Permission to Take Part in a Human Research Study
Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: ***Cerebral Palsy Research Registry, STU00021726***

Investigator: ***Julius P.A. Dewald, PT, PhD***

Supported By: This research is supported by Northwestern University.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in the Cerebral Palsy Research Registry (CPRR) because you have a diagnosis of cerebral palsy.

If you are joining the CPRR with your child, the word "you" in this consent form will refer both to you and your child.

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?
The Cerebral Palsy Research Registry (CPRR) was developed for two purposes: to support cerebral palsy research and to increase our understanding about cerebral palsy.

The first purpose is to connect interested individuals and families with researchers studying cerebral palsy or educating others about cerebral palsy. For this purpose, we store identifiable data such as your name, address, phone number and email address and share it with researchers who may be interested in contacting you to participate in other research studies about cerebral palsy.

The second purpose is to monitor data over time and analyze the data provided from the CPRR questionnaire. For this purpose, we collect a range of information that does not contain your name or other personal identifiers and cannot be traced back to you. Researchers may analyze this data to investigate surveillance questions, such as what is the natural aging process of persons with cerebral palsy, what is the prevalence of cerebral palsy subtypes, what are the environmental modifications and services needed for children and their families?

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How long will the research last and what will I need to do?

You will be in this research study for as long as you will allow us to keep your data. We will invite you to update your information each year.

You will be asked to provide researchers with some information about your medical history and how to contact you.

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

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

You may feel uncomfortable answering the questions that are on the questionnaire. Efforts will be made to be keep your information private, but there is a risk of loss of privacy.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me 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, possible benefits to others include improved coordination of current and future studies related to cerebral palsy, which can help us learn more about the cause, effects, and treatment of CP.

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

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Dr. Dewald by calling (312) 908-6788 or j-dewald@northwestern.edu or to the CPRR Coordinator by calling (312) 908-8160.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu 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.

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How many people will be studied?
We expect about 10,000 people here will be in this research study out of 100,000 people in the entire study nationally.

What happens if I say "Yes, I want to be in this research"?
You will be asked to fill out a questionnaire to the best of your ability. Completion of the questionnaire should take approximately 15 minutes. All information such as past and current medical status, demographic information, medical procedures, etc will be entered into the secure password protected database. You will be contacted on an annual basis to update the information in the questionnaire.

No information reported to the CPRR will be placed in your medical record.

As a participant in the CPRR, you may choose to receive information about other research studies that you might be eligible to participate in. Also, you will receive periodic newsletters regarding CPRR changes, information about research projects and other health-related information that may be of interest to you.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Detailed Risks: Is there any way being in this study could be bad for me?
You may feel uncomfortable answering the questions that are on the questionnaire. Efforts will be made to be keep your information private, but there is a risk of loss of privacy.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

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.

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, possible benefits to others include improved coordination of current and future studies related to cerebral palsy, which can help us learn more about the cause, effects, and treatment of CP.

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 secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. We will not ask you about child [or

elder] abuse, but if you tell us about child [or elder] abuse or neglect, we may be required or permitted by law or policy to report to authorities.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

HIPAA Authorization

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. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.

- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Julius Dewald PT, PhD
Institution: Northwestern University
Department: Physical Therapy and Human Movement Sciences
Address: 645 N Michigan Ave, Suite 1100 Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Optional Elements:

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

I agree	I disagree	
_____	_____	Health professional(s) nominated by me may be contacted to assist in completing and/or verifying details on the register. These health professionals are listed on the registration form.

Signature Block for Parent Permission and Child Assent:

Your signature documents your permission for the named child to take part in this research.

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_____ _____
Signature of Child Date

_____
Printed Name of Child

_____ _____
Signature of Parent or Individual Legally Authorized to consent for the child to participate Date

_____ _____
Printed Name of Parent or Individual Legally Authorized to consent for the child to participate Date

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's participation in the research. Contact legal counsel if any questions arise.

If signature of second parent not obtained, indicate why: (select one)

[ ] The IRB determined that the permission of one parent is sufficient.

[ ] Second parent is: [ ] deceased [ ] unknown [ ] incompetent [ ] not reasonably available

[ ] Only one parent has legal responsibility for the care and custody of the child

Assent:

[ ] Obtained verbally without a signature

[ ] Not obtained because the capability of the child is so limited that the participant cannot reasonably be consulted.