Adapted Toy Safety Check List
University of North Florida

Project Title: Biomechanical Changes Underpinning Stand-on Ride-on Power Mobility Devices for Children with Cerebral Palsy

Electrical Check list

- ☐ Unplug the battery and check that it has not been modified
- ☐ Check the battery and its wires for signs of damage
- ☐ Check that correct AWG wire gauge has been employ, e.g.:
  - Higher than 18 for 6V Battery
  - Higher than 14 for 12V Battery
- ☐ Check all wire connections: All wire connections must be insulated, and connectors checked proper fitting with wire gauge.
- ☐ Check for exposed wires: All wires must be insulated
- ☐ Check that all switches and crimp terminals are properly connected and fully operational
- ☐ Check that all sensors and electronic components are properly connected and fully operational

Mechanical Check list

- ☐ Check that all PVC modifications (cuts and drill holes) are smooth. There should be no burrs on the PVC
- ☐ Check that all PVC pipes and connectors are of proper size and properly fitted
- ☐ Check that all PVC used has an inner diameter of at least ¾ inches for structural elements
- ☐ Check that all bolts are at least ¼ inch and at least 2 inches long, and all bolt ends have been covered for structural elements
- ☐ Check that all components (seat belts, foam, switches, sensors, battery, and PVC frames) are securely attached to the toy

Operation Check list

- ☐ **Check that all components work appropriately together by strapping in a 40 pound weight and continuously activating the car for 10 minutes**

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Informed Consent Form: Child Participant

Title: Biomechanical Changes Underpinning Stand-on Ride-on Power Mobility Devices for Children with Cerebral Palsy

Principal Investigator *(Primary Contact)*: Guilherme (Gui) Cesar, PhD, PT

Research Collaborators: Juan Aceros, PhD

Sponsor: University of North Florida

Research Team Contact:

Name	Title	Department	Phone Number	E-mail
Gui Cesar	Principal Investigator	Physical Therapy	904.620-2664	g.cesar@unf.edu
Juan Aceros	Engineer	Engineering	904.620-1684	juan.aceros@unf.edu
Ligia Mochida	Research Lab Assistant	Physical Therapy	904.620-1058	l.mochida@unf.edu
Debra Depto-Hoffman	Physical Therapist	Physical Therapy	904.620-2262	d.depto.hoffman@unf.edu

Please know that participation is voluntary and there are no penalties for deciding not to participate, skipping questions, or withdrawing your participation. You may choose not to participate in this research without negatively impacting your relationship or your child's relationship with the University of North Florida.

If you have questions about your rights as a research study participant, you can contact UNF's Institutional Review Board at (904) 620-2498 or irb@unf.edu

1. Researchers' Statement:

You have the option of having your child join a research study. This is a parental permission form. The goals of this form are to give you information about what would happen in the study if you choose to have your child take part and to help you decide if you want your child to be in the study. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

Feel free to take notes, write questions or highlight any part of this form.

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2. What you should know about this study:

- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study at any time.
- If you say 'Yes' now, you can still change your mind later and it is OK.
- You can choose to have your child leave the study at any time.
- Your child would not lose benefits or be penalized if you decide not to have your child take part in the study or leave the study later.

3. What is the goal of this study?

The goal of any research study is to answer a few questions. We (the research team listed on the front of this form and our staff) are doing this research study to answer the following questions.

Does playing in a standing posture within an adaptive toy car help children with walking and balance issues due to cerebral palsy…

- …develop stronger legs?
- …develop better balance and coordination?
- …develop better standing posture?

We hope that playing with adaptive toy cars will do all these things; but, we don't know if it will.

4. Why do I have the option of having my child join the study?

You have the option to have your child join this research study because your child has a diagnosis of cerebral palsy and have an impairment that limits his/her mobility and balance. Your child's motor function is classified at Level 3 on the scale Gross Motor Function Classification System.

5. How many children will take part in the study?

Ten children will take part in this section of the research study.

6. If I agree to have my child join this study, what would my child need to do?

Your child will be required to come to the Physical Therapy Research Laboratory at UNF's Ann and David Hicks Hall building for **three visits**. During **Visit 1**, we will measure your child's heigh and weight, and he/she will undergo a dedicated physical therapy evaluation so we can gather information for the type of adaptations needed (for example, type of switches, paddings or supports) to the toy car that he/she will receive. We will also use this visit to explain to you all the steps of the research activities and respond to any questions you may have. We will ask you

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to fill out a general health screening form and contact your pediatrician to clear your child's participation in the study.

