD), which is a device that we use commonly for patients in the intensive care unit. If there are other monitors

placed on your body we will use that data as well, including your heartbeat (the electrocardiogram), electrical activity of your brain, etc. We will use this data to see if we can predict the pressure inside your brain using the other data we collect. If we come up with a way to do this, we may be able to monitor brain pressures without having to put a pressure monitor inside the skull and therefore make monitoring less invasive.

Who pays for this study?

The National Institute of Neurological Disorders and Stroke is providing funding for this study.

How many people will take part in this study?

About 443 patients will be enrolled in this study and 60 at Emory University.

What will happen if I take part in this research study?

A Transcranial Doppler Device (TCD) is a noninvasive FDA-approved device routinely used to measure cerebral/brain blood flow velocity will be used to measure blood flow velocity from both sides of the brain (from the middle cerebral and internal carotid arteries). At the same time, a computer device will gather data from your hospital monitors: including brain pressure, arterial blood pressure, electrocardiogram signals, and (if connected) electroencephalography and brain tissue oxygenation.

Before you begin the main part of the study...

The study team will determine if you can be in this study based on your health status.

During the main part of the study...

If you choose to take part in the study, then you will have the following things happen:

1. The study staff will bring the TCD and data acquisition system to the bedside.
2. The study staff will apply the probe of the TCD device to your neck (at the level of the Adam's apple) using ultrasound gel to measure the blood flow in your neck arteries (internal carotid arteries on each side). The study staff then will place the TCD probe and gel to your temple. The study staff will move the probe along your scalp to find the best position to measure the blood flow signal. Once found, either the handheld TCD probe or a headband to hold the probes in position will be used.
3. While your nurse sets your brain monitor to a setting to measure your brain's pressure, we will use a bedside computer to record information using the TCD device. Hourly, your nurse is setting your brain monitor to this setting and the standard time your nurse will take to perform this assessment is approximate 1 to 2 minutes. If you have already tolerated clamping of the catheter in your brain for 24 hours, if you have your catheter clamped for continuous measure of brain pressure or if you have a fiber optical ICP sensor, we will do a 60-minute recording.
4. The study staff will record any nursing interventions or medication dosing during the data acquisition period. The study staff will also note other interruptions that may influence the data acquired.
5. After the recording of the arteries in the brain, the study staff will place the TCD probe on both sides of your neck again to get the final recordings needed for the study.

6. The TCD probe or if applicable, the headband will be removed and all data cables between the TCD device and the monitors will be disconnected. The ultrasound gel will be removed from your neck and scalp with a towel.

Study location: All study procedures will be done at Emory University Hospital.

How long will I be in the study?

Participation in the study could take a total of 150-180 minutes per recording; from set-up to the removal of TCD device. A maximum of 4 recordings will be made.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor, nurse, or your study staff if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study doctor may stop you from taking part in this study at any time if he/she believes:

- it is in your best interest
- if the study is stopped

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Doctors do not know all the side effects that may happen. Side effects may be mild or serious. Everyone taking part in the study will be watched carefully for any side effects.

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to the procedure include:

1. Minor head discomfort after wearing the TCD headband
2. Ultrasound gel may get into your hair, but this is easily wiped off
3. **Unknown Risks:** There may be side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study may help doctors better understand brain pressure and develop better and noninvasive brain monitoring systems.

What other choices do I have if I do not take part in this study?

If you choose not to be in the study, your care will remain unchanged.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. Your signed consent form will be added to your medical record. Therefore, people involved with your future care and insurance may become aware of your participation. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

1. National Institute of Neurological Disorders and Stroke
2. University of California
3. SFGH Dean's office, if you are at San Francisco General Hospital
4. The US Food and Drug Administration (FDA)
5. Representatives of Emory University

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Purpose of this Authorization:
By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:
- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:

We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your IIHI. These include subpoenas or court orders.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory may use and disclose your IIHI to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- National Institute of Neurological Disorders and Stroke is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
  - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
  - Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration].
  - Public health agencies.
  - Research monitors and reviewer.
  - Accreditation agencies.
  - University of California San Francisco Institutional Review Board
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact your local principal investigator, [redacted] Ph.D., at [redacted] or co-investigator, [redacted], M.D., Ph.D at [redacted].

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke

your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers, the Sponsor, and people and companies working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

What are the costs of taking part in this study?

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

You can talk to the local principal investigator, [redacted] Ph.D., at [redacted] or co-investigator, [redacted], M.D., Ph.D at [redacted].

Treatment and Compensation for Injury:

If you believe you have become ill or injured from this research, you should contact Dr. [redacted] at telephone number [redacted] or Dr. [redacted] at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor have set aside money to pay for this medical treatment.

Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have be being in this study, including any right to bring a claim for negligence.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctors, [redacted], Ph.D., at [redacted] or co-investigator, [redacted], M.D., Ph.D at [redacted] about any questions, concerns, or complaints you have about this study. If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the University of California San Francisco Office of the Committee on Human Research at [redacted] or contact the Emory Review Board at [redacted] or [redacted] or [redacted].

CONSENT

You have been given copies of this consent form.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date/ Time	Participant's Name for Consent
Date/ Time	Participant's Signature for Consent
Date/ Time	Person Obtaining Consent
Date/ Time	Witness – Only required if the participant is a non-English speaker

If interpreter was used, provide signature or name and telephone service

AND/OR:

Date/ Time	Legally Authorized Representative's Name
Date/ Time	Legally Authorized Representative's Signature
Date/ Time	Person Obtaining Consent
Date/ Time	Witness – Only required if the LAR is a non-English speaker

If interpreter was used, provide signature or name and telephone service

Subject Re-consent

I have been enrolled in this study by a surrogate because my illness rendered me incapable of providing consent when I was initially enrolled. I have since regained my ability to provide consent and now would like to (please initial below):

_____Continue participation until the study is complete.

_____Terminate my participation in the study but allow the use of data collected to date.

If you wish to participate in this study, you should sign below.

_____	_____
Date/ Time	Participant's Name for Consent
_____	_____
Date/ Time	Participant's Signature for Consent
_____	_____
Date/ Time	Person Obtaining Consent
_____	_____
Date/ Time	Witness – Only required if the participant is a non-English speaker

_____

If interpreter was used, provide signature or name and telephone service