ID: 20-278-H

NCT05473182

IndieTrainer: Enabling individuals with cerebral palsy to receive gamified powered mobility training in their own manual wheelchairs

Original IRB Approval Date: 04/13/2020

IRB Approved Procedural Amendments (All Reflected in this Document): 06/28/2022 and 12/13/2022

GRAND VALLEY STATE UNIVERSITY
www.gvsu.edu

DATE:	April 13, 2020
TO:	Lisa Kenyon
FROM:	GVSU Institutional Review Board (IRB)
STUDY TITLE:	IndieTrainer: Enabling individuals with cerebral palsy to receive gamified powered mobility training in their own manual wheelchairs
REFERENCE #:	20-278-H
SUBMISSION TYPE:	IRB Initial Submission
ACTION:	Approved
EFFECTIVE DATE:	April 13, 2020
EXPIRATION DATE:	None
REVIEW TYPE:	Expedited Review

Thank you for your submission of materials for this research study. The IRB has approved your research plan application as compliant with all applicable sections of the federal regulations, Michigan law, GVSU policies and IRB procedures. All research must be conducted in accordance with this approved submission.

Please insert the following sentence into your information/assent/consent documents as appropriate. All project materials produced for participants or the public must contain this information.

This research protocol has been approved by the Institutional Review Board at Grand Valley State University. Study No. 20-278-H

Please remember that informed consent is a process beginning with a description of the study and assurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. *Federal regulations require that each participant receive a copy of the signed consent document.*

This approval is based on the IRB determination that no greater than minimal risk is posed to research participants. This study has received expedited review, 45 CFR 46.110 Expedited Categories 1, 6 and 7, based on the Office of Human Research Protections 1998 Guidance on Expedited Review Categories.

The following personnel are approved to work on this research:

- Lisa Kenyon - Principal Investigator
- John Farris - Co-Investigator, Faculty/Staff

The IRB made the following additional regulatory determinations:

1. **Subpart D risk determination**: This research has been determined to be of no greater than minimal risk to children consistent with 45 CFR 46.404.
2. **Parental permission**: The written permission of one parent or guardian is sufficient for the research to be conducted, consistent with 45 CFR 46.408(b).
3. **Assent**: Per 45 CFR 46.408(a), assent is required from children who have the maturity, psychological state and cognitive ability to be consulted. Assent will be documented by the researcher on the verbal assent script. Assent is not required from children whose capability is so limited that they cannot reasonably be consulted.

GRAND VALLEY STATE UNIVERSITY
www.gvsu.edu

4. **Waiver of documentation of consent**: Per 45 CFR 46.116(f), the requirement to obtain a signed consent form is waived for participants aged 18 to less than 21 years of age who are their own legal guardians and who lack the motor ability to sign their names. Verbal consent is permissible for these participants. The researcher will document the verbal consent on the consent form.

Please note the following are required in order to comply with federal regulations and IRB policy:

1. Any major change to previously approved materials must be approved by this office prior to initiation. Please use the *IRB Amendment Request* form for this submission. This includes, but is not limited to, changes in key personnel, study location, participant selection process, etc.

   See *IRB policy 1010, Modifications to approved protocols.*

2. All UNANTICIPATED PROBLEMS and SERIOUS ADVERSE EVENTS to participants or other parties affected by the research must be reported to this office within 7 days of the event occurrence, using the UP/SAE Report form. If the adverse event includes a fatality, hospitalization, or security breach of sensitive information immediately notify the Office of Research Compliance and Integrity (rci@gvsu.edu or 616-331-3197), the IRB chair, Dr. Kevin Lehnert at (616) 331-7471 **and** the Research Integrity Officer Jeffrey Potteiger at 616-331-7207.

   See *IRB policy 1020, Reportable events: protocol deviations, unanticipated problems and adverse events.*

3. All instances of non-compliance, including protocol deviations, or complaints regarding this study must be reported to this office in a timely manner. Use the *IRB Reportable Event form* in IRBManager to report this information.

   See *IRB policy 1030, Research non-compliance.* Refer to *IRB policy 1020, Reportable events: protocol deviations, unanticipated problems and adverse events* for examples of reportable protocol deviations.