We will then schedule the next visit, which will be approximately 3-4 months after Visit 1. During **Visit 2**, we will perform a more detailed evaluation with your child. First, we will measure your child's heigh and weight. Then, small reflective balls (like the size of a small marble, called markers for the three-dimensional analysis) and small sensors (like the size of your thumb nail, for the muscle activity assessment) will be taped to the child's skin over different body locations (for example, shoulders, hips, knees, foot, and over leg muscles). We will use a small amount of medical-grade tape to secure the reflective balls and small sensors to minimize any potential for skin irritation. This procedure may take up to 20 minutes and the child can sit at any moment. Your child will then perform the following tasks:

- Stand straight up for about 10 seconds;
- Sit to stand five times in a row;
- Stand up from a chair, walk about 10 feet and return to the chair; and
- Walk (five times) over a special mat that records your child stepping pattern.

Your child will be offered and allowed as many rest breaks throughout these tests as needed. After these tests, your child will receive his/her adapted toy car. We will dedicate a time to teach your child how to use the toy car and go over any safety concerns you may have.

Your child will use the toy car for 3 months. We will keep contact via phone calls.

After 3 months of toy car use, we will schedule **Visit 3**. During this visit, your child will go through the same procedures of Visit 2. After finishing Visit 3, your child can take his/her toy car with him/her home.

7. How long would my child be in the study?

If you choose to have your child take part in the research activities, your child would be in the study for approximately 7 months. After Visit 1, we will contact you and ask for you and your child to return to the Physical Therapy Research Laboratory after 3-4 months. Your child will then receive the toy car to use for three months. After this 3-month period, you and your child would return to the Laboratory for the final evaluation (Visit 3).

If your child joins the study, you can decide to stop **at anytime for any reason**. If you decide to stop, you would need to talk with Dr. Gui Cesar or Dr. Juan Aceros so you can leave the study with the information gathered on your child (up to the point you decide your child should not take part anymore) and who to contact if you have any further questions or concerns.

Dr. Gui Cesar or Dr. Juan Aceros could also decide to take your child out of this study. This might happen if your child cannot come to the study visits (assessment visits). If we ask your child to leave the study, we would always explain why. Also, if your child indicates through his/her behavior, or any other means, that he/she does not want to participate in one or any of the research activities, his/her participation will be stopped immediately.

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8. What are the potential harms or risks if my child joins this study?

The intervention of this study poses no more than minimal risk for physical or psychological harm to child than those encountered in daily life. For the assessments, there is a slight risk of skin irritation from the application of medical-grade tape on the child's skin to secure the reflective balls and small sensors.

9. What are the potential benefits if my child joins this study?

There may be no direct benefits if you and your child take part in the study. However, participation may benefit other children with difficulty with walking and controlling balance due to cerebral palsy by providing evidence for a change in clinical practice standards that would support appropriate adapted mobility toys to improve function, quality of life, and allow for independent play and exploration at a younger age.

10. What other options do I have?

If you choose not to have your child join this study, you can receive clinical, standard care evaluations of balance and walking via your child's clinicians.

11. How would you keep my child's information confidential?

If your child takes part, we will make every effort to keep his/her information confidential.

We will store all of your child's research records in locked cabinets and secure computer files. We will not put your child's name on any research data. Instead, we will label your child's information with a unique study code (letters and numbers together). The master list that links a person's name to their study number is stored in a locked cabinet or on a secure computer file.

If results of this research are published, we would not use information that identifies your child unless you specifically give us permission to do so. We would only use your child's information for research. Although we only intend to use your child's information for research, there are a few rare circumstances in which we may need to share the information with others:

- If it is required by law.
- If we think your child or someone else could be harmed.
- Sponsors, government agencies or research staff sometime looks at forms like this and other study records. They do this to make sure the research is done safely and legally. Anyone who reviews study records would keep your child's information confidential.

  Agencies or sponsors that may look at study records include:

  - The University of North Florida Research Office who is responsible for watching over the safety, effectiveness, and conduct of the research.

We would keep your child's data for 10 years after the study ends (or longer if required by law).

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

12. Would it cost me money to have my child join the study?

There is no cost to participant families with the exception of the time it will take to complete the assessments and be instructed in the operation and care of the adapted toy car. Additionally, there is no cost to your insurance company.

