INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Social Participation and Pediatric Mobility: A Study of the Impact of Wheelchair Skills Training for Wheelchair-Using Children
Indiana University IRB Protocol #10018

ABOUT THIS RESEARCH
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent and authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

If you are reading this form to consent and authorize on behalf of your child, please read you/your as your child.

STUDY SUMMARY
This study is aimed at understanding the impact of wheelchair skills training on social participation for wheelchair-using children. Therapists and physicians at Riley Hospital for Children will be implementing the Wheelchair Skills Training Program developed at Dalhousie University. The manual for the program is attached in supporting documents. The aim of this study is to assess the impacts as they relate to social participation as well as physical activity. Children will wear accelerometers one week prior and one week after participation in the program to measure transfers and physical activity. These accelerometers are non-invasive and are worn on a patient's wrist. Children will give their feedback of the benefits and drawbacks of the program to help the organizers evaluate changes. Finally, parents will report on the participation changes of their children over time as well as stated participation goals in areas such as home, school, and the community. The study will be a waitlist control design where control group participants and their parents will be assessed for social participation and activity level changes before eventually receiving treatment.

Please review the rest of this document for more details about this study and the things you should know before deciding whether to participate in this study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to examine the impacts of wheelchair skills training on pediatric wheelchair users. Currently there are no local training mechanisms in place to train children on best practices for wheelchair use. The wheelchair skills training program was originally developed by Dalhousie University in Nova Scotia as a method of training wheelchair users.

We are asking you if you want to be in this study because your child has interacted with Indiana University Health as the result of a spinal cord injury or diagnosis of spina bifida.

The study is being conducted by Dr. Tony Chase of the Indiana University Department of Occupational Therapy. It is funded by a Lilly Endowment Inc. fund.

HOW MANY PEOPLE WILL TAKE PART?

You will be one of 10 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Subjects will first be recruited by either their physician or occupational therapist from Riley Hospital. If they are interested, their parents will be instructed to email the principal investigator their name and phone number. List of potential subjects will be kept in a Microsoft Teams file shared on a secure server. They will then be given a series of home exercises and workouts to prepare them for the upper body strength. At the outset of the program, subjects will work with registered occupational therapists from Riley Hospital for Children to instruct them through these various skills. They will meet for 3 hours on 6 different Saturdays at the IUPUI Jungle gymnasium. They will be given an accelerometer to wear on their wrist to track activity levels for the first, third, and final weeks of the program. They will be given a pre assessment digitally for their parents to fill out about their goals and participation habits. They will take the same assessment at the conclusion of the program and 6 months after participating. Participation in this program will be for 6 weeks followed by a digital survey sent out 6 months after.

You will not receive the results of any of these tests or procedures because they are being done only for research purposes.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

There exists the possibility of certain changes to occur during the tests and activities. They include abnormal blood pressure, fainting, elevations of heart rate, and in very rare instances, injury. Skills being instructed will be done in such a way to avoid possible injury. However, there still exists the possibility that injury may occur. Every effort will be made to minimize these by the preliminary screening and by observations during testing and activities. Emergency equipment and trained personnel are available to deal with these situations should they happen.

Activities with a potential for wheelchair tips will always include the accompaniment of a spotter with a spotter strap in order to catch the participant before that occurs. These spotters will also accompany the participant through the entire process and be there for any questions or concerns. All personnel will be wearing safety equipment (masks) to protect from exposure to COVID-19. Further, all personnel will be vaccinated prior to the start of the program.

You may also be uncomfortable while answering the survey questions. While completing the survey, you can skip any questions that make you uncomfortable or that you do not want to answer.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

If you are injured as a result of participating in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent form.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

Many benefits may occur from your son/daughter/guardian's participation including increased cardiorespiratory capacity, increased physical fitness, increased confidence, improved skill level, opportunities for social interaction and enhancement, potential increases in community participation, and increased wheelchair mobility. Additionally, the clinic also provides parents/guardians to observe the activities and benefit from this observation.

WILL I BE PAID FOR PARTICIPATION?

Payment will be provided for participation in the research study. The payment schedule is as follows:

- Payment #1 will be a $25 Amazon gift card and distributed on the first day of the program for participation in pre-survey measures.
- Payment #2 will be a $25 Amazon gift card and distributed on the last day of the program for participation in post-survey measures.
- Payment #3 will be a $50 Amazon gift card and distributed 6 months after the last day of the program for participation in 6 month follow-up survey measures.

Payment is only for completion of the digital survey measures. Answers will in no way be reflected in eligibility to receive future payment or participate in the program.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?

The following individuals and organizations may receive or use your identifiable information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law

- Data safety monitoring boards and others authorized to monitor the conduct of the study
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - Office for Human Research Protections (OHRP)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. audio or video recordings will be made, only research personnel will have access to the recordings for the purposes of the study, education, and program description. Recordings will be destroyed 5 years after they are obtained. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies.

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher, Dr. Tony Chase, at (317) 278-9018. After business hours, please call (402) 672-2153.

In the event of an emergency, contact local authorities by calling 911.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Indiana University, IU Health, or any IU Health affiliate (e.g., Riley Hospital for Children).

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, send an email to chaseam@iu.edu with the request.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name **Date**	**Printed Name of Person Obtaining Consent** **Date**
Participant's Signature	**Signature of Person Obtaining Consent**

[**For research involving CHILDREN, use the following signature blocks, as applicable**]

Printed Name of Parent **Date**
Signature of Parent

Printed Name of Child **Date**
Signature of Child