4. All required research records must be securely retained in either paper or electronic format for a minimum of 3 years following the closure of the approved study. This includes original or digitized copies of signed consent documents. Research studies subject to the privacy protections under HIPAA are required to maintain selected research records for a period of at least 6 years after the close of the study.

5. Although IRB approval of this research does not expire, a Closure Form should be submitted through IRBManager upon completion of the research.

   See *IRB policy 1060, Closure of Approved Research Studies.*

If you have any questions, please contact the Office of Research Compliance and Integrity at (616) 331-3197 or rci@gvsu.edu. The office observes all university holidays. Please include your study title and reference number in all correspondence with our office.

1. General Project Information

1a. Study Title

IndieTrainer: Enabling individuals with cerebral palsy to receive gamified powered mobility training in their own manual wheelchairs

1b. Purpose of Research

Briefly describe the purpose of your project. Include the research question(s) to be answered and/or hypothesis/es.

Power wheelchairs (PWCs) offer children who are unable to independently opportunities for participation in social, educational, and leisure activities. Unfortunately, children who have severe cognitive, motor, or sensory impairments may need extended training to be able to master the PWC skills needed to "qualify" for their own PWC. To address this need, a PWC training system called the KWIC Trainer was developed. The KWIC Trainer used a platform-based design to temporarily convert a manual wheelchair into a powered wheelchair, thereby allowing children to remain in their own manual wheelchair and use their own custom seating system during training. To increase motivation to train, a videogaming mode allowed children to play videogames shown on a TV screen using the KWIC Trainer joystick. During videogames, the KWIC Trainer could be configured to both rotate the KWIC Trainer in place and translate it a small distance, thereby progressively teaching children the concept that moving the joystick resulted in movement of their wheelchair. In a pilot project, the KWIC Trainer showed promising results, allowing 2 out of 8 children with CP who had been previously excluded from power mobility training to gain the skills needed to qualify for purchase of their own PWC. Despite this initial success, the KWIC Trainer was bulky, had limited ground clearance, and took a long time to set up, which made it difficult to use in a real-world environment.

To address these concerns, a new PWC training system, called the IndieTrainer, will be developed as part of a Small Business Innovation Research Grant (SBIR). The IndieTrainer will build upon both the KWIC Trainer and the indieGoTM, a mobile platform device that also temporarily converts a child's manual wheelchair into a PWC (see section 8). The IndieTrainer will be a game-based training program that will allow licensed physical and occupational therapists to progress children throughout the continuum of learning to use a PWC.

As part of the SBIR, GVSU will be contracted to conduct an open-label, single-arm clinical trial to evaluate use of the IndieTrainer to improve a child's PWC skills. This proposal outlines this study.

1c. Study Location(s)

Indicate the primary site at which the research will be conducted.

Site: Grand Valley State University

1d. Project Timeline

Anticipated Start Date:

06/01/2021

Anticipated End Date:

05/31/2024

2. Protocol Personnel
Lisa Kenyon
John Farris
3. Review Type
3. Level of Review
What type of review do you believe your project falls under?
Expedited
6. Subject Population
6a. Subject Population Description
6a(i). Number of Subjects
25

6a(ii). Subject Population Characteristics
Briefly describe the subject population characteristics (i.e., age ranges, and where appropriate, gender, ethnic background, and health status).
Participants will be children (defined as 3 to <21 years of age) with cerebral palsy or other similar conditions who have mobility limitations (e.g., function at Gross Motor Function Classification System Level IV or V), are unable to functionally self-propel a manual wheelchair, and who do not have an individually prescribed powered wheelchair. Other inclusion criteria include: parent report that the child has beginning cause and effect skills (e.g. the child responds to games such as peek-a-boo or activates toys through motor activities such as pressing, hitting, batting, or squeezing), age =5 years and <21 years old, child currently uses a manual wheelchair or adaptive stroller that can be safely used with the IndieTrainer system (i.e. functioning wheel brakes to remain locked onto platform, etc.), and the ability to attend to visual stimuli as assessed by Dr. Kenyon (to ensure that the child was able to attend to the videogame activities) as assessed by Dr. Kenyon. Exclusion criteria include any condition or issue that would prevent a child from safely using the IndieTrainer system as determined by Dr. Kenyon. The child and his/her wheelchair combined must also weigh <300 pounds to safely use the IndieTrainer.