13. What if my child were injured while in the study?

In spite of all precautions, there is a possibility that your child could be injured while participating in this study. In the event your child has an illness or injury that is associated with his/her participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefit program. You will be responsible for any associated co-payments or deductibles as required by your insurance. If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. The University of North Florida and the researchers associated with this project will not provide compensation for research related injuries.

14. Would my child or I be paid if my child joins this study?

Neither you nor your child will be paid to take part in this study. However, your child will keep his/her adapted toy car after completing the study.

15. Who do I contact if I have problems, questions or want more information?

If I have questions or would like to know about …	You can call …	At …
General study questions, research-related injuries, or any research concerns or complaints	Gui Cesar	904.620-2664
	Juan Aceros	904.620-1684
	Ligia Mochida	904.620-1058
	Debra Depto-Hoffman	904.620-2262
Your child's rights as a research participant	Institutional Review Board This is a group of scientists and faculty members who make sure research studies meet legal and ethical standards.	(904) 620-2498 or irb@unf.edu

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16. If my child joins the study, can my child or I decide to leave the study?

Yes. Taking part in research is always a choice. If you decide to have your child in the study, you can change your mind at any time. We ask that you tell either Dr. Gui Cesar or Dr. Juan Aceros about your decision. You can contact them by emailing or calling them using the contact information on the first page of this form (or the phone numbers provided above).

You or your child will not lose any benefits or be penalized if you choose to have him/her leave the study. If you and/or your child decides to stop participating and your child has already received the car, he/she will keep the car as long as the car is safe for him/her to use. You do not need to return the toy car.

17. What if you find a health problem not already identified?

This study is neither designed nor intended to detect health problems. However, it is possible that this study will identify information about your child that was previously unknown, such as a specific limitation in joint mobility. This is called an "incidental finding." The costs for any care that may be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. The choice to be told about an incidental finding is up to you and so is the decision whether or not to proceed with further examination or treatment.

Please indicate below if you want to be informed of any incidental findings.

___ No, I do not want to be informed of any incidental findings as described above.

___ Yes, I would like to be informed of any incidental findings as described above.

18. What would my signature on this form mean?

Your signature on this form means:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you or your child may have about the study or your child's rights as a research study participant.
- Your child has rights as a research participant. We will tell you about new information or changes to the study that may affect your child's health or your willingness to have him or her stay in the study.
- By signing this parental permission form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
- You agree to have your child take part in this research study.

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Please Note: If the child is a foster child or a ward of the state, then please tell the researchers before signing this form.

_____

Printed Name of Research Participant

_____

Printed Name of Parent or Legal Guardian

_____

Signature of Parent or Legal Guardian

_____ _____

Date *Time*

18. Researcher's Signature

I have fully explained the research study described by this form. I have answered the participant and parents/legal guardians questions and will answer any future questions to the best of my ability. I will tell the family and the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

_____

Printed Name of Researcher Obtaining Parental Permission or Consent

_____

Signature of Researcher Obtaining Parental Permission or Consent

_____ _____

Date *Time*

19. Witness Information

Witness Statement

I have been present during the verbal presentation of this research study.

_____

Printed Name of Witness

_____

Signature of Witness

_____ _____

Date *Time*

Original form to: Research Team File

Copies to: Parents/Legal Guardians

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Oral Script to Child for Oral Assent

Title: Biomechanical Changes Underpinning Stand-on Ride-on Power Mobility Devices for Children with Cerebral Palsy

Hi, my name is [Gui Cesar, the PI]. I am a [teacher] here at the University of North Florida and I will be working with you and your [mom, dad].

Let me tell you what we will do today. [*Ask you some questions, play with buttons, put some little shiny balls on your arms and legs, ask you to stand up from the chair, ask you to stand still like a statue, ask you to walk a little*]. If you say "yes" you can stop at any time by telling me "I want to stop" or "no, I don't want to." You won't get in any trouble for stopping or telling me "no". I won't be mad at you, OK?

Your parent(s) know about all these things, and they can stay with you while you do them. You may ask questions at any time. Would you like to work with me today?

This oral assent applies to children who are 4 years, 0 months to 6 years, 11 months with cognitive/communication skills of at least a three-year old.

Name of participant _____ Age _____

I verify that I have read the assent script to the child.

They indicated Yes_____

They indicated No_____

Assent script read by:

_____
Signature

_____
Printed Name and Title

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MEDICAL HISTORY QUESTIONNAIRE

Participant ID: _____

Primary/Secondary Diagnosis: _____

Please indicate whether your child has/had any of the following medical problems by circling "yes" or "no." Explain "yes" answers on the next sheet.

