Kennedy Krieger Institute

Anatomical and functional imaging correlates of chronic pain in cerebral palsy

August 30th, 2021

JOHNS HOPKINS MEDICINE

Approved August 30, 2021

Date: August 30, 2021
Principal Investigator: Eric Chin
Application No.: IRB00181801

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Anatomical and functional imaging correlates of chronic pain in cerebral palsy**

Application No.: **IRB00181801**

Sponsors: **Cerebral Palsy Alliance of Australia**
Neurosurgery Pain Research Institute

Principal Investigator: **Eric Chin**
707 N Broadway
Baltimore, MD, 21205
Phone: (443) 923-9147
Fax: (443) 923-9165

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

2. Why is this research being done?

This research is being done to find risk factors for chronic pain in people with cerebral palsy (CP). We are also looking at effects of pain on function, independence and quality of life in people with CP. We are performing magnetic resonance imaging (MRI) brain and spine scans to help us understand how brain changes in CP may help explain pain symptoms.

Young adults at least 18 years old both with and without CP may join.

How many people will be in this study?
Up to 300 people will be in this study. We will recruit up to 30 people for MRI in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things. You may agree to all, some, or none of these.

•Allow review of medical records
You are being asked to allow the researchers to review your medical records.

Please indicate your decision below by checking the appropriate statement:

_____I **agree** to allow collection of medical records and imaging information for research.

_____I **do not agree**.

_____ _____
Participant Signature Date
(or Parent/Legally Authorized Representative Signature, if applicable)

•In-person MRI exam
You may be invited to have an MRI exam. MRI scans create images of the body using a magnet and radio waves. While the procedure is much like a CT scan, there is no radiation involved in an MRI exam. The MRI exam(s) in this study will take about 90 minutes.

To be sure that it is safe for you to have an MRI exam, you will be asked to complete standard MRI screening questionnaires.

Since the MRI machine uses a strong magnet that will attract other metals, you may not take part in this study if you have a pacemaker, an implanted defibrillator, or certain other implanted electronic or metallic devices, shrapnel, or other metal.

If you have a history of metal in your head or eyes, you cannot take part in this study.

Although the MRI machine is open at both ends, you may still feel confined (claustrophobic). If this bothers you, please tell the MRI staff. The MRI machine periodically makes loud banging noises. We will provide earplugs or headphones for you to wear during the MRI exam.

During the exam, you will be able to hear the MRI staff. They will be able to see and hear you.

Please indicate your decision below by checking the appropriate statement:

_____I **agree** to participate in a research MRI if/when deemed safe.

_____I **do not agree**.

_____ _____
Participant Signature Date
(or Parent/Legally Authorized Representative Signature, if applicable)

Incidental Findings
The imaging you are having as part of this research study will be reviewed by a qualified person just as it would be if you were having the imaging as part of your routine medical care.

There is a possibility that while reviewing your imaging we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.
- The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

How long will you be in the study?
Individuals typically are asked to come for one visit. If you get tired or would prefer to stop and resume at a later visit, this can add additional visits.

4. What are the risks or discomforts of the study?

Interview questions:
You may get tired or bored when we are asking you questions. You do not have to answer any question you do not want to answer.

MRI scans:
While no significant risks have been found from the use of MRI scans, you may be bothered by the MRI machine noise and by feelings of being closed in (claustrophobia).

Confidentiality:
There is the risk that information about you may become known to people outside this study.

Any physical data will be kept in a locked office in a locked cabinet to which only key study members have the key. Electronic data will be kept on a secure, password-protected server with access limited to key research team members. Image processing will occur on a dedicated, password-protected computer in a locked office with access limited to key research team members. Study documents and files outside of the linking document will be de-identified and identified only by a number.

5. Are there risks related to pregnancy?

There are no known risks from MRI imaging without contrast during pregnancy. There may be risks that are currently unknown.

6. Are there benefits to being in the study?

There is no direct benefit to you from being in this study.

If you take part in this study, you may help others in the future. Pain in individuals with CP is common and often under-recognized. With your participation in the study we aim to explore relationships between pain and underlying conditions such as CP.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected. If you are an employee or trainee, your decision whether to enter this study will not affect your employment, training, or education.

8. Will it cost you anything to be in this study?

No.

9. Will you be paid if you join this study?

You will be paid $20 per study visit. Parking at KKI is free for research subjects.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You will be asked to give us a list of other health care providers that you use.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

If you are a participant at Kennedy Krieger Institute, you may contact Karen Cox, Vice President and Research Administrator at 443-923-9302.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Chin at (443) 923-9147. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

15. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

For ADULT PARTICIPANTS (Age 18+) consenting independently:

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time

For ADULT PARTICIPANTS (Age 18+) not consenting independently:

Signature of Legally Authorized Representative (LAR)	(Print Name)	Date/Time
Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)		Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time

For CHILD PARTICIPANTS (Age < 18):

Signature of Parent	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

AUTHORIZATION TO CONTACT YOU ABOUT FUTURE RESEARCH STUDIES

You are being asked to read and sign this form because you are a patient in the Phelps Center. We have several research studies which aim to learn more about the diagnosis, evaluation and treatment of Cerebral Palsy. We also work with other researchers at Johns Hopkins ("JH"), the Kennedy Krieger Institute ("KKI"), or Mt. Washington ("MWPH") on other research studies intended to learn more about this area.

We are asking for your permission to allow the research team members in the Unit and other researchers working with the team to review your medical records in the Unit to determine whether you might be eligible to join any of these research studies. This is called "screening." If you agree, then we might contact you in the future and tell you about a research study. At that time, you could decide whether or not you are interested in participating in that particular research study.

Your permission to do this screening would be greatly appreciated, but it is completely voluntary. If you choose not to allow this screening, it will not affect your care at JH/KKI/MWPH. Giving your permission to do this screening is only for the purpose of helping us identify people who may qualify for a particular research study. It does not mean that you must join in any study. That is a separate decision that you would make at a later time.

The researchers and research team members know how important it is to keep the health information you share with us protected. We do not expect to share this information with anyone outside of JH/KKI/MWPH. If it is shared with anyone outside of JH/KKI/MWPH inadvertently, we will do everything we can to protect your information, but, in such an event, we cannot guarantee protection.

If you give us permission to do this screening, your authorization will remain in effect until you tell us in writing that you have decided to cancel your permission. You can do so at any time by sending a written notice to:

X The Johns Hopkins Privacy Officer, 1812 Ashland Avenue, Suite 300, Baltimore, MD 21205, Fax 443-529-1548 or sending a notice by e-mail to HIPAA@jhmi.edu, or by notifying your physician.

X The Kennedy Krieger Privacy Office, Kennedy Krieger Institute, 707 N. Broadway, Baltimore, MD 21205, Fax 443-923-1805 or sending a notice by e-mail to HIPAA@kennedykrieger.org, or by notifying your physician.

May we use your health information to see if you are eligible for a future research study and contact you to tell you about that study?

CIRCLE ONE: YES NO

This form applies only to contact about research studies conducted by the Unit at Johns Hopkins, KKI, or Mt. Washington. Please note that it is possible that you may be contacted by a researcher from another department about research studies conducted by that department.

If you have any questions about this authorization form please contact Dr. Hoon **at (443)923-9147 during normal business hours.**

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Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

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Signature of Person Obtaining Consent (Print Name) Date/Time

For CHILD PARTICIPANTS (Age < 18):

Signature of Parent (Print Name) Date/Time

Signature of Person Obtaining Consent (Print Name) Date/Time