6a(iii). Number of Subjects Justification
Provide a justification for why the number of subjects to be recruited is appropriate.
A sample size of 25 child-parent dyads was determined using an estimated effect size (Cohen's d) of 1.48 for T0 to T1 changes in the primary outcome measure, a significant within group difference at alpha = 0.05 with a 90% probability, and a 10% dropout/attrition rate, as based on our previous work.

6b. Vulnerable Populations
Will any vulnerable populations be recruited for this study? These include, but are not limited to, children under the age of 18, prisoners, mentally disabled persons, economically disadvantaged, or pregnant persons.
Yes

6b(i). Vulnerable Population Justification

Indicate the vulnerable population(s) to be recruited.

Children under the age of 18

Enter a justification for recruiting the vulnerable population(s) identified above. If you selected "Other," please describe.

Given that the IndieTrainer system is focused on improving PWCs in children who have severe motor and other impairments, the IndieTrainer system must be assessed for use with children. Project procedures will not be initiated without assent from any child who can provide assent and who is 7 years of age or over. Given that many of children in this may not have the motor ability to sign their own names, we will be requesting an alteration in signed assent as outlined later in this document. It must also be noted that not all children who may be involved in the study will have the ability to indicate "yes" or "no". Such children, even if 7 years of age or older, would not be capable of providing assent. Nonetheless, study procedures will be explained to all participants, even if they are not capable of providing assent. This will be done as a matter of respect. Given that the participants may not be able to communicate with the researchers or their families, all research activities will be discontinued if a participant demonstrates signs that he/she does not want to participate in the activity (crying for more than 2 minutes, etc.).

7. Subject Recruitment and Consent

7a. Recruitment and Selection of Subjects

7a(i). Recruitment Process

Briefly describe how participants will be recruited.

A non-probability, convenience sampling plan was used to recruit child-parent participant dyads. Specific recruitment techniques included posting virtual fliers on relevant websites, sharing virtual fliers via social media sites and platforms, and emailing fliers to local agencies, clinics, and professionals involved in the provision of medical, rehabilitation, or educational services for children with CP or other similar conditions.

7a(ii). Inclusion/Exclusion Criteria

Describe the criteria you will use to determine which subjects will be included and which excluded.

Inclusion criteria:

1. Age 3 years to <21 years old
2. Have a diagnosis of cerebral palsy or other similar condition
3. Be unable to walk effectively (As determined by Dr. Kenyon, a licensed physical therapist)
4. Unable to functionally self-propel a manual wheelchair (As determined by Dr. Kenyon, a licensed physical therapist)
5. Do not have an individually prescribed powered wheelchair
6. Parent report that the child has beginning cause and effect skills (e.g. the child responds to games such as peek-a-boo or activates toys through motor actions such as pressing, hitting, batting, or squeezing)
7. Currently uses a manual wheelchair or adaptive stroller that can be safely used with the IndieTrainer system (i.e. functioning wheel brakes to remain locked onto platform, etc.) as

assessed by Dr. Kenyon
8. Has the ability to attend to individually motivating visual stimuli for 5 seconds as assessed by Dr. Kenyon (to ensure that the child was able to attend to the videogame activities).
Exclusion criteria include any condition or issue that would prevent a child from safely using the IndieTrainer system as determined by Dr. Kenyon.
In addition, at least one parent or guardian must converse in English for their child to participate
in the study.

Given that many children in the target population are often non-verbal and unable to indicate "yes" or "no", to ensure child safety, the researchers will need input from the parent about if their child's response to research activities is typical for their child. The child and his/her
wheelchair combined must also weigh <300 pounds to safely use the IndieTrainer.
Dr. Kenyon will use the Eligibility Assessment form uploaded in text box 7a(iv) to assess all inclusion and exclusion criteria prior to the onset of any data collection activities.

7a(iii). Researcher/Subject Relationship
None

7c. Consent/Assent Process Description
7c(i). Consent/Assent Description
Provide a description of the process for obtaining consent/assent of the subjects or their representatives.
Dr. Kenyon will review study procedures and criteria privately with each family and make sure that any questions the family may have been answered. A parent will sign the consent/permission form only if he/she freely chooses to do so. If obtaining assent is applicable for the potential participant, Dr. Kenyon will obtain ethically appropriate assent as outlined in the assent process. Dr. Kenyon will also use the Eligibility Assessment form to assess all inclusion and exclusion criteria prior to the onset of any data collection activities.

