

PARENTAL PERMISSION FORM

Project Title: Tracking Kinematic and Kinetic Data during Horse Riding for Optimizing Therapeutic Outcomes

You are invited to take part in a research study being conducted by Dr. Pilwon Hur, a researcher from Texas A&M University and funded by Horses and Humans Research Foundation (HHRF). The information in this form is provided to help you and your child decide whether or not to take part. If you decide to allow your child to take part in the study, you will be asked to sign this permission form. If you decide you do not want your child to participate, there will be no penalty to you or your child, and your child will not lose any benefits they normally would have.

Why Is This Study Being Done?

The purpose of this study is to track the movement of the riders and horses while riding horses during hippotherapy sessions.

Why is My Child Being Asked to Be in This Study?

Your child is being asked to be in this study because Your child is a patient with cerebral palsy with ages between 3-14. Before Your child can enroll in the study, and after you sign this form, the study therapist will perform certain tests and procedures and ask your child (and you) to provide some information about your child's history to determine whether or not your child can continue in the study. Ask the study therapy for more information about what tests and procedures will be done.

How Many People Will Be Asked To Be In This Study?

Four people will be invited to participate in this study locally.

What Are the Alternatives to being in this study?

The alternative to being in the study is not to participate.

What Will My Child Be Asked To Do In This Study?

Your child will be participating the regular eight hippotherapy sessions which include functional motor tasks, and performing several tasks while riding horses. Therapist will instruct and guide your child on what to do. In the 1st, 4th and 8th sessions, small sensors will be attached at your child's helmet, vest and waist belt, and your child will perform the regular tasks for the therapy sessions. Since the sensors are about the size of a quarter, your child will not be distracted. Each session will last up to 45 minutes. If your child feels tired, enough rest will be provided.

Will Photos, Video or Audio Recordings Be Made Of My Child during the Study?

While your child is participating the 1st, 4th, and 8th sessions, the researchers will take photographs and make an audio and video recording so that the researchers can validate the sensor data. The videos will be deleted once the validation is completed. If your child (and you) do not give permission for the photograph/audio/video recording to be obtained, your child cannot participate in this study. If the researchers need some images for research presentations at academic and clinical conferences, the images will be deidentified by deleting the identifiable body parts.

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_____ I give my permission for photographs/audio/video recordings to be made of your child during the participation in this research study.

_____ I do not give my permission for photographs/audio/video recordings to be made of your child during the participation in this research study.

Are There Any Risks To My Child?

The things that your child will be doing are no more than risks than your child would come across in the regular hippotherapy sessions. The potential risks your child may experience during regular hippotherapy sessions include fatigue due to seating on horse during the sessions. Your child may have risk of falling from the horse. Two professionally trained therapists will be always on your child's side to assist your child to minimize the risk of falling.

Are There Any Benefits To My Child? (If there are no direct benefits, this section may be omitted*)**

There are no direct benefits. However, the population with cerebral palsy may benefit from the research results.

Will There Be Any Costs To My Child?

Aside from your child's time, there are no costs for taking part in the study.

Will My Child Be Paid To Be In This Study?

Your child will not be paid for being in this study.

Will Information From This Study Be Kept Private?

The records of this study will be kept private. No identifiers linking your child to this study will be included in any sort of report that might be published. Research records will be stored securely and only the PI and research investigators will have access to the records. Video/Audio files will be destroyed when the sensor data are validated.

Information about your child will be stored in locked file cabinet; computer files protected with a password. This consent form will be filed securely in an official area.

Information about your child will be kept confidential to the extent permitted or required by law. People who have access to your child's information include the Principal Investigator and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP) and entities such as the Texas A&M University Human Subjects Protection Program may access your child's records to make sure the study is being run correctly and that information is collected properly.

Who may I Contact for More Information?

You may contact the Principal Investigator, Dr. Pilwon Hur, to tell him/her about a concern or complaint about this research at 979-862-4461 or pilwonhur@tamu.edu. You may also contact the Research Investigators, Dr. Duane Steward at 979-436-0662 or

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steward@medicine.tamhsc.edu, Dr. Nancy Krennek at 512-930-7625 or nancy@rockride.org or Dr. Priscilla Lightsey at 512-930-7625 or priscilla@rockride.org.

For questions about your child's rights as a research participant; or if you have questions, complaints, or concerns about the research, you may call the Texas A&M University Human Subjects Protection Program office at (979) 458-4067 or irb@tamu.edu.

What if I Change My Mind About Participating?

This research is voluntary and you have the choice whether or not to allow your child to be in this research study. Your child may decide to not begin or to stop participating at any time. If they choose not to be in this study or stop being in the study, there will be no effect on their student status, medical care, employment, evaluation, relationship with Texas A&M University, etc.

STATEMENT OF CONSENT

The procedures, risks, and benefits of this study have been told to me and I agree to allow my child to be in this study. My questions have been answered. I may ask more questions whenever I want. I do not give up any of my child's or my legal rights by signing this form. A copy of this consent form will be given to me.

Child's Name

Parent/Legal Guardian Signature

Date

Parent/Legal Guardian Signature

Date

INVESTIGATOR'S AFFIDAVIT:

Either I have or my agent has carefully explained to the parent the nature of the above project. I hereby certify that to the best of my knowledge the person who signed this consent form was informed of the nature, demands, benefits, and risks involved in his/her participation.

Signature of Presenter

Date

Printed Name

Date