Allergies (Skin, Adhesive, Wrap, Other)	☐ No	☐ Yes			
Unexplained Weight Changes	☐ No	☐ Yes	High Cholesterol	☐ No	☐ Yes
Uncontrolled Bleeding	☐ No	☐ Yes	High Triglycerides	☐ No	☐ Yes
Blood Clots	☐ No	☐ Yes	Foot Ulcers	☐ No	☐ Yes
Congenital Heart Defects	☐ No	☐ Yes	Amputation	☐ No	☐ Yes
High Blood Pressure	☐ No	☐ Yes	Swelling (Edema)	☐ No	☐ Yes
Low Blood Pressure	☐ No	☐ Yes	Joint Pain	☐ No	☐ Yes
Hearing Loss/Change	☐ No	☐ Yes	Arthritis	☐ No	☐ Yes
Vision Loss/Change	☐ No	☐ Yes	Bone Disease	☐ No	☐ Yes
Chest Pain	☐ No	☐ Yes	Osteoporosis	☐ No	☐ Yes
Pacemaker	☐ No	☐ Yes	Recent fracture	☐ No	☐ Yes
Difficulty Breathing	☐ No	☐ Yes	Acquired Brain Injury	☐ No	☐ Yes
Frequent Nosebleeds	☐ No	☐ Yes	Traumatic Brain Injury	☐ No	☐ Yes
Asthma or Respiratory Problems	☐ No	☐ Yes	Gout	☐ No	☐ Yes
Other Lung Disease	☐ No	☐ Yes	Joint Replacement	☐ No	☐ Yes
Tuberculosis	☐ No	☐ Yes	Dizziness/Fainting	☐ No	☐ Yes
Kidney Stones	☐ No	☐ Yes	Stroke	☐ No	☐ Yes
Kidney Stones	☐ No	☐ Yes	Seizures	☐ No	☐ Yes
Hepatitis	☐ No	☐ Yes	Epilepsy	☐ No	☐ Yes
Liver Disease	☐ No	☐ Yes	Easy Bruising	☐ No	☐ Yes
Stomach Pain	☐ No	☐ Yes	Skin Problems	☐ No	☐ Yes
Blood Transfusion	☐ No	☐ Yes	Mental Illness	☐ No	☐ Yes
Dialysis	☐ No	☐ Yes	Muscular Dystrophy	☐ No	☐ Yes
Thyroid Problem	☐ No	☐ Yes	Developmental Delay	☐ No	☐ Yes
Diabetes	☐ No	☐ Yes	Learning Difficulties	☐ No	☐ Yes
Neuropathy	☐ No	☐ Yes	Down Syndrome	☐ No	☐ Yes
Heart Disease	☐ No	☐ Yes	Spina Bifida	☐ No	☐ Yes
Family History of Heart Disease	☐ No	☐ Yes	Spinal Cord Injury	☐ No	☐ Yes
Scoliosis	☐ No	☐ Yes	Autism	☐ No	☐ Yes
Back Problems	☐ No	☐ Yes	Other	☐ No	☐ Yes

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Please explain the above or any other past serious medical problems (include dates):

_____
_____
_____
_____

List any past surgeries (include dates): _____
_____
_____
_____

Is your child currently receiving therapy? _____

If yes, how many times/hours per week: _____

Is your child physically active? Yes / No

How many times per day or week? _____

How many minutes per day or week? _____

At home, school or in the community? Home / School/ Community

What activities did she/he do (e.g., active play, cardiovascular, strengthening, sports)?

_____
_____
_____

List all medications, if applicable, your child is taking (use back of page if necessary):

Name of Medication	Dose	Times Taken	Date/Time Last Taken

Other Notes/Comments:

Parent's/Guardian's Name: _____

Signature: _____ **Date:** _____

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PARTICIPANT INFORMATION FORM

CHILD'S NAME: _____

DOB: _____ **TODAY'S DATE:** _____

SEX: ☐ **MALE** ☐ **FEMALE**

PARENT'S NAME: _____

ADDRESS: _____

_____

_____

_____

PHONE NUMBER: _____

E-MAIL ADDRESS: _____

IN CASE OF EMERGENCY, CONTACT:

NAME: _____

PHONE: _____

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Photographic and Video Release Form

THIS AFFECTS YOUR LEGAL RIGHTS.
PLEASE READ CAREFULLY BEFORE SIGNING BELOW

TITLE: Biomechanical Changes Underpinning Stand-on Ride-on Power Mobility Devices for Children with Cerebral Palsy