For participants 18 to <21 years of age who are their own guardian, Dr. Kenyon will review study procedures and criteria privately with each potential participant and make sure that any questions the potential participant may have been answered. A participant 18 to <21 years of age consent to participate in the study only if he/she freely chooses to do so.

Ensuring Voluntary Participation
How will you ensure that the voluntary nature of participation is apparent to the subjects?
This is clearly outlined in the consent/permission form and in the assent process for children who can provide assent.

7c(v). Participant Withdrawal
How will you ensure that a subject can freely withdraw from the research aspects of

the study without concern about being penalized?
This is clearly outlined in the consent/permission form and in the assent process for children who can provide assent.

7c(vi). Consent Waiver/Alteration
Are you requesting a waiver or alteration of informed consent?
Yes

In order to be granted a waiver or alteration to informed consent, the federal regulations require additional criteria be met. The questions below will enable you to provide information to address these additional criteria.
Describe the waiver or alteration being requested.
For all child participants <18 years of age and for participants who are 18 to <21 years of age who are not their own guardian, the researchers request an alteration of assent and would like to request that verbal assent be obtained rather than signed assent. Many of children in this population may not have the motor ability to sign their own names. Children who are unable to physically sign their name may be embarrassed or may feel uncomfortable when asked if they are physically able to sign their name. Obtaining verbal assent will avoid having to ask the child if he/she is physically able to sign his/her name. Verbal assent will be documented on the assent
form.

Participants 18 to <21 years of age who are their own guardian may not have the motor ability to sign their own names. Therefore, if a participant is 18 to <21 years of age and his/her own guardian and is unable to physically sign his/her name, the researchers request an alteration of consent and would like to request that verbal consent be obtained rather than signed consent. Verbal consent will be documented on the consent form.

Additional Criteria: Minimal Risk Explanation
Explain how the research involves no more than minimal risk to the participants.
Standard of Care: Before discussing risks in this study, it is important for reviewers to have an understanding of the standard of care in the area of power mobility training. Dr. Kenyon has frequently provided power mobility training for children during her 30+ years of practice as pediatric physical therapist. The standard of care in this area is for therapists to obtain a standard power wheelchair (either from a wheelchair vendor or perhaps through donation or by borrowing one from a child who already has one) and use pillows, towels, etc. to temporarily modify the standard power wheelchair to accommodate a specific child as much as possible. Since a standard power wheelchair is not customized to the needs of the child trialing the device, the standard power wheelchair may or may not fit the child and may or may not adequately and safely position the child. During power mobility training, the therapist walks along-side the child while the child is practicing driving and if the child comes upon a dangerous situation or needs to stop moving the power wheelchair, the therapist simply removes the child's hand from the access device - either a joystick or switch(es). A standard power wheelchair does not have an attendant control or emergency stop buttons.

Power Mobility Training in the IndieTrainer: The IndieTrainer is intended only for use under the supervision of a licensed physical or occupational therapist as part of a power mobility-training program. Multiple safety features have been included in the design of the IndieTrainer to ensure user safety while at the same time allowing users to access, explore, and learn from their environment. A child's manual wheelchair is securely attached to the IndieTrainer platform using methods similar to those that secure a wheelchair in a school bus or van during transport. This allows the child to be optimally and safely positioned in their manual wheelchair with their own customized seating system while practicing power mobility skills. When safety or environmental factors necessitate that the therapist take total control of the IndieTrainer, an attendant control allows the therapist to override all drive functions and assume full operational control of the IndieTrainer. Emergency stop buttons are also provided to ensure safety. The driving speed of the IndieTrainer is set by the therapist and can be set to meet the needs of the individual driving to ensure that users are not going too fast.

Given the data storage methods used in the study (and outlined later in this document), the risk of a data breach is minimal. Should a breach occur, information about a child's power mobility skill is not of a highly sensitive nature.

Additional Criteria: Rights and Welfare of the Participants
Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

All participants will undergo the same consent and permission process. For children 7 years of age or over who can partake assent process, the assent process will be the same. The only difference relates to whether the consent or permission or assent form is signed. All participants will still receive a copy of the appropriate consent/permission or consent form.

Additional Criteria: Practicality of Conducting the Research
Explain why the research could not be practicably carried out without the waiver or alteration.

Many of children in this population may not have the motor ability to sign their own names. Children who are unable to physically sign their name may be embarrassed or may feel uncomfortable when asked if they are physically able to sign their name. Obtaining verbal assent
(defined as whatever communication system the child uses) will avoid having to ask the child if he/she is physically able to sign his/her name. Verbal assent will be documented on the assent form.
Many participants 18 to <21 years of age who are their own guardians may have the motor ability to sign their own names. Therefore, if a participant is 18 to <21 years of age and his/her own guardian and is unable to physically sign his/her name, the researchers request an alteration of consent and would like to request that verbal consent be obtained rather than signed consent. Verbal consent will be documented on the consent form.

Additional Criteria: Additional Information to Participants
Whenever appropriate, the participants will be provided with additional pertinent information after participation. Explain how this will be accomplished or why this cannot be done.
All information related to the study will be provided to all participants prior to the onset of any data gathering activities.
Additional Criteria: Identifiable Private Information/Biospecimens
Does this research involve identifiable private information or identifiable biospecimens?
No
8. Research Procedures and Methods
8. Research Procedures and Methods
8a. Frequency and Time Involvement
Describe the frequency and length of time subjects will be involved in the study.
The focused physical therapy examination will take 90-120 minutes. Each training session will take approximately 60 minutes. An additional 30-45 minutes will be added to the final training session. The single follow-up session will take 45-60 minutes. The total time involved in the study is between 8 hours, 45 minutes and 12 hours, 45 minutes.
8b. Description of Intervention/Data Collection
Describe step-by-step what will occur during your project, including any intervention(s). Include a description of the data you are collecting (i.e., the specific variables, the specific tests/surveys, data collection instruments, etc.), how it will be collected, and how it will be analyzed.

Research Design: The research design to be employed in the proposed is a single-arm, open label study without a control group involving the following components: (a) Baseline examination and baseline/pre-intervention testing (T0); (b) A three-week intervention period consisting of two, 60-minute PWC skills training sessions per week; (c) Post-intervention testing completed immediately after the completion of the intervention period (T1); and (d) A single session retention trial held 4 weeks after the completion of the intervention period (T2).

Prior to the onset of any data collection activities, Dr. Kenyon will obtain ethically valid consent, permission, and assent as appropriate using the procedures previously outlined in this document.

Prior to the onset of data collection, Dr. Kenyon as a licensed physical therapist will perform a focused physical therapy examination to determine whether the participant would best be able to drive using a joystick or switch(es) as well as how and where the joystick or switch(es) should be placed to best accommodate each participant's needs. Per the standards of the physical therapy profession, this examination will include obtaining a complete medical history via parental interview (this interview will not be recorded) and a systems review (including a screen of cardiopulmonary, integumentary, musculoskeletal, and neurological systems). Obtaining a complete medical history and completing the review of systems for each potential participant

will allow Dr. Kenyon to determine if it is safe for each potential participant to partake in power mobility training. The switches or joystick used will be placed on each participant's manual wheelchair only when he or she is driving and will not result in any permanent changes to the participant's manual wheelchair.

T0 data collection activities will also take place during this focused physical therapy evaluation. A demographic form will be completed. The primary outcome measure will be the Assessment of Learning Powered mobility use (ALP), a process-based assessment instrument reflecting the process of understanding how to use a PWC. Secondary outcome measures pertaining to PWC skill execution included the Wheelchair Skills Checklist (WSC) and the Canadian Occupational Performance Measure (COPM). A focused, two question parent/caregiver interview will be conducted and digitally recorded. The interview questions will be: 1) Can you describe (your child's name) for me?; and 2) How do you think your child will respond to power mobility training? Follow-up prompts to these two main questions will include the parent's perceived benefits and challenges of power mobility training for his/her child. Once parent-report data collection activities are completed, participant's power mobility skills will be assessed by Dr. Kenyon, a licensed physical therapist. The child will use the IndieTrainer during administration of the ALP and the WSC.