INVESTIGATOR: Guilherme M. Cesar, PhD, PT (904) 620-2664

SPONSOR: University of North Florida

You have already consented to participate in the research study. As part of this project, I may be taking photographs and/or video recordings of you helping (or your child) using the adapted toy or working with one of the researchers during your participation in the research. Please indicate what uses of these photographs or videos you are willing to permit, by initialing next to the uses you agree to and signing at the end. This choice is completely up to you. I will only use the photographs or videos in the ways that you agree to. In any use of the photographs or videos, you (or your child) will not be identified by name. You may choose to participate in the study without permitting the release of your (and your child's) photographs or videos. Also, if you decide to change your indications at a later point and withdraw your consent, you can do so and it is OK, we will not use the photographs or videos if you do not want to.

_____ Photographs / Videos can be reviewed by the research team.

_____ Photographs / Videos can be used for project illustrations.

_____ Photographs / Videos can be used for classroom presentations.

_____ Photographs / Videos can be used for academic conference presentations.

_____ Photographs / Videos can be used for fundraising presentations/proposals.

_____ Photographs / Videos can be used for newspaper or magazine publication.

_____ Photographs / Videos can be used for scientific journal publications.

_____ Photographs / Videos can be posted to a website.

I have read the above descriptions and give my express written consent for the use of the photographs / videos as indicated by my initials above.

Name (Printed): _____ parent/legally appointed guardian

Signature: _____ Date: _____

Witness (Printed): _____

Signature: _____ Date: _____

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Physician Medical Clearance Form

Physician Name: _____ Phone #: Fax #:

Participant Name: _____

I give permission for my physician to disclose any information relevant to my participation in research studies at the University of North Florida.

Participant Signature: _____

Dear Dr. _____

_____ has expressed interest in participating in a research study, in which the participant will engage in balance and gait evaluations before and after use of adapted ride-on, stand-on power mobility device (toy car) for three months. Each evaluation session will take approximately 1 hour and includes anthropometric measures and basic clinical tests such as the Timed Up and Go test, 5 times Sit-to-Stand, and standing balance tests. Rests will be provided as needed in between tests.

Currently, this participant exhibits the following health concerns or risks:

Researcher's Signature: _____

Report of Physician (PLEASE CHECK APPROPRIATE BOX BELOW)

☐ I know of no reason why the client may not participate.

☐ I believe the client can participate, but I urge caution because:

_____

☐ The client should not engage in the following activities:

_____

☐ I would like to see this client before they engage in physical activity.

Physician's Signature: _____ **Date:** _____

Please return to:

Guilherme M. Cesar, PhD, PT
Assistant Professor, Department of Physical Therapy
Brooks College of Health, University of North Florida
Office 39/2055A | Phone 904.620-2664
E-mail: g.cesar@unf.edu | Fax#: (904) 620-2251

1 UNF Drive | Jacksonville | Florida 32224-7699

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Adapted Toy Safety Check List
University of North Florida

Project Title: Biomechanical Changes Underpinning Stand-on Ride-on Power Mobility Devices for Children with Cerebral Palsy

Electrical Check list

- ☐ Unplug the battery and check that it has not been modified
- ☐ Check the battery and its wires for signs of damage
- ☐ Check that correct AWG wire gauge has been employ, e.g.:
  - Higher than 18 for 6V Battery
  - Higher than 14 for 12V Battery
- ☐ Check all wire connections: All wire connections must be insulated, and connectors checked proper fitting with wire gauge.
- ☐ Check for exposed wires: All wires must be insulated
- ☐ Check that all switches and crimp terminals are properly connected and fully operational
- ☐ Check that all sensors and electronic components are properly connected and fully operational

Mechanical Check list

- ☐ Check that all PVC modifications (cuts and drill holes) are smooth. There should be no burrs on the PVC
- ☐ Check that all PVC pipes and connectors are of proper size and properly fitted
- ☐ Check that all PVC used has an inner diameter of at least ¾ inches for structural elements
- ☐ Check that all bolts are at least ¼ inch and at least 2 inches long, and all bolt ends have been covered for structural elements
- ☐ Check that all components (seat belts, foam, switches, sensors, battery, and PVC frames) are securely attached to the toy

Operation Check list

- ☐ **Check that all components work appropriately together by strapping in a 40 pound weight and continuously activating the car for 10 minutes**

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