Participants will then partake in 2 training sessions per week over a 3-week period. NOTE: Should training sessions be cancelled due to child illness or inclement weather, missed training sessions will be rescheduled during the 3-week period. If this cannot be accomplished, the 3-week time period will be extended for up to 7 days. This 7-day extension would only be used when necessary to ensure the child's health, well-being, and safety.

A parent or guardian must accompany the child participant to each training session. Participants will be video-taped and photographed while using the IndieTrainer. These photographs and videos will allow the licensed physical therapist researcher (Dr. Kenyon) to determine how each participant is responding to the IndieTrainer program and will help he licensed physical therapist researcher (Dr. Kenyon) to determine when to progress a participant to the next stage of IndieTrainer program. As noted in the consent/permission form, the GVSU research team may ask permission to use photographs or videos in professional presentations or publications. In such instances, permission (and assent if applicable) would be obtained via a separate Video and Photography Release Authorization Form.

After completion of the final session, T1 testing will occur and will include re-administration of the ALP, the WSC, and the COPM. A focused, two question parent/caregiver interview will be conducted and digitally recorded. The interview questions will be: 1) Can you describe (your child's name) for me? How do you think your child responded to power mobility training? Follow-up prompts to these two main questions will include the parent's perceived benefits and challenges of power mobility training for his/her child. In addition, parents' impressions of the IndieTrainer system will be gathered using the Client Satisfaction Questionnaire (CSQ-8).

T2 testing will involve administration of the ALP and the WSC.

Data Analysis:
Frequency counts will be used to report categorical demographic variables. We will use SAS Studio 5.1 (SAS Institute Inc., Cary, NC, USA) to calculate descriptive statistics for continuous demographic variables and CSQ-8 total scores and to perform all statistical analyses. If appropriate, we will use parametric tests in our analyses. We will use a one-way repeated measures ANOVA to assess differences in ALP and WSC scores at T0, T1, and T2 at 0.05 α level. Post-hoc paired samples two-tailed t-test with a Bonferroni correction will be used as appropriate to assess mean differences between T0 and T1, T0 and T2, and T1-T2. Mean COPM Performance and Satisfaction scores will be assessed via a paired samples two-tailed t-test at 0.05 α level. Frequency counts for total CSQ-8 scores will be reported. The clinical significance of changes between T0 and T1 will be assessed using the following guidelines: an improvement of at least one ALP phase and an increase of ≥2 points in COPM performance. Cohen's d effect sizes will be interpreted as small = 0.20 to 0.49; moderate = 0.50 to 0.79; and large ≥0.80.

Data from the parent/guardian interviews will be transcribed verbatim by the researchers. Qualitative data will be analyzed using the Linguistic Inquiry and Word Count program (LIWC 2015), a text analysis program. LIWC 2015 examines each word in a transcript against an internal dictionary of 6,000+ words to place each word into appropriate linguistic and psychological categories and can objectively evaluate a transcript based on 4 summary language
variables: Analytical Thinking, Clout, Authenticity, and Emotional Tone.

8c. Compensation
Will subjects be compensated for their participation in the study?
No

8d. Deception and Incomplete Disclosure
Does this study involve the use of deception?
No

8h. Contribution to Existing Knowledge Base
How will the resulting information contribute to the existing knowledge base?
The IndieTrainer will be the first power mobility training system specifically designed to optimize
the training process, accommodate varying levels of cognitive capacity and motor impairment, and improve access to power mobility training for the thousands of children with cerebral palsy who are currently excluded from such training and therefore denied the opportunity to independently move and explore.

8i. Dissemination of Results
How will the results be disseminated (presented or published) to the public, scientific community, and research participants?
Findings will be presented at national and international conferences and submitted for

publication in a peer-reviewed journal.

9. Personal Identifiable Information
9. Personal Identifiable Information
9a. Use of Personal Identifiable Information
Will personal identifiable information and/or protected health information be collected and/or accessed during this study? This can include, but is not limited to: names, phone numbers, email addresses, medical information, educational record data, etc.
Yes
Select the type of personal identifiable information being collected/accessed. (Check all that apply.)
Names
Telephone numbers
Electronic mail (E-mail) addresses
Full face photographic images and any comparable images
For further information regarding data storage and transfer recommendations/requirements, please consult IRB Guidance G-16: Guidance on Data Management Requirements for Research Data.
9b. Data Acquisition
How will the personally identifiable data initially be obtained?
Each participant will be assigned a unique participant identification number that does not include any identifiable information. The participant ID code will instead reflect the research study: IndieTrainer-(number) - for example: IndieTrainer- 04. Dr. Kenyon will retain a participant key in a locked draw in her locked office. This key will be stored separately from any data or other participant information (demographic forms, etc.). Only Dr. Kenyon will have access to this key.
Interviews with parents will be audio-recorded. As soon as possible after the interview, the audio recording will be stored in a secure method (on encrypted jump drive or as an encrypted file) and the interview erased from the digital recorder. The audio recordings will be transcribed by the researchers. Once this the interview is transcribed, the secure file of the audio recording will be deleted.

Participants will be video-taped and photographed while using the IndieTrainer. As noted in the consent/permission form, the GVSU research team may ask permission to use photographs or videos in professional presentations or publications. In such instances, permission (and assent if applicable) would be obtained via a separate Video and Photography Release Authorization Form.

9c. Access to Personal Identifiable Information
Describe who will have access to the data.
Only Dr. Kenyon will have access to the participant key. GVSU researchers will transcribe the interviews. Only Dr. Kenyon will have access to the photographs and videos - however she may view these with other GVSU researchers to determine how a participant is responding to the IndieTrainer.

9d. Data Storage/Destruction

Where and how will the data be stored?

Contact information will not be stored. The participant key will be stored in a locked draw in Dr. Kenyon's locked office. This key will be stored separately from any data or other participant information (demographic forms, etc.). As soon as possible after an interview, the audio recording will be stored in a secure method (on encrypted jump drive or as an encrypted file) and the interview erased from the digital recorder. The audio recordings will be transcribed by the researchers. Once this the interview is transcribed, the secure file of the audio recording will
be deleted. As soon as possible after photographs and videos are obtained, they will be stored in a secure method (on an encrypted jump drive) and deleted from the camera.

9e. Data Destruction

For how long will subjects' identifying information be linked to the data and how will the data be destroyed?

As soon as possible after an interview, the audio recording will be stored in a secure method (on
encrypted jump drive or as an encrypted file) and the interview erased from the digital recorder.
The audio recordings will be transcribed by the researchers. Once this the interview is transcribed, the secure file of the audio recording will be deleted. As soon as possible after photographs and videos are obtained, they will be stored in a secure method (on an encrypted jump drive) and deleted from the camera.

9g. HIPAA Authorization Form

9h. HIPAA Waiver

If you wish to use HIPAA- and/or FERPA-covered data for research purposes, you must either obtain consent from the individual whose data you will be collecting/using, or in the case of HIPAA-covered data, the IRB must approve a HIPAA waiver. FERPA waivers are not available. Are you requesting a waiver or alteration of HIPAA authorization for this study?

No

10. Risks and Benefits

10a. Potential Risks and Discomforts

10a(i). Nature/Likelihood of Risks

Describe the nature and likelihood of risks to subjects and procedures to minimize risks. Include data breach as a potential risk and indicate what potential effects a data breach might have on the subjects.

10a(ii). Risk Response

Electronic data will be collected and/or stored for this research study. As with any electronic data storage, there is a minimal risk that your data could be lost or stolen. Some children may feel anxious or frustrated when learning to drive in a PWC.

Should an identified risk event occur, specifically, what action(s) will be taken?
Any and all adverse events would be reported per GVSU and NIH policies.

10b. Potential Benefits
10b(i). Potential Benefits to Society
Describe the potential benefits to society (e.g., people, academic field, etc.).
The IndieTrainer will be the first power mobility training system specifically designed to optimize the training process, accommodate varying levels of cognitive capacity and motor impairment, and improve access to power mobility training for the thousands of children with cerebral palsy who are currently excluded from such training and therefore denied the opportunity to independently move and explore.

10b(ii). Potential Benefits - Subjects
Are the subjects likely to directly benefit by participating in this study?
Perhaps

10b(iii). Benefit Justification - Subjects
Describe the potential benefits to the subjects and justify why it is likely the subjects will receive these benefits.

Although participants' power mobility skills may improve because of participation in the study, it is not known if participants will benefit from using the IndieTrainer system. This is clearly stated on the consent/permission form.